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Teva Pharmaceutical Industries Ltd.

(TEVA)

Q1 2024 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Hello, and welcome to the First Quarter 2024 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, Head of Investor Relations. Please go ahead.

Ran Meir

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

Thank you, Alex, and thank you, everyone, for joining us today. We hope you have had a chance to review our Q1 results press release, along with the press release announcing positive Phase 3 results from olanzapine LAI trial both issued earlier this morning. Copies of these press releases, along with the slides presented during this call are available on our website at ir.tevapharm.com.

Please review our forward-looking statements on slide number 2. Additional information on these statements and our non-GAAP financial measures can be found on our earnings release, and 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 first quarter results and business performance, recent events and our focus and priorities going forward. Then Dr. Eric Hughes, our Head of R&D and Chief Medical Officer, will discuss progress on our innovative pipeline. Our CFO, Eli Kalif, will follow up by reviewing the first quarter financial results in more detail. Please note that today's call will run approximately one hour.

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, everybody. I'm glad you could join us this morning. Excited to talk to you about our results for Q1 2024. Just to remind you, this is a year today almost since we launched the Pivot to Growth strategy, a strategy designed to get Teva back to growth. And I'm pleased to say that this is our fourth quarter in a row of continuous growth. So, the strategy is clearly having some effect, and I'll go into bit of detail as to why that is and what's driving it.

But just to remind you a bit about strategy, it's based on four pillars: step up innovation – sorry, deliver on our growth engine, step up innovation, create a sustainable generics powerhouse and focus our business. I'll walk you through what we've achieved on each of these areas. But obviously, we are starting to show that we can really commercialize innovative products. We are starting to show that we can take products through the clinic. And I think we'll talk a bit about olanzapine and the fact that we brought that to the clinic – through the clinic, nine months ahead of schedule. And we're showing good growth in our generics business, and then I'll finalize with a talk about TAPI and how we've got that back to growth.

But before I do that, I wanted to start with some exciting news on olanzapine, a long-acting treatment for schizophrenia, which is in the clinic. We had the data readout on the efficacy of this study and it met its primary and secondary endpoints on all dose groups versus placebo. So, we're very excited about this. And all those doses were generally well tolerated, safe, and there were no cases of PDSS.

Obviously, the full submission of the safety database will be available in the second half of this year, but this is a really important milestone for ourselves as well as the patients who suffer from this terrible condition. Now just to reiterate why we are excited about it. If I move on to the next slide and just to sort of coordinate you. On the left-hand side of this slide, you'll see all molecules that are used to treat schizophrenia. And as you can see, the largest of these is olanzapine, which treats moderate to severe. But also, you can see on the right-hand side of this slide, there is no effective long-acting treatment of olanzapine. So, there's a significant unmet medical need. And that's why we're so excited about this product and bringing this to the patients who clearly will benefit from it. So, more news on that from Eric later in the presentation.

But now, to dive into the results. So, the results in constant currency, we were up 5% in revenue, up 12% in adjusted EBITDA, 18% in non-GAAP EPS, and our net debt now stands at 3.38. So, a good start to the year because of that, we are reconfirming our 2024 financial outlook.

So, let's go into a bit more detail on all of these numbers. So, when it comes to driving this revenue, what I'm pleased to say is the fact that we're hitting it in all our business sectors. So, whether it's innovative medicines, whether it's generics or whether it's TAPI API, we're seeing good growth. And as you can see, AUSTEDO with 67% growth is a really good start to the year, 18% on AJOVY, and our Global Generics business has grown at a really healthy 9%, and TAPI API back to growth at 2%.

So, let me go into a bit more detail on all of these. So, starting with AUSTEDO. AUSTEDO continues to perform really well. $282 million for quarter one, up 67% versus quarter one 2023 and a good, strong TRx growth of 28%. And because of this momentum, we are confirming our guidance of $1.5 billion for 2024. But this momentum gives me more confidence and more excitement around our long-term goal, which is to get to $2.5 billion of revenue by 2027. And I just wanted to use this slide to remind you everybody of the potential we have around this product unfortunately, because so many patients are yet to get on treatment. And that is why we started our direct-to-consumer campaign at the start of this year to make those people aware that there is an opportunity to help address this difficult condition and they just need to seek help with their physician. So, very encouraging start to the year with AUSTEDO, and we look forward to that momentum continuing.

Now, moving on to the second part of our innovative portfolio, which is AJOVY. Once again, good continued growth of 18%, and we are growing particularly strongly in Europe and international markets. But what pleases me about this product is we continue to show market share gains both in the US, Europe, and in international markets, showing the competitiveness of Teva sales and marketing when we have a product like this. So, very pleased with that. And once again, I'm reconfirming the guidance of $0.5 billion for 2024.

Now, moving on to UZEDY, the newest member of our innovative family. So, we launched this product last year, and the momentum continues to build. We continue to see good access when it comes to a fee-for-service in Medicaid. We're working with Medicare. The hospital has continued to expand their coverage, and we're seeing good order – reordering from our hospitals. And this is driven by, once again, this very favorable product profile. We recently had the Association of Psychiatrist meeting in the US last week, I believe it was, and the feedback continues to be really strong, particularly that is related to therapeutic doses within 24 hours without any oral supplement. So, good momentum. And once again, I can confirm that the guidance of $80 million, we will be confident to achieving.

Now, moving on to a slide which gives me a lot of pleasure to talk about, which is our Generics business. Just to sort of orientate you, remember 65% of our business is outside the US, and we continue to see continued good growth in Europe of 5%, and international markets of 16%. But I have to say, particularly pleased about the US, and the growth of 8% there.

Now I think this highlights once again the Pivot to Growth strategy and the focus we placed on our Generics business to make sure we can bring products to the market more regularly on time, and we have a good supply chain that has good cost of goods. I think this is the start. We've got work to do, but this is very encouraging. I'm very pleased, and I want to congratulate the team on this.

Now moving on to another part of our business, which we're excited about, and that's our biosimilar business. We're excited to be in a position in quarter two to be launching our biosimilar Humira and SIMLANDI, and we're getting good interest from the payers, the PBMs, and the channel with regard to this.

Also pleased with the fact that our biosimilar Stelara is also approved, and we'll be launching that in February of 2025. But it is worth pointing out that we have a portfolio of biosimilars, and we'll be launching six by 2027. So, this is really an opportunity to support the Pivot to Growth strategy from a biosimilars perspective.

Now moving on to step up innovation. I won't go into some great details because Eric will, but olanzapine I've already touched upon. But the one thing I would like to highlight on this slide is the capability build and the execution ability that we have at Teva. Olanzapine was recruited nine months ahead of schedule. TL1A is recruiting incredibly well in UC and CD, and we've got ICS/SABA off to a good start, and that is now supported by the partnership we have with Launch Therapeutics and Abingworth. So, we understand these assets are important to the patients who need them, and we're focusing on them, and we're showing that focus can deliver performance.

But I want to take it a little minute now to talk to you a bit about our capabilities in CNS because obviously, I do talk a lot about AUSTEDO, UZEDY and AJOVY and rightly so. And olanzapine will get a lot of attention today. But we are building out a very good pipeline when it comes to CNS, and we'll be giving you more and more information on this as we move forward. But once again, building a real foundation to Teva in CNS.

Now moving on to our final pillar, which is focus the business around TAPI, that we obviously announced at the start of this year that we would be divesting TAPI, our API business. And I'm really pleased to see that the team with this freedom to operate outside of Teva, and in the global $85 billion API market, they've really started to deliver and got off to a good start with a 2% growth.

I see this momentum growing and this performance increasing because of the interest we've got from CDMOs and the interest is based on the fact that we have a broad technology base and our credibility of quality and supply reliability is clearly something that they're interested in. So good news and more to come, I think, on TAPI throughout the year.

To close on something that is important to us, which is about how we operate as a company and how we contribute to society. We launched our sustainability goals in 2023. I just wanted to give you an update on how we progressed. So, with regard to healthy people, we launched seven programs to increase access to medicine across the globe. Healthy planet, we have reduced our carbon emissions by 27% versus 2019. And when it comes to how we conduct ourselves in our business being ethical and compliance, 100% of people have completed their training, and that was achieved in 2023.

Now with that, I'll conclude my session, and I'd like to hand over to Eric, who is Head of R&D. Over to you, Eric.

Eric A. Hughes

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

Thank you, Richard. As Richard mentioned, we're very excited that today we announced the positive primary endpoint readout of our olanzapine LAI program. It also met its secondary endpoints – key secondary endpoints. I thought I'd start off today by describing and reminding you of the study design and where we are in executing the study today. Remember, the study had an eight-week period. It's a randomized placebo-controlled study with three dose arms. And today, we are talking about the primary readout at the end of that eight week. This study also includes a 48-week follow-up for safety that is now being executed with our full randomized patient size of about 675 subjects, slightly over-enrolled.

So, it's important to note that second half of the study will be read out for [indiscernible] (00:13:08) in second half of this year. So, when it comes to the primary efficacy endpoints, we are very excited to see that we met clinical significance and statistical significance on our primary endpoint using the PANSS score. You can see the score was between 9.7 and 11.3 points in change from the baseline score. That's the change from baseline to week eight. So right where we expected the efficacy to be and clearly efficacious on all three dose groups. Importantly, we are also out to about 80% of our total target injections at this point, and we've seen no PDSS. So, the injections were well tolerated throughout the study.

I should mention that the key secondary endpoints include the clinical global impressions for schizophrenia scale and the personal and social performance scale which both for all doses achieved clinical significance. I would like to also say that this study illustrates our ability to execute and accelerate our program in the innovative space. We brought this study out up by nine months. So, a real good job by the clinical team.

Moving on to AUSTEDO. We continue to do great work, informing our patients and our investigators about TD. We are running a study, a real-world observational study called IMPACT-TD. And this is something we're very proud of, where it's looking at both the patient voice and the caregiver perspective on what the impact of tardive dyskinesia is. This study is the largest study for tardive dyskinesia ever and it includes a wide range of ages, race and ethnicity, severities in their baseline movements and their treatment experience that's being run in 23 states in the United States.

As I mentioned, we're developing a scale that really is measuring both what the patients tell us and what the caregivers see when it comes to tardive dyskinesia. So understanding tardive dyskinesia is our goal and educating our patients and caregivers is our mission. The first set of data will be announced or presented at the second Elevate meeting later this month.

Now moving on to asthma. Asthma is a significant patient population. It's a very important chronic illness in the US and around the world, and the majority of these patients use rescue inhalers. There still is over 10 million asthma exacerbations every year. And we've learned now that combination rescue inhalers are what's needed. And in fact, the guidelines – the GINA guidelines have changed to the point where that's the recommendation for asthma exacerbations, that's the combination of both a beta agonist and a steroid. And that's why we're excited about our program, TEV-'248. This is a combination rescue inhaler using albuterol and fluticasone, two well-known medications by our treating physicians.

And the important thing is that this is a differentiated device. It's a dry powder inhaler, and that's important for when it comes to taking care of our pediatric patients, and that's what we're targeting in this study. We're excited that we started our Phase 3 study at this point. Enrollment is going well. But it's [ph] great to have collaborative (00:16:40) Launch Therapeutics, will help to accelerate the program even further, and importantly, get those patients in the pediatric population going in the study. So very exciting to be delivering in the future a new treatment for asthmatic exacerbations in accordance with the GINA guidelines.

Moving on to my last topic, the anti-IL15 program. This is a very important program because our first indication we'll be taking this compound into is celiac disease. Now IL15 is a key cytokine in the pathology of celiac disease. When these patients eat gluten, it cause an inflammatory reaction that releases IL15 and activates intraepithelial lymphocytes. It's a large patient burden in the US, about 2 million patients, only about half of those patients are diagnosed. But the important thing to remember that 50% of these patients still have symptoms even while taking a gluten-free diet. 20% of these patients never even respond to gluten-free diet and 50% of these patients still want treatment beyond a gluten-free diet. So, that's why I'm excited about our anti-IL15 program. I've shown you before that we have a very potent antibody that rapidly reduces free IL15 levels, and keep those levels suppressed out to almost 80 days. We're exploring the compounded celiac patients right now. We're enrolling a patient by the end of – study by the end of this year.

Looking at a celiac challenge study where we give a single dose of TEV-'408, and then two weeks later start a gluten-free diet for 14 weeks. So, we're very encouraged to see the results of the study, hopefully soon. And the important part about this study is really focused on the symptoms of the patients really, are we impacting what they see or when they eat gluten containing food. So we think we have a potentially differentiated product, it's a high affinity anti-IL15, it suppresses – it freezes IL15 rapidly, and has low immunogenicity to-date.

So, on my final slide, I just want to talk about we're achieving our milestones and accelerating them where we can. We've shown that our olanzapine LAI today has achieved its primary endpoint. We'll be curious or hopeful to see the final set of the safety data on injections in the second half of this year.

Our anti-TL1A program is right on target. The enrollment is going very well for both ulcerative colitis and Chron's disease, and we'll be looking for that interim analysis in the second half of this year. I just mentioned our anti-IL15 program, enrolling our celiac patients this year in our proof-of-concept study. I'm very excited for the end of this month or the next month where we see a first patient in our anti-PD1-IL2 program in oncology. And finally, we're enrolling our Phase 3 study now and working to accelerate our program for our dual action rescue inhaler for asthma. So, a lot coming, and we're looking forward to keeping up you updated.

So with that, I'm going to pass it off to Eli, and take away.

Eli Kalif

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

Thank you, Eric, and good morning and good afternoon to everyone. I'll begin my review of our Q1 2024 financial results with slide 29, starting with our GAAP performance. Revenue first quarter of 2024 were $3.8 billion, an increase of 4% in US dollars and 5% in local currency terms, compared to the first quarter of 2023. The increase was mainly driven by broad-based growth from generic products across all our segments globally, including strong contribution from generic segment in US, continued strong growth in AUSTEDO, as well as AJOVY in our Europe and International Markets segment. This was partially offset by lower revenue from COPAXONE, as well as from Anda, our distribution business in the US.

In Q1 2024, we recorded a GAAP operating loss of $218 million compared to an operating loss of $13 million in the same quarter last year. The increase in operating loss was mainly due to higher impairments of tangible assets and other items, as well as higher sales and marketing expenses in the first quarter of 2024, partially offset by higher gross profit, lower legal settlement and loss contingencies and lower intangible asset impairment in the first quarter of 2024.

As part of Teva's Pivot to Growth strategy, we have decided to divest our generic business in Japan, which is part of Teva's International Markets segment. The assets and liabilities in relation to this business were classified as

held-for-sale. In the first quarter of 2024, end result is an impairment charge of approximately $600 million this quarter. We currently expect the business to be sold within the next year.

Moving to GAAP net loss, which was $139 million and GAAP loss per share that was $0.12 this quarter, compared to a loss per share of $0.20 in Q1 last year. The lower GAAP net loss was mainly due to higher net loss related to non-controlling interest, which resulted from higher tangible asset impairment related to the business that was classified as held-for-sale.

Turning to slide 30. You can see the total non-GAAP adjustments in the first quarter of 2024 were $688 million, compared to $661 million in Q1 2023. A notable non-GAAP adjustment includes legal expenses of $106 million, mainly related to estimated provisions recorded in connection with certain litigation cases in the US. Other notable adjustments include amortization, purchased intangible assets of $152 million, the majority of which is included in cost of sales. And as I just mentioned, the impairment of tangible assets of approximately $600 million related to the business held-for-sale.

Now moving to slide 31 for a review of our non-GAAP performance. As I mentioned earlier, our first quarter revenues were approximately $3.8 billion, an increase of 4% in US dollars or 5% in local currency terms, compared to Q1 of last year. Our non-GAAP gross profit margin was 51.4% compared to 49.1% in Q1 2023. This increase in our gross margin was mainly driven by improvement in our portfolio mix, including strong continued growth in AUSTEDO, as well as decrease in our operational costs.

As expected and in line with the normal seasonality and revenue progression between the quarters, we started the year with a lower non-GAAP gross profit margin. For the full year of 2024, we continue to expect our non-GAAP gross margin to be between 53% to 54%. Our gross margins will gradually improve as we progress throughout the year driven by continuous improvements in our portfolio mix with a strong growth in our innovative portfolio and continuation of the ongoing cost optimization program.

Moving to non-GAAP operating margins in Q1 2024, which was 23.4% compared to 21.4% in Q1 2023. This increase was mainly driven by higher non-GAAP gross margin, as I just explained. This was partially offset by higher sales marketing expenses as a percentage of revenue, reflecting our increased investments to support our key growth engines including promotional activities related to AUSTEDO in line with our Pivot to Growth strategy. We ended the quarter with a non-GAAP earnings per share of $0.48 compared to $0.40 in Q1 2023, mainly driven by higher operating income.

The next slide shows our continuing efforts to transform and optimize our global manufacturing and operating footprint to drive efficiencies. During 2023, we closed three sites to bring our total footprint down to 49, and we have plans to continue this progress. By the end of 2025, we expect to close or divest four additional sites with a goal to bring down the total number of sites to between 40 to 42 sites by 2027. So, we're really focused on continuing to optimize our operations to drive efficiencies and improve margins.

Turning to free cash flow on slide 33. Our free cash flow in the first quarter of 2024 was $32 million. As a reminder, Teva's free cash flow tends to face headwinds at the start of the year due to the timing of annual bonus payments paid out in the first quarter of every year. In addition, our free cash flow for Q1 was also impacted by changes in certain working capital items.

Today, we are reaffirming our 2024 free cash flow guidance which we provided in January. Our 2024 free cash flow is expected to be in the range of $1.7 billion to $2 billion, and we expect this to pick up during the next three

quarters, driven by ramp-up in our profitability as I mentioned earlier, and as we continue to drive working capital improvements.

Turning to slide 34. Our net debt at the end of Q1 2024 was $16.7 billion compared to $16.6 billion at the end of 2023. Our gross debt was $19.6 billion compared to $19.8 billion at the end of 2023. The decrease in our gross debt was mainly due to exchange rate fluctuations of $193 million. Our net debt-to-EBITDA slightly improved coming at 3.38 times for Q1 2024, mainly due to higher EBITDA. Subsequent to the quarter close, in April 2024, we repaid $956 million of our senior notes at maturity. At the end of March 31st and as of today, there is no amount outstanding under the $1.8 billion revolving credit facility.

Last week, Teva entered into an amendment to our revolving credit facility to update the company's maximum permitted leverage ratio under the RCF for a certain period. Under the amendment terms of the RCF, the company's leverage ratio shall not exceed 4 times in 2024 and 2025, and in the first quarter of 2026; 3.75 times in the second, third, and fourth quarter of 2026; and 3.5 times in the first quarter of 2027 and onwards.

Now, let's turn our attention to our 2024 financial non-GAAP outlook on slide 35. As we guided in January, when we initially provided our full year outlook, we had expected our revenue and earnings to progress gradually throughout the year. That continues to be our expectation, as we reported today. For the full year of 2024, we continue to expect our revenue to be between $15.7 billion to $16.3 billion. We are also reaffirming our 2024 non-GAAP outlook for operating income, EBITDA, earnings per share, and free cash flow, as provided in January.

Like I said earlier, our non-GAAP gross margin is expected to be between 53% to 54% for the full year and we expected a gradual pickup in margins in the second quarter, with a further progress in the second half of the year, in line with the revenue trajectory and the portfolio mix as well as improvement from our ongoing cost optimization program.

In addition, we continue to make deliberate and thoughtful investments in our innovative portfolio and to progress our key pipeline assets to drive both the short- and long-term growth for the company. Similar to gross margin improvement, we also expected to see leverage in operating expenses as a percentage of revenue in line with the ramp-up in the revenue as we progress throughout the year. With this, I conclude my review of Teva's results for the first quarter of 2024.

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. Thank you for that. And so, based on what we've told you today, we continue to be confident about hitting our 2027 guidance, 30% operating income margin, net debt, two times and cash to earnings, 80%, and a CAGR of mid single-digit. The reason why we remain confident about that, I can highlight on the next slide. It comes back to the execution of our strategy. As we laid out over a year ago, we had a plan to return to growth, accelerate growth, and sustain growth. As you can see, we made good progress on return to growth, focusing on our growth engines, our biosimilars, and getting our generics business back to performance. To accelerate that, we clearly have laid the foundation for that with the olanzapine readout today and our focus on ICS/SABA. We also have highlighted the number of biosimilars coming by 2027. So, I think the momentum we're getting around Pivot to Growth continues to grow, and so that we remain optimistic about the future.

With that, I welcome to take questions from people on the phone. Thank you.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] . Our first question for today comes from Umer Raffat of Evercore ISI. Your line is now open. Please go ahead.

Umer Raffat
Analyst, Evercore ISI

Q

Good morning, guys. Thanks for taking my question. Congrats on the Phase 3 efficacy portion of the readout. I have three questions today, all three, very trial specific, if that's okay. First, I know the efficacy delta you're showing, placebo adjusted is about 9% to 10%. I know when Lilly ran their long-acting olanzapine, they were more in the mid-teens camp. Can you perhaps speak to what it is that clinicians want to see, obviously, PDSS far trumped any sort of trial to trial differences in placebo-adjusted efficacy knowing that you also got to low-teens in one of the arms?

Secondly, I know the trial that we just saw is acute phase of the study and patients rolled over to the safety. Is there any separate plans for a maintenance study as well? I think Lilly ran that and they ran the long-acting olanzapine, I'm curious and if that impacts the indication?

And then finally, I noticed when you guys developed UZEDY, which is the oral lung – sorry, which is a long-acting risperidone, there were some trial conduct issues, which led to FDA issuing a CRL because of some dosing errors and documentation issues, et cetera, volume of injection. And at the time, all the efficacy analyses ended up having to get either sensitivity analyses or potentially have to run a trial all over. Could you speak to how the trial conduct look different in this study in the efficacy portion versus the way UZEDY Phase 3 was ran? Thank you very much.

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

A

Thanks. Thanks Umer. Thanks for the questions. I'll hand that straight to Eric, over to you.

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

A

Yeah. So, Umer, thanks for the questions. Let me take the third one first, the CRL. So, that was a issue around common problems you see in schizophrenia from studies where you sometimes get patients double-counted. We learned a lot from that issue on that study and we've corrected that, and we actually monitor that extremely closely in the ongoing side. I would say that our ability to execute these studies is clearly one of the best in the industry. We brought this one up by nine months and accelerated very, very well. And we review all the data very carefully. So, that should not be an issue going forward.

Now, with regards to the deltas that we saw on our primary endpoint, that's the change in the PANSS score from baseline to week eight. So, to be very blunt, these were deltas that exactly where we expect them to be. We were very pleased to see that the placebo behaved the way it should, which is something that is challenging in these studies every year, but ours seems to be run very well with regards to the lack of response in placebo and the delta we saw on each of the three doses. So, you'll see that, that actually is very consistent with these exposures of olanzapine across many different studies.

Now, with regards to what the HCPs would look for, these are clinically significant changes. These are the expected deltas that a patient, an investigator would want to see to be able to treat their patients. The real benefit here is, we're getting the efficacy of olanzapine with just a single dose once a month in an easy subcutaneous injection. So, that's the real benefit for the program, and we're excited to see the results today.

Umer Raffat
Analyst, Evercore ISI

Q

Super helpful. Thank you very much.

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

A

Thanks Umer.

Operator: Thank you. Our next question comes from David Amsellem from Piper Sandler. Your line is now open, please go ahead.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Hey, thanks. So, just a couple of questions on biosimilars. So, first, can you talk to, and I apologize if I missed this earlier. Talk to the impact or how you're thinking about the impact of SIMLANDI as we move through the year with the Evernorth/Accredo contract. So, how should we think about that?

And then secondly, I know AbbVie, you talked about trying to enter into multiyear contracts. I think [indiscernible] (00:35:13). How are you thinking about how aggressive they're going to be over the long-term in defending the brand? And what you think that means for adoption of Humira biosimilars? So, that's the second question.

And then lastly, on the Stelara biosim, can you talk to, and I know it's early and this is sort of a next year question, but talk to how you're thinking about how that markets going to behave in terms of how aggressive the innovator is going to be with contracting and how you're thinking about adoption next year, particularly given that you're going to be launching very early on in biosimilar market formation? Thank you.

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

A

Thank you, David. Thanks for the question. So, I'll take those. So, how do we think about SIMLANDI this year? I think, firstly, we're excited to bring this to the market in Q2. What I would say and I sort of build a bit into second question, the interest we're getting from payers and PBMs is very high. And I think there's been a change in the market versus last year where there's an appetite to really utilize the benefit that biosimilars bring to the market with containing healthcare costs long-term. So, I think that dynamic is playing out.

We obviously built a certain amount of SIMLANDI into our forecast for the year. It was risk adjusted because there's many uncertainties. And obviously, we are launching this at this moment, not at the start of the year. So, from a contracting point of view, that is something to take into account. But I would say we remain optimistic about it. Let's see how it plays out.

And I think to your last question, how do we think about Stelara? Well, that's interesting from two factors. One is internal. So, we have got the approval. So, we're not going to be in the position where we are with biosimilar Humira coming to the market later. We'll be coming to the market at the start as you pointed out. That means we

can have discussions with the payers, the PBMs, six months ahead of coming to the market, which is obviously beneficial.

The other factor is, and I think this just show the dynamic nature of the market. We talked about no penetration into the market last year with biosimilar Humira in general. And now, we're starting to see what I think is a more dynamic situation where things are changing, and we're definitely hearing that from the payers and the PBMs. So, I believe there's a change in appetite and there's this change in strategic thinking, but we'll have to see how that plays out. I think I've been consistent in saying I don't have a crystal ball on this. And that's why I think having a broad portfolio that you bring to the market is a sensible approach. But I would say, optimistic both for this year and optimistic for next year. Thanks for your question.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Thank you.

Operator: Our next question comes from Ash Verma of UBS. Your line is now open. Please go ahead.

Ashwani Verma
Analyst, UBS Securities LLC

Q

Hi. Thanks for taking our questions. Congrats on all the progress. So, I have two. Just a quick follow-up on biosimilar [indiscernible] (00:38:23). Do you think the Sandoz biosimilar [indiscernible] (00:38:26) inflection is primarily because of CVS using an exclusionary contracting against the branded drug? And do you believe you can drive similar level of uptake just based of Cigna offering a $0 co-pay for biosimilars and but not necessarily getting into exclusionary contracting?

And then on TAPI, I see on your website, you do provide like the API for semaglutide and tirzepatide injectables, like what is your level of scale here? And is that something that could be of interest to the GLP-1 players that are looking for significant supply expansion? Thanks.

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

A

Thanks, Ash. Thanks for your call. [ph] That was good to talk (00:39:04). So, with regard to the contracting, and it sort of goes back to my comment earlier about it's just very dynamic. It's really changed, I think, versus last year. So, there are many different opportunities that are emerging, both in the normal channel and in this private label. And that's evolving almost weekly. So, I think for us, that's encouraging. I don't want to try to predict how that's going to play out, whether people are going to mirror other people because I think it's quite individual. I think the bigger picture, which I am encouraged by is this appetite for biosimilars as a whole. And I think that plays out well for obviously us. It plays out well, I think, for patients and society in reducing costs long-term. And I think everybody was waiting to see if something like this could happen. I don't think one swallow makes a summer, but I do think this is really interesting [ph] and going to (00:40:00) progress. So that's how I would probably [ph] phase (00:40:04) that. But obviously when we speak the next quarter earnings, I think we'll have more data and we'll continuously update you.

With regard to the API and what you just raised there, I think that – we don't go into specifics of each individual API and the potential for us to supply those and capacity. We obviously have hundreds of API that we manufacture and develop. So, it's more complex than that. So that's probably the best way I can answer that question. But thanks for the questions, Ash.

Ashwani Verma
Analyst, UBS Securities LLC

Q

Thanks.

Operator: Our next question comes from Balaji Prasad of Barclays. Your line is now open, please go ahead.

Balaji Prasad
Analyst, Barclays Capital, Inc.

Q

Hi, good morning and thanks for the questions. So, a couple from me, and apologies if some of these have been asked before. Richard, I had the opportunity to speak to half a dozen neurologists recently. The general feedback I got was that [indiscernible] (00:41:02) AUSTEDO and they do want to use it for some other indications, too. Generally, they think the feedback is that the insurance has been a challenge. And so, I want to get your experiences with payers and if there is scope for the commercial team to do better? One.

And two, can you also speak about the areas where you see off-label use our off-label potential for AUSTEDO and any plans around it? That's one. Two, on the biosimilar side, [ph] I couldn't (00:41:29) but I have noticed that management commentary on biosimilars had softened in the last couple of months.

Now, that you are – the approvals of SIMLANDI and SELARSDI are behind you, would you want to revisit your expectations around biosimilars and how would SIMLANDI play through into your 2024 guidance seeing that it's been reaffirmed even after the approval? Thank you.

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

A

Thanks, Balaji. Thanks for the questions and the interest. So, on the first question, the insurance challenge. Actually we're in a very good place with AUSTEDO and we're actually in a very good place with XR. So, I don't think insurance is an issue and access is an issue. Now, there's obviously pockets of that that could be different. So, depending on who you speak to, they can be. And I think XR is still lagging a bit behind our BID. But it's closing fast. But I think that's not something that I discussed regularly with the team. And by the way, it's not something I give them an excuse on when it comes to driving this business forward. So, hopefully that answers that question.

With regards to off-label, obviously, I don't want to get into any discussions on that. I think we always want to make sure that the product is used within its label. So probably that's as much as I'll say.

With regard to biosimilars, [ph] I'm smiling here (00:42:48) because I don't think my language is interpreted a softening in the past. It's more about – I think I've consistently said, this is an emerging market. This is dynamic, how this is going to play out. I don't want to try and predict because it can change all the time. It rarely happens. But maybe I was right on that one because it changed very quickly quite recently. So, I think maybe I was more – my language is more around how this market will evolve and as I said, I don't have a crystal ball. That is becoming clearer now, and that's probably why you hear, one, we have an approval of two of our biosimilars, so that's certainty, which I may not have when we last spoke. The second thing is I do believe there's a change in the market. Now, we'll see how that plays out across the whole market, but it does seem to be people are making interesting moves and the conversations we're having seem to have more purpose and energy than they've ever had. But – we'll have to see how that plays out.

It's interesting. But for us, it's about – once we start to get contracts, once we start to ship volume and once we start to get revenue, it's meaningful, then we know there's been a significant change. And I think we'll see how that evolves as we go through the quarters of this year. But Balaji, thanks for your questions.

Balaji Prasad
Analyst, Barclays Capital, Inc.

Q

Thank you.

Operator: Our next question comes from Jason Gerberry of Bank of America. Your line is now open. Please go ahead.

Jason Gerberry
Analyst, Bank of America

Q

Hey, guys. Thanks for taking my questions. First one for me is just on your 2024 guide. And I'm wondering really sort of what are the key variables to getting to the high-end [ph] really blowing (00:44:28) through your guidance? It seems like with Humira, there's some upside optionality. But you guys are taking a conservative stance just on how that will get adopted. And I guess you have some exclusive generics that either haven't launched yet or haven't gotten market share [indiscernible] (00:44:45). So that's maybe an upside lever. So just wondering, if you can comment on those dynamics if you agree with that characterization.

And then secondly, just on the olanzapine LAI program, you have 20% of injections left. I'm just curious the agreement with the FDA, was there any margin for error if you had a single PDSS event? I think the background rate was like 0.1%. So just kind of curious like if you got unlucky and there was like a single case, can you still avoid having the black box warning? Thanks.

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

A

Thanks, Jason. I'll take a stab at the first one, and maybe Eli can join, and then I'll hand over to Eric. So look, I think you sort of actually framed it really well. We have a bit of a range because we need to see how the biosimilars plays out. We have some product launches coming up, as you've highlighted in the US. Timing [indiscernible] (00:45:41) those, we have to see how those play out. And then we have to see how the momentum of our business plays out. So, I think all of those – some of those things we waited to happen. And as those start to happen, we'll get more clarity, and I think that gives us more opportunity to narrow the range, if that is what is required. But we think about it in a similar way to risk-adjusted biosimilars. We've risk adjusted some of our new product launches because they are based on timing and various other factors. And because of that, we think that's the prudent thing to do. As that changes and we get more certainty, we will come back very quickly and help you understand what that means and whether that means that the range narrows.

Maybe Eli, would you like to add anything more?

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

A

No, I don't have anything to add. Thanks.

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

A

Good job. I'll hand that one to Eric, then on the second one.

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

Yes. And there was a question about the PDSS and what are our discussions with the FDA. So the discussions we had were around 3,600 injections. That would be the point at which FDA was open into decision around not having this as a black box warning. We monitor this very closely. And I think it's important to start by saying, what's the scientific support and rationale and then what's the clinical data. Scientifically, it's very important to note that there's a completely different formulation. It's a subcutaneous formulation not an intramuscular injection, which might hit deep vessels. But on top of that, our formulation rapidly aggregates and keeps the API contained almost immediately after injection that has a slow release. So, that supports the notion that we should not see PDSS. We have not seen it.

Now, as you mentioned, we're up to about – let's say we're up to about 2,700 injections now. So we're over the 80% mark. We haven't seen it. If we see one that'll be a negotiation with FDA. The important thing is that we have an adjudication committee. So we should not see accidental PDSS at this point. And I think the [ph] science (00:47:45) supports no PDSS.

Jason Gerberry
Analyst, Bank of America
Q

Great. Thanks.

Operator: Our next question comes from Yifeng Liu of HSBC. The line is now open. Please go ahead.

Yifeng Liu
Analyst, HSBC Bank Plc
Q

Good morning. Thanks for taking my questions. I've got three questions. The first one is on olanzapine LAI. Could you just give us an update on the regulatory timelines and whether you have interest in filing outside the US? Second one is on TL1A. Just could you talk about your kind of thinking about leveraging diagnostic tools, specifically companion diagnosis upon your product launch or as you go later in the pipeline?

And the third one is on biosimilar. And Biden administration recently had some news about substitution without interchangeability. I just wonder, upon your next, probably six or more biosimilar launch, how that will play a role in your plan and whether that is going to change anything in the studies you run? Any color on that would be great. Thank you.

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

Okay. Yifeng, thank you for the questions. I'll hand the first two to Eric, and then I'll take the third one.

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

Sure. Thank you for the question. So, with regard to olanzapine LAI program – plans in the future, we're still running the long-term follow-up. We'll hopefully be presenting that data at a congress in the second half of this year. Other things drive submissions. We're planning to do the submission early in 2025, with our stability data and our product preparedness. So, that's the general timelines for olanzapine program.

With regard to TL1A and diagnostic tools. So, we'll need to see the data. We're going to have our interim analysis the second half of this year. We are including all different biomarkers that we could interrogate with regards to serum biomarkers, biopsy biomarkers, proteomics and genomics on predicting response at baseline or on treatment. And we also have the three TL1A. So, we have lots of data that we'll need to look at. If we find a diagnostic or a predictive value that could really help the program, we'll certainly use that. But our goal is to treat all-comers at this point because these patients need all the options they can get in both ulcerative colitis and Crohn's disease.

And the last question, I think you're going to handle with regards to the changes in the biosimilars plans by the FDA.

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

Yeah. No. So around interchangeability, I think this is something that's been discussed, but it actually hasn't been concluded. So it's been proposed, but it has – it needs to go to I think required legislation to change for this to happen. So, I think this – I'd say, let's see how this plays out. Obviously, when it comes to substitution and allowing biosimilars to have a fast track uptake for patients and payers and society, we would support that. But there's a long way to go. So, I think this is just in its embryonic stage, and we'll have to see how that plays out. And as there's more clarity, I'll update you on subsequent calls.

Yifeng Liu
Analyst, HSBC Bank Plc
Q

All right. Thanks very much.

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

Thanks for the call.

Operator: Our next question comes from Thibault Boutherin of Morgan Stanley. Your line is now open. Please go ahead.

Thibault Boutherin
Analyst, Morgan Stanley & Co. International Plc
Q

Yes. Thank you. So, three questions. The first one, just a quick follow-up on biosimilars long-term and your in-house pipeline. You mentioned the change in dynamics and how things are opening up for biosimilars. Is that changing in any way your willingness to invest in the kind of next generation of pipeline assets that you're developing internally?

Second question, just on the olanzapine and market potential. I mean, I think you gave in the past a kind of $400 million to $800 million potential for UZEDY. And given the broad use of olanzapine and clearly your excitement on the asset, is it fair to think about blockbuster potential for olanzapine injectable?

And last question, just on the reduction in sites. We saw interest in the industry for biologic capacity elsewhere. So, is there an opportunity for you to potentially [indiscernible] (00:52:20) site reduction exercise? Or is it just expected site closures? Thank you.

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

A

Okay. Thank you, Thibault. Thank you for those questions. So let me start with the first one, the biosimilar one. I think it was around capital allocation. Do you see the change in dynamics mean that we would invest more in internal development? I think first and foremost, capital allocation occurs when we partner as well. So, obviously, we – it's a lot less than when we do it internally. But I just want to make sure you're aware that we do allocate capital to our pipeline that is partnered, but it's less. I think we're in a very fortunate position at Teva, because the makeup of our business. And as you've seen from the innovative pipeline that we have, that allocating capital to this and accelerating this through the clinic, I think really drives potential to bring life-changing medicines to the market, but also helps us drive value for shareholders. So, I think we're always talking about our capital allocation. We take that into account as things change in our business, but I see nothing that creates a sizable shift in the strategy we have right now.

Then I think you moved on to olanzapine and what's our prediction around this and could this be a blockbuster. Look, I go back to start where there's clearly an unmet medical need there. There's no long-acting olanzapine as we've seen in the data. And clearly, a big percentage of patients would benefit from a long-acting olanzapine and we get the same feedback from healthcare physicians, which is one of the reasons why I think the study was so well recruited because people wanted to be part of it.

I think when it comes down to giving guidance, obviously, we want to do a bit of work on understanding the dynamics of the environment, and we will come back and maybe give some bookends up to that later, as we've done with AUSTEDO in the past. So, it's something, which we're open to do. But we want to give that more time. And obviously, we wanted to get the safety and efficacy readout under our belt before we started to do that.

With regards to the divestment of sites and monetizing that, firstly, I'd say we've always done that. Teva runs very good sites. And the fact that we're reducing our sites is more about our strategy, not about the quality of those sites, the quality of the people who operate in those sites. And so, on a regular occurrence, we divest and we sell our sites and people find them very attractive.

I think, obviously, you're talking about the change in environment around biologics and capacity. And so, that's something that may make manufacturing sites easier to sell, but we'll see how that plays out over the next few years.

Hopefully that answers all your questions, Thibault. Thank you for them, and appreciate the interest.

Thibault Boutherin
Analyst, Morgan Stanley & Co. International Plc

Q

Yeah. Perfect. Thank you.

Operator: Our next question comes from Chris Schott of JPMorgan. Your line is now open. Please go ahead.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Great. Thanks very much. Just two questions for me. And maybe first, just on the international markets and just a two piece here. Can you just elaborate, particularly what markets are driving the healthy growth we're seeing here as you just think about that business as a whole? And I think as part of the prepared remarks, you talked about

the Japanese generic business that you're divesting and just give us some sense of how large and the growth profile of that piece?

And then my second question was just coming back to TL1A, I kind of hear you in terms of the need for broad therapies given the unmet need in this space. But it does seem like a number of the KOLs we speak to are also excited about potential for a biomarker-driven approach to help better identify patients. So, I just want to sort of wrap my hands around, do you see the biomarker piece is something that's kind of secondary and that the studies will be kind of broad all-comers and that you'll kind of see how the biomarker sorts out? Or do you see there's a potential to differentiate on biomarkers? Because again, I'm just – I'm trying to balance that out of kind of entrenched therapies. People want something that's a little bit different versus still again a lot of unmet need here. Thanks so much.

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

Hi Chris. Thanks for the questions. So, with regard to [ph] churn in (00:56:20) international markets, actually, the encouraging thing about international markets is we have growth across all of them. And we've had growth across all of them for the time I've been here, a credit to the team and the quality of the team. We have done a bit of focus on investing capital and resources more specifically, and I think that's really helped international markets. But there's not one that stands out. And I think that's what – why we're delivering consistent quarter-on-quarter growth in international markets because of that. That's first.

Just [indiscernible] (00:56:52) Japanese business, we're not stepping out of Japan. We're divesting part of our generics business. And that goes back to once again to our capital allocation, and where we can make sure we're giving capital where we can generate a good return. And we have the ability to be thoughtful about that at Teva because of our scope in geographies and businesses we have. So, that's how that plays out in Japan.

And now with TL1A, I'll hand that over to Eric to answer.

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

Yeah. Yeah. Thank you for the questions about biomarkers and TL1A. So, the number of important things to consider when you're talking about biomarkers for one thing in my experience with biologics and discovery of biomarkers, it does take large numbers of patients to really understand and be confident in biomarkers effect. To-date, we haven't seen significant delta based on biomarkers. I'd like to see much bigger delta based on many more patients. But certainly, it's possible to identify biomarkers that are predictive of response at baseline. And more importantly, you can find strong ones that are predictive on treatment. So, we're focused on speed. We're focused on making sure that people have options for these patients. Like we said, these patients cycle through treatments for all sort of biosim Crohn's disease, and they need options that last. So, I don't want to disabuse patients as a possible treatment choice in the future. So, the choice, we'll always look for these biomarkers, but that's going to take much more data than we have today.

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

Thanks Eric. Thanks for the questions Chris.

Operator: Thank you. Our final question comes from Glen Santangelo from Jefferies. Your line is now open. Please go ahead.

Glen Santangelo
Analyst, Jefferies LLC

Q

Oh! Yeah. Thanks. Yeah, thanks for taking my question. Hey Richard, I just want to shift gears for a second. In your prepared remarks, it kind of seem like you are incrementally excited to talk about the generics business this quarter. And when you look at the results, obviously, solid growth across all your geographies. Maybe could you just give us a little bit more details maybe about product launches that may be driving that growth? And how we should think about maybe organic volumes in that business and pricing? Just so to help us assess the durability of these recent trends?

And maybe as my follow-up, I've asked about Revlimid specifically. I know that created some volatility in the results in 3Q and 4Q last year based on your contracts for that business. And so, I was curious if you could just give us an update there as well. Thanks.

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

A

Okay. Thanks for the question, Glen. I suppose I can't hide my excitement. And look, what's behind it? And I appreciate the question. So, I think I said at the outset when I write here that the generics business at Teva having all components to be a great business, which is why we use sustainable powerhouse as a pillar three of our strategy. That is not shying away from committing to something by calling it a powerhouse. The reason why we could do that is we have an extensive pipeline of generics at Teva. And we have a great high-quality manufacturing footprint, and we have a great go-to-market model. The reality was not all of those are working in perfect harmony and they're still not, to be honest, but we're making big progress. And I think some of that comes down to new product launches that you've seen in Q4, that you've seen this year, and you will see more this year. Hopefully, we don't always – [indiscernible] (01:00:24) some other people to give us approval for those. That's one.

And the second thing on our supply chain. Our supply chain is becoming more efficient and more able to deliver what is an ever increasing demand. So, those are things that make me excited. I don't think this is a linear projection. We're doing some hard work to make this happen. And I think each year, we'll get better and better and better, but we have the ingredients. And for me, this was the quarter that we started to see some of those things come together. And I don't think it will be, as I said, a clear path.

To your second about Revlimid, as you know, we don't split out our product sales. But I think Revlimid is a good example of the fact that when we get it right in R&D, when we get it right in our approach into the market first, we can maximize an asset. So, I think that is something which we're benefiting from this year, but we're also benefiting some of our other launches that we've talked about in other calls. So thanks, Glen. Thanks for your question, and I appreciate it.

Glen Santangelo
Analyst, Jefferies LLC

Q

Thank you.

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

Thank you for everybody. I think the time is up now. I'd like to thank everybody for their participation and their interest in Teva Pharmaceuticals. I look forward to giving you an update for quarter two later in the year. Thank you.

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