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Teva Pharmaceutical Industries Ltd.

(TEVA)

Q1 2020 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by and welcome to today's Teva Pharmaceutical First Quarter 2020 financial results. [Operator Instructions] I must advise you that this conference is being recorded today. And without any further delay, I would now like to hand the conference over to our presenter today, Kevin Mannix, Senior Vice President and Head of Investor Relations. Please go ahead, sir.

Kevin C. Mannix

Senior Vice President & Head of Global Investor Relations, Teva Pharmaceutical Industries Ltd.

Thank you, operator, and thank you everyone for joining us today to discuss Teva's first 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 just an hour ago. 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.

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 and Eli will provide an overview of the first quarter performance, recent events, and priorities going forward. This will be followed by a question and answer session. Today's call, which will run approximately one hour, is being webcast live and recorded. You'll be able to replay the call and view the transcript on the Teva Investor Relations website.

And with that, I'll now turn the call over to 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 thank you for your interest in our company. I hope you're all safe, no matter where you might be.

Before I go into the financials for the first quarter, I'd just like to address Teva's response to COVID-19. I've chosen to give you some insight into four elements where we've been focusing, business continuity, sourcing and production, our employees and our communities. It's been paramount for us to secure business continuity, not just because of the need of the business, but also because of the need of the around 200 million patients that we serve when essential medicines, every day. We've also wanted to minimize the impact on our R&D programs, and secure that we could progress towards new product launches.

In the process of keeping our commercial operation going, we have been seeing a lot of digital instruments being implemented. We have been instrumental in doing a lot of e-detailing, different new ways of communication in

order to keep the sales force effective. I'm also happy to report that we have not been seeing any job losses related to COVID-19. We have kept everything operational.

A big part of our operation is of course sourcing and production. I'm happy to report that all facilities remain open to meet demand for our essential medicines. I'd like to thank all our employees for the fantastic job they've been doing, securing that we could stay operational in all our facilities in these very challenging times. We do have adequate inventories of raw materials and finished products across our global network to live up to the demand from our customers. And we have been able, despite many difficulties, to secure safe supply and transport our medicines and we basically haven't interrupted supply chain worldwide.

For our employees, safety has been the paramount consideration. We have been able to secure a safe and healthy work environment. We have no reports of anybody being infected due to going to work. We have implemented many, many both local and global precautions in order to secure that we could stay operational and keep a healthy work environment. This is based on strict guidelines, both from our own side, but of course also living up to all local requirements from authorities.

It's been important for us to support our communities, both the local communities near our factories, near our offices, but also the global communities through different international organization, different healthcare organizations working with different governments, and we have been supplying millions of tablets both for investigational treatments but also for already approved treatments, supporting different healthcare systems in many, many parts of the world. We've also been changing our production schedules to take into consideration, those products that are more in demand now, securing both API and finished products to secure that we could live up to demand for the products that we have in our portfolio.

Let's move to the next slide. On this slide, I will try to give you just a very brief overview of some of the positives and some of the risks related to COVID-19. One clear positive for the industry is that industry and governments are now working together to ensure availability of essential medicines. And I think it's, for the pharmaceutical industry, it is a positive that society clearly realizes the importance of the pharmaceutical industry, both in supplying needed medications for various treatments related to COVID-19, but also of course, in doing research in order to secure new treatments, vaccines, new treatment modalities are being sought for.

There's also a underlying worldwide demand for new and existing medicines, and this has not changed. So we have to remember that despite all the news flow and everybody being focused on COVID-19, the broad healthcare situation, the broad health situation for the population hasn't changed because of this. So there's the same underlying demand for our different products. As I said before, we have seen new digital capabilities in our sales force, new ways of communicating and only the future will show us to what extent there will be a permanent change in the way we do the promotion of our products worldwide.

We have not seen any material impact on our ongoing clinical trials. And we are hoping to see results coming through in the coming months as planned. However, there are also some significant risks. We all know that raw materials and finished goods are concentrated in terms of manufacturing in a few countries, especially raw materials and API is concentrated very much in a couple countries for most of the global supply. I'm happy to report that we of course have our own API network with more than 15 factories, and that these factories are predominantly in Eastern and Western Europe.

There is a risk related to the fact that we have seen some strong, strong patient demand in March, in the month of March. And this patient demand could lead to a overstocking at the patient level, how to predict exactly. And this of course might bleed through for these specific products, lower sales of these products in the coming months and

quarters. It's also quite clear that there is a risk that the reduced physical interaction between our sales force and healthcare professionals could lead to a slower uptake on our new products. It's not something we've seen yet, but it is a risk.

And it's also quite clear that some of the clinical trials that we have been planning to initiate will be delayed, and the delays will then depend on how long the lockdown of hospitals and clinics will last in individual countries. So overall we have a dynamic situation with some positives and some risks. And we are of course working diligently to secure that we pursue the positives and we try to avoid the risks.

If we move to the next slide, I will now move to the financials. We saw revenues of $4.4 billion. This was helped by a strong underlying demand for all our key products and also high demand in March for our generics and OTC products. The non-GAAP EBITDA came out at $1.4 billion, a positive result that was affected by the higher revenues, but also by the lower cost, and the lower cost was partly influenced by the COVID-19 lockdowns, but also by our ongoing rationalization and optimization programs that I'll get back to.

The GAAP EPS came out at $0.06 and the non-GAAP EPS came out at $0.76.

We saw a strong cash flow at about $550 million. And just to repeat what I've said many times, the ongoing cash generation on a yearly basis is running at around $2 billion, slightly above $2 billion. We do have some swings per quarter. Eli will get into that later, but we see a steady level here above $2 billion. This also leads to an ongoing reduction of the net debt. This quarter, it was $600 million in reduction, and we are now down to $24.3 billion.

We have been looking very carefully at the changes, so the ups and downs, both from COVID-19, but also from the general business development and when we look at all the sort of upsides and downsides and all the changes, this leads us to reconfirm our outlook. So, our outlook that Eli will get into in more detail remains unchanged.

If we look at the business then, we've had some nice positive developments. We've had the AJOVY Autoinjector approved in the US, and we've just launched it. We have seen more launches of AJOVY in Europe, now in 12 countries. We were the first anti-CGRP product for migraine prevention. That got NICE approval in the UK, which was very positive. We've launched one more biosimilar in the US, HERZUMA. We have launched the last Digihaler product, which gives us now a full digitalized respiratory portfolio in the US, and we look forward to launching these products in the market in the coming months in the US.

And then we had our partner, Eagle, had an orphan drug designation win in court, which means that the BENDEKA/TREANDA orphan drug designation stands until December 2022. And we also, and BENDEKA saw a positive patent ruling, which means to the BENDEKA patents will stand until 2031.

If we move to the next slide, then you probably remember that since I presented the restructuring plan more than two years ago, I've told you that 2019 would be a trough year for Teva in terms of revenue and earnings. I also said that a trough is pretty flat at the bottom. So when we start getting out of the trough, it's not a dramatic increase but there will be an increase in revenue and earnings, and you're seeing that here. I have to say that you're probably seeing it a little bit more than the underlying really is, and that's because in Q4 2019, we did have a very strong quarter in North America due to several very strong generic launches including Rituxan, the biosimilar product.

And we also had a very strong first quarter in Europe, with a lot of generics and OTC being sold in March, as I mentioned. So, but even if you take these things out, and then sort of try to normalize things, I can just confirm to

all you that we are seeing the trough. We see that we've been past the bottom of the trough and we are seeing a slow improvement in both revenues and earnings.

If we turn to the next slide, then this describes, apart from our strong generic business, what are the key growth drivers for our business. And we've talked about these many times before, AUSTEDO and AJOVY. I would like to point to this very nice picture of the AJOVY Autoinjector. Now the autoinjector has just been launched, as I said, in the US and it's also just been launched in Germany. And I'll get back to what the benefits of this very sleek and nice device, easy to use and what the benefits are for patients, and also in terms of the business development.

If we move to the next slide. Then you can see how we're doing on AUSTEDO. The graph to the left, that's a patient or a script count for the quarter. And you can see here that we have a very steady, very positive development in the total scripts. If you look at the revenues, then it's a little bit more bumpy. I can tell you the underlying trend is just as steady as the scripts, but we did see a bit of stock swings between Q4 and Q1. And we also saw the doughnut hole having a small effect in Q1, but we are confident that the underlying trend continues, and that we are heading for the goal of $650 million of AUSTEDO sales in the US in this year. So we have a very strong development in AUSTEDO, both in of course chorea in Huntington's disease and also in tardive dyskinesia.

If we move to the next slide, here you can see the script count for AJOVY, the weekly normalized TRx count, and you can see how it actually has gone flat for quite a while. This is of course not how we wanted it to be. You can also see how the NBRx share went up nicely to around 25%, 30%, and then it came down. It is the unfortunate result of us not getting the approval for the autoinjector, basically being delayed with the autoinjector.

That meant that despite the fact that with our long-acting anti-CGRP product, which due to its long action is available both in a weekly and a quarterly version. Despite the benefits of this product and the good safety profile it has, we were losing out in the doctors' offices because we did not have an autoinjector. And since the two competitive products both have an autoinjector, we saw our neutral brand share decline. Now we've just launched the autoinjector, and I'm very confident that it will see an increase both in the user brand share, and also eventually the total share and our aim is to end this year with the long-term target for neutral brand of 25%, and have high hopes we can do that.

We're also seeing more European launches, as I mentioned, and we've just been approved in Canada. So I'm very confident that we will see a positive development AJOVY. And we are keeping an unchanged target for the AJOVY sales for this year at US$250 million.

If we move to the next slide, then you probably all remember that last quarter, I talk about a new long-term improvement program. We finished the restructuring, and we now started a gross margin improvement program. And you might ask, with all the COVID-19 things happening, what's happening to this program. And you might even ask since the target of this program is an operating margin of 28%, and we already surpassed that in the first quarter, is that because we finished the program. And I have to tell you no to both. No, we have not stopped the program. The program is running very well. We're doing all the different elements you can see here on procurement, the network, operational excellence, supply chain, organizational model. We have reorganized our entire manufacturing operation. So we are in full swing with the program.

The numbers for the first quarter is exceptionally good, so they're not you could say a sustainable level yet, but they do indicate that the 28% operating margin, that is the target for this program at the end of 2023. That is a achievable target, and that is still what we are going for.

And if we go to the next slide, then I'd just like to make it absolutely clear that there's no change whatsoever to our long-term financial target. We are very confident we can reach these. I just talked about the 28% operating income margin target. We also have a above 80% cash-to-earnings target. This is of course important because we still have a huge debt, and the only way to pay down debt is, of course, to generate cash and use it to reduce the debt. That's what we're going to be doing. That's what we are doing, we'll keep on doing. And as a consequence of that, our target is to have a net debt-to-EBITDA ratio below 3 at the end of 2023.

So, with these words, I will hand over to Eli, who will go through more of the financial details.

Eli Kalif

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

Thank you, Kåre, and good morning and afternoon to everyone. These are, indeed, very extreme times that we are living and operating in, to say the least. I hope that you are safe and healthy. We do have a lot to cover, and I want to leave as much time as possible to take your questions. So let's get started.

On slide 14, we highlight Teva GAAP results, including GAAP net income of $69 million and earnings per share on a GAAP basis of $0.06 for the first quarter of 2020. Our year over year improvements in our GAAP results was the result of an increase in gross profit and higher sales, lower operating expenses, legal settlements, federal tax benefit and minority and share in a profit, offset by increase in impairments and restructuring charges.

Turning to slide 15. Our detail impairments, restructuring and other charges, which totaled almost $770 million for the quarter, impairments of a long-lived intangible assets accounted for the majority of the non-GAAP adjustment with $649 million in the first three months of 2020. This includes impairments of the process R&D assets totaling $331 million, mainly related to AUSTEDO for the treatment of Tourette's syndrome in pediatric patients.

Also, included was the impairment of identified product rights of $318 million mainly due to Japan in connection with ongoing regulatory pricing reduction and generic competition and updated market assumption regarding price and volume of certain generic products for early market in the United States. Amortization was $258 million for the first quarter, which is right within the range of $250 million to $260 million per quarter that I guided to in February.

Turning to slide 16. We'll review our non-GAAP performance. Quarterly revenues were approximately $4.4 billion, up 5% compared to Q1 2019. The year over year increase was driven mainly by double digit sales growth in Europe due to higher demand of certain products resulting from the impact of the COVID-19 pandemic on the purchasing pattern, as well as continued growth in generics and new generic product launch. This was followed a low single digit growth in North America, primarily due to AUSTEDO and Anda and international market.

Also, in the first quarter, hedging positively impacted revenue by $60 million, which was partially offset by $5 million negative impact recognized under cost of sales. Hedging transactions against future projected revenue and expenses are recognized on the balance sheet at their fair value on a quarterly basis, while the foreign exchange impact on the underlying revenue and expenses may occur in subsequent quarters.

Non-GAAP gross margin came in at 53.1% for the first quarter versus 51.8% as a result of the continued network optimization and higher generic gross margin, as well as the positive impact from economic hedge activity partially offset by an increase in Anda, our distribution business, which is less profitable.

Our non-GAAP operating margin was 28.5% versus 24.6% a year ago. This was driven by the reasons that I just noted, coupled with the lower operating expenses as our overall spend base including COGS was $3.1 billion, a decline of 1% versus Q1 2019. We ended the quarter with a non-GAAP EPS of $0.76, which is $0.60 higher than

Q1 2019. I acknowledge that this is significantly higher than the Street consensus. Indeed, our sales came in much higher, especially in Europe due to the reasons that I just noted.

Turning to slide 17. I'd like to highlight just a few of the revenue trends we have been seeing throughout the different segments and the regions with my main focus being on the sequential trends. Starting with North America, our generic business generated $952 million in the sales, which was a sequential drop of 16% from fourth quarter. Please note that Q4 exceptionally strong following our exclusive launch of biosimilar TRUXIMA, and there were no notable launches in the first quarter. Looking ahead, the most notable launch is expected in the fourth quarter, which is the launch of our generic version of Truvada.

North America COPAXONE sales dropped as expected due to ongoing generic competition to approximately $200 million, a level similar to the year ago, and one we believe is a good quarterly run rate for the remainder of the year. At this point in time, based on what we had seen in the first quarter in all three regions, we are not changing our 2020 annual outlook for global COPAXONE sales to be approximately $1.2 billion.

AUSTEDO sales in North America were up 65% year over year totaling $122 million for the quarter. We did however see a sequential decline of 10%. As we have mentioned before, sales of AUSTEDO tend to fluctuate from quarter to quarter. In the fourth quarter, there was a particularly strong demand. We expect sales to continue to grow throughout the year, and reach on our full-year target of approximately $650 million. Meanwhile, AJOVY saw a modest increase of $29 million in quarterly sales. We expect sales to continue to grow as we fully launch the autoinjector in the US.

I did highlight earlier the strength of our revenue in Europe, which jump 18% compared to Q4 2019, almost entirely from the growth in generic and OTC. This sequential increase was fueled by higher demand of certain products and due to the impact of the COVID-19 pandemic on a purchasing pattern as well as continued growth in generics and in new generics products launches.

Our international market was basically flat sequentially from Q4 2019. While we did see expected weakness in our sales of generics in Japan due to the national health insurance price revision. This was offset by strength in Israel, Russia and other markets.

I would now like to touch on our spend base, what we have been seeing and why. Turning to slide 18, as you know, this company put forth tremendous efforts to reduce its overall spend base by $3 billion over the last two years and was quite successful in doing so.

Looking now on the year over year and quarter over quarter results, I would like to note a few observations. First, we see a nice reduction in operating expenses from the fourth quarter. Clearly, COVID-19 pandemic influenced this decline, but we are all still actively controlling the spend. Secondly, we see sequential drop in the cost of goods sold. Certainly, this is due to lower sales, but it is also the result of our ongoing efforts to improve our gross margin through the transformation of our network.

Turning to slide 19, we review our free cash flow for the quarter. As you know, our quarterly free cash flow tend to start the year off on the low side and then increase as the year progress. The slow start is usually the result of annual incentive payments for employees, which we did see this in Q1, as well as $70 million in cash payments for restructuring expenses. This was countered by the strong net income generated in the quarter.

We recognize there is some uncertainty about timing this year. This is effect of COVID-19 pandemic. But as you can see, we have now generated more than $2.2 billion in free cash flow over the last four quarters, and we are comfortable with the range we have guided to our 2020, which is $1.8 billion to $2.2 billion.

I would also like to briefly touch on our cash conversion. As you know, we have a long-term target of at least 80% for Teva cash conversion. This is a work in progress, but you are starting to see some positive signs with a year over year improvement in our cash conversion. This is a priority for Teva, something that we are actively working on each and every quarter, including and managing our working capital. This includes appropriate management of our inventories, which declined approximately $500 million year over year.

This is a good segue to discuss our liquidity, which you can see on slide 20. As we have consistently communicated, generating free cash flow is a priority for Teva as we work diligently to continue to reduce our debt load. You can see that our net debt declined by approximately $600 million compared to Q4 2019 to $24.3 billion, which include $700 million debt repayment during the quarter.

Our net debt-to-EBITDA ratio fell for the third straight quarter, dropping to 4.95 times, benefiting from the debt reduction and the stronger than expected quarterly EBITDA. This marks the first quarter that the ratio was under 5 times since the third quarter of 2018, an important milestone for Teva. Our expectation is that by the end of 2020, our net debt-to-EBITDA ratio will considerably be below 5 times. As we noted last November following our successful financing, and again on our fourth quarter call in February, we have the liquidity and cash flow to cover bond repayments for the next three years before looking to refinance the 2023 maturity.

Turning to our outlook, we begin with the review of the main assumption supporting our 2020 financial guidance on slide 21, which we first presented in February. Our team spent a significant amount of time assessing, analyzing and modeling the ever-changing environment due to COVID-19 pandemic and its effects, currently and potentially on both purchasing patterns of our larger global customers and overall utilization by patients. Based on this analysis, we're keeping our key assumptions including those for service COPAXONE, AUSTEDO and AJOVY. Clearly, these assumptions are best estimates at this time, but we believe this is the proper course of action.

These key assumptions from the foundation for our overall financial outlook for 2020, which you can see on slide 22. Based on the assumptions that we just reaffirmed, we are also reaffirming all five key metrics that make up our 2020 financial outlook, including total annual revenue of $16.6 billion to $17 billion, earnings per share in the range of $2.30 to $2.55 and free cash flow of $1.8 billion to $2.2 billion.

I would like to acknowledge that despite a significant performance in the first quarter, we are leaving our guidance for 2020 unchanged. We think this is prudent given the ever-changing environment due to COVID-19 pandemic. And while Teva does not provide quarterly guidance, we would highlight our expectation that the impact of the COVID-19 pandemic will likely be felt the most in our second quarter results, offsetting the first quarter out-performance. This guidance also reflect the expected volatility in the foreign exchange market, which can be headwind on revenue and income.

Before I close, I would like to thank to all Teva employees who have worked under challenging condition, including members of the finance team and other participants at Teva who worked hard to prepare our financial reports this quarter. It was a great effort.

And this concludes my review of first 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

Thank you. [Operator Instructions] Your first question comes from the line from Kevin Caliendo. Your line is now open.

Kevin Caliendo
Analyst, UBS Securities LLC

Q

Hi. Thanks for taking my call. I had a couple questions. Was there any stocking of the autoinjector in 1Q that may have impacted sales for the product?

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

A

So thank you, Kevin, for that question. I think the answer is quite very brief. No, there was not. So there's no financial impact in the first quarter results of stocking of the autoinjector into the market. And the simple explanation is that it was not available because it wasn't approved yet. So we were not sort of really shipping it in the first quarter. So we hope, of course, to see a nice uptake of the product here in the second quarter, but there was no effect in the first quarter.

Kevin Caliendo
Analyst, UBS Securities LLC

Q

That's great.

Operator: Thank you. We need to stay with one question. Thank you very much. Please re-enter the queue.

Kevin Caliendo
Analyst, UBS Securities LLC

Q

Thank you.

Operator: Thank you. Your next question comes from the line from Akash Tewari. Your line is now open. Please ask your question.

Andrew Newton
Analyst, WR Securities LLC

Q

Hi, this is Andrew Newton on for Akash. So first, I noticed TRx for the Gx business initially went up during COVID and then took a significant turn down over the last few weeks. That said on a relative basis, it seems like Teva's volumes haven't fallen to the same degree as Sandoz or Mylan. Do you have any color on what's occurring here? And what types of Gx portfolios and drug categories are being less impacted by COVID?

And then secondly, can you give any color on how COVID is impacting your Gx supply chain? Are you seeing any increased inventory hoarding or any cases of drug shortages yet? I know that you saw some significant inventory consumption which affected cash flow in the quarter. Thanks.

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

So, I can't really comment on the other companies in that situation. I haven't really looked into that, I must admit. But I can tell you that we did see in March, a couple weeks where there was very strong generics demand and OTC demand in Europe, especially in Europe. And we then saw it revert back to levels that are slightly below the norm. You could say it's nothing dramatic. But, and it's very different from individual product to individual product.

Just to give you a feel for it, we have some products now, I'm just mentioning something, of course, we have many thousand products, 20,000 different products. But the category of respiratory products, for instance, we see a steady increased demand of respiratory products in US and in some of the European markets, but in some European markets, we don't see it. In some European markets, governments made limitations to how many scripts you could go and fill at the pharmacy, in some markets they didn't.

So it's really a very, very mixed bag situation. I would say overall for us, we did probably see some extra patient-level demand in Q1, especially in March. I do expect that we will see a somewhat reversal of some of that demand here in Q2. It's not really dramatic, but it's the way the swing factor will be, to the extent there is one. But probably maybe all companies have seen it more significant.

Andrew Newton
Analyst, WR Securities LLC
Q

Thank you.

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

Yeah.

Operator: Thank you. Your next question comes from the line from Randall Stanicky. Your line is now open.

Randall Stanicky
Analyst, RBC Capital Markets LLC
Q

Great, thanks. Kåre, it sounds like the [ph] $5.3 billion (33:55) to $5.8 billion range, EBITDA range for 2023 is on track. You've got past the cost restructuring that the two primary things going forward, the COGS improvement and the revenue opportunity. COGS is pretty clear, revenue is less clear. You've pointed to biosimilars as a big part of this. Can you walk through how we should think about quantifying that opportunity over the next three years? Is there a $500 million opportunity from the pipeline here, $2 billion, $1 billion? How should we think about the support from biosimilars to your revenue line? Thank you.

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

Yeah. So, the elements you could say unchanged, but the dynamics are different. So if we talk about, I totally agree with you that our gross margin optimization project or the COGS, that's really very much in our own control. We're working diligently on it. I think there's a very high likelihood that just like we succeeded with the restructuring, we will succeed with this margin improvement program.

So that then leaves the revenue to be the key question. And what I've said is I'm confident that we've seen a trough also for the revenue. That's not the same to say that we will see dramatic increases in revenue. I never said that. But we will see single digit increase in revenue.

And then you might ask, what's the dynamics behind it. And sorry for repeating, but there really a couple of elements here. On the specialty side, you have COPAXONE that will keep on declining, but at a much slower pace than what you saw before. So we are now down. So we saw the guidance, $1.5 billion on COPAXONE and that number in the coming years will slowly come down.

For now we have a good strong patent position in Europe, which is maintaining a nice level there. We have generic competition in the US, but we have stabilization there. So all-in-all, we see a modest decline in COPAXONE going forward. Now that decline has to be balanced by the growth in AUSTEDO and AJOVY combined. And we believe we've come to the point now, where the growth in AUSTEDO and AJOVY this year will be higher than the declining COPAXONE and that dynamic will continue in the coming years.

So if you believe in that, then you could say then the rest of the business, which is all the generics and the OTC basically has to be flat in order to secure growth. Of course, if we can grow the total generic business including the biosimilars, that's good, but at least we need to maintain a stable, flat level there if we want to grow the total business, given that AUSTEDO and AJOVY are growing.

So you should see the biosimilars in that context. By us doing more biosimilars over the coming years, we secure that our total generic business will be growing, and that's because more and more of the products every year that come up for generic competition are biologics or biopharmaceuticals. So it's a way too secure that the totality of our generic business including biosimilars will be growing. It is not something that knocks it out of the park and all of a sudden creates fantastic growth, because there's also competition in biosimilars.

So every time you launch a biosimilar, you have also some competitors. Typically you have less competitors than you have on classical generics. You also have a higher investment in getting the product to the market, and you have a tougher fight for market share. So far, we launched the biosimilar Rituxan last year. We are very happy about the uptake we're seeing. We're into the double digit market share that I was explaining that was our ambition.

So we think we have a very sustainable generic business including the biosimilars. I'm sorry, it was a bit of a long answer, but I just wanted to highlight the key dynamics of the revenue and the firm conclusion is that we do expect to see modest growth of our revenue. Thanks for the question.

Randall Stanicky
Analyst, RBC Capital Markets LLC

Q

Thanks.

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

Zachary Sachar
Analyst, Piper Sandler & Co.

Q

Hi, everyone. This is Zach on for David. Thank you for taking my question. Just a quick one from me, would you mind providing an update on the generic FORTEO and NuvaRing filings and your latest thoughts on potential

launch timing? And specifically on the FORTEO generic, do you think that the [ph] Phoenix (38:33) product will ultimately be substitutable? Thank you.

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

Thanks for that question. I'll hand that over to Brendan, since it's a US-specific question. Brendan?

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

Yeah, thank you Kåre. And so I'll take FORTEO first. So as you all know, FORTEO is a complex generic product. We continue to work with the FDA on the product. It continues to progress. We expect FORTEO could be possible later this year or early next year. We'll see where that heads.

Regards to the other product, they've applied for an AB rating on the product. We'll see how long that takes and where that progresses. I can't really comment on that, because I don't know where that company is with that. It's possible they could get it and it's also quite possible we could launch prior to that. So we'll see where that goes.

In regards to NuvaRing, we're progressing and working through the final stages with FDA. So as soon as that product is approved, we will be operationally ready to launch.

Zachary Sachar
Analyst, Piper Sandler & Co.
Q

Great, thank you.

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

Thanks for the question.

Operator: Thank you. The next question comes from the line from Umer Raffat. Your line is now open.

Umer Raffat
Analyst, Evercore ISI
Q

Hi. Thanks so much for taking my question. I just wanted to ask about the gross to net and what's being baked into guidance, especially considering I would have thought AUSTEDO probably gets a lot of gross to net expansion into the balance of the year, Kåre.

And also I saw Amgen report Aimovig down quarter over quarter in 1Q. But it doesn't seem like that happened for AJOVY, so I'm just trying to understand the gross to net dynamic, what you're seeing and also what you're assuming giving the higher unemployment and more Medicaid. Thank you very much.

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

Thanks for that question, Umer. So we're basically not seeing any dramatic changes on the gross to net. We do sometimes in a quarter have small adjustments on specific products based on prior-period adjustments and things like that. We have not seen anything dramatic here in the first quarter. We are not expecting to see any major changes going forward.

As you know, we have quite a number of our products that are in the Medicaid space. And then we see the pretty stable situation there and also for Medicare. So I would say that our gross to net expectations, apart from the changes in contracting, which of course we bake into the outlook all the time, so whenever we enter new contracts, we calculate that into our gross to net predictions. But apart from that, we're not seeing any dramatic changes.

Operator: Thank you.

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

Is there a question?

Operator: Your next question comes from the line from Louis Chen. Louise Chen, I'm sorry. Your line is now open.

Jennifer Kim
Analyst, Cantor Fitzgerald Securities
Q

Hi, thanks for taking our questions. This is Jen Kim on for Louise. I'm wondering what's the latest update on the opioid litigation? Do you still expect track two to this year or do you expect any impacts or delays from COVID-19?

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

So on the opioid litigation, we're still working actively with the AGs on the framework that we agreed with them last year. We are seeing a delay due to the COVID-19 both in the sense that the work goes slower because everybody's at home, but also because you could say in these kind of matters, often when there's a trial approaching, that's a trigger for people to get the work done, so to speak.

And as I'm sure you're aware, the New York trial, that was the first upcoming trial, state trial. That has been delayed. So I think it's fair to assume that we'll see a delay. I do hope that we will reach a final firm settlement based on the framework agreement. This will be to the benefit of the US public and to people who suffer from substance abuse. So I'm still optimistic that that will be the case, but it will definitely be delayed.

Jennifer Kim
Analyst, Cantor Fitzgerald Securities
Q

Thank you.

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

Thank you for the question.

Operator: Thank you. Your next question comes from the line from Gary Nachman. Your line is now open.

Q

Hey, this is the [ph] Eli (42:52) on for Gary. Thanks for taking the question. Just a quick one on AUSTEDO. How much of the priority is it to add additional indications to apply for for that? And are you considering eventual international expansion for the product at all?

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

A

Sorry, I couldn't completely hear you. Could you try to repeat the question? The line is not so clear? Just repeat the question please.

Q

Yes, for AUSTEDO, how much of a priority is it to add additional indications to that? And are you considering eventual international expansion for that product?

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

A

Okay, thank you. Now I hear. So, indication expansion and international sales. So yeah, we are considering both. Of course, we had a disappointment, as you know, in the first quarter, that we were looking for an indication in Tourette's and that did not work out. So we are still considering whether we can expand the indications.

We're also looking as to whether we would be able to launch the product in other markets. Right now, we are working actually on Japan and China, looking to see if there's a chance of launch there. And we have filed in China, so we're optimistic that that might be possible. So we are still pursuing international expansion of AUSTEDO. I don't know, Brendan, if you want to comment on how you see the US in terms of new indications.

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

A

Yeah. So, you know of course, any time you get a new indication to a medicine, it can drive revenue and ultimately drive profits. But just to think about AUSTEDO today, there's still a significant opportunity in both Huntington's disease as well as tardive dyskinesia. The population of tardive dyskinesia is only maybe 10% to 15% treated. So there's significant upside there. So that's certainly our focus today, but other indications associated with movement disorder would provide further growth for us, though.

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

A

Thanks for the question.

Q

Yeah. Thank you.

Operator: Thank you. The next question comes from the line from Ami Fadia. Your line is now open.

Ami Fadia
Analyst, SVB Leerink LLC

Q

Hi, good morning. Thanks for taking my question. Can you provide some thoughts on the feasibility of bringing manufacturing back to the US for certain essential products? And how are you thinking about this in the context of Teva? And then just a follow-up from an earlier question with regards to AJOVY with the availability of the autoinjector, do you anticipate an expansion in gross to net with maybe some revised contracting? Thank you.

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

A

So that was an elegant way of getting two questions in, but that's fine. So, the manufacturing discussion, it is of course at the end of the day a political decision. It's a fact that API manufacturing has moved out of the US over the last 10 to 15 years and there's basically no real API manufacturing left in the US. The same thing goes for the early stage raw materials, starting materials. They're also produced not in the US. A big majority of these products have their raw materials or API produced in China.

In our case, we have a giant network where we have some manufacturing and raw materials coming from China. But we have quite a large part coming from Europe, where we have a network of some 15 manufacturing sites. If API manufacturing should be brought back to the US, then it would of course take some kind of preferential treatment from a political point of view, simply due to the fact that manufacturing costs in the US are higher and they are in China and India. And that means that nobody can be competitive. If you move the production back to the US, unless you get preferential treatment by the buyers, be it the government or be it the customers.

What we're doing at Teva is we're trying to secure a very sustainable safe supply chain. So we have a lot of our finished products being manufactured. In the US, we have a lot of our API being manufactured in Europe, in our factories there. So we believe we have a very safe and sustainable supply chain. Of course, we try to persuade our customers that there's a value to that. But it's up to the customers whether they want to pay for the extra supply chain security or not.

You could say I could have an optimistic hope that based on COVID-19, there will be more willingness to enter into longer contracts, where it's not just the price that's the only variable, but it's also quality and safety of supply. If that turns out to be the case, we will be in a good position. If we continue to only compete on price, like what we've seen in the past, then of course that's a benefit for the Chinese and the Indian manufacturers.

With regard to the other question, AJOVY Autoinjector, I think I'll refer that to Brendan.

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

A

Yeah. Thank you, Kåre. So, we just launched the AJOVY Autoinjector here at the end of April. So we're in the middle of that launch right now, but I think you can expect from an overall payer perspective that you won't see a decline in the gross to net. So on a per-unit basis it should be, prefilled syringe will look very much like the autoinjector. And of course, we've continued to see our overall percentage of paid prescriptions to increase. I think we're up into the high 70s now, so there won't be any dramatic impact. We continue to get increased payer coverage. We had a couple new formulary wins happen just recently. Part of that's being fueled by autoinjector.

The only thing that I think you might see is of course is as we gain new patients on the autoinjector that haven't been on a CGRP d4, they have to go through the prior authorization process. So there is, there will be some coupon cards out there for those individuals, which could have a slight impact on the total gross to net, but the number of paying patients increases. And of course the net revenue, you will continue to see that increase as well.

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

A

Thank you for the question.

Ami Fadia
Analyst, SVB Leerink LLC

Q

Thank you.

Operator: Thank you. The next question comes from the line from Elliot Wilbur. Your line is now open.

Elliot Wilbur
Analyst, Raymond James & Associates, Inc.

Q

Thanks. Good morning. Good afternoon. Just sticking with a CGRP-themed question for Kåre and for Brendan as well. Maybe just some initial color commentary on how the introduction of the orals has impacted this space. Seems to be largely a market expansive dynamic at this point, but just wanted to see if you would agree with that observation.

And then more specifically, I know it's still relatively early here, but there was a recent labeling change to one of the products in the category, Aimovig, with the addition of a hypertension warning that does not seem to be insignificant. Just wondering if you guys have had a chance to assess that and how you think that may impact market dynamics. Thanks.

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

A

So thanks for the question. I'll comment briefly and then Brendan can also chip in. So in terms of the orals, we don't really see any impact in the overall market. We have to remember that it's really two different, say, treatment modalities. One is preventive therapy, in our case with an injection every third month or every month, which you really take to reduce the number of migraine attacks. And on average, you get a reduction of 50%, in some cases up to 90%, 100%. So it's a really, really beneficial therapy for anybody who suffers from migraine to the extent of chronic migraine, four days or more a month.

The oral products are acute in connection with the attack. So you could say it's really two different situations. And I think that everybody who suffers from migraine to the level of four days or more, they definitely want to avoid the attacks if they can, no matter how they can treat them. So it's probably more of a competitive situation for the different acute therapies that these products might gain some share there, but it doesn't seem to impact the overall preventive market.

And on the labeling, I have not heard anything about this issue with regard to AJOVY, but I'll just hand it over to Brendan to hear what comments you have Brendan.

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

A

Yeah, thank you, Kåre. So I'll talk about the orals first. So I agree, Kåre, with obviously with what you said. I think that it is somewhat two different markets. If you think about a migraine or if you know migraine patients, depending upon the severity of the migraine, I think that these could be potentially additive products and your

assumption that this is probably going to create market expansion, I think is correct. We'll see. It's still early days. But of course, one's more acute and the other is more prevention. So, like I said, we'll see how that goes.

In regards to Aimovig's labeling change, of course if you think about AJOVY, our most prevalent side effect is a report in our label is injection site reaction which tends to be pretty mild and transient. So I think that that's good. And I think that overall, now with AJOVY in the marketplace, you know of course, we have the prefilled syringe which many physicians and patients wanted to make sure that that we would keep in the market with the launch of autoinjector, which we are going to continue to do.

So we have both of those offerings. We have a very good safety profile, a very good efficacy profile, and of course, the ability to offer quarterly dosing. So we do think that we have a very, very competitive offering in the marketplace. And we'll see what impact the label change with Aimovig has.

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

A

Thanks for the question.

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

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

Q

Hi, good morning. Hope you're all keeping safe. Congratulations on the very nice first quarter results. Wanted to ask you, Kåre, about the proposal to move some of the market onshore. I know you've broadly commented about where your network is. There's now an offer or proposal being formed that will push a lot of the manufacturing including API onshore in the United States. And some of your peers came out basically arguing that this should not be done that way, should be done through a network of international markets, it would be very costly. But it seems that there's, at least in Congress, a lot of effort to try to move that. Where does Teva stand on this? Are you in favor of shifting manufacturing of API and [indiscernible] (54:25) the United States, at least from the required medicine or should we rely on network-friendly countries to do so?

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

A

So thanks for that question, Ronny. What you are asking is really a political question and of course, I'm not a politician. I'm just a pharmaceutical executive who manufacture products.

So it's quite clear that the international globalization and competition has led to different parts of the value chain being in different countries. So you could say, the raw materials very much in India, in China, API very much in China, India, some of it in Eastern Europe in Europe. And research very much in the US, for instance, innovative new medicines very much being developed in the United States and Europe in different countries. So the pharmaceutical business is a globalized value chain.

Now, to the extent that politicians want to secure certain elements of certain manufacturing in their country, that's really a political choice where you weigh economic benefits up against benefits of security of supply, and so on. And I don't have a firm position on what the politicians should do. But I can tell you that it's impossible to move manufacturing back to the US unless the politicians takes some firm political action, because the competitive drivers of cost and you know, the price competition in generics has led to the current situation, the approval by

FDA of thousands of ANDAs for Chinese and Indian companies, the approval of hundreds of factories by FDA has led to the manufacturing moving out of the United States.

If you want to change that, you will either have to toughen up on GMPs, on environmental standards, or simply decide that this is a security issue in line with procurement of weapons and telecommunications and so on. So it's really not for me to decide. It is a political decision. Thanks for the question.

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

Q

Thank you.

Operator: Thank you. Ladies and gentlemen, we will now take our last question, and this comes from the line from David Risinger. Your line is now open.

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

Q

Yes, thanks very much. So I just wanted to start by saying, Kevin, if it's okay with you, I'd like to consider hiring the call operator given her effective call management to come and work in my household to manage our kids screen time?

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

A

Understood.

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

Q

Anyway, so my question actually is just on the IQVIA trend. So what we've seen in the IQVIA gross dollar figures recently is pretty high rate of decline year over year in terms of year over year trends. Could you just comment on whether we should be looking at those at all, whether those trends are consistent with how you see the business trending in the US year over year in sort of the current quarter and any implications for how we should think about forecasting the business as we're updating our models. Thank you.

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

A

So, thanks for that question, David. And you're right, the efficient operator made sure you got the question in, otherwise I guess it would have been skipped. But just please clarify what IQVIA trend are you thinking about, the volume or specific products or what is it you're thinking about?

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

Q

Sorry, yes. So the IQVIA trend that I'm talking about is the gross sales dollars trend, which was declining about 40% year over year recently according to IQVIA for US generics for Teva.

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

A

So, I would say that it's very difficult for us on a quarterly basis to reconcile the IQVIA gross numbers with our actual numbers. And so I think the best way you can look at it is to look at our reported generic sales in North America. And I think I've stated now for two years in a row, eight quarters in a row, that we have a run rate of roughly $1 billion a quarter on North American generics. I don't see any change to that. So, how these fluctuations in the IQVIA numbers, I don't really know, but it could be that there's something about the gross numbers and the gross to net and so on.

As you know, there's very, very high rebating rates in generics. So there might be some kind of disconnect there. And there might also be a disconnect on what gets reported, what volumes actually gets picked up by IQVIA. So I can just confirm that we are still seeing the North American generic business the same way with a run rate of around $1 billion a quarter plus or minus, and there's really no change in that. But I agree with you, it's difficult to reconcile the IQVIA numbers with our actual numbers.

Kåre Schultz

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

So with that, I would like to thank everybody who listened in and wish you a nice and safe day. Thank you.

Operator: Thank you. Ladies and gentlemen, that does conclude our conference for today. To listen to the replay of this conference, please dial 00443333009785 and enter the conference ID 9735219. Thank you for participating. You may now all disconnect.