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MANAGEMENT DISCUSSION SECTION

Operator: Hello, and welcome to the Q2 2023 Teva Pharmaceutical Industries Limited Earnings Conference. My name is Alex, I’ll be coordinating the call today. [Operator Instructions]

I will now hand it over to your host, Ran Meir, Head 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 our website at tevapharm.com.

Let’s review our forward-looking statements on slide number 2. Additional information regarding these statements and our non-GAAP financial measures is available on our earning 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 Q2 2023 results and business performance as well as recent plans and our 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 financial results in more detail, including our 2023 financial outlook. Joining Richard, Eric and Eli on the call today is Sven Dethlefs, Teva’s Head of North America business, who will be available during the question-and-answer session that will follow the presentation. Please note that today’s call will run approximately one hour.

And with that, I 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 thank you, everybody, for joining our call. I'm very pleased to update you on our Q2 performance and the progress we are making on executing our Pivot to Growth strategy. It's been an exciting quarter, with the launch of our AUSTEDO XR, our once-a-day formulation and the launch of the UZEDY, our long-acting treatment for schizophrenia.

Now moving to slide 4, let’s start with our results. Revenue was up 4% in local currencies to $3.9 billion, and non-GAAP gross margin was at 52.2%, up 3.1% versus Q1. Adjusted EBITDA was at $1.1 billion. Based on this, we are increasing our revenues outlook for 2023 to $15 billion to $15.4 billion. I'm also pleased to highlight that we've got good momentum on our Pivot to Growth strategy, with good execution across the four pillars driving this growth. And I'll give you an update on those in the presentation as well.

Now digging down a bit into this performance and this 4% on the next slide. This was driven by our growth engines. And as you can see here, there's a 51% increase in revenue for AUSTEDO, strong performance there. AJOVY continues to perform and, in North America, grew 16% and, in Europe, 32%. We continue to see good growth in our International Markets at 13% for our Generics business, and Europe came in at plus 2%.
Now maybe to dig a bit deeper on AUSTEDO’s performance on the next slide, I believe we’re on-track to hit the $1.2 billion target we set for 2023. As you can see, revenues for Q2 were $308 million, and that was a 51% increase, strong continued TRx growth. And I’d like to point out, we did launch our once-a-day formulation in this quarter in May, which we’re very pleased to bring this to patients [ph] with this condition (00:03:50). But this obviously required us to put some stock in the channel. [ph] So if you allow for this (00:03:56), the revenue growth was probably around about 35% to 40%, so still strong growth. We continue to believe in the potential of AUSTEDO.

We can move to the next slide, I talked about back in May at our strategy launch, the $2.5 billion that we will achieve in 2027, and we are reaffirming this. And this is based on two particular points. One is the unmet medical need that’s out there, the undertreated population. As you can see from this slide on the right, there’s 785,000 patients suffering from tardive dyskinesia, and only 120,000 are actually diagnosed and only a small amount of those are treated, so there’s a significant unmet medical need.

So obviously, we at Teva here have put a lot of focus around AUSTEDO both in resources and in managerial focus, and this is allowing us to increase our sales force, increase the support we’re putting around patients, we’ve launched the once-a-day, and we continue to raise awareness so we can get some of these patients who are not on treatment into the physician’s office to get onto AUSTEDO. We also are still confident that we will be able to take AUSTEDO to the European market. So we reaffirm our belief that we can hit $2.5 billion by 2027.

Moving on to the next slide and another member of our innovative family is AJOVY. Now AJOVY continues to grow 17% versus Q2 2022. And I think this highlights the capability that we have here at Teva to launch products into competitive market and perform. We will hit our guidance of $400 million for 2023, and we continue to see that we either hold or grow market share across many of our markets.

Now moving on to slide 9 and the newest member of our innovative family, UZEDY, risperidone, our long-acting treatment for schizophrenia. Now to remind everybody this is a $4 billion market and we’ve only just launched UZEDY, but we’re very pleased with the feedback were getting from health care professionals. And they’re confirming that the profile that we have with UZEDY is unique and advantageous. Now we’re seeing this in the fact that our NBRx is 40%, so already we’re getting 40% of the risperidone long-acting market. We’re also seeing hospitals look to use our free samples and free trial requests, and we’re having good discussions with our payers. So once again, I think excitement around UZEDY, early days, but initial feedback is very positive.

And if I move on to slide 10 to give you probably a reason why we’re getting this feedback, we already had reports that show the product profile that we’ve put forward, subcutaneous needle, a lack of need for refrigeration, prefilled syringe, has allowed us to have a product that 9 out of 10 patients are very satisfied with. And obviously, when it comes to physician, we have the same, 9 out of 10. And what we have found already that’s particularly advantageous is the fact that we don’t need a loading dose and there are no oral supplements needed. One injection, and the patient will get to a therapeutic dose within 24 hours. Now clearly that’s advantageous when it comes to a patient having a relapse and needing to get that efficacy quickly. So good patient profile, good product profile and physicians’ excitement for UZEDY continues to grow.

Now moving on to our generics business on slide 11. Good growth in International up 13%, continued growth in Europe, a bit softer than the prior quarter, and this is down to a couple of factors. One is we did have a strong prior year and there is some seasonality in our business, and that’s impacted. That said, H1 will still show a 7% growth versus H1 2022. And I remain confident in this business going forward based on our portfolio and its scale, our pipeline, and our commercial expertise.
Moving on to slide 12, on our biosimilars, I'd like to update you on the progress we're making on our Pivot to Growth strategy. Now if you remember, the focus here was about having a broad biosimilar portfolio, and we've made some progress here. We have expanded our partnership with Alvotech. We have four new biosimilar candidates. We've also strengthened our operational relationship with Alvotech, helping them on manufacturing and quality where they can really leverage the scale and expertise we have at Teva. We will continue to seek to expand our portfolio, and as we do this and engage in more relationships, we'll update you as and when they happen.

Now moving on to slide 13, Eric will obviously go into some detail on our pipeline which we're very excited about and we continue to make good progress, but I really wanted to highlight the fact that the three late-stage assets we have, have favorable product profiles at the markets they're entering into, but also these are significant markets. So with olanzapine, I've already highlighted the fact that it's a $4 billion market, but if we do manage to bring this to the market with a favorable safety profile, I think we have a real opportunity to have a significant product on our hands here. ICS/SABA, it's a $2.5 billion market, and then obviously, anti-TL1A, this will be well discussed, and this is a significant market which could help long-term growth for Teva.

Now moving on to next slide on our ESG, we remain very committed to our ESG strategy, and we've made good progress across a number of goals. Just to highlight a few, I'm pleased that we've donated nearly up to 17 million doses of our medicines to improve access. We've also seen on our environmental goals a 24% reduction in our greenhouse gas emissions. And actually in quarter two, we recently signed an agreement with an energy supplier in Israel to make sure that 100% of our electricity is from renewable sources, and that includes all our manufacturing sites as well.

Moving on to slide 15, our final slide before I hand over to Eric, this just highlights the progress we're making on our Pivot to Growth strategy which we launched back in May. It's based on four pillars. On our first pillar to deliver on growth engines, as I've highlighted, AUSTEDO is performing well, and we're confident about hitting $2.5 billion.

Eric will talk to you a bit about the progress we're making in the clinic on our late stage assets, but he's put together a world-class leadership team to help make sure we can drive our complex generics business as well as our innovative pipeline. When it comes to creating a sustainable generics powerhouse, we're making good progress on focusing on our R&D portfolio and our portfolio in – our manufacturing setup to make sure we can drive efficiencies there. And finally, TAPI, we've made the decision to move that business to a stand-alone unit, and that is progressing very well.

With that, I'm going to hand over to Eric to walk us through some of those assets I've touched upon. Over to you, Eric.

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

Thank you, Richard. First on to AUSTEDO XR. Next slide, we were very happy to see the efficacy of AUSTEDO at the time of our Phase 3 approval. We're very excited to see the long-term data recently presented at the American Academy of Neurology. You can see in this slide that over this three-year period, there is a durability of response, and in fact there is a slight improvement over those three years irrespective of the psychiatric underlying condition.

Now our goal now is to make these responses, this durability, convenient for all patients. So with our approval of AUSTEDO XR this year, we're excited to bring a lower pill burden and the convenience of once-a-day dosing to
patients. And we will continue to provide AUSTEDO and AUSTEDO XR to our HCPs to provide as much flexibility in our treatment as possible.

Go to the next slide. As Richard noted, the product profile of UZEDY is very attractive to our HCPs. It’s a subcutaneous injection. It’s a small needle. No loading dose. No supplemental oral therapy. And it’s provided in a prefilled syringe. But it's also important to note the efficacy. We have shown an 80% reduction in the risk of relapse and a significantly longer time to relapse. But when we talk about our data to our experts, one of the things that we note is that after this stabilization of patients on oral risperidone in the study, we actually saw a slight improvement on the long-acting injectable of UZEDY in our study. So these are early days but this is very encouraging to see such activity and improvement with the long-acting injections.

Go to the next slide. So we have now a portfolio of products throughout the lifecycle of drug development. We’re excited to be bringing our anti-PD1-IL2 program into the clinic early next year in oncology. We’re advancing our anti-IL 15 program in celiac disease through our Phase 1 studies, and we have initiated a proof of mechanism study this year. We’re excited to be in our Phase 2b study of anti-TL1A in IBD. And we’ve already started our olanzapine LAI study which is actually enrolling very well, and we’ll be starting our ICS/SABA Phase 3 program next month.

Go to the next slide. Now a little bit more on olanzapine LAI. We’re very excited by this product. Olanzapine as an oral agent accounts for 20% of the patients being treated today, but only less than 1% of patients on the long-acting form are using that product. And that's primarily because of the safety profile. The Zyprexa Relprevv has a black box warning for PDSS. And we’ve noted before why we’re very confident that our long-acting injectable olanzapine will not have PDSS. Unlike Zyprexa Relprevv, our product is a subcutaneous injection which avoids deep penetration as an intramuscular injection, of Zyprexa Relprevv, and that will prevent, in general, a lack of spikes in the PK exposure of the drug.

In addition, our formulation rapidly aggregates into a slow release formulation. And to add to our confidence, we did this in vitro study here you see in the graph. And this is the worst-case scenario. We took human serum. We injected Zyprexa Relprevv directly into the serum, and we could show a rapid dissolution and measurement of olanzapine in the serum. However, when we directly injected our formulation, which rapidly aggregates and forms a slow-release formulation, even in this worst-case scenario, we have only a slow release and a clear differentiation from the Zyprexa Relprevv. So very encouraging results in vitro, and we’re excited to have our Phase 3 study ongoing right now.

Go to the next slide. So moving on to anti-TL1A, IBD remains a large, underserved patient population. There are over 4 million patients diagnosed. Of those, about 2.7 million patients are treated. These patients frequently receive oral therapies as well. And in the biologics that they have, they frequently cycle through those biologics due to lack of response. We’re excited by our anti-TL1A program. We believe we have a best-in-class preclinical profile. We have well-characterized the safety of our product, and we have also noted a low antidrug antibody profile. We’re accelerating our program in anti-TL1A in IBD, and we’re allocating more resources and capital on this program. And we’re excited to see in 2024 our interim results. This will drive our decision to start Phase 3 in 2025.

Go to next slide. So just to review why we believe we have a best-in-class compound. These in vitro assays here that you see on the screen are directly comparing our antibody to comparative reagents that we created that represent other clinical candidates in development. You can see that we have a greater selectivity of the DR3 receptor, which is the inflammatory receptor, while maintaining the decoy receptor, providing a clear differentiated
biology of our antibody. We also demonstrate that we have greater potency compared to the other two clinical candidates.

And then last slide. So just to summarize, our key pipeline assets are on track and progressing quickly. Our anti-PD1 IL2 will enroll its first patient at the beginning of 2024. Our anti-TL1A program will read-out its interim analysis from the second half of 2024. And as I noted, our anti-IL15 program is moving rapidly through Phase 1, and we have initiated a proof of mechanism study this year in celiac patients. Our olanzapine Phase 3 study, as I noted, is actually enrolling very quickly, and we hope to see that data readout in the first half of 2025. And finally, we're initiating our ICS/SABA Phase 3 program next month with a read-out focused on the second half of 2026.

With that, I will hand it over to Eli Kalif.

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**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 Q2 2023 financial results with slide 25, starting with our GAAP performance. Revenue in the second quarter of 2023 was $3.9 billion, representing an increase of 2% compared to Q2 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 strong performance with 5% growth in Q2 2023 compared to the second quarter last year. This growth was mainly driven by higher revenue from certain innovative products, primarily AUSTEDO and AJOVY as well as Anda, our distribution business, which benefited from higher demand in secondary wholesaler markets. It was partially offset by lower revenue from our generic products in COPAXONE, BENDEKA and TREANDA. Revenues in our generics business in North America decreased by 6% in Q2 2023, mainly due to increasing competition to parts of our portfolio. The overall pricing environment in North America Generics remained stable.

Revenue in Europe segment were flat in local currency terms. We continue to see a solid growth in our Generics business and from AJOVY in second quarter. It was however largely offset by lower revenue from our legacy brand, including COPAXONE. And revenues from our International Markets segment increased by 13% in local currency terms. This was mainly driven by higher revenue from generics product coming from price increases largely as a result of rising costs due to inflationary pressures. This increase was partially offset by regulatory price reduction and generic competition [indiscernible] (00:20:26) products in Japan.

GAAP operating loss was $646 million in the second quarter of 2023, compared to an operating loss of $949 million in the second quarter of 2022. The lower operating loss in the second quarter of 2023 was mainly due to higher legal settlement and goodwill impairment charges in the second quarter of 2023. We had net loss of $863 million compared to the net loss of $232 million in Q2 2022 and a GAAP loss per share of $0.77 compared to a GAAP loss per share of $0.21 in the same period a year ago.

The higher net loss in the second quarter of 2023, mainly due to a lower tax benefit in Q2 2023 compared to Q2 2022, due to effect of a portion of a realization of losses related to an investment in one of our US subsidiaries last year, partially offset by lower operating loss, as discussed above. Foreign exchange rates movement during the second quarter of 2023, including hedging effects negatively impacted our revenue and GAAP operating income by $51 million and $38 million respectively, compared to the second quarter of 2022. This was primarily a result of an impact of a stronger US dollar against the currencies of certain international markets in which we operate, partially offset by the benefit of euro appreciation. Approximately 46% of our revenue in Q2 2023 came from sales denominated in non-US dollars currencies.
Turning to slide 26. You can see the total non-GAAP adjustments in the second quarter of 2023 were approximately $1.5 billion compared to $986 million in Q2 2022. Notable non-GAAP adjustments included a goodwill impairment charges of $700 million related to our International Markets reporting unit, mainly due to an increase in the discount rate due to higher risks associated with several countries, as well as legal settlements and loss contingencies expenses of $462 million, mainly related to estimated provision, recorded in connection with certain litigation cases in the US, including a $200 million provision related to the US DOJ criminal price-fixing case based on advanced settlement discussions with the DOJ. Other notable adjustments include amortization of purchased tangible assets of $162 million, the majority of which is included in cost of sale.

Now moving to slide 27, for our review of our non-GAAP performance. As I mentioned, our second quarter revenue were a total approximately $3.9 billion represented a growth of 4% in local currency terms compared to the second quarter of 2022.

Now let's move down to P&L, starting with the gross profit margin. Our non-GAAP gross profit margin was 52.2% in the second quarter of 2023, compared to 54.4% in Q2 2022. This decrease in non-GAAP gross profit margin was mainly driven by higher costs due to inflationary pressures, FX, and other macroeconomic elements. And increasing revenues with lower profitability from Anda, in our North America segment and lower revenues from COPAXONE, partially offset by higher revenues from AUSTEDO.

As I mentioned last quarter, and as expected, this was an approximately 300 basis point sequential improvement in our non-GAAP gross profit margin in Q2 2023 compared to the first quarter of 2023. This improvement was driven by an anticipated shift towards more balanced and normalized portfolio mix, mainly driven by strong growth in AUSTEDO, growth in AJOVY, as well as sequential improvement in our cost of goods sold due to the expected easing of the inflationary pressures and other measures that we are taking to drive our productivity in our supply chain.

Our non-GAAP operating margin in Q2 2023 was 26.1% versus 26.9% in Q2 2022. This decrease was mainly driven by lower gross profit margin, as I just mentioned, partially offset by a decrease in operating expense. We ended the quarter with a non-GAAP earnings per share of $0.56 compared to $0.68 in 2022, mainly due to higher financial expenses in Q2 2023, as well as a lower tax rate in Q2 2022 due to the effect of higher tax benefits last year, as I mentioned earlier.

Now let's take a look at our spend base on slide 28. As you can see, our quarterly spend base increased by $100 million or $115 million on a local currency basis. Most of this increase was due to a higher cost of goods sold related to higher revenues and the factors I just described earlier, partially offset by lower operating expenses.

As I highlighted last quarter, we continue to transform our global manufacturing and operating footprint. We have made significant progress over the last five years to consolidate our sites to get more efficient, going from 80 manufacturing sites down to 51 sites today and have two additional sites, then, for closure or divestiture by the end of 2023. Moving forward, we expect these optimization efforts to continue and reach a normalized sites count between 40 to 44 sites over the near and medium term, to help drive efficiencies in our operation and improve margins.

Turning to free cash flow on slide 29. Periodically, as part of our cash flow, commercial relationship management activities, we made decisions in our commercial and supply chain activities which may drive an acceleration of receivable payments from customers or deceleration of payments to vendors. In our efforts to continually seek to improve the efficiencies of our working capital management, we obtained more favorable payment terms of many of our vendors, which are expected to continue in future periods.
Our free cash flow in the second quarter of 2023 was $632 million compared to $301 million in Q2 2022. The increase in free cash flow in the second quarter of 2023 resulted mainly from changes in working capital items, including positive impacts from accounts receivable net of SR&A and from inventory levels, partially offset by negative impact of accounts payable, as well as higher proceeds from sale of business and long-lived assets.

Today, we are reaffirming our 2023 free cash 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 continue to progress in the second half of this year, as we have a gradual ramp-up in our profitability and continue to drive working capital improvement.

Turning to slide 30. Our net debt at the end of Q2 2023 was $18 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 that was due on March 31, partially offset by exchange rate fluctuations of $166 million.

Subsequent to the second quarter close, we withdrew a total amount of $700 million under our $1.8 billion revolving credit facility. The proceeds of which were used to repay $1 billion of our senior notes at maturity on July 21.

Our net debt-EBITDA improved compared to Q1 2023, coming in at 4.14 times for Q2 2023, mainly due to a free cash flow generation in the second quarter, partially offset by movement in foreign exchange rates. Debt reduction continues to be our focus, and we expect to continue to work towards our long-term financial target of being 2 times net debt to EBITDA by the end of 2027.

Turning to slide 31, which represents our upcoming debt maturities. If you recall, we successfully refinanced approximately $2.5 billion of our debt through sustainability-linked senior notes during the first quarter of 2023, with an objective to align our near-term debt maturities with our free cash flow guidance for this year. With our ongoing cash flow generation, we believe we are well positioned to continue to service our debt and meet these upcoming maturities. As I mentioned earlier, in July 2023 we repaid $1 billion of our 2.8% senior notes at maturity, so there is no additional maturity payment due in 2023.

Now, turning to our 2023 non-GAAP outlook on slide 32. As Richard highlighted earlier, and as we reflected in the first half of this year, we have made solid progress in terms of earning revenues while we continue to navigate gradual improvements in our margin. This include solid momentum in our key growth engine, especially AUSTEDO, the launch of UZEDY, continued growth in AJOVY and a solid performance in our generics business, especially in Europe and International Markets.

In addition, since we’ve provided our initial guidance range in February this year, we are seeing relatively higher demand in certain businesses including our distribution business in Anda, which benefited in the first half of this year from higher demand in the secondary wholesaler market, the generics business in our Europe and International Markets segment, and as well as relatively favorable foreign exchange rate environment.

Therefore, to reflect our revenue performance in the first half along with expected continued development in the second half of 2023, we are increasing the lower end of our full year revenue guidance range by $200 million. We now expect that our revenue to be between $15 billion and $15.4 billion for the full year of 2023. We are also reaffirming our 2023 non-GAAP outlook for operating income, EBITDA, earnings per share and free cash flow as provided in February.
As I mentioned, during the first quarter earnings call and in line with the subsequent improvement that we actually saw in the second quarter of 2023, we continue to expect a gradual improvement in our margin in the second half of the year. We believe this will be driven by further improvement in our cost of goods sold, as we navigated the impact of the inflationary pressures that we saw in the second half of the year and drive improvements in our operating expenses, as well as by changes in our portfolio mix with a further ramp-up in revenue from our key growth drivers, including AUSTEDO.

With that, this concludes my review of Teva's results for second 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, and thank you, Eric. So in summary, as I said earlier, a solid Q2 performance-wise, driven by our growth drivers of AUSTEDO, UZEDY, and AJOVY, good, stable business from our generics portfolio. Eli’s talked about upping the guidance, which we’re pleased about, and we’ve made tangible progress in our Pivot to Growth strategy to get us back to long-term growth.

So, with that, I’ll hand it back to the floor to take some questions. Thank you for your time.

**QUESTION AND ANSWER SECTION**


**Jason M. Gerberry**

*Analyst, BofA Securities, Inc.*

Hey, guys. Thanks for taking my questions. I guess just curious with AUSTEDO and the growth ambitions that you've laid out, I'm wondering if you could identify like sort of the singular biggest driver to this under-treatment dynamic. Do you think that these patients are sitting in psychiatrist's office and just haven't been made aware, or just choosing not to get treatment? Or do you think that maybe the population is just more dispersed, and it's just going to require more of a larger field force to get the word out around these therapies?

And then maybe, Richard, just curious. There's a lot of media reports about API and the TL1A assets being explored as potential divestiture candidates. Wondering if you could add any color to that topic and willingness to part ways with either of those. Thanks.

**Richard Francis**

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

Thanks, Jason. Thanks for your question. I'll answer both but also give maybe Sven an opportunity to comment. On the untreated patients for tardive dyskinesia, it's a bit of all of what you said actually. There are patient sitting in the office that don't get diagnosed from the psychiatrist, and some of that can be quite simple. The symptoms of tardive dyskinesia, they aren't visible to the physician, and the physician has to explore them. So that's one.
Another part is they actually don't make their way into the physician's office to seek actual treatment. And we see that because when we do direct to consumer programs, we see a significant influx of patients into physician office. So I think what our process going forward is to make sure we constantly educate physicians about identifying these patients and asking them the right questions. I think we see a good traction on that. And the second is to make sure patients actually enter the physician's office to ask questions about some of the symptoms they have. So, yeah, it's a journey, I think we're making good progress.

Now moving on to API and TL1A. Look, as we said with regard to our TAPI business, we set it up as a standalone business because we see if we focus this business, we have ability to drive top line growth, which will help us on our Pivot to Growth strategy. We started the progress on that, and that's doing very well. And we remain committed to that. I think the attraction then and the discussion that's being talked about outside, I think, merely highlights how, I think, attractive this business is, and how with the right focus it can perform.

When it comes to the TL1A, as I've said on a number of calls, we are committed to this asset. We fully funded it through this clinical development. Very excited about it. We do, as Eric highlighted, believe we have a differentiated best in class. But obviously it's a hot topic. So everybody's talking about TL1As. And in particular, I think [ph] ours gets both belong (00:36:28). But our aim is to once again develop that asset and use that as another lever to get ourselves back to growth. And it will be one of those things that drive growth in 2028 and beyond.

So thanks for your question. Would you like to add anything else, Sven, to that?

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

Well, I think you covered it well. What I may want to add is that we already saw in the last years a significant expansion of the prescriber base for tardive dyskinesia. Please keep in mind that these patients have multiple diseases, they have a mental health condition that is already difficult to treat and tardive dyskinesia, that needs to be recognized by physicians. It is, of course with the VMAT2 inhibitors, very well treatable. And we have seen physicians that start to treat tardive dyskinesia also are able to identify more patients. For that reason, we believe we can tap into this enormous patient potential and help even more patients in the future.

And then other factors that, in particular, are contributing to our growth is, of course, now the availability of the once daily formulation because we couldn't participate in a market segment which is very much focused also on patient convenience, and we are quite happy now that we can address that market segment as well. So it will contribute to our growth, in particular.

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

Thanks, Sven. Thank you, Jason.

Jason M. Gerberry  
Analyst, BofA Securities, Inc.

Thanks, guys.

Operator: Thank you. Our next question comes from Umer Raffat of Evercore ISI. Your line is now open. Please go ahead.
Hi, guys. Thanks for taking my question. I think 2026 was the date you mentioned on slides regarding a possible EU entry that you are investigating. My question is, considering the US approval was on a 505(b)(2) basis, there has to be an additional trial. And I'm curious what specific feedback or any early feedback [ph] do you mind (00:38:16) sharing on that note.

Secondly, it looks like EBITDA for the full year as much as it's tracking ahead of consensus so far, it's not quite annualizing at what the low end of the full year guidance is. And even versus first half last year it's slightly lower partially because of the gross margin in first quarter. But to get to above $4.5 billion last year in EBITDA there was a one-time charge called other non-GAAP of $200 million, which kind of enabled the full year to get to just above $4.5 billion. And I'm curious. Are you modeling some sort of other non-GAAP charge to enable getting to above $4.5 billion EBITDA this year? Thank you.

Thank you, Umer. Thanks for the questions. So, yes, we've made a lot of progress on AUSTEDO and making sure tardive dyskinesia and Huntington's disease patients can benefit from that in Europe. And on the particular timings and the path, I will hand that over to Eric.

Thank you, Umer. So we are working on the package for the EU with AUSTEDO. The requirements are, we believe, sufficient with the data we have to date. That's an ongoing discussion with the health authorities. I will be working on that through the following year.

Thanks, Eric. And then, Eli, do you want to touch on the questions on the EBITDA.

Yes. For sure. Umer, thank you for your question. I think, first, we are not considering any non-GAAP adjustment for second half in order to make sure that we are actually landing in the $4.5 billion, $4.6 billion EBITDA that we are expecting. What I will mention that the second half will be more accretive in terms of the gross margin that will flow to the EBITDA line, and this is mostly due to the mix and the fact that we actually now narrow the guidance on the top line and that get us kind of at least to be at the midpoint, just for the modeling of $15.2 billion. Other than that, we are also not banking too much on FX. They're rebounding. We are using the same average of FX for the first half.

Thanks, Eli. Thanks for your questions, Umer.

Operator: Thank you. Our next question comes from Balaji Prasad from Barclays. Your line is now open. Please go ahead.
Hi, everyone. This is Mikaela on for Balaji. Thanks for taking our questions. Just two from me. What does Teva aim to achieve with more control on the biosimilars facility? And if you could just provide some more color on what you've seen till now. And then my other one is just on the pricing stabilization that you mentioned. Was generic pricing in the US stable quarter over quarter or year-over-year? Thank you so much.

Thank you. So with that I'll start on those, and I'll hand over to Sven. I think, look, on the Alvotech partnership, I think what we mean by operational involvement is it means that when it comes to the manufacturing and the quality aspects, obviously with Teva with 50-plus sites, we have a wealth of experience in this area. And so we’re actually having people on the ground working with Alvotech to help them obviously in the areas that have been identified by the FDA. So that is something which we've set up, and we even have a committee set up, so it's formalized GSC. So I think that's well-structured and Alvotech are very excited about the help they're getting from us.

When it comes to the generic pricing, I'll hand that to Sven to talk about that from quarter to yearly.

Yes. Thank you for the question. So the US generics price decline has indeed slowed down over the last quarters. If you look at the pure core Generics business that Teva has in the US, we actually had six very stable quarters now which was also supported by the slowdown in price decline. It's not driven by a change in price bidding on the side of wholesalers or on the side of buying groups. That did not change in the last quarters.

What we've seen is that of course generics [indiscernible] on supply and demand, and since we see more supply chain disruptions or supply discontinuities, also on behalf of our competitors, it helps slow down the price erosion. And what we also notice is that not only Teva but also other companies are looking into portfolio consolidation, and if you do that, typically it supports the price decline slowdown. And then we've seen too many large generic launches which is the third factor typically influencing price decline. And for that reason, we overall see a stable situation at the moment, and we have to see if this continues over the next quarter. So far, we have no indication for a change.

Thanks, Sven. Thanks for your question.

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

Hey. Thanks for taking my questions. I had two. So on AUSTEDO, so XR is a nice step to kind of minimize the gap between you and the other key competitor. Is titration something that you can simplify as well in the near term and that can minimize that gap further? And then second one, just on generic Symbicort, I think there was a
Thank you, Sven. Thank you, Ash. Thanks for your question.

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

Thank you, Sven. Thank you, Ash. Thanks for your questions. So I'll start with AUSTEDO, and then I'll hand over to Sven for Symbicort. So you're right to highlight that titration is important for AUSTEDO, to make sure the patients end up on the efficacious dose. What we have done, and actually it's occurred this month in August, is we have continued to approve our titration offering with a titration pack that can be prescribed by the physician. So it just makes it simple. It doesn't rely on the sample having to be left in the physician's office.

So I think that's going to help the patients move through that titration to end up on the optimal dose for them, from an efficacy point of view. So we just see that as another one of the offerings that were laid on to AUSTEDO to go with many others, which is going back to what I said about the investment we're putting into AUSTEDO. It was multichannel, different areas, and that's why we have confidence in hitting the $2.5 billion in 2027. But on the Symbicort, if I can hand that to you, Sven?

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

Yes. Maybe adding also to AUSTEDO that we eliminated the 6-milligram titration step. So that has already been simplified, and we are working on a more simplified titration schedule. Also what we do this month on August, we launched a titration package, a blister package that can be prescribed by physicians to initiate patients. So that will also help with effective titration. On generic Symbicort, we are working on this complex development. It's an inhaler. It's a combination inhaler. The FDA, of course, has high hurdles to get these product approved for that reason. Our expectation is that this launch will be more driven by approvability of the product itself than any other considerations.

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

Thank you, Sven. Thank you, Ash. Thanks for your question.

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

Thibault Boutherin  

Hello. Thank you for taking my questions. I had some technical difficulties. So I apologize if it has already been asked. But my first question is on biosimilar Humira. It now seems that you will enter the market most likely in 2024, after most of your competitors have already launched. So what opportunity do you believe the biosimilar actually represents? Could it still be a meaningful contributor to your revenues next year, or should we be conservative and assume that it will be challenging to compete in this market with a late entry? And if you do think that it’s a meaningful opportunity, if you could highlight the factors that would enable you to compete despite being a little bit late to the market?

Second question on UZEDY, just if you could give us an update on coverage in the US and the position of formularies compared to key your competitors in the injectables schizophrenia field? Thank you.
Richard Francis
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

Okay. I'll hand both those questions to Sven. I think before I do, when we think about Humira, just to sort of outline, I think this is an evolving market so I think it's going to be interesting to see how 2023 plays out. And it's important to also understand the product profile that we have [indiscernible] (00:47:15) Alvotech is really highly differentiated based on interchangeability and the quality of our [indiscernible] (00:47:24).

But maybe, Sven, if you can add a bit more depth to that.

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

Yes. Of course, we have seen now that on July 1, we had the market formation for biosimilars in the US, with several companies entering the markets so far, but it's very early. There's only been a slow uptake of biosimilars versus the originator [ph] Epi (00:47:42). What we expect is that we have in 2024 more decisions coming up on the side of PBMs about formulary changes or eventually also have changes to the formulary taking the originator out of the programs.

So we have to work with Alvotech now on the FDA approval for our drug. That's a prerequisite for us to enter the markets but we believe there's still an opportunity to be captured also in 2024 because we always said there is a two-phase market formation, now one in July and one coming more with the natural formulary changes in January 2024. And then we will see how our very comprehensive product profile will work out. But overall, currently, our focus is on the FDA approval of the Alvotech site in Iceland.

And I think you asked the second question about UZEDY and build market coverage.

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

Coverage, yeah.

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

So we are working, of course, with the target on a parity position in all the payer plans. The majority of patients comes from Medicare and Medicaid. They have longer decision timelines than in the commercial segment but we are making very good progress here. In our market access discussions, we're actually right on plan or slightly ahead of our market access strategy targets. And we are very happy with the launch, how it's progressing.

We've seen, so far if you get a prescription for UZEDY, about 80% are filled also, and they have very high interest on the hospital sites for the free sampling program. That's an important segment for us as well because many patients are initiated on that side. So overall, I would say our launch is right on target and progressing well.

Thibault Boutherin
Analyst, Morgan Stanley & Co. International Plc

Thank you very much.

Richard Francis
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
Teva Pharmaceutical Industries Ltd. (TEVA) 
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Thanks for your question, Thibault.

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

David Amsellem
Analyst, Piper Sandler & Co.

Hey, there. So I had a couple high-level questions about the neuropsychiatry business. Can you talk about your willingness or the wherewithal to bring in pipeline assets or even smaller scale commercial stage assets where you can leverage the commercial infrastructure that you have in place for AUSTEDO? So just talk about your psychiatry focus in terms of BD, M&A, and what you can and can't do.

And then secondly, and just a broader strategic question, do you think that there is a possibility or does it make sense to potentially explore a separation of the neuropsych business into a standalone business as a means of unlocking value just given where AUSTEDO is and how the broader markets think of businesses with novel CNS assets? Thank you.

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

Thank you. Thank you for those questions, David. So in answer to your first question, yes. I think we've started to build a real franchise with the psychiatric community. And actually when we were at the recent American conference of psychiatry, people actually said, you are now the company in this area. And obviously they see that with AUSTEDO. They see that with UZEDY. And obviously olanzapine that Eric spoke about.

So, yes. And we are actively out there looking at BD and opportunities. Some of those are about in-licensing, and some of these are constrained a bit by our balance sheet and where we are right now. But the advantage we have is we have an infrastructure that we can bring, plug-and-play products into. So I think for us it is beneficial, it could be cost-effective, and for potential partners, they see that leverage that we have with the community and the relationships we have. So I think that's something which we are active in but obviously we need to find the right asset at the right price or the right company even.

Now moving on to your second question around the separation of the neuroscience business. No, that's not a consideration, just to be very clear about that. I think Teva really benefits from putting Teva as a complete Teva. We are fueling a lot of our growth in our innovative business from the support of our generics business and our other businesses, and so there's a lot of synergies that are at play here. And even in R&D, the work that's being done on the complex generics, the support they get for the innovative part of our business here is very helpful.

So right now, I think where Teva is, it will actually stay as it is, and we'll continue to grow as Teva as one. But thank you for your question.

Operator: Thank you. Our final question for today comes from Chris Schott of JPMorgan. Your line is now open. Please go ahead.

Chris Schott
Analyst, JPMorgan Securities LLC

Great. Thanks. Just two questions for me. First, can you just elaborate a little bit more on gross margin progression as we think about the second half of the year? I'm just trying to get a sense of what's a good number
to think about as we kind of think about this obviously nice improvement relative to 1Q. But just how much of a normalization should we think about in the second half?

And then my second question was just a follow up on UZEDY. Given some of the payer dynamics and these processes taking a little bit longer, when can we think about revenue ramping for the product? Is that something we could see in 2023, or is that more 2024 before you expect the coverage to come into place? Thank you.

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

So thanks for those questions. Before I hand over the gross margin to Eli, I just want to sort of lay out how people should start to think about our gross margin as our company evolves.

So one of the things about gross margin, as Eli's highlighted already, it's driven by obviously our cost of goods, our COGS but also our portfolio mix. And one of the things that I think is important for people to start to think about as we grow our innovative business, our portfolio will change, and with that, changes our profitability and our gross margin from that innovative business. And so obviously growing AUSTEDO, growing UZEDY, growing AJOVY which is still happening [indiscernible] (00:54:11) that will continue to move gross margin in the right direction.

The second thing which is important to understand in 2023 is H2 will have a higher revenue, based on what Eli's just said, than H1. So if you take those factors together, it leads us to improving gross margin. But I'll hand over to Eli to give you maybe some more of the specific numbers.

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

Yeah. So thanks, Chris. And, Richard, I will continue what you mentioned. So first of all, there are a few dynamics there if you look on the second half of the year. First of all, in terms of the mix of the revenue, we are setting up with AUSTEDO as we're heading into the second half. And the majority of the increasing revenue that came from the distribution in Anda happened already in the first half which means that mix actually going to change significantly in the second half, or the second half in the distribution business in 2023 will be the same back in 2022. So that increase actually already happened in first half and will not keep diluting the gross margin.

With that said, there is other activities that we are doing in terms of our cost elements, and we see some also, I would say, a gradual decrease in the inflationary pressures mostly related to costs like logistics freight and energy as well, other elements related to direct material pressures we got in the second half of the year last year on procurement for our inventories.

Now the numbers to think about it, we are actually yielding for the 53% for the year which means that gradually we'll see Q3 and Q4 increasing most likely close to 53.5% range in Q3 and very close to the 54% in the Q4.

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

Thanks, Eli. And, Chris, to answer your last question on UZEDY and uptake of it in 2023 or 2024, thanks for that question, 2023 is more of the setting up of UZEDY, getting access to payers but also onto formulary committees at hospitals, we have two D&T committees and making sure people are aware of the product. So I think don't think of 2023 as the growth driver from a revenue point of view. It's more as we enter 2024. That's when high
dosing will get in place [ph] with payers, and specifically (00:56:44), the hospitals, then we see that's when the real revenue growth will start.

But really pleased with the physician – and actually Sven highlighted the amount of sampling that the hospitals are using and the physician interest and uptake now. And that obviously helps us get through those formulary committees because the support of the physician is really important. So those early signs are very encouraging. But think about modeling it in 2024. But thanks for the question, Chris.

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

And I think that concludes all the questions we have today. So I'd like to thank everybody again for taking the time to call in and people to ask their questions. Hopefully, you found this informative. And we look forward to updating you later in the year on quarter three. Thank you.

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

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