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# Teva Pharmaceutical Industries Ltd.

(TEVA)

**Q1 2021 Earnings Call**


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# MANAGEMENT DISCUSSION SECTION

**Operator**: Good day, and thank you for standing by. And welcome to the Teva Pharmaceuticals First Quarter 2021 Financial Results Conference Call.

At this time, all participants are in a listen-only mode. After the speaker presentations, 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, 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, Annette. Thank you, everyone, for joining us today to discuss Teva's first quarter 2021 financial results. We hope you've had an opportunity to review our press release which was issued about an hour ago. A copy of the release as well as a copy of the slides being presented on this call can be found on our website at www.tevapharm.com.

Please note that the discussion on today's call includes certain non-GAAP measures as defined by the SEC. Management uses both GAAP financial measures and the disclosed non-GAAP financial measures internally to evaluate and manage the company's operations to better understand its business. Further, management believes the inclusion of non-GAAP financial measures provides meaningful supplementary information and facilitates analysis by investors in evaluating the company's financial performance, results of operations, and trends. A reconciliation of GAAP to non-GAAP measures is available in our earnings release and in today's presentation.

To begin today's call, Kåre Schultz, Teva's Chief Executive Officer, will provide an overview of the first quarter, recent events, and priorities going forward. Our Chief Financial Officer, Eli Kalif, will then review the results in more detail, including our 2021 financial outlook. Joining Kåre and Eli on the call today is Brendan O'Grady, Teva's Head of North America Commercial, 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.*

Good morning and good afternoon to all of you, and thank you for dialing in. We are presenting today Q1 2021, the financial highlights, and we have a set of solid numbers to present to you.

Our revenues came in at $4 billion, which we see as a good result given the continued COVID-19 pandemic and the effects it is having in the marketplace. We're seeing our adjusted EBITDA coming in at $1.2 billion, meeting


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our expectations and in line with what we see as the continued improvement of our business. The GAAP diluted EPS came in at $0.07, and the non-GAAP diluted EPS came in at $0.63, again in line with our expectations. We continue to reduce our debt. We had one pay down on some convertible bonds in the period, and net debt is now reduced to $23.2 billion. And then last but not least, we reaffirmed our 2021 outlook, and Eli will show you some more details on that later in the presentation.

Next slide, please.

Now, if we take a look at the quarterly revenue, then I'd like to remind you of a couple of things that's been happening when we look back and compare. We have a normal run rate of around $2 billion in North America and of around $1.2 billion in Europe. But if you go back to the first quarter of last year, then you see on the dark green that the European numbers, they were significantly higher than normal, coming in at $1.4 billion. Now, that was the $200 million patient-level hoarding of products related to the start of the COVID-19 pandemic. That reversed in Q2 last year. So you see Europe dropping down to $1 billion instead of the normal sort of $1.2 billion. So that swing factor, of course, means that compared to – is more challenging in the first quarter of 2020 than it is in the second quarter of 2020.

Apart from that, we have a couple of special cases that you can also see in the numbers, and that's really both in North America. That's the first quarter of 2019. That was the very successful launch of TRUXIMA, and the fourth quarter of 2020, that was the very successful launch of the generics to TRUVADA and ATRIPLA. So those things kept in mind, we see a good result for the first quarter of 2021.

We still see that the underlying volume is reduced in Europe simply due to the fact that less people go to the doctor, less people go to the hospital due to the continued lockdowns in the first quarter of this year. We do expect the COVID-19 lockdowns to slowly ease here during the second quarter, but really see the hopeful return to normal volumes in the third and the fourth quarter of this year in Europe.

If we move to the next slide, please. On AUSTEDO, we saw US sales of $146 million in the first quarter. This is an increase of 20% versus last year. We always have a dip in the first quarter. You can see that also happening in 2020 and in 2019, and that's a consequence, really, of the insurance system in the US where you have these resets of deductibles and other elements that typically lead to lower script volumes in the first quarter and then a resumption of growth once you get into the second, third, and fourth quarter. We are expecting to see that also this year.

We are seeing more than 35,000 prescriptions now in the first quarter, and we continue to see future growth of this number. We are also focusing on expanding access and maybe be able to build AUSTEDO especially to the tardive dyskinesia patient population. As you know, there is around 500,000 patients suffering from tardive dyskinesia in US, and we are so far targeting, or not targeting, but actually only delivering AUSTEDO to a fraction of this population. So we will be starting DTC advertising in the coming months, and hopefully this will be a further driver behind the strong growth of AUSTEDO that we foresee for this year.

Next slide, please.

With regard to AJOVY, as you can see here, we continue to see a growth in our TRx count. Of course, some small variations, but underlying a strong development of the total number of TRx. And we do see sales globally of $48 million in the first quarter: $31 million in North America and $16 million in Europe. We've seen an uptick in our neutral brand scripts rate, NBRx, and it's right now around 25%. We want to try and drive this higher, and we'll be working hard to do so in the coming months.


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In January this year, we just launched a triple pack which is a further sort of example of our quarterly dosing and the convenience that we offer to patients who are seeking preventative therapy for their migraine by taking AJOVY once a quarter.

Next slide, please.

We also now at a stage where we have launched in the majority of European markets, so have now launched in 19 European markets. And as you can see from this slide, the European market is now growing. You have it to the left the total market is basically doubled within the last year, and we expect it to continue to grow.

We're seeing a nice growth in our share. We did not launch as the first company in this class in Europe, but we can see that when we launch, we start taking share. And it's been growing very, very steadily, and we expect it to continue to grow. We have especially strong positions in Germany, Nordics, UK, and some of the other main markets.

So, with regard to AJOVY, I'll just repeat what I said last time, that we are still bullish on our market share, and we do have an aim to have one-third of this market as a target over the coming years.

Next slide, please.

I showed you the nice effect we had on sales when we launched TRUXIMA, and we continue to see a very large penetration of TRUXIMA. We are now up to more than a quarter of the market. 26% is the latest data point we have on our share of the market. And as you know, we're the only rituximab biosimilar that also has an indication for RA, so we are very optimistic that we'll continue to see strong position for TRUXIMA in the market in the coming years.

Next slide, please.

Our portfolio, as we've discussed earlier, we see it as nicely balanced between biosimilars, novel biologics, and different improved versions of small molecules. And I'm especially happy that we got such good results on Risperidone LAI. This is a long-acting novel therapy where you can subcutaneously dose for a month or two with Risperidone, and this will be very, very beneficial for people suffering from schizophrenia. Leads to better compliance and a better therapy for these people. So very much looking forward to filing this very soon, and hopefully launching it next year.

Apart from that, we have, as you know, a long list of biosimilars moving into the market over the coming years and some exciting lifecycle management both for fremanezumab and for AUSTEDO.

Next slide, please.

One of our key long-term financial targets that we've set for the end of 2023 is our operating margin, and as I'm sure most of you know, the target is 28%. And we are also showing this year at the end of the line, so to speak, on this graph. The reason why the margin came down, as you probably also all know, was really the significant loss of revenue from COPAXONE going generic in the US and in Europe, and that really drove our margin down from the level of around 28% down to 24.5% in 2019, we had bottomed out. We continue to see a nice improvement. We are still standing firm on the target for 2023, and this quarter is an example. We had an actual margin of 27.1%.


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Next slide, please.

So, talking about the long-term financial targets, not much new here. They're completely unchanged. The target for operating income margin is 28%, cash to earnings above 80, and net debt to EBITDA below 3 times. So, nothing new here. We're still committed to utilizing cash flow to pay down debt, and we do not plan to raise equity.

Next slide, please.

Now, at Teva, ESG is everyone's business, and it actually always has been. We've always been very focused on both environmental, social, and governance issues, but we are getting better at reporting what we're actually doing. And our next report on this, our next ESG report, will come out soon on May 4, and I can only encourage you to take a look at it. It will explain in much more detail how we are minimizing our impact on the environment, how we are taking a lot of steps to secure equity and good access to our medicines, how we're dedicating ourselves to quality, ethics and transparency, and a lot of other good topics. You can see some of them here, but it's a whole long report that will be coming out in a week's time that shows our strong progress and dedication to ESG.

With that, I'll hand it over to Eli who will give us some more details on the numbers.

## 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're all having a great start to 2021.

I'll begin my review of the first quarter 2021 financial results on slide 15, starting with our GAAP performance. Revenue in the first quarter of 2021 were approximately $4 billion, a decrease of 9% compared to the first quarter of 2020. This decrease was mainly due to a lower revenue from generics, OTC, respiratory, and COPAXONE in our Europe segment as well as lower revenue from our distribution business of COPAXONE and BENDEKA, TREANDA in our North America segment. This was partially offset by higher revenue from generics in our North America segment as well as from AUSTEDO.

Revenues were also affected by the impact of COVID-19 pandemic. I would like to remind you that when comparing the year-over-year performance, please note that the first quarter of 2020 benefited significantly from the high COVID-19-related revenues. Furthermore, please note that Q1 2020 included the generic product sales in Japan totaling $41 million and approximately $240 million for the full-year 2020. As we communicated on our Q4 2020 earnings call, as of February 1, 2021, these products were divested along with the manufacturing site in Japan.

Exchange rate movement during the first quarter of 2021 net of hedging effects positively impacted revenue by $74 million compared to the first quarter of 2020.

In Q1 2021, we recorded a GAAP operating income of $434 million versus $191 million in Q1 2020, GAAP net income of $77 million versus $69 million in Q1 2020, and GAAP earnings per share of $0.07 versus $0.06 in the same period a year ago. The year-over-year improvement in GAAP operating income, net income, and earnings per share was mainly due to a lower intangible assets impairment charges partially offset by lower profit in Europe along with the higher legal settlement and the loss contingencies.


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Turning to slide 16, you can see that the net GAAP adjustments in the first quarter of 2021 were $621 million versus $766 million in the first quarter of 2020. Non-GAAP net income and non-GAAP EPS for the first quarter of 2021 were adjusted to exclude these items with the largest being amortization of purchased intangible assets totaling $242 million, the majority of which is included in cost of goods sold. This quarterly amount for amortization is slightly below the range of $250 million to $260 million per quarter that we guided to at the start of the year.

Impairment of assets and accelerated depreciation totaled $134 million in the first quarter of 2021. This includes an expenses of $79 million for identifiable intangible assets impairments compared to expenses of $649 million in the first quarter of 2020. I would also note that in the first quarter of 2021, we recorded an expenses of $104 million in legal settlements and the loss contingencies. The expenses in the quarter was mainly related to a provision for a potential patent settlement.

Now moving to slide 17, we'll review our non-GAAP performance. Kåre and I have already reviewed the first quarter revenues, which total approximately $4 billion, so let's move down to the P&L and look at the margins.

Despite the 7% year-over-year decline in total non-GAAP gross profit, our gross profit margin improved to 53.8% compared to 53.1% in the first quarter. The year-over-year increase in the non-GAAP gross profit margin was due to a favorable product mix as well as our ongoing efforts to improve our cost of goods sold.

A relatively flat operating expenses base helped to partially counter $167 million decline in our non-GAAP operating profit versus Q1 2020 and resulted in a non-GAAP operating margin of 27.1%. We ended the quarter with a non-GAAP earnings per share of $0.63, a decrease of 70% versus Q1 2020 mostly due to the lower operating profit. While I will touch on the guidance later in my presentation, I will note that the first quarter came in as we had expected it to and as we guided in February.

Now, let's take a brief look at our spend base on slide 18. Year-over-year, our quarterly spend base declined by more than $200 million. The main driver for this exchange was a reduction in our cost of goods sold as operating expenses were flat. Decline in sales had the greatest impact on the reduced cost of goods sold, supported partially by our ongoing efforts to improve our gross margin through the transformation of our network. Based on the first quarter as well as an expected modest uptick in operating expenses in the second half of the year, we believe our spend base will come in at approximately $12 billion for 2021.

Now, turning to free cash flow on slide 19. Teva's free cash flow in the first quarter was $59 million versus $551 million in Q1 2020. As you know, Teva's free cash flow tends to face headwinds at the start of the year due to usual timing of annual bonus payments paid out in the first quarter, but the headwind was especially large in the first quarter mainly due to timing of working capital items resulting from increase in the net accounts receivable and inventories as well as lower profit in our Europe segment.

Please recall our 2021 free cash flow guidance, which we provided in February and are reaffirming today. 2021 free cash flow is expected to be in the range of $2 billion to $2.3 billion. We expect this free cash flow to pick up during the next three quarters as we are driving inventory improvements as part of other working capital items. While our free cash flow was relatively lower for the first quarter, we remain on our objective of 80% or greater free cash flow conversion as part of our long-term financial target.

Turning to our outstanding debt on slide 20. Net debt declined to $23.2 billion versus $23.7 billion at the end of 2020. Our net debt to EBITDA slightly increased to 4.9 times versus 4.83 times at the end of 2020. It's worth noting the sequential drop in EBITDA moving average totaled from $4.9 billion in Q4 2020 to $4.7 billion in Q1 2021. Recall that the first and fourth quarters of 2020 were particularly strong, benefiting from higher COVID-


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related sales in Q1 and the launch of generic TRUVADA in Q4. The second quarter of 2020 saw a reversal of the COVID-related stocking at the first quarter of 2021, saw a lower sales of generic TRUVADA resulting in the sequential decline in EBITDA moving annual total.

Debt reduction continues to be our primary focus and main use of cash as we continue to push forward in our efforts to bring our net debt to EBITDA ratio under 3 times by the end of 2023. Upcoming maturities include $1.5 billion in the third quarter and $1.2 billion in the fourth quarter, both which will be covered by our liquidity and expected cash flow.

So, now turning to our financial outlook for 2021 on slide 21. Today, we are reaffirming all components of our annual guidance that was presented in February, including total revenues between $16.4 billion to $16.8 billion and earnings per share of $2.50 to $2.70. Looking at the progression of both sales and earnings throughout the year, we're not changing the color that we provided in February. We still expect a gradual pick-up in the second quarter following the first quarter, which is expected to be the lowest of the four quarters for the sales and earnings. 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.

And this concludes our review of Teva's first quarter 2021 results.

We'll now open up the call for questions and answers. Operator, if you will, please? Thank you.

# QUESTION AND ANSWER SECTION

**Operator**: Thank you. [Operator Instructions] The first question comes from the line of Balaji Prasad from Barclays. Please ask your question. Your line is now open.

**Balaji Prasad**
*Analyst, Barclays Capital, Inc.*

Q

Hi. Good morning, and thanks for the question. This is Balaji from Barclays.

So firstly on AJOVY, just wanted to understand a sense of what would be the key growth drivers in Europe considering that you have touched almost all the core markets there. And what's going to drive the market share from 22% to 33% goal, and by what timeframe?

And on the generics side, just one quick question on deflationary comments which have come through from the likes of Walgreens and Sandoz yesterday. And Teva doesn't seem to have been touched by it especially this quarter. So can you kind of help us understand what were the offsetting factors here which helped you weather any generic deflationary trends recently? Thank you.

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

A

Thank you very much for those two questions.

So, if we start with the first one on Europe and AJOVY and how do we see the growth drivers, the key growth driver is or there are two key growth driver, one, is the underlying market growth. As you saw, the market grew


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more than 100% in volume over the last year. We expect this to continue. There's a nice uptick in almost all markets of this class, so that's one element.

Then, as you know, Europe, you have quite stable, quite good pricing. That doesn't really matter so much. It just means that there's no real change there expected. And then we really have a very, very good product offering. We have the fact that we have the longest-acting product which basically means that it's possible to take it once a month or once every three months. The experts, they like that. We have the fact that we have a really nice auto-injector. It's a product we get from Switzerland. It's a really sleek device. And we have the fact that we have an unbeaten safety profile in our labeling. We don't have any issues in our labeling on the safety side. That's not the case for all of our competitors.

So all these factors combined with the fact that we have a strong historic position with our sales force and with neurologists in Europe basically means that we see that the market shares continues to tick up. So when I say we expect to reach 33%, it's really a continuation of that graph you're seeing in our deck. And I expected that with some smaller deviations we'll see a continued uptick in market share over the coming years, and that means that it will not be very many years before we will hit those 33% in the European market.

With regard to your second question, I'll get back to the ice machine that I introduced before, at a previous call. So it's – so that with all generics in the US market, there is this ice machine where the new ice cubes in the machine drops down, and they are big. And they contribute a lot to revenue and profitability because they're brand new. And if you're lucky, you had a first-to-file, so you're alone for 180 days. Otherwise, you're maybe one out of one, two, three companies that hit the market with a new generic once it goes off-patent. And then gradually, more competition comes in, and the ice cube starts to melt and becomes less and less significant. And there's price erosion as more competitors enter into the marketplace.

Now, we had some classical ice cubes, you could say, in the fourth quarter of last year, with the generics of TRUVADA and ATRIPLA that we launched, and they made a good contribution in the fourth quarter. They also made a nice contribution in the first quarter. And then we have some I would say slower-melting ice cubes, and that's typically what you see within what I would call complex generics.

When you talk complex generics, then you will sometimes see that the products will not get as much competition because it's simply complicated to make the product. And that's the case, for instance, for EpiPen. So we have a generic version of EpiPen, and that is still having nice revenue, nice market share. We also have an authorized generic of ProAir. That's also a complicated product because it's an inhalator respiratory product. So that also has a good position.

So you can say that there's a little difference in how fast the ice cube melts. If it's a traditional solid, all-dosage form generic, then typically you get a lot of competition which means relatively faster price erosion. If it's a complex generic, it goes a little slower. So it's really a combination of these factors that we had a nice performance of our generic business in the first quarter.

Thanks for the question.

**Balaji Prasad**
*Analyst, Barclays Capital, Inc.*

Q

Thanks, Kåre.


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**Operator**: Thank you. And the next question comes from the line of Gary Nachman from BMO Capital Markets. Please ask your question. Your line is now open.

### Gary Nachman
*Analyst, BMO Capital Markets Corp.*

Q

Hi. Good morning. What have you been doing to help make the TRUXIMA launch successful? So talk about the dynamics behind the scenes, how you've been able to navigate with the payers and physicians which gives you more confidence. Biosimilars can be big contributors for you going forward.

And then a follow-up, just the much lower free cash flow in the first quarter. Could you explain some more how the working capital impacted that? And what you're doing to change that throughout the year to get to the target that you talked about in the guidance? Thank you.

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

A

Thanks, Gary, for those two questions. Brendan will answer the first one, and then Eli will answer the second one. So over to you, Brendan.

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

A

So thank you. I don't want to give away too much for our commercial strategy really on TRUXIMA, but I will just comment in general to say when you think about TRUXIMA, or you think about biosimilars in general. There's biosimilars that'll go through kind of a medical channel, and there will be biosimilars that go through more of a retail pharmacy channel. So the strategies are somewhat different as to how you navigate that.

And if you think about Teva, Teva has a strong specialty business. And of course, obviously, we have a very strong dominant position in generics. So I think it's the capabilities of both of those organizations, the way we're structured, bringing those together that have made us successful in the way that we've approached the biosimilar launches of recently with TRUXIMA. So I think I'd probably leave it there.

I think that we are well-positioned. As we continue to do well with TRUXIMA, we'll grow TRUXIMA in 2021 over 2020. We'll probably flatten out in the out-years and then a slow decline which we'll replace as we launch new biosimilars. So I think that probably answers the question.

Over to you, Eli.

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

A

Thanks, Brendan. Let's have Eli's comment on the cash flow.

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

A

Eli, are you on mute?

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

A


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Yeah. Sorry. Thanks for the question. I would say that if we will trend the working capital in average versus our revenue, I would say that we are up by 1% to 2% over annual revenue. And this is mainly due to sequential increase a bit on the inventories due to demand behavior. And also the mix in Q1 in terms of revenue and how this one resulted with actually payment terms instead revenue that actually contributed as one. Although those one we consider it as a nonrecurring event swings that we actually are working to stabilize it already with a lot of actions under way.

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

Thank you, Eli. Thanks for the questions.

**Gary Nachman**
*Analyst, BMO Capital Markets Corp.*
Q

Thank you.

**Operator**: Thank you. And the next question comes from Jason Gerberry from Bank of America. Please ask your question. Your line is now open.

**Jason M. Gerberry**
*Analyst, BofA Securities, Inc.*
Q

Hey, guys. Thanks for taking my questions.

I guess first question was just on gross margins. Just kind of curious if you could talk about conceptually how you're thinking about quarterly phasing. It seems like TRUVADA was an offset against a seasonally soft AUSTEDO which has the 1Q from a seasonality dynamics. So just curious how you're thinking about progression of gross margins as the TRUVADA exclusivity comes off.

And then my second question is just coming back to TRUXIMA from a biosimilar perspective. Can you give us a sense right now what proportion of the US oncology market where prescribers aren't operating to prescribe the drug with the highest average selling price, given the markup dynamics, effectively, where providers participate in sort of capitated or value-based constructs where lower-cost alternatives could potentially gain traction? Thanks.

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

Thanks, Jason, for those two questions. I'll address the gross margin, and then we'll get back to Brendan on TRUXIMA again.

So on the gross margin, just to clarify, TRUVADA is not a main element to the gross margin in the first quarter. And basically, the reason is, just to explain a little bit again about the ice cubes, that TRUVADA launched in the fourth quarter with 180 days exclusivity. But technically how that works in the marketplace is then you know out of the 180 days you'll get competition. And then in order to make sure you have a steady flow of products in the market, you sell the product. And some of the sales you have you don't record because you know that the moment that the generics number two, three, four, five launch, then you will have to give a rebate to the wholesalers who bought your TRUVADA and ATRIPLA for that matter.

So that means that the TRUVADA sales, they are there in the first quarter, but they are more significant in the fourth quarter. That's why I mentioned them in the beginning that you could see the [indiscernible] (00:32:45) US


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sales in the fourth quarter. And then of course there's something in the first quarter, but not really something that dramatically influences the gross margin.

So I would rather say that the underlying performance is driven by the constant efforts to rationalize and optimize our manufacturing footprint, our manufacturing operation, and then you will see, like you said, some small swings from quarter to quarter. Of course, based on – if all of a sudden you have some patient level hoarding, you sell a couple of hundred million more, then that can maybe affect it a little bit. Or you have a product launch that affects it a little bit. But the reason why we are committed to improving our operating margin is really because we know that there are thousands of small sub-projects we have in manufacturing, it is improving our gross margin. And the way we handle our total product portfolio is improving our gross margin.

This is something that doesn't come easy. It doesn't come overnight. And I've said many times that you should expect that we can do this to the tune of 50 basis points to 100 basis points per year. But you could also expect that once we get to 2023 and we hit the 28% operating margin, then of course we don't really want to stop there. We want to keep on improving the way we operate and keep on improving our gross margin as we go further.

So some quarterly fluctuations. Nothing dramatic. Underlying steady improvements, 50 basis points to 100 basis points per year.

With that, over to you, Brendan, on TRUXIMA.

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

Sure. So when you look at biosimilars and you think about the commercialization of those products, launch order matters. So if you launch first or second, you're going to get significant value. You launch third or fourth, you're going to get some value. You launch after fourth, and the value declines rapidly. So TRUXIMA launched first. We were able to make significant inroads in the market. And then when the second product came out, they had some difficulty getting traction. But then of course we got an ASP. They don't have ASPs, as you've talked about. So they had an advantage, grew share, and it cost us more to keep the share that we had.

So that's really the dynamic. It's very much like generics. Each time a new entrant comes into the market, there will be a period of time where they have an ASP advantage where they don't have one and the others do. That allows them to gain traction, some share in the market, and it makes it more expensive to keep your share because it erodes your price and your discount, so to speak. So that's really just the dynamic. It works very much like a generic market.

I think when you look at TRUXIMA, again, we'll continue to grow share as we go through 2021. And as we get into 2022 and 2023, we'll see that flatten and then probably decline slowly over time.

Thanks for the question.

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

Thanks for the question.

**Operator**: Thank you. And the next question comes from the line of Umer Raffat from Evercore. Please ask your question. Your line is now open.


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**Umer Raffat**
*Analyst, Evercore Group LLC*

Q

Hi. Thanks so much for taking my question. Kåre, a couple for you, and a quick one – a couple for you really.

One, have the cities and counties' lawyers come back with a counter offer yet on the opioid side? I'm very curious about where things stand on that. And also, on generics, just wanted to understand what you guys are baking in for full year for Europe. And I ask because the commentary coming out of Sandoz appeared far more guarded than what I'm hearing on this call. So thank you so much.

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

A

Yes, Umer. As I'm sure you're keenly aware of, we are in active litigation in California with four entities there. So I can't really make any specific comments due to the fact that we are in active litigation. I can tell you that we have all the time since we sort of went into the framework agreement in supporting settlement to the benefit of people suffering from substance abuse in the United States, and we're still seeing that as the only good solution to this issue. So that's really how much I can say. Sorry that I can't give you more details on that.

With regard to generics and Europe, then, as I commented in the beginning of this call, we are seeing here in the first quarter a continued volume reduction in Europe OTC and generics, as we also saw in the third and fourth quarter of last year. So we have not come out of lockdowns in the big markets. That's still the case here in the second quarter. So we're still seeing, for instance, France, Italy, Germany having some level of lockdowns. However, we're also seeing vaccination rates come up very fast now eventually in Europe.

So we're basically sticking to the prediction which I gave last quarter, which is that the first and second quarter, Europe will be sort of affected by reduced volumes on OTC and generics, and that we are expecting the lockdowns to basically ease such that third and fourth quarter this year we'll see more normal patterns of doctor visits, hospital visits, and so on, and a normal volume of OTC and generics in Europe.

Thanks for the questions.

**Umer Raffat**
*Analyst, Evercore Group LLC*

Q

Thank you.

**Operator**: Thank you. And the next question comes from the line of Gregg Gilbert from Truist. Please ask your question. Your line is now open.

**Gregg Gilbert**
*Analyst, Truist Securities, Inc.*

Q

Thank you. My first one is perhaps for Brendan on generic Narcan. Can you update us on the opportunity and what happens next there? And whether that could become part of a broader settlement framework discussion, given its sort of potential benefit?

And then, Kåre, a bigger picture question. With the turnaround phase of the company well under way and the margin progression and the good progress we've seen, I'm curious how much time and energy you and the Board are spending on thinking about positioning Teva for growth later in the decade, beyond the assets you've already


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identified, as worthy of your investment. Are you considering licensing, bolt-ons et cetera things that you can bring to the party beyond what you already have?

And as part of that, I'm curious as to whether your answer would be different if you had a settlement in hand with a set amount of cash outflows over X number of years. Is it sort of we can make a list now, but we can't execute on it because of that uncertainty? Just curious if your answer would be different if you had the bird in hand in terms of a knowledge of liability, size, and pacing. Thank you.

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

A

Thanks for the questions, Gregg. So the first one goes to Brendan on Narcan.

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

A

Yeah. So I really don't have much of an update on Narcan. We continue to work on it. I think we still have some legal issues that we're working through with it. But as to whether it could be part of a broader settlement or not, I'll leave that to Kåre to answer. But just real basically continue to work on Narcan. And when we're ready to introduce it into the market, I will certainly let you know.

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

A

Yes. And with regard to potential settlements and Narcan, it's the same boring answer that really due to the fact that we're in active litigation, I can't comment on it.

I can comment on your second question about how do we see the strategy going forward. And as you probably know, it's really our vision for the company to continue to be leaders in generics and strive for leadership in biopharmaceuticals including biosimilars, and that's really our focus now.

That, of course, might include, as you suggested, in-licensing M&A and so on. However, our financial position – and that is really not related to whether we have a settlement on opioids or not. Our financial position is such that we are totally committed to reducing net debt below 3 times EBITDA. And once we get past that point, then you'll probably see that we will continue to be very capital disciplined, very cash disciplined, and probably want the debt to continue further down before we consider things such as M&A or dividends or share buybacks. But that really all lies in the period after 2023 when we're going to get below 3 times net debt to EBITDA.

And if we then think about the strategy we have which is linked to our vision and mission, then to the extent it's possible within those targets, we do of course do in-licensing. We have been in-licensing early-stage assets. We have been in-licensing different biosimilars. So it's not that we don't do it. But we just don't do any M&A, we don't go out and buy Phase 3 products, or already launched products. So we're very disciplined in how we allocate the capital, and we will stay the course with that at least until we hit the end of 2023 where we will hit our long-term financial targets.

Thanks for those questions, Gregg.

**Gregg Gilbert**
*Analyst, Truist Securities, Inc.*

Q

Thanks.


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**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

Thank you very much, guys, and thanks for taking my question. Just a quick clarification, and then a couple of questions.

The clarification is around QVAR. Have you stopped reporting that? And why?

And then the two question I have is, what happened in the CGRP market? It looks like two of the three companies, the way we track the scripts, looked like had a significant reduction in the price [indiscernible] (00:42:50) by dividing revenue by scripts in the first quarter. I was wondering if this is just inventory or an agreement [indiscernible] (00:42:56) agreements that drove that down. If you can comment on that?

And then more broadly, Kåre, some of your peers have adopted that strategy of licensing second-wave products in established markets from China. For example, you know Coherus adopted there with the PD1. And that seems to be a logical strategy if you have a sales force in the oncology market. And I was kind of wondering if you guys considered doing those kind of licensing deals for second-wave branded products as opposed to biosimilars, or is there a reason why that strategy does not match Teva?

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

A

Thanks for those questions, Ronny. Could you just clarify once more exactly your first question? I didn't completely get it.

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

Q

Oh. QVAR; QVAR is not anywhere in your reporting, and I was wondering [indiscernible] (00:43:46) just simply stopped reporting that number.

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

A

Okay. So, I don't have a firm answer to that. I guess it's something to do with the thresholds of revenue and so on. That's my guess. But I'll just refer to Eli, and he can maybe fill us in on what the thresholds are and why it really isn't there. But it's not something that I've been involved in discussing, just to let you know.

So, Eli, do you have any comments to that QVAR, why is it not specified?

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

A

Yeah. Ronny, this is Kevin. Just it is really just a threshold. And we are still supporting the product, but the sales has dropped [indiscernible] (00:44:27). We just did not include it.


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

Q

Okay. Got it.

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

A

Okay. So Ronny – so nothing dramatically happening there.

Then on the licensing, we're really not pursuing this, you could say, second wave of patent-protected specialty products. It's really not within our strategy. So what we are pursuing is our own specialty products. And of course given the size of our portfolio that is a limited number of launches that you'll be seeing. Once a year, once every second year we'll have probably a product that we can launch. And then we are pursuing biosimilars and generics. So it is a possible strategy you could have adopted, but that's really not what we're trying to aim at.

Thanks for the questions, Ronny.

**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 & Associates, Inc.*

Q

Good morning. First question for Kåre and perhaps Brendan. Just thinking about full-year guidance for AJOVY, AUSTEDO, in light of 1Q performance in recent prescription trends, particularly with AUSTEDO, seems like obviously there has to be a significant acceleration in the back half of the year to kind of get to those numbers. Just help us think about your confidence in those numbers given what we've seen sort of year-to-date. And I guess what has to happen there? Is it just mainly script volume or is there something that I might not be thinking about in terms of net pricing that may swing in your favor fairly substantially in the second half?

And then for Kåre, just maybe thinking about potential hidden pockets of value in the company's proprietary pipeline, you have a couple of novel biologics programs in the respiratory area, TEV 48574 and TEV 53275. Anything you can say about where those fit kind of in the current asthma treatment paradigm? And what may be some of the competitor products out there that those would be going up against? And when might there be data or an update there? Is it late 2022 or potentially earlier? Thanks.

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

A

Elliot, thanks for those two questions.

The first one, I'll just say I'm very confident in our guidance for both AJOVY and AUSTEDO, but I'll hand it over to Brendan to give you some color on how we're seeing US piece of it. I'll just add that on AJOVY we see a steady growth in Europe, which we are very positive about, and we also expect to see our partner Otsuka getting the approval and do the launch of AJOVY in Japan at the end of this year. But of course the bulk of the business for AJOVY will still be in the US. This is also the case of course with AUSTEDO.

But over to you, Brendan.


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

A

Yeah. Sure. Take AJOVY first. So if you think about AJOVY, we continue to grow share nicely. I mean, we're up till we – basically since the launch of auto-injector, we've doubled the total prescription share as well as the new-to-brand share, and new-to-brand share right now is hovering at around 25%. We think we can get that into the 28% to 30% range, but to do that, as we've grown share we made significant investments in access and inpatient assistance to facilitate that share growth.

As we move to the back half of 2021 and into 2022, as we improve our access, then we'll have a more balanced approach in regards to share growth as well as revenue generation. So I think you can think of it that way. And as Kåre said, we still believe that the guidance that we put out is certainly achievable.

If you think about AUSTEDO, AUSTEDO also had a 20% share growth quarter over quarter. It started out maybe a little bit slow in January and February, which is not unusual. Typically, you see increased demand in the fourth quarter as [indiscernible] (00:48:30) benefits they know they're going to change in the first quarter, so you see somewhat of a slow start. But we do think that the $950 million is an achievable target.

And something that is built into that number which you're not aware of, and I'll make you aware of it here, is that we're starting a DTC campaign, a direct-to-consumer campaign, around tardive dyskinesia and AUSTEDO that will kick off with Mental Health Awareness Month here in the month of May, just starting here in the next couple of weeks. So we think that that'll be a significant catalyst to helping us get to that guidance that we put out.

Thank you for the question.

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

A

Thanks, Brendan. With regard to the two products you mentioned in respiratory, these two products are biologics that are in Phase 2 clinical development. And the thinking behind them is really that what they offer is better efficacy and better convenience for patients. So what we're hoping to do with them, and it's too early to give any details on it, but what we're hoping to do is really to be able to position them in a way where they're both superior in efficacy and convenience. But also by being so we're able to expand the share of the population that really gets biologics. Because right now, as I'm sure you know, there's a certain part of the asthma and COPD population that is not on biologics, and we think that these products might be a way to expand the share to the benefit of patients.

We will not have Phase 2 data publicized this year on these, but we hope to see some of it. I can't remember the exact dates, but I think some of it in 2022 and some of it in 2023.

Thanks for the questions, Elliott.

**Operator**: Thank you. And the next question comes from the line of David Amsellem from Piper Sandler. Please ask your question. Your line is now open.

**David Amsellem**
*Analyst, Piper Sandler & Co.*

Q

Thank you.


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So high-level question as a starting point. As the business evolves into more of a focus on biosimilars and complex generics, and we hear those terms thrown around a lot by the US majors, including yourself, how do you think about the potential for divestitures? And I'm asking that question broadly given how you're thinking about the evolution of the business. So that's number one.

And then number two on AUSTEDO, I just wanted to drill down on the direct-to-consumer campaign. To be clear, is that a function of any sort of worry about maturation and volume trends? And is that a signal that even though penetration rates [indiscernible] (00:51:18) are low, perhaps there needs to be more heavy lifting in terms of winning over hearts and minds in the psychiatry community? Just help me understand your thought process there. Thank you.

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

A

Thanks, David. I'll answer the first one, and then I'll pass the AUSTEDO question on to Brendan.

So when we talk about divestitures, then it's important to explain the process we've been through in connection with our restructuring. We really looked at all our businesses, and we have basically sold everything that we thought was not strategic. There might be some small bits and pieces left, and we've just sold a few bits and pieces. The old generics we had in Japan, we've sold those. We've sold a few OTC products in Scandinavia. But there's nothing major left, so don't expect us to announce all of a sudden that we're selling a big chunk of the business.

We are committed both to the complex generics and biosimilars, but we're also committed to solid oral dosage forms, classical generics. And we have to remember that biologics will be an increasing part of our dose off-patent over the coming years as it has been in the last five years.

**Operator**: Thank you. And we will now take our next question from the line of Nathan Rich from Goldman Sachs. Please ask your question. Your line is now open.

**Nathan Rich**
*Analyst, Goldman Sachs & Co. LLC*

Q

Thank you, and good morning. Kåre, could you remind us your expectations for generic price erosion in the US that's assumed in guidance this year? And do you expect this to be fairly stable over the course of this year? Just wondering if you think there will be any change in the competitive dynamics in the US as the FDA gets back to more normalized inspection activity.

And then I wanted to ask a follow-up on gross margin. Eli, do you think that you guys can kind of continue to build off of this level that you set in the US? You've made nice progress on gross margins over the past several quarters. I think you also called out some mix dynamics that were favorable in the first quarter here. And so I just wanted to get a sense of kind of what the key moving pieces are on the gross margin line over the balance of the year. Thank you.

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

A

Operator, can you hear us?

**Operator**: Yes. We can.


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

A

[indiscernible] (00:54:50). Annette, can you hear us from the backup?

**Operator**: Yes. We can hear you.

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

A

Okay. Can we continue?

**Operator**: Nathan, you might need to ask your question again. Please continue.

**Nathan Rich**
*Analyst, Goldman Sachs & Co. LLC*

Q

Yes. Sure.

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

A

No. Please, operator. We need to answer the questions from David. We answered about the divestitures, and then we got cut off by you introducing the next question before we answered the question about AUSTEDO in the DTC in the US.

So, David, you'll get your answer now on AUSTEDO DTC in the US. I'll introduce by saying we're not doing this due to any weakness in AUSTEDO but simply to reach more people with tardive dyskinesia.

But, Brendan, please fill us in on the DTC for AUSTEDO in the US.

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

A

Yeah. Kåre, I think that's exactly right. The reason for the DTC in AUSTEDO, we've been looking at DTC for a period of time, and the real reason is we see strength in this market and we see a lot of opportunity in this market. There are 500,000 patients estimated with tardive dyskinesia in the US. We've got about 30,000 patients currently treated. About 6%. So the upswing and the potential is huge. So it has been shown to be sensitive to DTC advertising, and it's really just a matter of resource allocation.

So we think that the trends that we've seen with AUSTEDO are strong. We think it makes a significant impact on patients' lives. And to be able to put some direct-to-consumer advertising out there to educate patients who may not even be aware necessarily that they have it, that there's something available for this treatment, could be of tremendous value. So that's really the rationale behind the DTC, and we look forward to seeing those results which will probably start to show up in Q3 and Q4 this year.

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

A

Thank you, Brendan. Now we'll move to the next two questions that were asked and the first one is about the erosion on generics, and I'll answer this one.


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And just to reiterate that in our two key markets it's of course different. So in Europe, we don't see much price erosion. It's really a question of when things go off-patent they shift to another price level, and then that price level is relatively stable. So no dramatic changes there. In the US, of course, we do see price erosion. And I won't repeat the whole ice machine analogy, but just say that some ice cubes melt a little faster than others. And it's basically like we've been discussing. So that the complex generics often get less competition, so they keep an attractive pricing for a longer period of time, where more simple products in a few years, they get two, three, four, five competitors, and the price goes down significantly.

There's no dramatic change from the way we analyze the business this year compared to last year. We see of course the normal level of erosion of pricing on generic products as they get older, but we also see good launch prices for new launches of generics. So all-in-all, no big changes there.

Then we have a question on the gross margin, and I'll refer that question to Eli.

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

Yes. So on the gross margin, as we did in 2020 when we topped 1% on gross margin that actually contributed additional one point to our operating margin. This is what we see now in our planning for the year. So expect it to be at least by 1% versus 2020, so call it like 53.5%, and that will actually contribute to the level of 27-plus in OP. So it's still on track.

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

Thank you, Eli. So I think we have time for one more question.

**Operator**: Thank you. And the last question is from Daniel Busby from RBC Capital Markets. Please ask your question. Your line is now open.

**Daniel Busby**
*Analyst, RBC Capital Markets LLC*
Q

Sorry about that. Can you hear me?

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

Yes.

**Daniel Busby**
*Analyst, RBC Capital Markets LLC*
Q

Yeah. Connection issue. Thanks for squeezing me in.

First question on fasinumab. Just curious if your plans or outlook for that product have changed following last month's Advisory Committee meeting for denosumab. And we're still waiting on long-term safety data there. When should we expect that data?


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And second just on generic price fixing litigation, could you remind us what the next steps are here? And when's the earliest date we could see a potential trial, whether that be on the civil side or the DOJ side? Thank you.

### Kåre Schultz

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

A

Thank you for those two questions.

So of course, we were watching the denosumab AdCom, and the vote that came out there was of course disappointing, was a vote on the REMS [indiscernible] (01:00:06) sufficient for denosumab. There hasn't been any sort of complete clarification on FDA's point of view on the product itself, so to speak, with the different REMS, but it's definitely a negative for the product class. And right now with fasinumab, we're having you can say all nonessential cost on hold, and we're looking forward to discussing the product together with Regeneron. We're looking forward to discussing the product with FDA. So it remains to be seen. But of course we're disappointed about the results of the AdCom for denosumab as an indirect indicator that it is a difficult path forward for fasinumab.

On the generic price fixing litigation, I think it's fair to say that the COVID-19 pandemic in the US has slowed down proceedings in the legal system, and it basically means that on the criminal side, we don't have any clear time schedule for when this will move to trial. But it will be a, I would say, significant period of time before that happens. And I think on the civil side, it's pretty much the same. So no real updates on the timing. We'll just have to wait and see how things progress with the legal system in the US getting back in gear now as the pandemic is reducing its impact in the US.

So thanks for those two questions, Daniel.

### Kevin C. Mannix

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

Thanks everybody for joining us. As always, we'll be available to take questions throughout the day, rest of the week, and we look forward to connecting with you all soon. Take care.

**Operator**: Thank you, ladies and gentlemen. That does conclude our conference for today. This conference will be available for replay within the next couple of hours after today's call. You may access the remote replay system at any time by dialing 00443333009785 and entering the access code 8347148. Those numbers again, the dialing number is 00443333009785 and the access code is 8347148. Thank you for today.


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