10-May-2023

Teva Pharmaceutical Industries Ltd.

(TEVA)

Q1 2023 Earnings Call

Copyright © 2001-2023 FactSet CallStreet, LLC

CORPORATE PARTICIPANTS

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

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

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

Eric A. Hughes
Executive Vice President-Global R&D & Chief Medical Officer, Teva Pharmaceutical Industries Ltd.

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

OTHER PARTICIPANTS

Umer Raffat
Analyst, Evercore Group LLC

Balaji Prasad
Analyst, Barclays Capital, Inc.

Ashwani Verma
Analyst, UBS Securities LLC

Nathan Rich
Analyst, Goldman Sachs & Co. LLC

Chris Schott
Analyst, JPMorgan Securities LLC

David Amsellem
Analyst, Piper Sandler & Co.

MANAGEMENT DISCUSSION SECTION

Operator: Hello and welcome to the Q1 2023 Teva Pharmaceutical Industries Limited Earnings Conference Call. My name is Alex. I'll be coordinating the call today. [Operator Instructions]

I'll now hand it over to your host, Ran Meir, SVP of Investor Relations. Please go ahead.

Ran Meir

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

Thank you, Alex. Thank you, everyone, for joining us today. We hope you have had an opportunity to review our press release which was issued earlier this morning. A copy of this press release as well as a copy of the slides being presented on this call can be found on the website at www.tevapharm.com. Please review our forward-looking statements on slide number 2. Additional information regarding these statements and our non-GAAP financial measures is available on our earnings release and in our SEC forms 10-K and 10-Q.

To begin today's call, Richard Francis, Teva's CEO, will provide an overview of Teva's Q1 2023 results and business performance, recent events and priorities going forward. Our CFO, Eli Kalif, will follow up reviewing the financial results in more detail, including our 2023 financial outlook. Joining Richard and Eli on the call today are Sven Dethlefs, Teva's Head of North America business; and Dr. Eric Hughes, our Head of R&D and Chief Medical Officer. They 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.

Copyright © 2001-2023 FactSet CallStreet, LLC

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

Richard Francis

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

Thank you, Ran, and good morning and good afternoon, everyone. Thank you also for joining us today. Now, before I start getting into the Q1 results, I thought I'd just take a bit of time to give you my thoughts and impressions of the last few months I've had at Teva. Now, in short, impressed by many of the things I've seen and discovered while being around the world talking to many of our people, and it's because of this that I think we have real opportunity at the company and maybe the company is underappreciated currently.

Now, let me go into sort of four areas I'd like to focus on here. Now, I know most of you think of us as a generics company; and in truth, we are more than that. We have an emerging innovative business, primarily driven by AUSTEDO and AJOVY, but recently about to be supported by UZEDY, our long-acting schizophrenia product, and this is going to fuel continued growth going forward. And already this is 10% of our total revenue. We also have a biosimilar portfolio, which I'll talk a bit about later, which is an opportunity to benefit from $4 billion of brand value coming off patent in the next few years.

Second, our pipeline. Now, I definitely know this is not fully known and understood, but I can tell you we have some exciting assets here. And as I've sort of dug deeper, I've seen some unique capabilities in our R&D organization, particularly when it comes to antibody design and formulation expertise. And as we go through our pipeline, I think you'll see that we have a balanced risk profile on many of our assets. Now, coming to our core business, our core generics business. This is a strong global business. And what I've discovered, this is more than the US. In fact, 60% of our business is outside the US, in Europe and in emerging markets, and this is a strong business and that it generates significant cash which obviously we're currently using to pay down debt.

Now, then moving on to our people, which is probably the thing that's inspired me the most. We've got a great group of people here at Teva and a great culture, the real can-do attitude, and this is something we're going to leverage as we move forward with Teva on our new strategy for growth. Now, that said, we have some headwinds and some short-term challenges which we'll discuss today, particularly around our cost of goods, but we have plans to deal with these going forward and because of that, we are reaffirming our guidance for 2023.

Now, moving on to the next slide. I would just like to invite everybody to our Investor Day which we're going to hold in New York next week, where we're going to introduce our new strategy for growth for Teva. Now, this strategy will be built on some of the strong foundations that I described in the previous slide and I've been working hard with the executive management team here at Teva, along with many others in the company, to really challenge ourselves to look at how we can, with a changing market, unlock accretive, real value for Teva going forward.

I'm excited by the outcome. We have made some clear choices in this strategy, some clear prioritization, and we have a focused company going forward where the capital allocation will follow this. So, as I said, please join us next week where we unveil the new chapter of Teva. Now, moving on to Q1 performance. Let's start with revenues. Our revenues for Q1 versus Q1 2022 were $3.7 billion, up 4%. AUSTEDO was up 10% and AJOVY up 35%, driving our innovative business that I mentioned earlier. And in European generics, in local currency we're up 12%; in local currency in International Markets we're up 9%, so I think a solid performance for Q1 on the revenue.

Copyright © 2001-2023 FactSet CallStreet, LLC

Now, taking a look at it from a regional perspective. As you can see, all regions were up in local currency on growth, 2% for North America, 9% for Europe, and 8% for International Markets. Now, keep in mind that our revenues are still affected by the strengthening US dollar and we did have a negative impact of $128 million in quarter one versus 2022. Now, moving on to the next slide to talk about AUSTEDO as part of this innovative portfolio that I talked about. Revenues were $170 million, up 10%. And what's particularly pleasing is TRx was up 28% versus last year. I'm very excited about AUSTEDO and particularly because I see this as an untapped opportunity. We have roughly 800,000 people suffering from this condition and only 120,000 diagnosed and then only 50,000 treated. So, we have significant opportunity to grow this product and help patients suffering from this condition.

On the next slide, you'll see this has been further improved, this patient offering with the launch of AUSTEDO XR. This is the once-a-day formulation. Now, I think this is the final piece of the puzzle for AUSTEDO because obviously, as you appreciate, many of these patients are on multiple medications. And us having a once-a-day offering I think really offers some advantage for them and strengthens the product offering for those patients and caregivers. So, now moving on to another part of our innovative portfolio is AJOVY. Now, AJOVY is almost reaching $100 million a quarter, currently sitting at $95 million; up 36% in North America, up 17% in Europe, and up 74% in International Markets.

So, we're growing across all regions which we're very pleased about. And what I've mentioned before and I'll reiterate, what I like about AJOVY is the fact that this was not a product we managed to bring to the market first in its category. In fact, in many areas we were not and we were last. But what we've shown with our commercial capability and muscle that despite this, we can achieve growing market share and a significant position in many of the markets, often number two. And so, I still see growth going forward for AJOVY through geographic expansion and expansion of market share.

Now, the new product to this innovative family is UZEDY, risperidone, which was approved about two weeks ago and we're excited about this long-acting risperidone. I was recently on a field ride in the US with some of our sales representatives and speaking to psychiatrists and clinical nurse practitioners actually about AUSTEDO, but many of them were asking when this long-acting risperidone would be available. And in discussing with them why they were so enthusiastic about it, it came back to our patient-friendly profile. The fact that we have rapid absorption within 6 to 24 hours of administration was important to them, the sub-Q, smaller needle, lower volume, all of these made it an easy-to-use product for them in this patient population.

Now, keep in mind that the long-acting market is a $4 billion opportunity when it comes to schizophrenia, and so with UZEDY, this profile, we think we have real opportunity to generate some revenue going forward. Now, pivoting back to our generics business. As I mentioned before, we have a big business outside the US, over 60%, and we're seeing continued strong growth in both of those regions, 12% in local currency in Europe and 9% in International Markets. And this is attributed to our core capabilities. We have a good pipeline, we can regularly launch products into our portfolio, we have a good supply chain, and we have a good commercial infrastructure. So, I see no reason why we cannot continue to leverage this capability going forward.

Now, to move on to our pipeline. And you'll notice for this call, I've separated the innovative pipeline from the biosimilar pipeline, and that's really to start to highlight the pipeline of some of the exciting assets we believe [indiscernible] (10:29). Now, I'll just call out a few here. Olanzapine long-acting, another long-acting medication for patients – people suffering from schizophrenia which we'll add to our franchise. ICS-SABA in asthma which is in Phase 3 and anti-TL1-A in Phase 2. I'll describe these in a bit more detail in a couple of slides, but obviously looking forward to presenting more depth in our pipeline next week at our Strategy Day where Dr. Hughes, our Head of R&D, will be talking about these in far more detail.

Copyright © 2001-2023 FactSet CallStreet, LLC

Now, moving on to our biosimilar pipeline and franchise, I think what I've said in the past is you need to have a good pipeline and a good portfolio to succeed in biosimilars and to have a good commercial footprint. I think you can see we have both of those. Now, to address a question which I think is going to come up today is about biosimilar Humira and where we are with that. So, maybe I could take a few moments to talk about that. So, as many of you know, the FDA issued a CRL to our partner Alvotech based on certain reinspection observations in their facility in Iceland. Now, Alvotech is expecting communication from the FDA shortly assessing their responses for their recent observations. Now, once Alvotech receive communication from the FDA, we will have a better understanding of the timings of a potential launch of biosimilar Humira.

Now, going back to those promising late-stage assets from our innovative portfolio. Now, I don't want to step on Eric Hughes' toes for next week when we launch the new strategy at Investor Day, so I'll keep it brief, but maybe just give a slight headline on some of these programs. So, olanzapine, we're excited by this because obviously, I've mentioned to you already with UZEDY there's a significant opportunity to move the schizophrenia market to a long-acting therapy. Now, this olanzapine product leverages our BEPO technology with MedinCell, which is the company we work with on UZEDY. So, I'd like to think this has been proven because of, obviously, the recent approval of UZEDY.

Now, moving on to ICS-SABA. This clearly leverages our respiratory expertise and our ability to bring complex products to the market. It brings together two well-characterized and well-used products for a subset of the asthma market, which we believe is worth around $2.5 billion and it will only have one competitor. Then lastly, moving on to the anti-TL1-A asset, which I'm sure you're all familiar with, it seems to be a very hot topic right now. We see this as a good opportunity because it's a validated target and we see because of the number of indications that it could potentially go after a significant opportunity around $25 billion. And we believe we have a best-in-class profile, but more to come on those assets on the Investor Day.

In closing, I want to talk about an important priority of ours which is our commitment to ESG, and I just want to take a bit of time to give you an insight to the progress we've made. So, let me just pick a few of these out. But when it comes to greenhouse gas emissions, we had a goal to reduce these to 25% by 2025. As you can see, we're closing on that already. Another area of focus has been on compliance and business integrity and we have met our goal of 100% of all our employees trained on compliance policy. Finally, I can highlight the economic impact we've had: $44 billion in savings from Teva's generic medicines across 21 countries, and we've contributed $20 billion to GDP across 24 countries. So, I think we've made very good progress with regard to our ESG commitments.

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

Eli Kalif

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

Thank you, Richard, and good morning and good afternoon to everyone. I'll begin my review of our Q1 2023 financial results with slide 18 starting with our GAAP performance. Revenue in the first quarter of 2023 were $3.7 billion. In dollar terms, they were flat compared to the first quarter of 2022. In local currency terms, revenue increased by 4%. To provide you some color on our revenue performance by region, in North America, we had overall solid performance with 2% growth in Q1 2023 compared to the first quarter last year. This growth was mainly driven by higher revenue from certain innovative products, mainly AUSTEDO and AJOVY, as well as Anda, our distribution business. This was partially offset by lower revenues from our generics business and BENDEKA and TREANDA.

Copyright © 2001-2023 FactSet CallStreet, LLC

Our generic business in North America decreased in Q1 2023, mainly due to increased competition to parts of our portfolio and timing of certain customer bids. The overall pricing environment in North America generics is stable and in line with historical trends. Revenues in our Europe segment grew strongly by 9% in local currency terms, mainly driven by higher revenue from our generic business, including new product launches. And revenue from our International Markets segment increased by 8% in local currency terms, mainly due to higher revenues in our generics business coming from price increases, largely as a result of rising costs due to inflationary pressures.

Operating income was $2 million in the first quarter of 2023 compared to an operating loss of $713 million in the first quarter of 2022. We had a net loss of $205 million compared to a net loss of $955 million in Q1 2022, and a GAAP loss per share of $0.18 compared to GAAP loss per share of $0.86 in the same period a year ago. This improvement in our GAAP operating income, net loss and net loss per share in the first quarter of 2023 were mainly due to the higher impact of legal settlements and loss contingencies that we had in the first quarter of 2022.

Foreign exchange rate movements during the first quarter of 2023, including hedge effects, negatively impacted our revenue and GAAP operating income by $128 million and $72 million, respectively, compared to the first quarter of 2022. This was a result of the impact of stronger US dollar against other currencies of main markets in which we operate, mainly the euro and other related currencies. As a reminder, approximately 50% of our revenues in Q1 2023 came from sales denominated in a non-US-dollar currency.

Turning to slide 19. You can see that total non-GAAP adjustments in the first quarter of 2023 were $661 million compared to $1.564 billion in Q1 2022. A notable non-GAAP adjustment was legal expenses of $233 million mainly related to estimated provisions recorded in connection with certain litigation cases in the US. Other notable adjustments include amortization of purchased intangible assets of $165 million, the majority of which is included in cost of sales, and impairments of long-lived assets totaling $188 million.

I also want to provide you with an update on the progress with a nationwide opioid litigation settlement. During the previous quarter, we had confirmed a high level of state participation, 49 out of 50 states. Based on the strong state participation, we decided to move ahead to the next phase with a subdivision participation, which I'm happy to report is also going very well. To-date, we have confirmed participation from over 99% of the litigating subdivisions from those participating states. Overall, with the level of broad support we have seen by the states and subdivisions, we expect to move forward [ph] favorably (19:58) in the process and we anticipate making the first settlement payment in the second half of 2023.

Now, moving to slide 20 for a review of our non-GAAP performance. I've already discussed our first quarter revenue, which totaled approximately $3.7 billion and represented a growth of 4% in local currency terms compared to first quarter of 2022. Now, let's move down the P&L and look at the margins. I would like first to drill down and analyze our gross profit performance this quarter. Our non-GAAP gross profit margin was 49.1% in Q1 2023 compared to 54.2% in Q1 2022. And the decrease in non-GAAP gross profit margin was driven by two main factors, our portfolio mix and the macroeconomic factors. Our first quarter came in with a different and unfavorable portfolio mix than we expected.

While we continue our solid growth in our key focus area, including AUSTEDO, AJOVY and our generic business in Europe and International Markets, this is being offset by margin-dilutive growth of Anda business and lower contribution from our legacy brands. As we progress through the year, we anticipate a shift towards a more balanced and normalized portfolio mix in the coming quarter, mainly driven by growth in AUSTEDO and AJOVY. As for the impact of the macroeconomic factors already mentioned on our previous earning calls, we faced

Copyright © 2001-2023 FactSet CallStreet, LLC

inflationary pressures in the second half of 2022 and much of that impact from last year was held in our inventory and sold this quarter. This resulted in a higher cost of goods sold in Q1 of this year.

In addition, we also had some unfavorable impact from hedging activities, which impacted our gross margins, with the majority of the impact in our European and International Markets segments. Going forward in 2023, we expected improvement on certain elements of the inflationary pressures, including on cost of energy and freight. In addition, we also expected a sequential improvement in our COGS, driven by certain measures we are taking in our supply chain. Our non-GAAP operating margin in Q1 2023 was 21.4% versus 27.7% in Q1 2022. This decrease was mainly driven by the lower gross profit margin as I just mentioned, as well as the higher other income in the first quarter of 2022, which mainly included one-time settlement proceeds in our International Markets segment. We ended the quarter with a non-GAAP earnings per share of $0.40 compared to $0.55 in Q1 2022, mainly due to the lower gross profit which I referred to a moment ago.

Now, let's take a look at our spend base on slide 21. As you can see, our quarterly spend base increased by $229 million or $224 million on a local currency basis. Most of this increase was due to a higher cost of goods sold related to the factors I described earlier, as well as the higher other income in the first quarter of 2022, which mainly included settlement proceeds in our International Markets segment. Our next slide, 22, shows how we have been transforming our global manufacturing and operating footprint over the last five years to consolidate our sites to get more efficient. And here, you can see over the last five years we have gone from 80 manufacturing sites down to around 52 sites, and we have plans to continue this progress. By the end of 2023, we expect to close or divest three additional sites, with plans already in place to close or divest four additional sites beyond 2023. So, this evolution will continue as we drive ongoing optimization of our operations for efficiencies and improving margins.

Turning to free cash flow on slide 23. Our free cash flow in the first quarter of 2023 was $41 million. Teva's free cash flow tends to face headwinds at the start of the year due to the unusual timing of annual bonus payments paid out in the first quarter. In addition, our free cash flow for Q1 2023 was also impacted by lower profit and changes in working capital items, including an increase in accounts receivable net of SR&A, partially offset by an increase in accounts payable. Today, we are reaffirming our 2023 free cash flow guidance which we provided in February. Our 2023 free cash flow is expected to be in the range of $1.7 billion to $2.1 billion. We expect our free cash flow to pick up during the next three quarters as we see a ramp-up in our profitability and as we continue to drive working capital improvements.

Turning to slide 24. Our net debt at the end of Q1 2023 was $18.5 billion compared to $18.4 billion at the end of 2022. Our gross debt was $20.7 billion compared to $21.2 billion at the end of 2022. The decrease in our gross debt was mainly due to $646 million senior notes repaid at maturity, partially offset by exchange rate fluctuation of $176 million. Our net debt-to-EBITDA slightly increased, coming at 4.25 turns for Q1 2023 mainly due to lower EBITDA. Looking at slide 25. Debt reduction continued to be our focus. As you can see, we have made significant progress in the last six years to reduce the level of debt on our balance sheet, and we expect this progress to continue and our net debt further decline as we work towards our long-term financial target of being 2 times net debt-to-EBITDA by end of 2027.

Turning to slide 26 which represents our upcoming update maturity. During the first quarter of 2023, we successfully refinanced approximately $2.5 billion of our debt through sustainability-linked senior notes. This was done to mainly address the 2023, 2024, and 2025 maturities and to align our near-term debt maturities with our free cash flow guidance for this year. These notes are linked to sustainability performance targets and reinforms our continuing intention to establish a direct link between our corporate responsibility commitments and our

Copyright © 2001-2023 FactSet CallStreet, LLC

funding strategy. If we combine this recent issuance with our previous SLB bond financing of $5 billion, Teva is now the second-largest corporate SLB issuer worldwide and the largest in the pharmaceutical industry.

Given the interest rate environment, this will result in higher financial expenses for the remainder of the year which was already accounted for in our 2023 annual guidance that we provided in February. Now, let's turn our attention to our 2023 non-GAAP outlook on slide 27. As we guided in February when we provided our full year outlook, we had expected Q1 to be the lowest of the four quarters both in terms of revenues and margin. For full year of 2023, we continue to expect our revenues to be between $14.8 billion to $15.4 billion. We are also reaffirming our 2023 non-GAAP outlook for operating income, EBITDA, earnings per share, and free cash flow as provided in February. We continue to expect a gradual pickup in margin in the second quarter, with a further progress in the second half of the year.

Our company is fully engaged in navigating and addressing the ongoing impact of the macroeconomic headwinds. The inflationary pressures that we saw in the second half of last year continue to have an impact in 2023. As indicated, we are working around certain measures to offset the collective increase in our cost of goods sold. In the coming quarter of 2023, we expect a gradual increase in our gross margin with improvements in our portfolio mix as I mentioned earlier as well as easing of inflationary pressures, including the cost of energy and freight. In addition, we expect to continue our ongoing efforts to drive improvements in our operating expenses.

With that, this concludes my review of Teva results for the first quarter of 2023, and now I will hand it back to Richard for a summary.

Richard Francis

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

Thank you, Eli. Thanks for that. So, in summary, [ph] at Teva (30:13) we are reaffirming our 2023 non-GAAP guidance for the year. We believe AUSTEDO and AJOVY are going to continue to drive good growth. With the launch of AUSTEDO once-daily, we believe that's going to add to that. And obviously as I mentioned, the upcoming commercial launch of UZEDY gives opportunity for more growth from our innovative portfolio. We had strong performance in Europe and International Markets in Q1, and we continue to focus on cost discipline and working capital management. And as of next week, I look forward to introducing our new strategic framework and key priorities to many of you in person.

And so, with that, I'd like to open up to questions. Thank you.

Copyright © 2001-2023 FactSet CallStreet, LLC

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Our first question for today comes from Jason Gerberry from Bank of America. Jason, your line is now open. Please go ahead.

Q

Hey, guys. Thanks for taking our questions. This is [indiscernible] (31:27) for Jason. So, first one on the anti-TL1-A antibody. We saw the preclinical data that you published back in 2018. And from a head-to-head perspective, what do you think drives your confidence that this may compare favorably to maybe Prometheus' or Pfizer's anti-TL1-A antibody. And then the second question on biosimilar Humira. We know that the revenue is risk-adjusted in your 2023 guidance and last quarter you mentioned that you have some other hedging elements that might allow you to maintain the guidance if the product was delayed. And so, can you share what those elements are? Thank you.

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

A

Okay. Thank you for your questions. I'm going to hand the first one on TL1-A to Eric. So, Eric, can you get back on TL1-A and why we're so excited about it?

Eric A. Hughes
Executive Vice President-Global R&D & Chief Medical Officer, Teva Pharmaceutical Industries Ltd.

A

Yeah, sure. Thank you, Richard. We're very excited about our TL1-A program. The potential to bring a new class of biologics to people suffering from inflammatory bowel disease is very exciting for us. We believe our anti-TL1-A antibody is highly differentiated and has the potential to be best-in-class and this is really built on the potency of the antibody and our strategy in the way that we targeted the molecule. We've increased our resources and our efforts to bring this program forward as fast as possible. We understand the interest in this program and I think we have the best one. So, we'll hear more about this next week, as Richard alluded to, our new strategy and our pipeline, so we'll talk about that more next week.

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

A

Thanks very much, Eric. And to answer your second question on biosimilar Humira, you're right, we did risk-adjust it in our forecast because of the uncertainty that we knew existed. What I'd say is that the reason why we're maintaining guidance is one that was just adjusted, so it's a relatively small amount. The other is we have launches of UZEDY and our growing innovative pipeline, so because of that, we feel very clear that keeping guidance is the right thing to do. So, hopefully that answers your questions.

Q

Yes. And if I could just ask one follow-up. Should we expect to see any updates to the long-term 2027 targets at the upcoming R&D Day?

Copyright © 2001-2023 FactSet CallStreet, LLC

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

A

So, I suppose there's one thing I could say is that I could not answer that question to make you come to the Investor Day, but we haven't changed our guidance for 2027, so we're committing to the operating 30% net debt ratio and also the growth.

Q

Thank you.

Operator: Thank you. Our next question comes from Umer Raffat of Evercore ISI. Your line is now open. Please go ahead.

Umer Raffat
Analyst, Evercore Group LLC

Q

Hi, guys. Thanks for taking my question. Maybe if I could spend a quick second on the Phase 3 olanzapine program. Could you speak to what level of alignment you have on FDA on what exactly is it that you need to show in your trial to not get the type of black box Lilly got on their prior attempt at long-acting Zyprexa. And then secondly, on the risperidone program, I know you've shared commentary a few times, but the question I have is J&J barely did about 300-ish million on from a branded sales perspective on that program. So, how much could a sort of follow-on to that risperidone long-acting molecule truly do? What's the true commercial potential look like? Thank you very much.

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

A

Thank you. Thank you, Umer. Thank you for those questions. And I'll hand the first one to Eric again.

Eric A. Hughes
Executive Vice President-Global R&D & Chief Medical Officer, Teva Pharmaceutical Industries Ltd.

A

Yes. Yeah. Thank you, Umer, for asking about our olanzapine program. We're very excited about this program. The prospect of bringing another treatment to patients with schizophrenia is really in our wheelhouse, so we're excited by it. The olanzapine long-acting injectable is building upon our formulation technology that we developed for UZEDY. It's really an ingenious formulation that provides real advantage to both caregivers and patients. It's given subcutaneously, and given the characteristics of the formulation, we really hope to have a favorable safety profile compared to other injections that are available for olanzapine.

I think you're referring specifically to the post-injection delirium and sedation that has a black box warning on intramuscular injection of olanzapine. Obviously, we've developed our Phase 3 program in conjunction with feedback from FDA and we're confident in the way that we've designed the study with a number of patients and the total number of injections that we'll have what we believe to be a very good safety profile to avoid these side effects. So, the study is initiated. I'm very proud to say it's going well, and we're looking forward to the results.

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

A

Copyright © 2001-2023 FactSet CallStreet, LLC

Thanks, Eric. So, maybe I'll start by answering your question, but I'll also ask Sven, Head of North America, to come in because obviously it's his team launching the risperidone long-acting, UZEDY. So, I think we think because of the favorable patient profile we have to the product and the feedback we've got from the physicians and the clinical nurse practitioners already and the unmet medical need, we think we can make some inroads based on the product characteristics I just laid out. So, we see the opportunity definitely. We think this has an opportunity to catch between – to grab between 10% to 20% of that $4 billion market, but I would maybe give the call to Sven to add a bit more flavor to that.

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

Yes. Thank you, Richard, and thank you, Umer, for the question. So, there are around about 1.6 million treated schizophrenia patients in the US; [ph] 10 (37:33) of them, as we know, receive long-acting injectable products. The category itself is growing at around about 4% to 5% per year, so it's always good to launch a new franchise into a growing category. We actually believe that we can compete with UZEDY across the LAI spectrum, which means that we do not see UZEDY as being limited to the risperidone molecule alone. And the main reason that we believe that is that the product profile makes it ideal for the use in the hospital setting where the majority of the new patients gets initiated with LAIs.

Among the many key attributes in patients' convenience, it's subcutaneous, it has several injection site options, short and narrow needle, small injection volume, we are actually most excited about the pharmacokinetic aspects of the product and especially here the therapeutic levels that can be reached within 24 hours, which is quite important for emergency treatment in hospitals. And we have, as compared to other drugs in the category, no oral supplementation or a loading dose, so you can discharge the patient right after first treatment and you're safe that you have here therapeutics levels for one or two months. And for that reason, we believe we have a highly competitive product in the LAI category. And as I said, we believe we can compete here across all molecules and to set a new standard for LAI treatment.

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

Thank you, Sven. Thank you, Umer. Thank you for the question. Next question?

Operator: Thank you. Our next question comes from Balaji Prasad from Barclays. Your line is now open. Please go ahead.

Balaji Prasad
Analyst, Barclays Capital, Inc.
Q

Hi. Good morning and thanks for the questions. A couple for me. Firstly, on biosimilar Humira. I want to understand how much of a setback did Alvo's CRL posed you in your discussions with the PBMs. What is the tone of the negotiations now? And is it fair to assume that 2023 is not the focus of your PBM discussions? One. Two, could you also clarify about the legal settlement that you've taken a provision for? What litigations are these related to? And lastly, if you could just maybe comment further on UZEDY and the market potential for this that you see currently. Thanks.

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

Okay. Thanks for the question, Balaji. So, as you know, on the PBMs, Sven, I'll hand that one to you.

Copyright © 2001-2023 FactSet CallStreet, LLC

Sven Dethlefs

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

A

So, of course, we had intense discussions with all major customers, PBMs and all the downstream customers for Humira this year and, of course, changed the situation because our customers had to prepare for the market entry happening end of June and July 1, so now we received the CRL. That is, of course, transparent and known to all our customers, and we now have to wait for the outcome of the FDA discussions that Alvotech has concerning the approvability of the biosimilar BLA and also of the interchangeable BLA and then we will see how we take it forward with the PBMs.

Richard Francis

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

A

Thanks, Sven. And the legal settlement, Eli?

Eli Kalif

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

A

Thanks, Balaji, for the question. Yeah. So, we had some – few adjustments mainly on two cases. One, we're actually progressing on the patient assistance program on COPAXONE with the DoJ, and currently our estimation are around $100 million. That is what we are actually working on and trying to settle it, so this one – this quarter, we actually [ph] had this one (41:15). And the other element that we're actually looking now, it's kind of a tiny element related to the HIV on the reverse payments [ph] we're actually participating with Gilead (41:28). This is at $50 million and the rest is kind of mostly about the timing and other elements relating to a very certain molecules, but that's the high level.

Richard Francis

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

A

Thanks, Eli. And then on the UZEDY, maybe to clarify a bit what Sven said and I said earlier. We think this is a great opportunity based on the product profile we have, the very patient-friendly profile. It's a $4 billion market based on what we understand about the needs of the patient and the physician feedback. I think we have a very good solution when it comes to our long-acting formulation.

We see ourselves getting to between 10% and 20% of the market. We'll see how that plays out. I think one thing I would say when it comes to the schizophrenia market and maybe Sven can add a bit of flavor of this. It will take a bit of time. This is a secondary care. This is in hospitals as Sven alluded to. So, there's a bit of time to get on formulary, to get into those hospitals, to get into those departments and outpatient clinics to make sure it's ready and available for when these patients come in. So, there is a bit of setting up the system to make sure that happens, but once that's in place we see this product having a good trajectory. I don't know whether you want to add anything to that, Sven.

Sven Dethlefs

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

A

Yeah. I think, Richard, you covered everything. As you said, we are prepared for launch. It will happen in the next days. We have a dedicated sales team both for in the field but also for hospital coverage. We're working through the hospital listing, getting reimbursement in all places. And then we believe, of course, the molecule itself is well-known, the efficacy is well-established; that's clear. And I think we can communicate our product attributes also in a very clear and compelling way. We've done extensive market research to prepare for this launch, so I believe we will have good uptake. Although, you have to see that in schizophrenia, in these indications, you typically have a slower development like in other indications. But I think we are well-prepared here.

Copyright © 2001-2023 FactSet CallStreet, LLC

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

Thank you, Sven. Thank you, Balaji.

Operator: Thank you. Our next question comes from Ash Verma of UBS. Ash, your line is now open. Please go ahead.

Ashwani Verma
Analyst, UBS Securities LLC
Q

Hi. Good morning. Thank you for taking our questions. So, I had two. One, just on biosimilar STELARA. Are you planning to pursue interchangeability here as this can be an important feature in this self-administered market? And I think Amgen has already filed for interchangeability. And the resolution on the Iceland manufacturing site is still going on and we understand, I think, STELARA is also coming from that site. So, can the STELARA launch timeline get impacted here? That's my first one.

And then second, so for the free cash flow guidance that you provided, how confident are you on the reaffirmed outlook here? I mean, typically, gross margin improvements can be gradual and this level of EBITDA deterioration in 1Q. Can you reach the free cash flow guide on gross margin improvement alone or do you think you need to cut some OpEx as you progress in the year? Thank you.

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

Thank you, Ash. Thanks for your question. I think on the STELARA one, Sven, if you'd like to give an answer and then Eli going on to the free cash flow.

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

Yes. On STELARA, of course, we are also preparing for this launch. Our launch is, of course, dependent on FDA approval but also on clearance of all the patent aspects around it with J&J. Like for all biosimilar license applications, a site inspection will be part of the review process, so the site in Iceland from Alvotech will be inspected for approval of this drug. Concerning your question about interchangeability, we are still looking into that aspect of the drug. We will also see now, of course, with the market formation from HUMIRA how our customers look at interchangeability, but we believe we will have a competitive offering when we come to market with STELARA.

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

Eli?

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

Yeah.

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

Copyright © 2001-2023 FactSet CallStreet, LLC

Free cash flow?

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

A

Hello, Ash. Thanks for the question. It's Eli. Yeah, so it's a fair question and I will split it into two. First of all, what we see in the P&L. And I look earlier in the guidance for the year, I said that consensus now is really close to $15 billion. We are well-seated in terms of revenue and we are in the range and very well-seated there, which mean that we are growing in our innovative and we will see more growth also on our generics as well outside of the US, the European, and International Markets that's going to help us this year in terms of free cash flow.

The gross margin will pick up gradually. But currently, we don't see now any departure from our view on the range on the free cash flow. The second part of it is the working capital element. We actually have a certain enhancement in place in the last year or so and it's mostly about our optimizations on inventories and the supplier base. So, we will see from there also a certain level of benefit helping us to support our working capital and free cash flow, so the answer is that we are in the guidance.

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

A

Thank you, Eli. Thank you for your questions, Ash.

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

Nathan Rich
Analyst, Goldman Sachs & Co. LLC

Q

Great. Thanks for the questions. Maybe just following up on the last one. Eli, how much of the gross margin pressure was mix-related versus inflation-related? And can you maybe just talk about the level of visibility you have into the inflationary pressure given there seems to be some lead time there? Just in terms of confidence of that kind of easing as the year progresses? And then I'd be curious how AUSTEDO compare to your expectations for the quarter. I know there's some seasonality to sales, but revenue per script looked lower than we expected. So, can you just expand on what drove that in the context of your full year expectations? And how do you think the once-daily dosing improves your positioning with physicians going forward? Thanks for the questions.

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

A

Thank you, Nathan. So, handing the first one to Eli.

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

A

Yeah. So, Nathan, thanks for the question. So, percentage-wise, if you look year-over-year, this is a 5-point decrease in gross margin. The first element related to inflationary pressure; this is around 2.5 points, like half of the impact. This is mostly related, as I mentioned in my prepared remarks, to inventory that we received on the second half of 2022 that embedded inflationary costs, and that actually went and we consumed and sold the goods during this quarter. And that main impact really came with, I would say, cost of labor and other elements related to direct material cost embedded in the sourcing pricing and as well energy and freight.

Copyright © 2001-2023 FactSet CallStreet, LLC

Now, we see freight and energy rebounding. We had a successful hedging program last year on energy that help us to secure certain rates, and we see the benefit this year. We're going to see a very nice benefit as well in freight in terms of [ph] combinations (49:21) and how we're managing long and short lead time items in order to optimize more on the ocean versus the sea as well consolidation of shipments. That's for that element. The other element is around, I would say, the product mix. It's kind of between 1 to 1.5 points, and the rest is coming really from hedge and FX, so that's how you should frame and think about that difference.

And as we look forward in terms of your question about inflationary pressures, some shortages on labor that happened in the industry in Q4 are getting more eased now. A lot of other elements starting to rebound, we see it in the pricing, we see it in our sourcing. So, we believe that this one will get kind of at least half effect throughout the rest of the year. As well if you look on our product mix and expected revenue mostly in our innovative portfolio, this one will rebound and give us more accretive margin going forward.

Richard Francis

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

A

Thanks, Eli. And then to answer your AUSTEDO questions. Q1 AUSTEDO was in line with our expectations, what we had forecast. As we're sure you're aware, there is a swing factor between Q4 and Q1 largely because of speculative buying and inventory build that happens. But if you look at the sort of fundamentals, the metrics, the leading indicators, TRx up 20%, NRx up 30%, so as I said in my opening remarks, very excited about AUSTEDO and the potential.

Then your question about what does once-a-day do, I think if we had any one slight weakness with AUSTEDO and it's any one, it was once-a-day and now we have that. I think the product profile is very strong and is accepted by our physicians as a favorable product profile. So, now with the once-a-day, I think that strengthens that. And the other thing is we have reallocated resource and capital to AUSTEDO to match the expectations we've placed on it and allocated resource to make sure that can happen. So, I think we're well set for AUSTEDO for the rest of the year and it's building a bit to Eli's question and answer there on margins.

I do see with the combination of UZEDY coming and launch of that, the growth of AUSTEDO, the continued growth of AJOVY and that's going to change our product mix into the high-margin innovative business. So, strong expectations and confident about AUSTEDO. Thank you for your question.

Operator: Thank you. Our next question comes from Chris Schott of JPMorgan. Chris, your line is now open. Please go ahead.

Chris Schott

Analyst, JPMorgan Securities LLC

Q

Great. Thanks so much. Just two questions for me. I'm just trying to get my hands around the gross margin update. So, maybe if you could just help us a little bit of what is a reasonable gross margin target for the year when we kind of balance maybe sort of the dynamics in 1Q with what sounds like kind of gradual improvement for the rest of the year. So, is something like 51% or 52% kind of the right ballpark or is it going to bounce back more than that? Just be helpful so we don't meet more surprises there.

And the second question I had was a bigger picture one. I think you're highlighting kind of pipeline capabilities as one of the underappreciated pieces of the Teva story and [indiscernible] (52:55) number of pipeline assets that you're going to be talking in more depth next week. How do you think about the overall level of investment that Teva's making in R&D? I know you have kind of a hybrid business between generics and brands. But when I think

Copyright © 2001-2023 FactSet CallStreet, LLC

about level of investment as a percent of sales and that's not a perfect metric, but Teva is at kind of the low end of the industry on that front. I'm just trying to kind of balance the resources you're allocating to R&D versus the desire to maybe push this pipeline and maximize pipeline value appropriately going forward. Thanks so much.

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

A

Thanks for the questions, Chris. So, Eli, start on the gross margin and then...

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

A

Yeah. Thanks, Chris, for the question. So, yes, as I mentioned, in the second half of 2022, most of the impact was actually coming from, what we call, sustained cost related to inflationary pressures and now it's really depend on the mix that's coming in the quarter on element that you consumed for your inventory. What we see for the rest of the year, I will say that we are at the low of the 53% currently and considering on rebounding, I will say, at least half of the impact on the inflationary pressures from the reasons that is starting from mid of Q2, start actually to source as well new inventories that actually embedded a different pricing now as more of the stuff is starting to ease. So, I will say it will actually become low 53%.

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

A

Thank you, Eli. Now, moving on to the pipeline assets, so if I understand your question correctly, Chris, is are we allocating enough capital and resources to execute on what we've highlighted a good pipeline. So, it's a great question, and we'll give you a bit more flavor to that next week in New York, but yes, in short, we are; we're making sure we prioritize and allocate capital to where the opportunity is to drive growth and profitable growth. And as Eric's alluded to, we have some really exciting assets that we think, to a certain degree, are de-risked or validated. So, to allocate capital to that seems a very sensible thing to do. So, when it comes to that, we are making sure those assets are funded well to go to.

And then on our Capital Markets Day, we'll probably give you a better idea of how we're thinking about capital allocation across the two different types of business we talked about there from our generics pipeline to our innovative pipeline and how we're managing that. So, we'll get into more detail next week. So, I hope it answers your question, Chris, and thank you for it.

Operator: Thank you. Our final question for today comes from David Amsellem of Piper Sandler. David, your line is now open. Please go ahead.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Hey, thanks. Maybe just expanding upon the last question. In the past, you've talked about 505(b)(2) opportunities, and I guess I wanted to ask about the balance between 505(b)(2) products, brand products versus new molecular entities and how you're thinking about it. Or maybe asking differently, how far along the innovation spectrum are you looking to go? And then secondly, on AUSTEDO, can you just talk about the mix between tardive and Huntington's chorea and how you're thinking about the potential impact of INGREZZA to the extent that it gets its label expansion for Huntington's? Thank you.

Copyright © 2001-2023 FactSet CallStreet, LLC

Richard Francis

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

A

Thank you, David. Thank you for your question. So, if I understood your question correctly, sort of how do we balance that focus for effort and resource on pure innovation to 505(b)(2)s. And I think we balance that based on the opportunities that we see that we have already, and then going forward, where we apply resource and capital. So, I think the 505(b)(2)s we see as complex generics were difficult to make and so that falls in our wheelhouse nicely. And from an innovative point of view, we're leveraging our capability in neuroscience and immunology with particular focus on this antibody engineering capability we have.

So, we don't think we have to sacrifice one for the other. I think what it comes down to is how do we reallocate capital from the other aspects that are not 505(b)(2)s, that are innovative to make sure we can fund the opportunities we have. Right now, we're doing that well and as you'll see from the strategy next week, we have a clear strategic and operational plan as to how that's going to be done over the longer term. So, I think that's how we're approaching it now. And then with regards to Huntington's disease and tardive dyskinesia and the mix of that and INGREZZA with potentially an upcoming label expansion, I'll hand that back to Sven in the US.

Sven Dethlefs

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

A

Yes. Thank you, Richard. So, Huntington's disease is around about 50% of our sales, so 85% is for tardive dyskinesia. As you look at the size of the patient population, tardive dyskinesia is, of course, the larger market which is still significantly under-penetrated and underserved, so that's clearly our strategic focus. For Huntington's disease, of course, we are here well established because that was the first indication that we launched. We know that the prescribers that treat Huntington's disease are highly scientific. They value the dose options that we provide, the titration ability, and they also value the long-term efficacy data combined with the safety profile that we have. For that reason, we believe that we are highly competitive in this category, despite the anticipated label expansion from Neurocrine.

On the other hand, also we now have with AUSTEDO XR exactly the drug formulation with the once-daily, as Richard explained, was missing. We did extensive market research here about the prescriber segments that value these convenient sectors and I think we will have a very competitive product going forwards, being it now in tardive dyskinesia or in Huntington's disease. So, for that reason, we are quite optimistic for the year 2023 and our growth in both categories going forward.

Richard Francis

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

A

Thank you, Sven, and thank you again, David, for your question.

Richard Francis

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

I think that concludes all the questions we have time for today. So, I want to thank everybody again for dialing in and listening and the ones who asked the questions for doing so. I'd just like to remind you all of the Investor Day we have on May 18 in New York next week, starting at 12:00 PM Eastern Time. I look forward to seeing some of you in person there and look forward to hearing and seeing you online if you can't make it in person. Thank you again for your time and attention today and look forward to catching up next week.

Operator: Thank you for joining today's call. You may now disconnect your lines.

Copyright © 2001-2023 FactSet CallStreet, LLC

Disclaimer
The information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete or error-free statement or summary of the available data. As such, we do not warrant, endorse or guarantee the completeness, accuracy, integrity, or timeliness of the information. You must evaluate, and bear all risks associated with, the use of any information provided hereunder, including any reliance on the accuracy, completeness, safety or usefulness of such information. This information is not intended to be used as the primary basis of investment decisions. It should not be construed as advice designed to meet the particular investment needs of any investor. This report is published solely for information purposes, and is not to be construed as financial or other advice or as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Any information expressed herein on this date is subject to change without notice. Any opinions or assertions contained in this information do not represent the opinions or beliefs of FactSet CallStreet, LLC. FactSet CallStreet, LLC, or one or more of its employees, including the writer of this report, may have a position in any of the securities discussed herein.

THE INFORMATION PROVIDED TO YOU HEREUNDER IS PROVIDED "AS IS," AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, FactSet CallStreet, LLC AND ITS LICENSORS, BUSINESS ASSOCIATES AND SUPPLIERS DISCLAIM ALL WARRANTIES WITH RESPECT TO THE SAME, EXPRESS, IMPLIED AND STATUTORY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY, COMPLETENESS, AND NON-INFRINGEMENT. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER FACTSET CALLSTREET, LLC NOR ITS OFFICERS, MEMBERS, DIRECTORS, PARTNERS, AFFILIATES, BUSINESS ASSOCIATES, LICENSORS OR SUPPLIERS WILL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING WITHOUT LIMITATION DAMAGES FOR LOST PROFITS OR REVENUES, GOODWILL, WORK STOPPAGE, SECURITY BREACHES, VIRUSES, COMPUTER FAILURE OR MALFUNCTION, USE, DATA OR OTHER INTANGIBLE LOSSES OR COMMERCIAL DAMAGES, EVEN IF ANY OF SUCH PARTIES IS ADVISED OF THE POSSIBILITY OF SUCH LOSSES, ARISING UNDER OR IN CONNECTION WITH THE INFORMATION PROVIDED HEREIN OR ANY OTHER SUBJECT MATTER HEREOF.

The contents and appearance of this report are Copyrighted FactSet CallStreet, LLC 2023 CallStreet and FactSet CallStreet, LLC are trademarks and service marks of FactSet CallStreet, LLC. All other trademarks mentioned are trademarks of their respective companies. All rights reserved.

Copyright © 2001-2023 FactSet CallStreet, LLC