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Teva Pharmaceutical Industries Ltd.

(TEVA)

Q4 2021 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good day, and thank you for standing by, and welcome to the Teva Fourth Quarter and Full Year 2021 Financial Results Conference Call. At this time, all participants are in a listen-only mode. After the speaker presentation, there will be a question-and-answer session. [Operator Instructions] Please be advised that today's conference is being recorded. [Operator Instructions]

I would now like to hand the conference over to your speaker today, Ran Meir, Senior Vice President, Head of Investor Relations. Please go ahead, sir.

Ran Meir

Senior Vice President-Investor Relations & Corporate Communications, Teva Pharmaceutical Industries Ltd.

Thank you, Annette. Thank you, everyone, for joining us today to discuss Teva's fourth quarter and full year 2021 financial results. We hope you've had an opportunity to review our earnings press release, which was issued earlier this morning. A copy of this press release as well as a copy of the slides being presented on this call can be found on our website at tevapharm.com.

Please review our forward-looking statements on slide number two. Additional information regarding these statements and our non-GAAP financial measures is available on our earnings release and in our SEC forms, 10-K and 10-Q.

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To begin today's call, Kåre Schultz, Teva's CEO, will provide an overview of the 2021 performance, recent events and priorities going forward. Our CFO, Eli Kalif, will follow up by reviewing the fourth quarter financial results in more detail, before providing an overview of Teva's 2022 financial outlook. Joining Kåre and Eli on the call today is Sven Dethlefs, Teva's Head of North America Commercial, who will be available during the question-and-answer session that will follow the presentation. Please note that today's call will run approximately one hour.

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

Kåre Schultz

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

Thank you very much, Ran, and welcome, everybody, and thank you for your interest in our company. I'll start by commenting on the 2021 highlights. We came in with revenues at $15.9 billion. We did see some headwinds compared to our initial guidance, basically coming from COVID that resulted in less volumes in general in the marketplace of generics and OTC both in Europe and US.

And we also had a bit of headwind from the fact that the US doctors didn't see as many patients as normally. So, we saw a slightly slower penetration of some of our products than we predicted from beginning of the year. But all in all, we are happy with the $15.9 billion that we ended up with as revenues.

The adjusted EBITDA came in at $ 4.9 billion, which is very much within the guidance. GAAP diluted EPS came in at $0.38 and non-GAAP diluted EPS came in at $2.58, came in the middle of our guidance. Free cash flow at $2.2 billion, also within our guidance and the debt reduction continues. And the net debt is now reduced down to $20.9 billion. So, it won't be long before we get below $20 billion, which [ph] we guided (00:03:15).

If we look at the business highlights, of course, we had to handle the COVID-19 pandemic, which continued. We were hoping at the beginning of the year that it would be over. But as we all know, it wasn't, it continued. And we did see, of course, a lot of challenges, which we overcame operationally. So, our whole operations worked out really, really well. I'd like to thank all our employees for a fantastic job all throughout the years.

Then we did do a refinancing, which I'll comment on. We saw nice growth of AUSTEDO, nice growth of AJOVY, and we are excited about launching Risperidone LAI later this year, and I'll comment on all of those in the following slides.

So, if we go to the next slide, please. The number one question I always get from analyst, investors is, of course, on the litigation side. And as you all know, we had legacy opioid litigation, dating back to somewhere between 2000, 2010. And there's a lot of this – more than 3,500 different cases are pending, so to speak.

Now, we've been making some progress recently. And if I start with the court decisions, then to be very brief about it, we had a court decision, which was a bench trial in Orange County, California, where it basically was stated that if you do everything correct and the prescriptions are correct, products are in compliance with FDA regulations and DAE regulations, then there's no basis for claiming public nuisance liability. So, that was a clear win for us.

Then J&J had a verdict in the Oklahoma Supreme Court, which was again a clear win, again, saying that cannot use public nuisance when you have products that are completely in compliance with all rules and regulations.

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And then there was a jury trial in New York, where we lost, and we were found to be liable, so was actually the State of New York as well. So, that was an interesting verdict. There's a mistrial motion pending due to arguments from the AG at the end of the trial, which were not correct.

So, if we then switch to the settlement front, then you all know we had a settlement in Louisiana some time ago, and now we've had a settlement in Texas. Both these settlements combine a cash compensation and providing products. In the case of Texas, it's generic Narcan spray. And that's a product you use when you have an overdose situation. So, we're very happy about this settlement. We think it's a good way forward. It makes sense for Texas to get some resources to take care of people suffering from substance abuse, and it makes sense to get a generic Narcan spray, which can help people in an overdose situation.

So, I'm always optimistic, as you know. So, I'm still optimistic that we can reach a nationwide settlement within the next 12 months. I've said that before. I'm still believing in that. And I think that the Texas settlement will be a good starting point for those ongoing discussions.

If we move to the next slide, and here, you can see our revenues throughout the year. And you will see that we had a bigger revenue in Q4 2020 than we had in Q4 2021. And the reason for that is really that we launched Truvada and Atripla – generic Truvada and Atripla back in Q4 2020. And we didn't have the similar big launch in Q4 2021. Other than that, you could say, it's really a very steady business. And you can see from the different components, Europe, international markets and so on that they are very steady and performing quite well.

If we go to the next slide, so in the US marketplace, we have two main growth drivers, and that's AUSTEDO and AJOVY. And let's look at AUSTEDO first. You can basically see that we continue to increase our script count per quarter, basically more and more people are getting on the therapy. And you can see that we also, on an average basis, continue to increase revenues quarter-by-quarter. It's a little up and down. As you can see, we have some swings here. And that's basically because you see some volatility sometimes with the wholesalers.

We did see some, what you call, spec buying in the fourth quarter. That's basically in anticipation of a price increase, which is traditionally taken at the beginning of the year, so early January. Wholesaler sometimes buy product, of course, to avoid the price increase, and we saw a bit of that. But underlying, there's a very strong correlation between the nice growth in the scripts and patients and the nice growth in revenue. And we expect revenue, of course, to continue to grow throughout this year.

Why can we expect that? Let's look at the next slide, basically, because AUSTEDO is indicated for Huntington's disease, chorea and Huntington's – so involuntary movements in Huntington's, but it's also indicated for tardive dyskinesia. And tardive dyskinesia are these significant involuntary movements that are socially debilitating, and that can really be a big problem for the patients suffering from it.

There is around 500,000 patients or persons in US suffering from tardive dyskinesia. It's under-diagnosed and it's undertreated. Our estimate is that less than 6% is treated as we speak. And of course, we are working to broaden that base, making sure that the benefit of the product will reach more patients. This will drive increased scripts, and will, of course, also drive increased revenues for AUSTEDO. So, we are also, like I said before, optimistic that we'll see increased patient numbers throughout the current year.

If we move to the next slide, then we are looking at AJOVY. As you know, AJOVY is preventive therapy for migraine. We are competing with two other products. We have the longest-acting product profile, which basically means that our product can be used both monthly and quarterly, which is, of course, a benefit that [indiscernible]

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(00:09:52) patients, and the long duration also means that you have a very steady clinical action profile. So, good efficacy on the product.

We continue to grow scripts in the US. As you can see, a lot of users in the US, and we continue also to grow our scripts in EU and also our market share. And here, you see that our market share, the last one we have for November, I believe, is now around 28%. And we have changed our ambition.

We started out with an ambition some years ago because we launched as number three of having more than 20% share, then we moved it to 25%. And now we have an ambition of at least having a third of the market both in US and Europe. We also just launched in Japan with our partner, Otsuka, and we are very happy about the performance of AJOVY and confident that the product will keep on increasing revenues in the current year.

If we take a look at our pipeline, then we have a lot of exciting products here. There's a very big biosimilar portfolio, which I'll comment on in just a moment. We have some exciting biopharmaceutical products in development. And then we have the Risperidone LAI, which has been filed with FDA, and where we're looking forward to getting an approval, hopefully, in the middle of this year. And let me just talk a little bit more in detail about Risperidone LAI.

If we move to the next slide, then Risperidone LAI is for patients with schizophrenia. It's an antipsychotic. And in the Phase 3 trial, it showed phenomenal efficacy. So, you see here the risk of relapse was reduced by up to 80% versus placebo. So, that's one of the best results you can find for long-acting antipsychotics. So, it's a really, really efficacious product.

And it's also the easiest product to use. And what do I mean by that? Well, many of the long-acting antipsychotics have, what you call, intramuscular injection, which means you have a relatively long needle and you need to make a depot in the muscle tissue. That is relatively painful and complicated. So, the administration of the products is not that easy.

This product, you inject subcutaneous with a very small short needle and it's a low volume of injection, and you can inject in different places. So, it's basically an easy way to get your therapy that is efficacious, if not more efficacious than anything else.

So, we expect to see a very good launch of this product once we get approval, and we are very much looking forward to this and bringing the benefits to the patients suffering from schizophrenia, who needs stable therapy in order to avoid relapses, which can really hurt their cognitive function capability.

So, let's go to the next slide, where I'll give you just a little heads up on our biosimilar portfolio. So, we have 13 biosimilars in development, about half of them are in-house programs, half of them are programs that we have in-licensed. It's a very strong portfolio.

Roughly, we are addressing some 80% of the value that goes off patent in the coming years. And we believe we can grab a good share of that value. Of course, there are other competitors, but if you look at TRUXIMA, which was the biosimilar, or which is the biosimilar of Rituxan, our biosimilar. And right now, we have 28% volume market share, which we think is very good. And it's a nice product for us.

It has shown stability in the marketplace also on the pricing. So, we're very optimistic about the commercial potential of our biosimilar portfolio. And it will, of course, also add increased access for populations around the world, just like generic products does, so does biosimilar products, ensure access to important medicines

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worldwide. Also in Europe, we are launching products now, and we'll have a Lucentis biosimilar that we launch during this year.

Now, we've also always been focused on our gross margin and operating margin. And I won't go into all the details here, but what I will tell you is it's not a coincidence when you see our margins improving. It's a lot of work by thousands of people in our organization, in our manufacturing organization, in our procurement organization, basically optimizing all the classical elements of manufacturing. And you see some of the headlines here, procurement, network, operational excellence, end-to-end supply chain, agile operations.

So, these are all the classical things. And if you're interested in manufacturing optimization, you can rest assured that we're doing all the things that you can do. It takes time. It's not something that happens overnight, but we are well underway, and we have hundreds of specific projects that will contribute to a continuation of margin expansion over the coming years.

Now, one of the very simple ways to explain this is to look at the number of sites. So, if you take the next slide, here, we're showing you how we have been integrating the company since I joined in 2017. You have to remember that Teva as a company is created by more than 20 acquisitions over more than 20 years. And that leaves a very complex footprint of offices, of manufacturing sites, of R&D sites. But it also leaves a lot of capabilities.

So, the trick here is to keep all your capabilities, keep all your operational strength, but consolidate your sites so that you get more efficient, bigger sites, fewer sites. And here, you can see over the last five years, how we've gone from 80 manufacturing sites down to around 50. And we have plans to continue this. Over the next couple of years, we will be divesting or decommissioning probably around another 10 sites. So, this evolution will continue. The same thing will, of course, happen for our office sites and our R&D sites. So, continued optimization, more to come in the coming years.

Now, if we take an – look at an example here, our European business, then you will notice here that the operating margin is improving. Now, the operating margin basically improves for two reasons. One is the gross margin improvements that I just talked about. But the other one is, as you consolidate your commercial offices, as you consolidate your commercial operation and optimize that, and of course, also, you could say, your commercial cost, as a percent of sales, also comes down.

And those two factors have been driving up the operating margin in Europe. You can see here from 25% to 31%, a very, very nice and strong development. And again, something that we'll continue to improve, mainly now with the contribution from the gross margin as we're getting closer to having optimized the commercial footprint in both Europe, US, and international markets.

But I've talked a lot about margins, let's just take a look at the operating margin here. You can see here how we had a bad run down from 28.8% (sic) [27.8%] (00:17:27) in 2017, down to 24.5% in 2019. That is really driven by a significant drop in COPAXONE revenues as a consequence of the patent expiry on COPAXONE.

Now, COPAXONE is now down. As you know, this year, it will be less than $1 billion in revenue. So, it's not a major factor in our market anymore. And we've been working hard to improve the gross margin, as I told you, and the operating margin. And we set a target five years ago – or actually four years ago, but for the end of 2023, then it will be a five-year target from 2018 to 2023 and that target is 28%. And as you can see, we are very well on our way to hit that.

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And I've always said that we won't bring out new targets until we hit our target, but it might just be that we get so close that in the later part of this year, we will actually share with you future targets so that you don't get the wrong impression that we will be stopping at 28%. We will continue to drive up operating margin since that's a key element of our strategy.

And why is it so important? Well, the next slide tells you something about why it's important. It's because we have starting point with too much debt. So, we need to drive down the debt. And the only way to drive down the debt is to generate cash flow and allocate the cash to reducing debt. And the way to generate the cash flow is, of course, to have a higher operating margin. So, therefore, the whole thing, of course, fits together.

And you see here how we've been taking down debt since 2017, with some roughly $13 billion. In the same period, we have, of course, been paying interest rates, about $1 billion a year. So, you could say that we have paid $17 billion to the bondholders over the last years. This will continue in the coming years.

And then, of course, you can all calculate that there will be a nice time when we don't need to allocate all our excess liquidity and cash to bondholders, but we can, at some point in time in the coming years, start allocating cash to the shareholders, which will, of course, be a big [ph] pressure (00:19:41) to reach that point.

Now, on the way to that, we, of course, need to manage our debt and our – what we call, the debt stacks. That's really how much debt you need to repay every year, you need to have a good balance between your operational cash flow and the debt you are paying back every year.

And last year, we did a successful refinancing of $5 billion. So, basically, we borrowed $5 billion by selling bonds, and we repaid debt by $5 billion by taking out existing bonds from the market, all with the purpose of getting a more flat repayment profile so that we are repaying for the next three years, what matches our operating cash flow, and that means that liquidity-wise there's a good balance between the liquidity we generate and repaying the bonds over the next three years.

Now, we did this in a new fashion. We issued what's called sustainability-linked bonds. And that's a new thing, which makes a lot of sense for us. Because you know we are the world's leading generic pharma company. And what do we do? Well, we really supply medicines to hundreds of millions of people in high quality, so they can take care of their health issues. How can we do things better for the world? Well, basically by supplying more high-quality medicines at a low cost to societies all over the world.

And if you look at the sort of targets we set up for these sustainability-linked bonds, and the first target is a classical climate change target. So, it's a reduction in greenhouse gases by 2025, and we are well on our way to do that. And actually, it's funny because the reduction in greenhouse gases goes hand-in-hand with improvement of the gross margin, because the best way to improve your climate footprint is to use less resources. So, the more efficient you manufacture, the less resources you use in manufacturing, the less burden you are to the environment, and the better is your gross margin. So, the financial targets go hand-in-hand with the environmental targets.

On access, this is a thing we can do better than probably anybody else. We can manufacture the medicines that are on WHO's Essential Medicines List, really what society need to have a basic healthcare system. We can ensure that these medicines get regulatory approval in low and middle-income countries. And then, we can ensure that actual volumes of the medicines are brought to the patients in these countries, all helping the healthcare systems. So, that's what we're committed to doing, and that's what we will be doing in the coming years and reporting on, of course, so that everybody can see that we meet the targets of these new bonds.

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Now, I talked about the debt maturity profile. Just a quick look here of what we did. So, we took out, you could say, bonds maturities in 2022, 2023, 2024, and we pushed it into 2027, 2028 – sorry, 2027, 2029 and 2030. And you can see basically taking the next three years down to around the $2 billion mark.

And you can also see here that we will need to do one last refinancing before we get to 2025, 2026 and 2027, probably of around $3 billion to $4 billion. Again, taking those debt stacks to a level of around $2 billion by pushing something into 2031, 2032 and so on. And that will be the last time we need to do that, then we'll have balance for the rest of the time between the debt repayments, the maturities and our operating cash flow.

Now, that takes me to my last slide, which is a nice, boring, good slide, which has been there since 2018. It just tells you that we are sticking to our long-term financial targets. Operating income margin, I talked about it already, 28%, cash to earnings above 80% to secure we have the cash for the debt repayments. And net debt, of course, coming below 3 times EBITDA by the end of 2023.

And all this is, of course, predicated upon what you see here that we are committed to utilizing our cash to pay down debt, and we don't plan to raise any equity. We think our patient equity holders deserve to see the opioid litigation go away and the debt come down and get the full value benefit of that when that happens eventually.

And with that, I'll hand over to our CFO, Eli Kalif.

Eli Kalif

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

Thank you, Kåre, and good morning and afternoon to everyone. I'll begin my review of our 2021 financial results with my main focus being on the fourth quarter performance. This will be followed by the introduction of our 2022 non-GAAP guidance and some of the important assumptions behind it. While most of the discussions around 2022 guidance will come at the end of my presentation, in a few spots along the way, I will touch upon our expectations regarding forward-looking trends to assist you with your modeling.

Beginning on slide 23, I would like to start with our Q4 GAAP performance. Revenue in the fourth quarter of 2021 were $4.1 billion, a decrease of 8% in both US dollars and local currency terms compared to the fourth quarter of 2020. This decrease was mainly due to a lower revenue from generics products in North America and COPAXONE, partially offset by higher revenues from AUSTEDO and AJOVY.

As Kåre mentioned earlier, our revenue continues to be affected by the ongoing impact of the COVID-19 pandemic on markets and on customer stocking and purchasing patterns. For the sake of year-over-year comparison, I would like to note that Q4 2020 included generic product sales in Japan, totaling $73 million and approximately $240 million for the full year of 2020.

As we have previously communicated, these products were divested as of February 1, 2021, along with a manufacturing site in Japan. As we have discussed in the past, the decrease we are seeing in our revenues from generic products in North America was mainly driven by the fewer generic product launches in 2021 compared to 2020.

Foreign exchange rate movements during the fourth quarter of 2021, net of hedging effects negatively impacted revenues by $19 million compared to the fourth quarter of 2020. GAAP operating income was $78 million in Q4 2021 compared to $406 million in Q4 2020. We had a net loss of $159 million in Q4 2021 compared to the net income of $150 million in Q4 2020.

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Turning to slide 24, you can see that the non-GAAP adjustment in the fourth quarter of 2021 were $1,012 million, with approximately $630 million Q4 2020. Non-GAAP net income and non-GAAP earnings per share for the fourth quarter of 2021 were adjusted to exclude these items.

In Q4 2021, the liability related to the opioid litigation was increased by approximately $600 million. Additional notable non-GAAP adjustments include amortization of purchased intangible assets, totaling $188 million, the majority of which is included in cost of goods sold, and impairment of long-lived assets totaling $183 million.

Moving to slide 25 for a review of our non-GAAP performance, I have already discussed our fourth quarter revenues, which totaled approximately $4.1 billion. Annual revenues were $15.9 billion, a decline of 5% compared to 2020.

Now, let's move down the P&L and look on the margins. Year-over-year, total non-GAAP gross profit margin improved to 54.2% compared to 52.4% in 2020. Our Q4 2021 non-GAAP gross profit margin improved to 56.1% compared to 52.3% in Q4 2020. The increase in non-GAAP gross profit margin, both for the quarter and the year-to-date was mainly driven by improved profitability from the change in our generic product portfolio mix, mainly in our North America segment, higher sales of AUSTEDO and AJOVY, as well as higher profitability in Europe and international markets, partially offset by lower revenue from COPAXONE due to generic competition. The increase in our non-GAAP gross profit margin was also driven by improved profitability due to our ongoing efforts to optimize our cost of goods sold.

Our non-GAAP operating margin was 30.4% versus 25.6% in Q4 2020. This increase was driven mainly by higher gross profit margin mentioned above. 2021 non-GAAP operating margin was 27.7% versus 26.3% in 2020.

Our non-GAAP financial expenses in 2021 were mainly comprised from interest expenses, were $930 million. Looking ahead to 2022, following our recent refinancing, we expect our finance expenses to increase marginally to an annual run rate of approximately $1 billion.

We ended the quarter with a non-GAAP earnings per share of $0.77 compared to $0.68 in Q4 2020, mostly due to a lower spend base.

Turning to slide 26, we see that our quarterly spend base declined by approximately 14%. Looking at the year-to-date comparison, our spend base declined $794 million or $971 million net of FX. Most of the annual decrease was due to a lower cost of goods sold, partially related to a lower annual sales, as well as our ongoing efforts to transform our global operational network.

Lower operating expenses also contributed to the decline in our spend base, mainly due to the ongoing active management of such expenses. Looking ahead to 2022, we expect the overall spend base to remain below $12 billion as we continue to focus on our efforts on reducing our cost of goods sold through procurement cost of excellence, network optimization and restructuring, operational quality excellence, end-to-end supply chain integration and an agile operating model and organization. This ongoing effort will lead to stabilizing the operating margin above the level of 27% in 2022, with the ultimate goal being 28% operating margin by end of 2023.

Turning to free cash flow on slide 27, our free cash flow in the fourth quarter of 2021 was $716 million, extending the sequential rebound we saw in Q2 and Q3 versus Q1. The full year 2021 free cash flow was $2.2 billion compared to $2.1 billion in 2020. The increase in 2021 resulted mainly from higher cash generated from

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divestitures and – of businesses and other assets, partially offset by lower profit in North America segment during 2021.

Turning to slide 28, our cash to earnings for full year 2021 was 77% versus 75% for full year 2020. The increase was mainly driven by higher free cash flow, partially offset by higher net income.

Turning to slide 29, as Kåre showed before, our debt continued to decrease. Our net debt at the end of Q4 2021 was $20.9 billion compared to $23.7 billion at the end of 2020. The decrease in the gross debt was mainly due to the debt repayments as well as exchange rates fluctuations. The increase in our net debt was mainly due to our free cash flow generation during the year. Upcoming maturities include $1.4 billion in 2020.

Our net debt to EBITDA continued to decline, coming in at 4.25 times for Q4 2021 as we continue to make progress towards our 2023 target to be under 3 times by the end of that year.

We are very pleased with the successful refinancing that took place in November 2021. We completed $5 billion [indiscernible] (00:32:32) bond offering and $4 billion tender offer. As part of our SLB offering, we have set ambitious KPIs to measure our contribution to social and environmental measures. Our intention is to establish a direct link between our corporate responsibility commitments and our funding strategy. This was a debt-neutral transaction that Teva has been very clear and consistent with its long-term financial strategy, which includes the commitment to continue deleveraging.

As Kåre explained earlier, looking ahead, we are pleased with our maturity profile for 2022, 2023 and 2024 as it's aligned with our liquidity strategy and help us focus on our long-term financial targets.

Now, let's turn our attention to our 2022 non-GAAP outlook, which we are introducing for the first time today. Here on slide 30, you will find the five main components of our outlook; revenues, operating income, EBITDA, earnings per share and free cash flow as well as additional components, including expected revenue range for key products.

Our company worked hard through 2021, navigating the ongoing impact of the pandemic. While we cannot predict the exact magnitude of COVID-19 in [ph] 2029 (00:33:52), we expected to continue to face somewhat volatile environment with regard to the purchasing pattern of our larger global customers, overall utilization by patients, generic product launches and foreign exchange rates.

With this in mind, we begin 2022 total revenue, which we expected to be between $15.6 billion and $16.2 billion. This reduction in revenue guidance compared to 2021 includes the impact of foreign exchange, and specifically the impact of the stronger US dollar on our results, since approximately 50% of our revenue came from sales denominated in a non-US dollar currency.

We have factored into our guidance the continued erosion of global COPAXONE revenue, which we expect to decline during 2022 by approximately $150 million to approximately $850 million. The majority of the decline is expected in the US.

The expected ongoing growth of AUSTEDO and AJOVY should be greater than the offsetting effect by the decline in COPAXONE sales. We expect continued momentum of AUSTEDO, with a total annual revenue to grow to approximately $1 billion in 2022. Furthermore, AJOVY is expected to benefit from continued patient growth in the US, Europe and international markets. Global sales of AJOVY are expected to be approximately $400 million in 2022.

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With a modest decline expected in our spend base, our non-GAAP operating income is expected to be between $4.2 billion to $4.5 billion, and our non-GAAP EBITDA is expected to be between $4.7 billion to $5 billion. Using a share count of approximately 1.1 billion shares, we expected earnings per share to be in the range of $2.40 to $2.60.

As you know, we do not provide quarterly guidance, but I thought it will be helpful to share with you how we are thinking about the progression of both sales and earnings throughout the year. Based on our expectation today, we expect that the first quarter will be the lowest of the four quarters for sales and earnings, with a gradual pick-up in the second quarter. Overall, we expect that approximately 45% of our 2022 revenue to be generated in the first half of the year and approximately 55% in the second half. I hope this color will assist you with your modeling.

2022 free cash flow is expected to be in the range of $1.9 billion to $2.2 billion. Similar to 2021, we expect about one-third of the annual free cash flow to be generated in the first half of 2022 and two-thirds to be generated in the second half of 2022.

Lastly, looking at tax, in 2021, our non-GAAP tax was 16.4%, which was below the 17% to 18% range we originally guided to. As we look ahead to 2022, we expected our tax rate to be in the range of 18% to 19%. This increase is mainly driven by the mix of products year-over-year, as well as other items, which carries higher than average tax rate.

This concludes my review of Teva results for the fourth quarter and fiscal year 2021. We will now open the call for questions and answers.

Operator, would you please open the call for questions?

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QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] To allow everyone opportunity to ask a question, please limit yourself to one question per person with a minimum of one follow-up question. And the first question comes from the line of Umer Raffat from Evercore. Please ask your question. Your line is now open.

Umer Raffat

Analyst, Evercore Group LLC

Q

Hi, guys. Thanks so much for taking my questions. I guess, I'm a little confused about the AUSTEDO number reported. It's up 4% in volume quarter-over-quarter, but sales are up 40%. And it looks like the dollars per Rx are up almost 35% versus Q3. Is there something unique that happened as it relates to inventory and/or a favorable gross to net change or reconciliation? That would be very helpful.

Also, perhaps on opioid theme, I noticed the headline you put out to Texas is $225 million, which is really interesting because J&J's headline for the global settlement to Texas was $290 million, meaning you're not so far off versus the headline J&J was able to successfully negotiate.

So, if you're really tracking as close as you are to the headline numbers versus J&J, presumably, that should form the basis for a lot more interest nationwide, especially considering your financial status, and they probably appreciate it. So, why aren't we seeing more traction on a potential nationwide settlement?

And just finally, just a quick one, I noticed fibromyalgia for CGRP, did that trial not work, because I know it wasn't even fully recruited yet?

Kåre Schultz

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

A

Thank you, Umer, for those three questions. I'll start from the last one and – take the two last ones, and then I'll let Sven answer the one about AUSTEDO. So, on fibromyalgia, it's correct that we have had a, what we call it, a futility analysis done. And the conclusion of that by the experts who looked into it was that it would be futile to continue the trial. So, we will not be continuing looking into fibromyalgia. So, that's absolutely correctly observed.

On the opioid piece, you could say that we are still optimistic, as I said, that we can reach a nationwide settlement in the coming 12 months. We have been, of course, in constant dialogue over the last couple of years. And you, of course, remember the initial framework, which was less cash and more product, was $250 million nationwide in cash and $23 billion in product. And then we didn't really fly. And I think it's fair to say the reason why I didn't really fly was mainly because the plaintiff lawyers, they basically did not see any fees coming in from the product part, and that means that it was not attractive to them.

Whereas the new balance we have in Texas, where you could say we have a third in products, $75 million of Narcan – generic Narcan spray, which is a very good thing for treatment of opioid overdoses. And then the other two-thirds, $150 million in cash over a period of years. I think that's a more appealing set-up.

So, I would agree with you that based on us doing this, there's probably now a higher probability that we can reach a nationwide settlement. And I will then pass on to Sven on answering the AUSTEDO question.

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Sven Dethlefs

Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

A

Yeah. Thanks, Kåre. So, Umer, in the second half of 2021, we had a 63% higher script count for AUSTEDO than in the first half of 2021. So, we had a very good trajectory. Actually, December was our strongest month in the year, and it also saw the strongest step-up.

So, in context of that, we also know that the Q4 quarter is always the strongest one for AUSTEDO. We have spec buying by the wholesalers, as Kåre alluded to earlier, due to the price increase that we took for January 2022. And that was one factor. The second one, as I explained, was the script count, and we saw a slight improvement in daily dose per patient, which also contributed to a strong quarter four in last year. Thank you.

Operator: Thank you. And the next question comes from the line of Ronny Gal from Bernstein. Please ask your question. Your line is now open.

Ronny Gal

Analyst, Sanford C. Bernstein & Co. LLC

Q

Good morning, everybody. Thank you for taking my questions. If you don't mind, quick three ones. One, Risperidone LAI, do you own this royalty-free or is there some stream that comes out of that?

Second, can you give us a feel for the biosimilar margins in your partnerships, given those are becoming a bigger product? Is this dilutive or accretive to your gross margin?

And third, can you talk a little bit about your sensitivity to interest rates? Essentially, there's a 1% increase in interest rates in 2022. How much will that impact your earnings if we think about 2023 and beyond just to give us a feel for the sensitivity there? Thank you.

Kåre Schultz

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

A

Thank you very much, Ronny. I think I need you just to repeat the first question about Risperidone LAI. What is the specific question?

Ronny Gal

Analyst, Sanford C. Bernstein & Co. LLC

Q

Do you own royalty on this or do you own it royalty-free?

Kåre Schultz

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

A

Okay. So, this product is developed by us based on in-license technology from MedinCell. They have a prolongation technology that we're using for this product. And we also have olanzapine LAI in development using the same technology. And we are paying a small royalty on the product. It's not dilutive to our margins when we launch Risperidone LAI, the product, we expect the overall margin of Risperidone LAI to be good and healthy.

So, we are very optimistic about the fact that we can grab a reasonable volume share and also market share in value of the long-acting segment, simply by offering a more convenient and better dosing with unbeaten efficacy. So, I guess that covers the first two questions because that was also the question about the margin. And please correct me if I'm wrong there, Ronny. Then on the interest...

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

Q

Yeah. The second question was around the biosimilar partnership margins.

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

A

Okay, okay.

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

Q

Is this accretive or dilutive to your gross margin? Yeah.

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

A

So, no, they're not. It's basically so that, I'd say, biosimilars, of course, have higher development costs. But the – once you get into the actual market, even with a split with a partner, it's a margin that can compete with traditional generics. So, it's not diluting. It's, of course, not the same margin as a specialty patented product such as COPAXONE, for instance. But if you look at our overall margins, then our biosimilar in-licensed products can match the overall margins we have.

Then the last question on the interest rate, first, I'll just note that all our debt is based on bonds that have been sold in the marketplace. So, they are not really in any way influenced by any moves in interest rates. So, the simple question is that all the $20 billion of debt we have, the interest rate is locked. So, there's no effect of interest rates going up and down over the coming years, which means we can predict our finance cost extremely precise.

The only swing factor is, in a way, the exchange rate between dollars and euros because some of the debt is in euros. And of course, there's a conversion there into dollars, which can affect both the size of the net debt, whether the euro goes up and down versus the dollar and also a little bit the size of the yearly interest rate payments. But other than that, it's very, very predictable due to the fact that it's all locked in, and we don't have any variable interest rate on any of our debt. Thank you for the questions.

Operator: Thank you. And the next question comes from the line of Elliot Wilbur from Raymond James. Please ask your question. Your line is now open.

Elliot Wilbur
Analyst, Raymond James Financial, Inc.

Q

Thanks. Good morning. Good afternoon. First question, perhaps for Eli, in light of a strong gross margin performance and the roughly 180-basis-point year-over-year improvement, could you just provide us with some color or insight into expected gross margin trends in 2022? Just trying to get a little bit better sense of the ongoing benefit from manufacturing rationalization versus the lighter top line outlook, and probably what is going to be a more favorable mix impact.

Then a follow-up question for Kåre on AUSTEDO trends, obviously, this is going to be the key growth driver within the branded segment for the next several years, the TD population remains very underpenetrated, under

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captured. I know you guys have initiated some patient activation efforts to capture more of that market, and we're starting to see some incremental gains there, but perhaps slower than expected.

The question really is if you look at external expectations, the market does not really see that product growing much over the next five to seven years. And you guys really haven't said anything about peak expectations for the product. So, if there's any color you can provide in terms of sort of where you think this product can be in five to seven years versus the roughly $1.3 billion that external estimates project? Thanks.

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

A

So, Eli, you first with the margin?

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

A

Yeah. Thanks, Elliot, for the question. So, just back a bit to the prepared remarks of Kåre, you saw how we're getting reduced mostly our manufacturing sites. And as Kåre mentioned, we still on top of the 50 that we're able to be that position, we have more planned around that one, which means that the core manufacturing cost is going to reduce as well in 2022.

So, when we are doing our kind of the modeling, we're not really heavily considering on getting a benefit on a mix of products, which means that in 2022, we're most likely going to talk between 50 to 100 additional basis points on our gross margin.

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

A

Thank you, Eli. Yeah, we keep on pushing and you should expect also longer term that we'll keep on pushing the gross margin up by classical consolidation, optimization, rationalization.

Now, on to AUSTEDO, five to seven years out, as you probably know, I never get peak sales on any product because there are so many assumptions. People always forget the assumptions and just think about the number. But I'd love to discuss what we think will happen with AUSTEDO over the coming years.

And we think that AUSTEDO will keep on growing nicely, basically due to the clinical benefits of the product and the large unmet medical need that you alluded to yourself that I also showed on a slide.

If you want to think about it conceptually, then we will probably get more patients. And there's also a chance we'll keep them longer and they will be titrated faster. So, we will see growth, which this year, we are estimating that it will be growing $200 million. I don't see any reason why that absolute growth should slow down over the coming years. And then you can do your own math and see what peak sales you get to five to seven years out. But I do agree with you that that number is higher than $1.3 billion for sure.

But maybe Sven, you can just comment on what are we seeing in terms of the plans to optimize both titration and product presentation and so on, on AUSTEDO?

Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

A

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Yes. I think we – I see there three sources for growth for us. One is, of course, the patient number. We need to activate more patients and improve the diagnosis rate for tardive dyskinesia with our physician group. That's number one. That's what we're already doing with our field force and with our recently launched TV campaign.

The second element for growth for us is working better with the patients to reach an optimal titration so dose per day level because that's directly correlated with the clinical benefits of this drug. And there, we see – when you look at the current treatment rates and where the long-term data for this product stands, there's still an ability to optimize the treatment rate.

And the third element is something that we learned, of course, also with our COPAXONE franchise is [ph] adherence (00:50:44) here is a key element for a chronic disease, especially for this patient population. And that's, I think, the third element for growth for us.

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

Thank you, Sven. Thank you for the questions.

Operator: Thank you. And the next question comes from the line of Navann Ty from Citi. Please ask your question. Your line is now open.

Navann Ty
Analyst, Citigroup Global Markets Ltd.
Q

Hi, good morning. What are your COVID assumptions behind the 2022 guidance? So, do you assume a lingering impact on the generics business?

And then my second question is on costs. So, the midpoint 2022 EBITDA margin will be slightly lower. So, can you comment on your SG&A and R&D assumptions for 2022?

And then just a quick one on opioids, the Texas settlement, was it in line with your expectation? Was it driven by, say, by market share in the state, especially if we compare versus your peer Endo? Thank you.

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

Thank you for those three questions. I will handle the first and the last, and then Eli will comment on the SG&A piece. So, our assumptions for COVID this year is a relatively optimistic assumption, you could say, in the sense, but also cautious on the guidance range that, you would say, the lower end of the guidance will only happen if we see a continued negative effect from COVID.

And we are optimistic that we are seeing now openings in – of society in US, in Europe and in general, a high level of economic activity. And we see prescription levels in Europe getting close to what they were in 2019, still a little bit below, but we're optimistic that we will get back to the 2019 level and above in terms of the total volumes in the marketplace, not specifically for us, but just in general. So, that is really our assumption.

But you will see also that we have, like Eli alluded to, we have widened the range on our revenues, because there is, of course, the risk that we will see some kind of continued new lockdowns or whatever. And we have to be able to manage that within our guidance if that happens. So, that's on the COVID piece.

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Then I'll handle the opioid piece. The way you should think about it when we think about the possibilities of a nationwide settlement is really we are thinking along the lines of the way it was done by J&J and the three big distributors. And that is really a formula where you say that it's mainly population-based, but it's skewed a little bit so that the smaller population states get a slightly higher percentage than the straight out population calculation.

What does that mean? It basically means that, if you do a straight out population calculation, then you would say that with the population in Texas, a nationwide settlement would be 12 times the Texas settlement. If you do the percentage that went into the nationwide settlements of J&J, then you would roughly have to multiply by 16.

But it's really population based. It's not related to anything specific about individual products or anything like that. That's the principle that we expect. If we are successful with a nationwide settlement, that's the principle that we expect will be used there. And then the last question about SG&A. Eli?

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

Yeah. So, thanks, Navann, for your question. You asked both on R&D and SG&A. So, I think that overall, if you look on the first half of 2021 versus the first – the second half of 2021, it's more or less the same in terms of dollars. There are some variable elements in between Q4 that we're able actually to manage in terms of priorities. Overall, our OpEx went down to 26.5%, same for the R&D. It's all about [indiscernible] (00:54:51) of projects, so nothing there in specific.

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

Thank you for the questions.

Operator: Thank you. And the next question comes from the line of Chris Schott from JPMorgan. Please ask your question. Your line is now open.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Great. Thanks so much. Just two for me. First, I just wanted to confirm, I think you mentioned that the first half sales would be 45% of total for the year. I think it's a bit more skewed kind of first half versus second half than we've typically seen. And I'm just trying to elaborate maybe a bit more of what's driving that swing.

And the second one is maybe a bigger picture question on North America generics. I think in the past, you talked about kind of a $4 billion run rate as your target here. I think you've been below that for the past few quarters. Can you talk a little bit about what needs to happen to get back to that type of level? And is that something reasonable to think about as we go through 2022 as you think about whatever launches you have, et cetera, as we go through the year? Thanks so much.

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

Thanks for the questions, Chris. I'll comment on the first one, and then Sven will comment on the second, North American question. So, it's correct that it is probably a bit more skewed than what we've seen in other years, but it's very sensitive to when we have launches.

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And what we're estimating this year? And Sven can comment on some of the North American ones. We are estimating that we will see more launches that will affect the second half, then we will see affect first half. So, we're not really caring like we carried Truvada and Atripla into the first quarter of 2021.

If you look at our US generic sales, we still had some of that tail in the first quarter of last year. We don't have a big launch that we did, I would say, fourth quarter of 2021 that we are carrying into the first quarter of 2022. We do have launches coming up, Risperidone LAI, several generic launches. So, those will mainly affect the second half.

And then we do have the basic seasonality that we've had always that most pharma companies have that we have the doughnut hole on those various things on rebate schemes and so on. That takes down the first quarter. And you typically have the reverse thing happening in the fourth quarter. So, it's maybe slightly more skewed than normal, but there's nothing really extraordinary behind it other than our operational plans.

And maybe Sven, you can comment on the $4 billion run rate for US [indiscernible] (00:57:20) North American. We should just make sure we always make it clear that we're talking about North America, so it's really US and Canada. But over to you, Sven.

Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.
A

Yes. The North American generics sales are reported in three segments: biosimilars, Teva Canada and the US generics business. So, in 2020, we were above the $4 billion target. And in 2021, we were below the $4 billion target. And I think the two years, I'd tell you how it goes. In 2020, we had quite a strong biosimilar business and an excellent launch of generics with Truvada and Atripla, and that was absent from 2021. And that gives you an idea how we think about the $4 billion as it – basically, in a year where you have a good generics launch in complex generics with a large originator value to address or you have a biosimilar launch, we're quite confident that we get to the $4 billion sales.

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

Thank you. Thank you for the questions.

Operator: Thank you. And the next question comes from the line of Gary Nachman from BM (sic) [BMO] (00:58:27) Capital Markets. Please ask your question. Your line is now open.

Gary Nachman
Analyst, BMO Capital Markets Corp.
Q

Kåre, we were previously talking about 2021 as the trough year. Are you confident now that 2022 should be a trough year in terms of revenue and EPS, especially if COVID normalizes? That's first.

Second, on the opioid litigation, if the nationwide settlement ends up being, I guess, one-third product, one-third cash, is that something that you can actually absorb with your balance sheet, that type of mix? It seems like you're sort of going down that path.

And then with Risperidone LAI, just curious, do you have the sales force in place to launch this product, talk about maybe some pre-launch activities that you're doing, and if there'll be any real incremental spend on this in the back half of the year. Thank you.

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

A

Thanks for those three questions. I'll address the first two ones and then Sven will address the Risperidone question. So, I can confirm that I am expecting that 2022 will be the trough years, so to speak. Or the combination of 2021 and 2022, you could say, unfortunately, will be the two trough years. And the reason being that is, of course, that I'm expecting that we will see a normalization of the volumes in Europe and US. And what we're talking about is probably that volumes in 2021 were, let's say, 4%, something like that, 4% to 5% below what we would have expected if we had seen zero effect of COVID on the volume of doctor visits, hospital visits and so on for diseases not related to COVID-19.

And you combine that with the dynamics of COPAXONE now [ph] have (01:00:20) come down to around below $1 billion this year. And it will keep going down, but of course, the absolute amount is less and less. And the growth number on AUSTEDO and AJOVY is getting higher and higher. So, I'm confident that that's the case also because we had a good grip on the margins, as you can see. That means that if we just get a marginal increase on revenues, then we will also see an increase in EPS. So, that's with regard to the trough year.

With regard to the opioids and the balance sheet, then what you have seen in Texas is a payment schedule over 15 years or the cash component, which is two thirds of the settlement value and then a – we provide products over 10 years, and that's a third of the settlement. And by, you could say, spreading it over many years, we're basically able to manage this within our balance sheet structure.

If we were to pay it all tomorrow, that would, of course, not be possible given the debt we have. So, it's a way of finding a way to get a settlement that benefits everybody, including the American people, the people suffering from substance abuse. And actually by adding the product component in there, you get the benefit directly to people suffering from substance abuse and having an overdose situation.

And you actually have a nice twist to this because the generic Narcan spray product is actually manufactured in the US on a dedicated manufacturing setup that we've created in Salt Lake City in one of our manufacturing plants there. So, it's also good for US manufacturing that you have here something that helps the US population being manufactured in the US. So, I think it's a very good settlement. I hope it can inspire everybody to reach a nationwide settlement and we will be able to manage that within our balance sheet.

Now, the last question on Risperidone, over to you, Sven.

Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

A

Yes. So, the commercial organization is in place, including the sales force and we finance this by reallocating resources within our budget. And yes, we would see a step-up in the SG&A spend when we launch the product.

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

A

Thank you very much for the questions.

Operator: Thank you. And there is one more question from Jason Gerberry from Bank of America. Please ask your question. Your line is now open.

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Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

Hey, guys. Thanks for squeezing me in. Just one other follow-up on the opioid front. I think there's a February 25 deadline for final implementation for the J&J distributor side of the equation. So, is that too little time for Teva to negotiate its way into the deal? Or would participation in a global deal have to happen subsequently? I'd imagine your counterparties would love a much bigger top line to announce to its constituents. So, I'm just curious if we're too late in the game there.

And then ultimately, how do you leverage the existing framework? And then ultimately, when we look at the final opt-in later this month, how much residual litigation burden after the settlement would be unsatisfactory versus what – how would you characterize [ph] true global piece (01:03:44) in a global settlement? Thanks.

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

A

[ph] They're (01:03:52) aiming, of course, at reaching a nationwide settlement within the next 12 months. It's not our aim to join into communication around the settlements that J&J and the three distributors have been reaching. We see that as our settlement will most likely be communicated separately. And it's also different in that we have a product component, which nobody else has. So, that's how we see that.

In terms of how do you get [ph] piece (01:04:26), so to speak, how to get a comprehensive holistic settlement. It's really all about the subdivisions. So, if you look at what we did in Louisiana and what we did in Texas, it basically includes all the subdivisions. So, if you think about nationwide settlement, you have the same situation for us, as you've seen for J&J and the distributors. You need to get into the 90s in terms of how many stock divisions go along with it because otherwise, you will just have too much of a tail of litigation out there.

What I've been seeing, and I'm not – I don't have any insights over and above what's publicly available is, of course, that we are seeing increasing participation rates for the J&J and the distributor's settlements from the subdivisions. And from what I've been reading, we are in the 90s and we're really seeing majority of states and majority of subdivisions going along with this. And I think that it just makes sense because it makes sense for the population. It makes sense for the states. It makes sense for the plaintiff lawyers, it makes sense for the companies. And I don't see a lot of subdivisions eventually actually trying to go to trial and going up against their states has a whole legal twist to this, which I won't get into, but it's problematic for a county or a city to really pursue this once the state has settled. And I don't think we'll see much of that. I hope that answers the question. Thank you.

Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

No, it did. Thank you so much.

Operator: Thank you. Please continue with your closing remarks.

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

So, thank you, everyone, for joining the call. It was a pleasure taking the questions and talking to you, and I wish you all a nice and safe day. Bye-bye.

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Operator: Thank you. That does conclude our conference for today. Thank you for participating. You may all now disconnect.

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