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Teva Pharmaceutical Industries Ltd.

(TEVA)

Q4 2020 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by. Welcome to today's Teva Fourth Quarter and Full Year 2020 Financial Results. At this time, all participants are in a listen-only mode. There'll be a presentation, followed by a question-and-answer session. [Operator Instructions] I must advice you that this conference is being recorded today, Wednesday, 10th February, 2021.

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

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

Thank you, Sharon, and thank you, everyone, for joining us today to discuss Teva's fourth quarter and full year 2020 financial results. We hope you've had an opportunity to review our press release, which was issued one 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.

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.

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Further, management believes the inclusion of non-GAAP financial measures provides meaningful, supplementary information and facilitates analysis by investors in evaluating the company's financial performance, results of operations, and trends. A reconciliation of GAAP to non-GAAP measures is available in our earnings release and in today's presentation.

To begin today's call, Kåre Schultz, Teva's Chief Executive Officer, will provide an overview of the fourth quarter and full year performance, recent events, and priorities going forward. Our Chief Financial Officer, Eli Kalif, will then review the results in more detail before providing an overview of Teva's 2021 financial outlook.

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

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

Kåre Schultz

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

Thanks, Kevin, and welcome, everyone, to this call and thank you for your interest in Teva. I will review some of our key business highlights, and then Eli will review the financials, and then we'll have time for Q&A.

I'm very happy to report that we met all our key components of our 2020 financial guidance. As you've seen, our revenues came in at $16.7 billion, the non-GAAP operating income at $4.4 billion, and the non-GAAP EBITDA at $4.9 billion. The non-GAAP EPS came in slightly above our guidance at $2.57 and the free cash flow came in at $2.1 billion.

On the business side, a lot of important things happened. You could say, the overarching theme for 2020 was the COVID-19 pandemic, and the successful navigation of the pandemic by the company and by the employees. We did our utmost to protect the employees and by doing so, we were able to protect our supply chain with minimal disruption and also continue our R&D programs and our product launches.

I'll get back to AUSTEDO, AJOVY and TRUXIMA on the following slides, but I'd like to mention the very successful launch of the first versions of the treatments Truvada and Atripla for HIV treatment. So generic versions of those products were launched by us in the fourth quarter in the US, a very successful generic launch. We also just launched in the US NuvaRing and we're very happy to have this approval for complex generic.

We're also very pleased with the phase 3 results from our risperidone LAI. As you know, patients suffering from schizophrenia really need better long-acting therapy, where they don't have to have intramuscular injections, where they don't have problems with reconstitution, and this product is a ready-to-use, long-acting product, subcutaneously injected by a thin needle. So it will improve convenience and compliance, hopefully, with strong benefits for people suffering from schizophrenia.

We also launched the whole Digihaler portfolio in the US, and in these times of e-health, we are very optimistic that the Digihaler portfolio of products can help people suffering from asthma and other respiratory diseases to improve the treatment and the compliance with their treatment to the benefit of their health outcomes.

If we move to the next slide, then I'll just give you a few comments to our revenue development. And we did have a strange year, in the sense that in Q1 2020, as you can see from the European green bar, there we had a unexpected extra sales in the form of patient-level hoarding as the pandemic hit and the first lockdowns happened

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in Europe. So we basically sold $200 million more in the first quarter in Europe than we would normally do. And then, that came back as $200 million less in Q2, and then we sort of normalized in Europe at the end of the year in Q4.

In the US, we didn't have the same swings. We didn't have the same hard lockdowns as we saw in Europe, and you basically see we were sort of going at the normal run rate of around $2 billion per quarter. And then in Q4, we had the lift-up basically coming from the launch of Truvada and Atripla. And the rest of the business was pretty steady over the quarters, no dramatic changes there.

If we move to the next slide, and I now give a few comments to AUSTEDO. AUSTEDO keeps growing very strongly. We had a 65% increase over 2019 in our revenues in 2020, and we also expect this to keep on growing strongly, as you will see from our guidance. We had a good growth in prescriptions, good growth in our sales, and what I always mention when we talk about AUSTEDO is the huge potential.

There's a huge unmet medical need in the form of tardive dyskinesia. We're estimating that we have around 500,000 patients suffering from tardive dyskinesia in the US. Of course, not everybody will be treated at all times, but as you can see from our patient numbers and if you look at the numbers of our one and only competitor, then we are only scratching the surface in meeting the medical needs of people suffering from tardive dyskinesia. So, for that reason I'm optimistic that AUSTEDO will continue to grow also in the coming years.

If we move to the next slide, then we have a bit of a rollercoaster story for AJOVY in the US. We had a really good launch and then we lost competitive power, you could say, due to the fact that we did not have an auto-injector. Our two competitors both launched with an auto-injector. We were delayed regulatory-wise and you saw our NBRx here go from 30% all the way down to 11%. Then we finally launched our auto-injector, which I think is best-in-class, very high-quality Swiss product, really easy-to-use. And if you combine that new and better device, which then meant that we got back into a better capture rate with an NBRx share of around 25%.

If you combine this better device and the increase in our capture rate, with the fact that we do have unbeaten efficacy and we have a longer duration of actions than any other competitors, and due to the longer duration of action, we can offer both quarterly and monthly therapy, then I'm actually quite optimistic about the potential for AJOVY in terms of market share. And I've been saying since the launch that we would be happy to get 25% of the market.

I'm sort of upping that ambition a bit and saying that I really think with the unsurpassed efficacy, the longer duration of action and a clearly high quality, very convenient auto-injector, I don't see why we cannot have a long-term aspiration in the US of having a third of the market. And that, by the way, fits very well with Europe, where in some of the countries where we've launched – and that's many by now – in some of the countries where we launched early, we are already now getting close to a third of the market. So, good development on the market share for AJOVY.

If we move to the next slide, then many of you probably remember that I've been talking about biosimilars as a future cornerstone of our presence in, you could say, the overall generic space. And here we had to prove ourselves with the launch of TRUXIMA, because we had to prove that we could get a good market share. There has been, you could say, some disappointment on the penetration rate for biosimilars in the US over the last 5 to 10 years.

I think with TRUXIMA, we have proven that we can get the volume share. We are up to 24% now. I don't think that we will go from 24% to 48% in the next 12 months, but I do think we have a sustainable market share that we can

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increase. There's more competition now. We have two competitors and the originator, but this is a very good business for us. It's a solid market share we have already; we think we can expand it. And we're very optimistic also about the benefits of our broad future portfolio in biosimilars, which I'll actually address on the next slide.

So, if you look at our overall biosimilar and specialty pipeline, then you can see here that, by now, we have a very broad biosimilar pipeline, roughly 10 products; half of them are own internal developments, half of them what came in with the in-licensing deal we made with Alvotech. And we're very excited about this and we think it will be a very good business for us for the coming many years.

I could also mention here that you can see that risperidone LAI, of course, we're getting ready for submission there. Hopefully, we can submit, get approval, and launch sometime next year. And, of course, we're also waiting to see the outcome for the competing product to fasinumab, tanezumab, which has an advisory committee coming up, so it'll be exciting to see there what happens. And together with our partner, Regeneron, we'll be following that closely, hoping that we can file the product this year. I won't give anymore comments to all the details, but you can see we have a broad portfolio of both biopharmaceuticals and biosimilars.

If we move to the next slide, then another cornerstone of our strategy is to continuously improve our manufacturing in terms of efficiency and cost, and thereby increasing our gross margin and our operating margin. Now, I won't talk about all these elements. I've talked to you about it before. It's really not rocket science. It's what you do when you want to improve your manufacturing operation. It's more than 1,000 sub-projects under these five categories. I'll just mention two things where you can clearly see and where we're sharing with you what we're doing.

On the network side, I'll show you just in a minute how we've developed by reducing the number of manufacturing sites we have and we'll continue that, and that, of course, benefits by increasing the scale effect on the remaining sites increasing and concentrating the volumes. And also on the supply chain, just given COVID-19 and everything that's been happening, you could say consolidation and the overview and the smart use of IT for reviewing your supply chain at all times, securing both your manufacturing supply chain and distribution supply chain, is critical.

And I'd like to mention here that also the supply chain from manufacturing to patient is critical, and we are very happy about the support that Teva has been able to give to the state in Israel in its vaccination program, where we are playing a key role being the company doing all the logistics, getting the vaccines from the airport into the warehouse, into all the 400 vaccination centers in Israel, and thereby securing a very fast vaccination process in [ph] Israel (00:12:38) based on logistics and, of course, supply of products.

If we move to the next slide, then I promise you to give you a short look into our consolidation of our manufacturing sites. What you can see here is that over the last three years, we've gone from 80 to around 60 manufacturing sites, but we're not stopping there. As you can see here at the bottom, we have additional 11 sites where we have announced that they will either be divested or closed, and that of course sets us up for reduction down to 50 sites. And then I'm sure later on we can do even more consolidation.

And we have different examples. We have recently divested in countries such as Japan, Thailand, Russia, Serbia, and so on. So, it's a lot of small sites that we are closing and concentrating the volume on our bigger sites, and thereby getting better manufacturing efficiencies.

And you can see that on the next slide. Here I'm showing you the operating margin, and you can see the negative development from 2017 to 2019, basically as a consequence of the loss of revenue on COPAXONE, which was a

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very high operating margin product. And then you can see how we are fighting our way back, moving from 24.5% operating margin in 2019 up to 26.3% in 2020. The midpoint of our guidance for this year is 26.8%, and our long-term target at the end of 2023 is 28%, and that's a target we are firmly committed to.

If you move to the next slide, then you can see another development that we are firmly committed to, the reduction in our net debt. And you can see the development since I joined the company in Q3 2017 until now, where we have reduced the debt by some $10 billion. You should continue to see that going forward.

The only reason why the graph has gone a little flat the last two quarters is actually the currency adjustment on our euro-denominated debt, which has led, of course, to some increase in the dollar converted number for that debt, which has slowed down the debt reduction a little bit, but it will pick up again strongly here in 2021.

And if we move to my last slide here, then I'm happy to repeat the long-term financial targets and there's no change here, apart from the design; we moved to three green round circles. And that's, of course, you could say our little contribution here warming up to the next slide, which is an ESG slide. But these are financials, 28% operating income margin at the end of 2023, we're firmly committed to that. More than 80% cash earnings and a net debt-to-EBITDA below 3 times, and in order to secure that we will, of course, use our cash flow to pay down debt. And as a side remark, which I've said for the last three years, we don't have any plan to raise equity. We want the current shareholders to get the full benefit of improvements in the business.

Now I have a last slide on ESG, which I like to show you. I won't comment on all the great things we're doing. I'll just take the E, so to speak, the environmental piece. I just want to review briefly our 2030 environmental long-term targets. One is focused on greenhouse gasses, to cut our emissions by one-third. Another is focused on the energy, both the energy efficiency and also the continued increase and use of renewable energy sources.

And then the last one is really focused on waste and recycling of waste, and then reducing and minimizing antimicrobial discharge. It's a project we do together with a lot of other companies in the pharmaceutical industry to basically secure that we won't have problems with a resistant bacteria, and to ensure that we have a reduction in the risk of this happening to all of us by working together across the pharmaceutical industry.

So with this, I would like to hand over to Eli, who will review the financials.

Eli Kalif

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

Thank you, Kåre, and good morning and afternoon to everyone. I hope you all have a safe and healthy 2021.

I will begin my review of our 2020 financial results with my main focus being on the fourth quarter performance. This will be followed by an introduction to our 2021 non-GAAP guidance and some of the important assumptions behind it. While most of the discussion around 2021 guidance will come at the end of my presentation, in a few spots along the way I will touch upon our expectation regarding forward-looking trends to assist you with your modeling. So please take the notes of these.

Beginning on slide 17, we start with a review of our GAAP performance. The fourth quarter was the strongest quarter of 2020 with regards to net revenues, totaling $4.5 billion. While relatively flat compared to the fourth quarter of 2019, sales were up 12% compared to the third quarter of 2020. The strong sequential performance was supported by growth in all segments, especially North America, which benefited from the strong launches of our generic version of Truvada and Atripla, as well as the continued strength of AUSTEDO and TRUXIMA.

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In Q4 2020, we recorded a GAAP operating income of $406 million versus $148 million in Q4 2019, GAAP income of $150 million versus $110 million in Q4 2019, and a GAAP earnings per share of $0.14 versus $0.10 in the same period in 2019. The year-over-year improvement in GAAP operating income, net income, and earnings per share was mainly driven by the successful launch of generic Truvada and Atripla in the US, coupled with the lower level of intangible assets impairments.

Turning to slide 18. You can see that the net GAAP adjustment in the fourth quarter of 2020 were $603 million. Non-GAAP income and non-GAAP EPS for the fourth quarter of 2020 were adjusted to exclude these items, with the largest being amortization of purchased intangible assets totaling $262 million, of which $231 million included in cost of goods sold and remaining $31 million in selling and marketing.

This quarterly amount for amortization is aligned with a range of $250 million to $260 million per quarter that we guided to at the beginning of 2020 and we expect it to be the same in 2021. Impairment of assets and accelerated depreciation totaled $236 million in the fourth quarter of 2020, which was mainly associated with the impairment of identified product rights of $127 million in the US.

Turning to slide 19, we review our non-GAAP performance. As I mentioned at the beginning of my remarks, quarterly revenue was $4.5 billion, which was flat compared to Q4 2019, and annual revenues were $16.7 billion, a decline of 1% compared to full year 2019. Non-GAAP gross profit was $2.3 billion in the fourth quarter of 2020, flat compared to the fourth quarter of 2019.

Non-GAAP gross profit margin was 52.3% in the fourth quarter of 2020 compared to 50.6% in the fourth quarter of 2019. The year-over-year increase in non-GAAP gross profit margin was due to our efforts to reduce our cost of goods sold as part of our long-term financial target and due to the strong launches of our generic versions of Truvada and Atripla in the US. Full year 2020 non-GAAP gross margin was 52.4% versus 51.5% in full year 2019.

Non-GAAP operating income in the fourth quarter of 2020 was $1.1 billion, an increase of approximately 7% compared to the fourth quarter of 2019. Non-GAAP operating margin was 25.6% in the fourth quarter 2020 compared to 23.8% in the fourth quarter of 2019. The increase was mainly due to the aforementioned strength of our generic launches in the US, continued growth of AUSTEDO, and continued focus on an efficient, disciplined cost structure. Full year 2020 non-GAAP operating margin was 26.3% versus 24.5% in full year 2019.

We ended the quarter with a non-GAAP earnings per share of $0.68, an increase of 10% versus Q4 2019, mostly due to the higher operating profit, as well as the lower tax rate. For the full year 2020, non-GAAP earnings per share was $2.57, an increase of $0.17 compared to the full year 2019 and $0.02 above the high-end of our 2020 guidance.

Now, let's take a moment to discuss our overall spend base. We declined for the third straight year. On slide 20, you can see that we had a modest decrease in our spend base in the fourth quarter, but for the full year it declined $474 million.

More than half of the annual decrease was due to a lower cost of goods sold, partially related to a lower annual sales, as well to our ongoing efforts to transform our global operational network. Lower operating expenses also contributed to the decline in spend based on due to the ongoing active management of our operating expenses.

Looking ahead to 2021, we expect the overall spend base to continue to decline, but at a more gradual pace, mainly due to our effort to reduce our cost of goods sold through procurement cost excellence, network optimization and restructuring, operational quality excellence, end-to-end supply chain integration, and agile

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operating model and organization. This ongoing efforts, along an increase in the top line, will lead to further growth of operating margin improvement in 2021, with the ultimate goal being 28% operating margin by end of 2023.

Now turning to free cash flow on slide 21. Teva's free cash flow in Q4 2020 was $471 million versus $974 million in Q4 2019. Please keep in mind when considering the year-over-year decline that Q4 2019 was unusually high, mainly due to onetime sale of assets, as well as $95 million benefit from an interest rate swap transaction.

For the full year 2020, free cash flow was $2.1 billion, which was flat versus full year 2019. I'm very pleased with the work our team has done to minimize the large quarterly swings in our free cash flow, which we had experienced in previous years. As you can see here, the quarterly free cash flow results were fairly consistent throughout 2020.

Turning to slide 22. Our cash-to-earnings for full year 2020 was 75% versus 79% for full year 2019, as free cash flow was unchanged, but net income was $200 million higher in 2020 versus 2019. Despite the drop, we're on track to achieve our long-term goal of at least 80% cash-to-earnings a year by end of 2023.

Turning to our outstanding debt on slide 23. Net debt declined to $23.7 billion versus $24.9 billion in 2019. This reflects repayment of $1.9 billion during 2020, which was partially offset by a $900 million negative foreign exchange impact.

Our net debt-to-EBITDA at the end of 2020 was 4.8 times versus 5.3 times at the end of 2019. We're very pleased with the progress we have been making each year to bring our overall debt load lower than the net debt-to-EBITDA ratio closer to our long-term targets of under 3 times by the end of 2023.

Looking ahead to 2021, it will be another year of debt reduction totaling $3.2 billion, including our 0.25% Convertible Senior Debentures over 2026. Due to the net share settlement feature, this Convertible Senior Debentures were classified on the balance sheet under a short-term debt.

Holders of the convertible debentures were able to cause to Teva to redeem the debentures on February 1, 2021 and $491 million of the convertible debentures were redeemed on that date. As we have stated since 2019, our liquidity and expected cash flow will cover bond repayments for the next two years before having to refinance later maturities including for 2023.

Now, let's look at the development of 2020 results versus our guidance here on slide 24. We present the full year 2020 performance compared to the original guidance issued at the start of 2020 as well as the revised guidance from November, where we lowered the midpoint of our revenue guidance by $150 million while bringing up the bottom and the end of the range for operating income, EBITDA, and earnings per share.

We're very pleased with the overall performance in 2020, especially giving the uncertainty that was created by the global pandemic. Despite these challenges, the efforts of our employees around the world allowed us to meet the five main components of our 2020 outlook, as well as to continue to make progress towards our long-term financial targets.

Now, let's turn to our attention on our 2021 non-GAAP outlook, which we are introducing for the first time today. Here on slide 25, you will find the five main components of our outlook: revenue, operating income, EBITDA, earnings per share, and free cash flow, as well additional components including expected revenue range for key products.

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As I just mentioned, our company work extremely hard throughout 2020 anticipate and navigate the pandemic, its effects. And despite the significant amount of progress made around the world, especially by our industry to battle the spread of the virus, we expect to continue to face an evolving environment for the purchasing partner of our larger global customers and overall utilization by patients.

With this in mind, we begin with 2021 total revenue, which we expect to be between $16.4 billion to $16.8 billion. Please note this range reflects the divestment of $240 million in 2020 revenues from generics product in Japan along with the manufacturing sites. The divestment was announced in July 2020 and become effective on February 1, 2021.

We have factored into our guidance the continued erosions of global COPAXONE revenue, which we expect to decline during 2021 by approximately $300 million to approximately $1.050 billion full year 2020. The majority of the decline is expected in the US due to a third generic entrant later this year.

The expected decline in COPAXONE sales should be more than offset by the ongoing growth of AUSTEDO and AJOVY. We expect continued momentum of AUSTEDO in both tardive dyskinesia and Huntington's Disease with a total annual revenue to grow to approximately $950 million in 2021. Furthermore, AJOVY is expected to benefit from continued patient growth in both the US and Europe, bolstered further by our auto-injector device, which we began to roll out last April after offering AJOVY in a prefilled syringe the first two years. Global sales of AJOVY are expected to be approximately $300 million.

With modest decline expected in our spend base, non-GAAP operating income is expected to be between $4.3 billion to $4.6 billion, and then a GAAP EBITDA is expected to be between $4.8 billion to $5.1 billion. Using a share count of approximately 1.1 billion shares, we expect earnings per share to be in the range of $2.50 to $2.70.

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 do not expect to see the same trends that we experienced last year, when we saw big swings both up and down due to the global pandemic.

Looking on 2021, we expect that the first quarter will be the lowest of the four quarter for sales and earnings, with gradual pickup in the second quarter. Overall, we will expect that approximately 48% of our 2021 sales will be generated in the first half of the year and approximately 52% in the second half. For annual earnings per share, approximately 45% will come in the first half of 2021 and approximately 55% in the second half of the year. Hopefully, this color will assist you with your modeling.

2021 free cash flow is expected to be at the range of $2 billion to $2.3 billion. We expect about one-third of the annual free cash flow to be generated in the first half of 2021 and the two-thirds to be generated in the second half of 2021. This is due to unusual timing of annual bonus payments paid in the first quarter and inventories coming down due to a normal course of business.

Lastly, looking at the tax, in 2020 our non-GAAP tax was 16.6%, which was below the 17% to 18% range we originally guide to. As we look to 2021, we expect the rate once again to be in the range of 17% to 18%.

And this concludes our reviews of Teva's fourth quarter and full year 2020 results and 2021 financial guidance. We will now open up the call for questions and answer. Operator, if you will, please. Thank you.

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QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Your first question today comes from the line of Umer Raffat from Evercore. Please go ahead, your line is open.

Umer Raffat
Analyst, Evercore ISI

Q

Hi. Thanks so much for taking my question. If I may, the CGRP trends quarter-over-quarter on a reported sales basis versus what we're seeing in IMS, there seems to be a bit of – there seems to be more going on than what volumes would tell us. I was curious if you could shed some light on that. As well as I noticed there's an antibody, gastrointestinal is all you guys disclosed on it, which is now in Phase 1 on your specialty pipeline. If you could give us any color on that. Thank you very much.

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

A

Thanks for those two questions. I'll address the last one, and then I'll let Brendan address the first one.

So, I can't give you a lot of color on our pipeline, the early pipeline we don't really disclose a lot. But I can tell you that this specific project that is for celiac disease and it's an exciting project. We might, about a year from now, have a day where we focus on the R&D pipeline, and then we'll give you some more color. But until then, that's about all I can tell you. So, Brendan, will you comment on the CGRP trend?

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

A

Sure, happy to and good morning. So, I assume what you're talking about is the increase in share with AJOVY. As you've seen, our total prescriptions and new prescriptions have basically doubled over 2020, and I assume that you're looking at when the revenue will kind of follow that.

So, if you think about the market, if a patient gets on a product, gets on AJOVY, oftentimes they're given a sample, and then they may enter our savings program for a period of time while we work through the – while they work through the prior authorization process. So revenue tends to lag share by a bit, and we've increased our access quite a bit in 2020. We'll continue to do so in 2021. So, the expectation is that as our share continues to grow and rise, you'll see revenue follow that, but it's a lagging indicator. Thank you for the question.

Umer Raffat
Analyst, Evercore ISI

Q

Thank you.

Operator: Thank you. And your next question comes from the line of Gregg Gilbert from Truist. Please go ahead, your line is open.

Gregg Gilbert
Analyst, Truist Securities, Inc.

Q

Thank you. Kåre, in the past I've asked you about the melting ice cube that is the generic business and you corrected me by calling it more of an ice bucket. So my question is, do you still think you could keep that business

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stable over the coming years based on what you have? And is that sort of dependent on biosimilars or any other factors you'd point out?

And then secondly, on opioids, it seems like the wholesalers are getting close on a settlement, as evidenced by their comments and their accruals, et cetera. Do you have anything new to say about where Teva stands in its opioid discussions? And are you open to settling maybe in different ways, perhaps carving states out separately from other parties? Thank you.

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

A

Thanks for those two questions. I would say, on the ice cube question, I would more call the North American generic business a well-working ice machine. These machines you have in a bar where ice keeps coming out, so you always have ice. It doesn't overflow, so you don't get dramatically more ice. It doesn't melt and go away, so you don't lose the ice.

That's the same way with the North American business. And I think I've said for, I think, really two years, maybe three years now, it's roughly a $4 billion business in North America and it's roughly $1 billion a quarter with the natural swings from launches, various other swing factors. So I have great confidence in this business going forward.

I have also said many times, the prices are not going to get back to where they were. We do have the world's – if not the world's lowest, but at least we have lower prices in US than we have in Europe. It was just proven once more by the Rand Institute that issued a report recently, you might have seen it, where they conclude that generic pricing is lower in the US than it is in Europe, which, as a side remark, is interesting when we are being accused of rigging and doing a cartel on generic pricing in the US. That would be the worst cartel in history resulting in lower prices, but that's another discussion for another day.

But it leads me to your other question, which is also about litigation about the opioid situation. So, I think that we are close to a settlement, so can you say are the other companies involved in the framework, but there's a difference between being close and getting something signed finally. And I've said before, unfortunately, I think we need some kind of pressure for everybody to get together and do final settlements in this space of opioid litigation, and so far all the trials have been delayed.

It's probably a year ago I was talking about the New York trial that was still at that point probably scheduled or maybe had just about to get moved due to the COVID-19 pandemic. And since then, we've had one year of delays in the legal system, for good reasons, of course, due to the pandemic.

So I'm still optimistic about the framework settlement. I'm still very optimistic about Teva finally reaching an agreement. But I'm not so optimistic about the timing simply due to the fact that the legal system is not really up and running. And that means that that event pressure, that will probably get people to sign on the dotted line is really not right there right now. Hopefully, as the pandemic gets better in the coming quarters, we will see a return with – some pressure from some upcoming trials, and that will result in a final settlement.

With regard to settling parts of it, then I think the best for everybody is a framework that includes both the states and the subdivisions. That will be the most elegant way to do it. But, of course, you can imagine all kind of different other ways of settling it. Thanks for the questions.

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

Elliot Wilbur
Analyst, Raymond James & Associates, Inc.

Q

Thanks. Good morning. Good afternoon. If I could just ask you to provide some additional color, Kåre and Brendan, around your commentary regarding the trends in North American generics business. Just specifically thinking about the headwinds in terms of volume, price erosion, what's your expectation for 2021 versus 2020? And more specifically, what should we be thinking about in terms of new product launches, new product contribution?

We've been talking about generic versions of Forteo, Restasis, and NuvaRing for quite some time, obviously realized NuvaRing, but there must be some other key launches that have kind of moved into the target range here that we should be thinking about in 2021. And just wondering if there's also any date – certain launches based on settlements that would give us a little bit more visibility into trends there.

Follow-up, just get your commentary around generic EpiPen market dynamics, seeing pretty strong increase in demand, unusually strong for this time of year. Assuming there's some tie into COVID vaccinations, but just wanted to see what you're seeing sort of at the stocking level versus what we're seeing in terms of retail prescriptions. Thanks.

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

A

Thanks for those two questions. So I'll give an overall take on the North American generics, and then Brendan will give you some details on that and also answer the question on EpiPen.

So if I go back to this analogy of the ice machine, then you can say the way I look at it is we have an effective machine that makes new ice cubes all the time in form of launches, be it biosimilars, complex generics, simple generics. And that means we have a steady flow of launches into the market. Of course, they don't come every day. They come here and there. And sometimes there's more launches in one quarter than another, but on an MHE basis we have a steady machine launching products, really adding revenue all the time.

We also have the ice cubes melting down in the container for the ice cubes, and they're not melting very fast or very slow compared to how they used to. They're melting at a steady rate. So we don't have this phenomenon we saw, I think, in 2017/2018, where they melted really fast, so we had really big price erosion. That's not what's happening, but it's not that they're not melting at all either. So I think we have a normal level of price erosion as we get more competitors on products and products get sold. And that whole balance, I think, is very steady and natural, and that's why I keep repeating this.

I know it's kind of oversimplifying it and Brendan will give you some more details, but I keep repeating this that we're doing $4 billion on generics in the US and Canada, and I think we'll keep on doing that. I don't see that going to $6 billion. I don't see that going to $2 billion. I see that staying around the $4 billion mark. And then we have the growth, of course, from our specialty products, and we have modest growth in our generic business in Europe and in the rest of the world. But enough on the big picture. Over to you, Brendan, on the specifics for generic launches and EpiPen.

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

A

Sure. Thanks, Kåre. So, there's a couple ways to think about the generic business and when you think about launches, it's both number of launches and value of the launches. In 2019, we launched I think 45 or 46 products. In 2020, we launched 15, but the value of those products was much different. So, 2020 was a good year for us and that was led by Truvada and Atripla.

As we think about 2021, we've already launched two products. We have another six or eight that we know we're going to launch, we're preparing to launch. And then we have a stable of complex generics, up to maybe 11 that are possible this year. But, of course, we won't get all of those and we're not certain which ones we will get.

So I like Kåre's ice machine analogy. I think that that's very relevant. I think that we will launch more products this year than we did last year. It was nice to start out January with the approval on NuvaRing and launch that. That should be a very good product for us. We're a little late to market, so the value isn't going to be this year what it would have been two years ago had we launched it, but it still should be good.

And as we think about the rest of 2021, as I mentioned, there's the stable of 10, 11 complex generics, and some of them we've talked about for a while. It's – teriparatide is possible. Octreotide is possible. Cyclosporine's possible. Exenatide is possible. So there's some products in there. Will they all come? No. But we're working with the FDA on all of those. And I agree with Kåre's comment, it is a $4 billion business that we can likely grow in the low single digits. And it will be $1 billion a quarter kind of ebbs and flows depending upon the launches that occur and the timing of those launches. So, hopefully that provides more color for you.

On the EpiPen comment, EpiPen we're still seeing that as a significant product and revenue generator for us. I think that you're right, there could be some stocking with the COVID-19 injections, but I wouldn't necessarily think of that as a major event. I think that that could be a slight boost here and there, but I don't think that that's going to add significantly to the overall EpiPen franchise. So, thank you for your question.

Operator: Thank you. Your next question comes from the line of Ami Fadia from SVB Leerink. Please go ahead, your line is open.

Ami Fadia
Analyst, SVB Leerink LLC

Q

Hi. Good morning. Thank you for taking the question. I had one follow-up, and then one main question. So the main question is, as you think about deleveraging over the next couple of years, how do you think about maybe adding additional growth drivers to the product? What are you doing in terms of thinking about refocusing R&D or any inorganic opportunities to drive growth in the coming years?

And then secondly, just with regards to your comment on growth outside the US, can you talk about some of the pushes and pulls as we think about Europe and rest of the world? Thanks.

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

A

Thanks for those two questions. So when it comes to deleveraging, then as you saw in the presentation, we're fully committed to using our cash flows to reduce debt and to get below the 3 times net debt-to-EBITDA. Now, that does not mean that we're not doing any in-licensing, that we're not doing any early-stage R&D in-licensing, but it

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does mean that we're not buying any companies and we're not buying big late-stage assets that have maybe already been approved and so on.

We are, however, working with companies where our commercial footprint is attractive, and that means that the upfronts are not needed, but that together we can generate value. And if you look at the in-licensing, for instance, of the Alvotech biosimilar portfolio for the US, then that's a good example of that. No dramatic big upfronts, but big value if everything works out well, so that's the kind of deals that we like.

We also do a lot on early research collaboration, early leads, so we take products into our early development. Of course, that doesn't lead to products in the market until 10 years from now or something like that. So I would say don't expect us to do big moves that will drive additional growth on the next two-to-five years basis. We will be doing small in-licensing, which can help us, but we'll not do anything big, because we will stay committed to reducing the debt and the net debt-to-EBITDA ratio.

On the terms of growth outside of the US, then you could say in Europe, we have a very steady business. We had last year in 2020, once again, the highest absolute profit ever in Teva Europe and we're very optimistic about the future in general. We do see, as it was reported also by Eli, that we still – in the second half of last year, so in the third and the fourth quarter, volumes in Europe were still below where we would naturally see them, not dramatically, but maybe 3%, 4% in the overall generic market in Europe.

And we think that will continue for the first couple of quarters this year, simply due to the fact that we still have a lot of lockdowns in Europe, and that means that we won't get back to the completely normal market situation. We are optimistic that after the summer, we'll see a more open European economy, which means that patients will return probably in full volume to hospitals, to doctors, and that means that we'll see some higher volume in the second half.

Longer term, we do expect to see low single-digit growth in Europe. And the same thing goes for the rest of the world: Japan, China, Southeast Asia, Latin America, we do see volume growth and also value growth in the generic space there. And then, of course, we see growth from our specialty products being launched. So for instance, AJOVY is going to be launched in Japan together with our partner Otsuka. We've just launched AUSTEDO in China, it's come on the National Drug Reimbursement List. So we are, of course, also expanding with AJOVY, AUSTEDO around the world, which will also contribute to growth outside of the US.

So overall, we are expecting to see low-single-digit to mid-single-digit growth over the coming years. Thanks for the two questions.

Ami Fadia
Analyst, SVB Leerink LLC

Q

Thank you.

Operator: Thank you. Your next question comes from the line of David Risinger from Morgan Stanley. Please go ahead, your line is open.

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

Q

Yes. Thanks very much, and congrats on the very strong performance. So my two questions are; first, obviously the company's financial progress has been impressive. Could you discuss the company's flexibility to manage

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potential future cash litigation payments? And second, there's been discussion of a comprehensive settlement. Kåre, could you please provide a little bit more color on that, how you define that and ensure that it covers all US claimants? Thank you.

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

A

Thanks for that question or those questions. So, first of all, of course, we have a situation, as we've just been reviewing, where we had more than $20 billion in debt, which basically means that we don't have any free cash laying around. Of course, that doesn't mean that we can't have a cash component in a settlement, but it just means that we don't have the capability of paying $5 billion tomorrow in cash. That's not the kind of balance sheet that we have. And this is why we've been negotiating with the State AGs and agreeing on a framework that's based on us basically providing what we're good at providing, which is generics. So we are offering to provide generic Suboxone to all states in the United States. That means that they can get going on therapy for people who are suffering from substance abuse and they can save lives with the use of generic Suboxone.

So we think that's a really good way to help the situation, to improve the situation. And then we are aware of other companies who will not be able to contribute like that, and they will be contributing cash. And I think it's to the benefit of the American people that this thing gets settled. Because we can discuss it forever, we can have litigation forever but that doesn't help anybody of the individuals that are suffering from substance abuse.

Now in terms of what is the likelihood of a comprehensive settlement, of course, it has to be understood that there's a framework that involves five companies, but technically, each company is settling on its own. There's coordinated negotiations, discussions, and so on, but at the end of the day, it's a legal entity – a company is a legal entity and each settlement will be done on its own. And, of course, we would like to settle with everybody, so both the subdivisions and the states. We think that should be [ph] plausible, (00:52:05) that should be beneficial for everybody to get this thing off the table, so to speak, and start helping people all around in all the states.

So I'm still optimistic that the framework is the right solution. And as I told you, I'm a little pessimistic on the timing. And a key reason for that is that you have 50 states involved, you have a lot of companies involved, you have maybe 1,500 plaintiff lawyers involved, so you have a lot of people who needs to get together. But it would be a good idea for everybody, I think, if we were to push this framework over the finishing line and get it signed, sealed, and delivered. Thanks for the question.

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

Q

Thank you.

Operator: Thank you. Your next question comes from the line of Nathan Rich, Goldman Sachs. Please go ahead, your line is open.

Nathan Rich
Analyst, Goldman Sachs & Co. LLC

Q

Great. Good morning. Thanks for the questions. First, I just wanted to dig into the operating margin guidance for this year, the 50 basis points of improvement. Eli, could you maybe help us think about how you're thinking about gross margins next year? It seems like you have several kind of positive tailwinds with the specialty business continuing to grow, additional facility rationalization. You talked about a stable kind of North America generics business. So I was just kind of wondering why we wouldn't see maybe more – or gross margin improvement kind

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of consistent with 2020, given those tailwinds. I know there is the Japan divestiture in there too, so just wondering what kind of the swing factors are on operating margins that we should keep in mind.

And then as a follow-up on [ph] although the (00:53:44) guidance was stronger than we had anticipated, I think it implies about 40% growth year-over-year off of a very strong year this year. So, Kåre, maybe just where do you see the biggest opportunities to continue to grow AUSTEDO? And I know you've talked this year about it being impacted by the ability to get into doc offices. Have you started to see that improve? And is that one of the factors that led to the guidance that you gave?

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

Yeah. Thanks for those two questions. I think, Eli, you'll start with the question on operating margin, and then I'll take AUSTEDO.

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

Yeah. Okay. Thanks for the question, Nathan. So, if you look on the trajectory on the slide that Kåre in his part on the operating margin moving from 24.5% on 2019 when we actually really introduced last year our plans and heading to 26.3% and actually looking to the 26.8%, you can see that 2020 become kind of a pivotal year for us. So, I will say the OP margin [ph] over the (00:54:52) gross margin in 2019 was kind of 47%. Now we actually came to kind of 50/50. And heading to 2021, you should think about our margin to be – flow from the gross margin on the OP more than 50%. Really close to what we're saying there, midpoint 26.8%.

And you can actually look on, okay, we did kind of more than 1 point year-over-year, but heading less than 1 point. One of the elements here we need to remember is that actually we're looking for, going forward, midpoint on the revenue versus last year if you remove the divestment on Japan. What we did this year, we worked heavily on the OpEx to make sure that we have really, really great cost structures. We are looking on moving forward to supporting some better mix on the revenue, and that's actually kind of a bit higher percentage-wise in terms of the OpEx for next year.

So, we still kind of looking to grow and looking on how we actually can support it with sales, marketing, and other activities. But I would say that the direction is to actually flip it and flow-through more than 50% from the gross margin into the OP, so I think that's the way you should think about it.

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

So on AUSTEDO, I'll just give the overall comment, and then, Brendan, you can also give some details if you want. So, basically we're continuing the very strong trend we've seen on AUSTEDO, so it's not a dramatic change. What is important here is that we can continue to grow and the reason why we believe so is the big unmet medical need. There's a lot of patients out there suffering from tardive dyskinesia who can be treated, who are not being treated, and they can get a huge help in their everyday quality of life. And therefore, we see that new patients are coming on it all the time.

Of course, we've had some hurdles on our communication with doctors face-to-face during the pandemic. We expect that will continue to some degree, but we've also overcome some of that through different tactics. And maybe, Brendan, you can comment a little bit on how do we see tactically that we will keep on driving the growth of AUSTEDO in the US.

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

A

Sure. Happy to, Kåre. So, at the outset of the pandemic, I think we were able to move quickly to virtual and video detailing with physicians. And it's certainly not necessarily as impactful as in-person face-to-face detailing as far as generating a new-to-brand prescription, but certainly it played a role. We've been able to return to the field where state and local guidelines will allow, so we're continuing to engage with physicians.

As far as the unmet medical need that Kåre talked about, the patient population for tardive dyskinesia is probably in the 500,000 range, number of patients. About 26,000 patients today are treated between the two products in the market, so it's a little more than 5%. So there's still significant opportunity in the tardive market.

And then when you think about chorea associated with Huntington's disease, there's about 38,000 patients in the US with Huntington's. About 30,000 of them have chorea associated with Huntington's, and only about 2,600 of those patients are treated, so a little less than 10%.

So, there's still significant opportunity with both tardive dyskinesia and Huntington's disease. I think we've really just scratched the surface on this market. As we continue to grow through 2021 and the pandemic improves, we'll have a greater percentage of our details being face-to-face. So, we certainly see some good upside and some good growth coming from AUSTEDO both in 2021 and the outyears 2022 and beyond. So thank you for the question.

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

A

So I think now we'll take the last set of questions, because we're getting close to the hour.

Operator: Thank you. Your final question comes from the line of Jason Gerberry from Bank of America. Please go ahead, your line is open.

Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

Hi. Good morning and thanks for squeezing me in. Yeah. So I guess my first question, Kåre, is just is there an opportunity for Anda distribution in 2021 to play a bigger role in COVID-19 vaccine distribution? You talked a little bit about the Israeli experience. Was that a one-off or are these opportunities not available to Teva more broadly?

And then my other question or follow-up question is, as it pertains to the DOJ legal matter that you referenced earlier with the price fixing suit, I know that there was an attempt to get the civil matter stayed pending resolution of the DOJ case, and I think the court balked at that. But is there still the potential for getting the civil matter stayed, or could we anticipate both legal matters sort of proceeding in parallel this year? Thanks.

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

A

Thanks for those two questions. I'll try to answer them relatively briefly. The first question on Anda, it's a yes. Yes, Anda can potentially play a role in helping states to get vaccine distribution going in a good and safe and reliable way. We know how to do it. We're doing it, as you know, in Israel. And Anda has the capability to distribute nationwide to any pharmacy, as you can imagine, or any location you can imagine. So there's a possibility.

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Whether there will be a need for it, I'm not sure, but it's definitely something that we are offering to the health care systems right now if they need help on that front.

With regard to the DOJ criminal case on price fixing and the civil case, there was actually a development yesterday, I believe, where in the civil case we explained to the judge that – or we have been explaining to the judge that it doesn't make sense to focus on Teva, since we have denied any wrongdoing and we have a criminal case waiting; whereas some of the other defendants, they have already said that they did something wrong, such as Heritage and other companies. So it doesn't make sense to focus on us in the civil case. It would be much more relevant to focus on the companies that have said they've done something wrong, and then dig into what have they actually done.

And in layman's term, then the judge has agreed to that, and that means that Teva won't be at the forefront of that case. It will be some of the other companies. And then you could say, in that sense, the case is not stayed, because there's 15 different defendants, including Teva, but it will not focus on Teva. It will focus, I think, on Heritage and some other companies. And then the criminal case will, of course, take its time, and we'll have to see how that develops over the coming years.

Kåre Schultz

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

So, thank you for those two questions. And with this, I think we will end the questions, and thank you all very much for your interest in Teva. Thank you.

Operator: Thank you. Ladies and gentlemen, this conference will be available for replay from 2:00 PM Eastern Standard Time today through until 2:00 PM Eastern Standard Time on Tuesday, the 9th of March, 2021. You may access the remote replay system by dialing +44-3333-009-785 and entering the access code 5458315. That number again is +44-3333-009-785 using the access code 5458315. That does conclude our conference for today. Thank you for participating. You may all disconnect.

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