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Teva Pharmaceutical Industries Ltd.

(TEVA)

Q2 2022 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good day and thank you for standing by. Welcome to the Teva Second Quarter Financial Results Conference Call. At this time, all participants are in a listen-only mode. After the speakers' presentation, there will be a question-and-answer session. [Operator Instructions] Please be advised that today's conference is being recorded.

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

Ran Meir

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

Thank you, Sondra. Thank you everyone for joining us today. We hope you have had an opportunity to review our press release, which was issued yesterday. 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. I am joined today on the call by Kåre Schultz, Teva's CEO; Eli Kalif, our CFO; and Sven Dethlefs, Teva's Head of North America Business.

We have today quite a busy agenda. We will start the call with an update from Kåre on the progress achieved on opioid litigation front. This will be followed by Kåre's and Eli's review of the second quarter business and financial results, as well as the updated outlook for 2022. And we will end the presentation part of today's call with a

strategy update from Kåre and discussion of our new long-term financial targets. Please note that today's call will run approximately 70 minutes.

Before we begin, please see our forward-looking statements disclaimer on slide number 2. Additional information regarding these statements and our non-GAAP financial measures is available on our earning release and our SEC Forms 10-K and 10-Q under Risk Factors.

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

Kåre Schultz

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

Thank you, Ran. Welcome, everybody. It's a pleasure to update you on the opioid litigation. As you have seen in our release, we reached an agreement in principle with the working group of the states, the tribes and the plaintiff lawyers representing the states and subdivisions and reached financial terms for a nationwide opioids settlement. We will be paying $4.25 billion over 13 years. This includes the already settled cases. As you've been seeing, we've settled a number of states during the last half year. We'll be paying $100 million for the tribes, also spread over 13 years.

As you've seen in the settlements we've been doing on a state by state basis so far, we have also committed to donate generic version of Narcan, which is a product that can be used in case of overdosing to help people survive. We'll be donating these products over 10 years, and there will be the option for states to go for a cash value instead of the actual product donation. Of course, we are hopeful that many will accept the donation and in that way help combat the opioid epidemic.

We revised our provision to reflect all the details of the agreement we have in principle on a nationwide settlement. The agreement is contingent upon final documentation among the working group and us. And of course, like other big nationwide agreements, it's also predicated upon it that you will need a certain participation from the states and subdivisions, which will be set forth in the final agreement.

The agreement is also contingent upon us reaching an agreement with Allergan with respect to any indemnification obligations and Allergan reaching a nationwide opioids settlement. Once the documentation is finalized, the nationwide agreement will need to be adopted by a sufficient number of plaintiffs, which would then resolve in the vast majority of opioid-related claims and litigation by states, subdivisions and Native-American tribes in the United States to be settled.

There are no remaining trials currently scheduled against us in 2022, with the possible exception of the relief phase of the trial in New York opioid litigation. Additionally, Teva, New York State and its subdivisions are engaged in ongoing settlement negotiations. We expect that the documentation for the nationwide settlement agreement will be finalized in the coming weeks, with the actual nationwide settlement sign-on process for states, subdivisions and tribes to follow.

Next slide, please. Let me now turn to the second quarter and the financial highlights. Revenues came in at $3.8 billion. Adjusted EBITDA came in at $1.1 billion. The GAAP diluted loss per share was $0.21. The non-GAAP diluted EPS was $0.68, and the free cash flow came in at $301 million. We continued to reduce our debt, and the debt has now been reduced to $20 billion. Our 2022 revenue outlook has been revised mainly due to continued foreign exchange headwinds. We've seen the dollar appreciate significantly during the last year against the euro as much as 14%, 15%. Our guidance for operating income, EBITDA, EPS and free cash flow remains unchanged.

On the business side, we will comment on AUSTEDO and AJOVY in the coming slides, but I would like to point out that North America generics had a strong quarter with good contribution from the generic version of Revlimid, but also continued strong sales of EpiPen, as well as the biosimilar TRUXIMA, which is the biosimilar version of RITUXAN, where we still have a high market share. In Europe, we also saw a very strong volume uptick of both our generics and OTC, and we actually saw that the revenue in local currency was up 12%. So, we're seeing normalization of volumes following the COVID-19 restrictions that have been lifted. We also had a biosimilar product launch in the UK, the biosimilar to LUCENTIS.

Next slide, please. If you look at the revenue development here, then you need to be aware that we report this in ongoing currency – ongoing realized currencies, which basically means that when you're comparing to Q2 2021, we do see a decline in US dollar terms. Had we reported it in the local currencies, then the revenue would basically be flat. And that means that in Europe, we do not see in local currency a decline. We rather see a small increase. And in North America, we see stable revenues as well as International Markets. In International Markets, of course, there has been a negative influence on our revenues in Ukraine due to the conflict there. But overall, the revenue in International Markets is in line with expectations.

Next slide, please. AUSTEDO continues to grow very nicely. We see a continuous growth in the TRx and in the patient numbers. On the revenue side, we have some quarterly ups and downs as we've always had. But we are happy about the revenue in the second quarter, and we reconfirm our outlook for the full year, where we expect to sell $1 billion.

Next slide, please. AJOVY is also doing very fine. You can see here how the scripts are continuing to grow in the US, and you can also see how the market share in Europe continues to grow. We now have a market share of above 30% in Europe, and we have a aim now of a third of the markets. We are now number two in the European market coming from a late launch position as number three. We strongly believe that the efficacy and safety of AJOVY is very, very good, also compared to competition, and we are optimistic about the future sales growth of this key product.

Next slide, please. The margin continues to evolve positively along with our operational plans to optimize manufacturing, optimize our commercial operation. You see here that the first half year margin is above the first half year margin last year. And the reason why we have a difference between the first half year margin and the full-year margin is that we always had a strong fourth quarter in terms of revenue for a lot of practical reasons, and that means that we still expect to see an uptick for the full year compared to the first half and means that we are on our way to hit the long-term financial target for 2023 of 28% as operating margin.

Next slide, please. The debt, as I alluded to earlier, continues to decline. We're now down to $20 billion. Of course, we won't stop here. We will continue to drive down debt, and I'll be commenting later on what our long-term target will be for the debt development. We are very committed to our patients. As you know, we serve around 200 million patients every day. But we also try to serve these underprivileged people around the world with medicine, because that's what we can do to help people.

And here, you can see some examples around the world, how we support vulnerable groups with mental health, with oncology treatment in both Africa, North America, Europe. And if you're interested in this, then there's a lot more information on all these programs on our website as part of our ESG reporting, where you could also see all the things we're doing to meet the targets we've set for our bonds, our sustainability-linked bonds, where we have targets both for access and for climate.

With this, I'll hand over to Eli Kalif, who will comment on the numbers for the second quarter.

Eli Kalif

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

Thank you, Kåre, and good morning and good afternoon to everyone. I'll begin my review of the second quarter of 2022 financial results on slide 15, starting with our GAAP performance. Revenues in the second quarter of 2022 were $3.8 billion, representing a decrease of 3% compared to Q2 2021. In local currency terms, revenue increased by 1% compared to the second quarter of 2021. This increase was mainly due to higher revenues from generic products in Europe and North America, partially offset by lower revenue from COPAXONE and BENDEKA/TREANDA in North America.

We saw higher demand for generic and OTC products in Europe, mainly resulting from the removal of restrictions related to the COVID-19 pandemic, together with a higher revenue from generic product launches. The increase in generics revenue in North America was mainly related to the revenue from the generic version of Revlimid.

In Q2 2022, we recorded a GAAP operating loss of $949 million compared to an operating income of $582 million in Q2 2021; GAAP net loss of $232 million compared to the net income of $207 million in Q2 2021; and a GAAP loss per share of $0.21 compared to the earnings per share of $0.19 in the same period a year ago. The significant year-over-year decline was mainly driven by goodwill impairment charges, which I will discuss in the next slide. It was also driven by higher legal settlement expenses related to an update of the estimated settlement provision recorded in connection with the remaining opioid cases, as Kåre just mentioned.

Foreign exchange rate movements during the second quarter of 2022, net of hedging effects, negatively impacted revenue and GAAP operating income by $162 million and $6 million respectively compared to the second quarter of 2021. This was a result of the impact of a stronger US dollar especially versus the euro. In the second quarter of 2022, approximately 47% of our revenue come from sales denominated in non-US dollar currency.

Turning to slide 16, you can see that the net non-GAAP adjustments in the second quarter of 2022 were $986 million versus $444 million in Q2 2021. The majority of this amount was a result of a $745 million goodwill impairment charge that was booked to our International Markets and Teva api reporting unit used to increased discounts and country risk premium rates. Additional notable non-GAAP adjustments include legal settlement of $729 million, mainly due to an update of the estimated opioid settlement provision.

In Q2 2022, according to the agreement in principle that Kåre mentioned, the overall opioid provision was updated to $3.2 billion to reflect the discounted cash flow for all elements of the nationwide legal settlements on the assumption that we finalize the relevant outstanding terms and get a full participation. Non-GAAP adjustments also include amortization of purchased intangible assets totaling $212 million, the majority of which is included in cost of goods sold. Corresponding tax effect includes a portion of realization of losses related to an investment in our – one of our US subsidiaries.

Moving to slide 17 for a review of our non-GAAP performance, I've already discussed our second quarter revenues, which totaled approximately $3.8 billion. Now, let's move down to P&L and look on the margin. Our non-GAAP gross profit margin improved to 54.4% compared to 53.3% in Q2 2021. Despite 1% quarter-over-quarter decline in non-GAAP gross profit, the increase in non-GAAP gross profit margin was mainly driven by a favorable mix of products in our Europe segment and the positive impact of hedging activities, partially offset by lower revenue from COPAXONE and the change in the mix of products in our North America segment.

Our non-GAAP operating margin in Q2 2022 was 26.9% versus 26.4% in Q2 2021. This increase was driven mainly by a lower spend base, which I will discuss in the next slide. We ended the quarter with a non-GAAP earnings per share of $0.68 compared to $0.59 in Q2 2021, mostly due to lower financial expenses and income

taxes. Now, let's take a look to our spend base on slide 18. We see that our quarterly spend base declined by $110 million, although it increased by $41 million net of FX. Looking at our total spend base for the first half of 2022, it declined by $367 million or $142 million net of FX.

We continue with our ongoing efforts to transform our global operational network and ongoing activities on the management of operating expenses. We expect the overall annual spend base to remain well below $12 billion, as we continue to focus our efforts on reducing and optimizing our cost of goods sold. As I mentioned last quarter, these ongoing efforts are expected to continue to help us partially mitigate the global macroeconomic headwinds, including inflation and higher cost of labor, and eventually lead to stabilize our operating margin above the level of 27% in 2022, with the ultimate goal of 28% operating margin by the end of 2023.

Turning to free cash flow on slide 19, our free cash flow in the second quarter of 2022 was $301 million. As I've mentioned in the past, Teva's free cash flow tends to face headwinds at the start of the year. In addition, we faced challenges due to timing of certain items related to our working capital as a result of operational ramp-ups in relation to our annual production plan. The decrease in our free cash flow in the second quarter of 2022 resulted mainly from lower cash flow from operating activities, as well as lower proceeds from sales of assets which we saw in Q2 2021.

The decrease in cash flow from operating activities was mainly due to payments related to legal settlements in the second quarter of 2022, partially offset by an increase in accounts payable. Today, we're reaffirming our 2022 free cash flow guidance which we initially provided in February. Our 2022 free cash flow is expected to be in the range of $1.9 billion to $2.2 billion. We expect our free cash flow to pick up during the second half of the year as we continue to drive working capital improvements. We remain on track to achieve our objective of 80% or greater free cash flow conversion by the end of the 2023 as part of our long-term financial targets.

Turning to slide 20, our net debt at the end of Q2 2022 was $20 billion compared to $20.9 billion at the end of 2021. The decrease in our gross debt related to the bond maturities paid in Q2 2022, as well exchange rate fluctuations. Our net debt to EBITDA ratio decreased, coming in at 4.16 times for Q2 2022. We expect it to further decline as we continue to make progress towards our 2023 target. Debt reduction continues to be our primary focus and main use of cash. Upcoming maturities include $1.1 billion in the remainder of 2022, out of which CHF 350 million, which is equivalent to $260 million, will be repaid tomorrow at maturity.

So, now turning to our non-GAAP financial outlook for 2022 on slide 21, as you can see, we continue to see strong foreign exchange headwind affecting our results. At current rate, we still expect foreign exchange fluctuations to have an unfavorable impact on revenue, and therefore, we believe that consistent with what we had communicated in May, at this time, it's also prudent to adjust our guidance range for full-year revenue from the previous range of $15.4 billion to $16 billion to the new range of $15 billion to $15.6 billion. This lowers the midpoint of our range by $400 million.

The new range includes an adjustment to our full-year expectation of global sales of COPAXONE, of which we're lowering our guidance by $50 million to $700 million, due to increasing generics competition in the United States and the availability of alternative therapies, as well as continuing effects of foreign exchange fluctuation.

Our non-GAAP tax rate in the second quarter of 2022 was mainly affected by the realization of losses related to an investment in one of our US subsidiaries. This led us to update our non-GAAP tax rate guidance from the previous range of 18% to 19% to the revised range of 13% to 14%. For other key 2022 financials, operating income, EBITDA, earnings per share and free cash flow, we're reaffirming the range provided in February, as we continue to expect a gradual pickup in the second half of the year.

This concludes my review of Teva results for the second quarter of 2022. And now, I will move back to Kåre to discuss our strategy update and our 2027 long-term financial targets. Over to you, Kåre.

Kåre Schultz

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

Thank you, Eli. It's a pleasure to share with you our strategy update and our new long-term financial targets. If we start by looking a little back on the background for our current targets, and they were set, as you know, developed by management and the board at the end of 2017, beginning of 2018 in order to create a five-year outlook for how to stabilize the business. In the meantime, the opioid litigation grew in complexity and size, but I'm very happy that we today can announce the agreement in principle, which basically is the beginning of putting this behind us.

We've also, in those five years, had a huge debt to handle and we've been paying it down consistently, as you've seen in all our presentations, also today. Actually, from a cash point of view, the last four years, we paid $18 billion to the bondholders in the form of debt reduction and interest payments. And of course, we will continue to do so, which means that we will now be taking the debt below $20 billion and we'll continue to see a reduction of it. The way we've done it is of course partly by a very strong focus on cash flow and optimizing the business.

And if you compare to 2017, then the annual spend base is down by nearly $5 billion on an annual basis. And we've been able to generate consistently more than $2 billion in cash every year, and we expect to continue to do so going forward. The way we've done it is really by optimizing the business from the beginning. We have created a unified organizational structure. It's the [ph] One Teva concept (00:22:24) we call it, basically meaning that everybody works together in order to optimize the synergies in the organization between generics, OTC, specialty, between all the different sites, but it also includes a dramatic reduction of our footprint through consolidation.

One example here is that we've gone from having 80 manufacturing sites to around 53, and we have operational plans for further reductions, reducing with around 10 sites over the coming years. The same kind of numbers, you will see if you look at the number of office locations, if you look at the number of R&D sites. So, all-in-all, we've had a dramatic consolidation of the business, leading to more efficiencies and helping us to generate the cash and the earnings every year.

Now, if you look at the next slide, you will see that the foundation of our business is unchanged compared to how we formulated it back in 2018. Our mission is to be a global leader in generics and biopharmaceuticals, improving the lives of patients. And our patient focus, like I mentioned earlier, is really the key, you could say, raison d'être of the company, the key reason why we're here. We're here to help patients with medicines, be it generic medicines, be it OTC, be it new innovative medicines.

And we help a lot of people. Roughly, we support around 200 million patients every day with all kind of different products, again, across a very broad geographical range of countries and across a very broad range of products. We have core values, which I will comment on in details. But these are unchanged and they secure that we have high employee retention. It secures that we live our lives in an ethical way and it secures that we stay in compliance.

If we move to the next slide, then you can see here that our strategic focus is really to continue to be leaders in generics, to build a uniquely strong position in biosimilar, and in specific areas to continue to drive our specialty business with new innovative products and with further penetration of the great products that we have already launched.

If we talk about the generics and look at the next slide, then you can always debate what's the sort of fundamental business model of generics, and the fundamental business model is of course very, very simple. Innovative products are developed all the time. They're launched. Some are very successful. Eventually, the patent expires and you get generic competition. So, you would say what feeds the generic market is the value of products going off-patent.

This is a very simple overview, showing you how many products went off-patent in the years 2017 to 2021, so in a five-year period, roughly $110 billion. And you can see the mix between small molecules and biologics, $86 billion small molecules, $25 billion biologics. And you've heard me say many, many times that there's a gradual shift in the marketplace, where more and more new innovative therapies are biologics, and therefore, there's also a gradual shift in which products go off-patent. And this is very clearly illustrated here.

This is the IQVIA forecast for the next five years, so 2022 to 2026. And you can see here that we're talking about nearly $200 billion going off-patent, and now it is like $120 billion small molecules, $70 billion biologics. So, the biologics are getting close to being 50% of what goes off-patent. If you do a projection further out, it gets a little more uncertain how revenues will actually be of the different products. But my prediction is, if you do the next five years, you will be close to 50/50 between small molecules and biologics and the value will be even bigger than it is for this five-year period.

So, the short message here is there's plenty of business to be made in small molecules going off-patent, having generic versions being launched, but also in biologics going off-patent and having biosimilars being launched. If we just look at the next slide, then this is another way to look at it. This is the sort of prediction for the total generic market worldwide, and you can see here it's a huge market and it's predicted to grow around 4% on an annual basis.

Now, if you look at the next slide, we try to give a picture here of why we are the leading generic company in the world and what you need to do to stay as the leading company. And of course, one of the things you need to do, you need to address by far the majority of the $400 billion that's going off-patent over the next 10 years. And you do that by having a lot of projects of course.

So, we have more than 1,000 projects covering 80% of what's going off-patent, and that's really our guidance internally. We can't cover everything. There will be too many products, too many projects, but we want to cover 80% of the world value going off-patent. That means you need to have a full range of technologies, some of them simple, some of them very complex technologies, including things such as inhalers, patches, long-acting injectables, sterile injectables, all kind of different technology platforms for doing pharmaceutical products.

It also means that you need to be fast, because a lot of the value is by being first-to-file in the US and by launching early in Europe, so that you get a good market share and a good position within the generic space for whatever product that goes off-patent. And it also, in order to be profitable, means that you need to continue to optimize your manufacturing footprint and your R&D footprint, and we're doing that by global integration, scalability. You need to make sure that you have efficient factories that can produce for the whole world. Now, we have all these elements. We are continuing to improve them, and I'm 100% confident that we will stay the world leader in generics also going forward.

Now, a new thing in the marketplace over the last five years is really the growth of biosimilars, and this will continue to grow strongly. And it's very simple. Why is it growing? Because more and more biologics are going off-patent. So, as you saw before, when more and more products go off-patent, of course, there's more and more

business to be had by [ph] the generic products (00:29:34), and in this case, it's biosimilars products. And we of course see that it's growing all over the world, including North America. And we recently saw how strong that market segment is with our big success with TRUXIMA, where we gained something around 25% volume share and saw very strong revenues, already now accumulated more than $1 billion in revenues of TRUXIMA.

Now, if we move to the next slide, then you can see there are some other skills that you need in order to be a leader in biosimilars. But in a way, it's not radically different. It's technologically a little bit different, because you need of course, again, to have the same strong portfolio, it's typically less products, less projects, because each product in the biosimilar space – or in the biopharmaceutical space are typically bigger. So, you have biologics products today and the products that will sell $5 billion, $10 billion, $15 billion, $20 billion on a worldwide basis. And therefore, we have the same philosophy. We want to cover 80% of the value going off-patent, but you can typically do that with less projects.

The projects are somewhat more complex. So, you need, you could say, a different set of technologies. We have all those technologies, the full value chain in-house. We're expanding significantly in Germany in Ulm, our capabilities here, our volume capacity. So, we're very, very well focused for this going forward. There's a huge overlap between the practicalities of doing new patented, innovative biopharmaceuticals and doing biosimilars. The whole, you could say, value chain of the actual manufacturing is actually the same. The future demand will be strong, and we believe we are very well positioned to become a leader in biosimilars both in US and Europe and in the rest of the world.

Now, let's take a look at our specialty pipeline. We have a focused specialty pipeline. We have two areas where we focus the most. That's in neuroscience and immunology. And I won't go into details about the projects today. That would take too long. But within the coming year, we will plan to have an R&D Day, where our new Head of R&D, as well as other members of management will tell you much more about the projects that we have here. But just as a little teaser, you can see here, we have projects, for instance, in MSA and in Parkinson's disease, an area where we have a strong tradition with the launch of AZILECT years ago and where we really have focused for many, many years.

Movement disorders, as you know, is a key area for us also with AUSTEDO marketplace. So, that's very, very exciting. Other exciting projects also in neuroscience, and in immunology, we have some very interesting Attenukine projects in oncology, where you – as you know, you down-regulate the effect of the immune stimulating agents, so that it works only in the right spot. And that means that you overcome some of the safety hurdles. We are working also together with Takeda. They have in-licensed a product in that category, and that's also doing very well, going into Phase 2. So, a lot of exciting things that we will get back to in more detail sometime during the coming year.

Now, let's move to the next slide, because as you know, I like to set out long-term targets, stick to them and make it relatively simple, because otherwise it gets too confusing. And if you change your targets all the time, it also gets too confusing. And I've been saying the last year that we're getting close to the end of 2023. So, it's probably a good idea to share with all of you, analysts and investors, how do we see the longer term future for Teva. And these are the new long-term targets for 2027. There are no really big surprises, I would say. We will continue to improve the operating margin. We are heading now past the 28%, that's the target for next year, heading for 30%.

We continue to take down the debt. So, we will [indiscernible] (00:34:07) going below 2 at the end of 2027. And we will of course need strong cash-to-earnings. Otherwise, we can't do any of this. And we're now also focusing on revenue growth. This basically means that we will ensure that we have a compounded annual growth rate of the revenues in this period in the mid single-digits. And of course, that might mean that we'll do some small bolt-

on acquisition of products or we'll do some geographic expansion of our portfolio. And we're very focused on this, so that we ensure both better margin, strong cash flow, less debt and growing revenues.

So, just to sum it all up on my last slide, we think we have a very sustainable foundation, which means we can return to growth both on revenue and earnings, and thereby, increase shareholder value. The reason why we believe in the growth is what I showed you about, the very strong and predictable generic business, strong growth in our biosimilar business based on our pipeline, and a focused specialty pipeline combined with AUSTEDO and AJOVY, which are doing well in the market. We'll continue to drive the margin up. It's not a miracle. It's just hard work. And we'll continue with our solid cash flow generation, and thereby, reducing our leverage in the years to come.

Thanks for listening in, and we will now move on to Q&A.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] And the first question comes from the line of Balaji Prasad from Barclays. Please go ahead. Your line is open.

Balaji Prasad
Analyst, Barclays Capital, Inc.

Q

Hi. Good morning, everyone, and thanks for taking the question. Kåre, firstly congratulations on getting the settlement in place. So, I'm curious to know what are the next steps and timelines for the settlement, specifically focusing on the caveat with Allergan, and is there a time limit by when the Allergan settlement needs to happen? If it doesn't, is there a chance that the current settlement could be rendered moot? And if you could also just speak about the longer term growth that you're guiding to. We've now almost been conditioned to think of Teva's generics growth as flattish, centered around a $4 billion size. So, as we look out to the longer term generics growth of 4%-plus, is it fair to assume that Teva can deliver growth equal to or greater than this longer term generics market growth? Thank you.

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

A

Thanks for those two questions. Let me start by the opioid settlement. So, our expectation for the timing is that in the coming weeks, the agreement in principle will be finalized in actual wording. And as you know, the mechanics is actually there is an agreement for the states and the subdivisions to enter into an agreement, because the way it works is that you're agreeing all the terms and how to do it, and then you ask all the states and the subdivisions to sign up to this agreement. And then, of course, they get included and they get the money and the product and so on.

And the way it typically has been working, if you look at J&J and the three big distributors, how they did it, and we will do it very similarly. Then, it works the way that there's, I'd say, a clock start, and then you have some months where people can opt in. And then, after those months have passed, you have an evaluation, do you have enough participation for this to be meaningful. We would definitely expect to have that, given all the information we have from both states and plaintiff lawyers and given what we saw with J&J and the three distributors. And then, once that gets done, then state by state, subdivision by subdivision, you sign and you start implementing. And that means that the actual implementation will start sometime next year. In terms of Allergan, of course, the

assumption here is that there will be a agreement where they will be also taking part in that, and I think that's by far the most likely, and of course, also the best for everybody involved.

In terms of the growth rate, then you're absolutely right that the sort of run rate for generics and biosimilars in the US is around $1 billion a quarter, so around $4 billion. But that's of course not our entire business. We also have the specialty business and we also have the generics and biosimilar business in the rest of the world. And I do not think that the generic piece, so you could say the [indiscernible] (00:39:18) generic piece in North America and Europe will not be growing. But the biosimilar piece will be growing significantly, and that basically means that you will have a flat, maybe 1% or 2% growth on traditional generics. But then, you'll see some complex generics, you'll see biosimilars adding to the growth rate, not dramatically, but taking it up into single-digit.

At the same time, we had this dynamic we've discussed so many times that we've had a drag for five years now from COPAXONE that went from close to $5 billion now to – you just saw the number, $700 million, and we've had the growth of AUSTEDO and AJOVY coming in. And if you look at the guidance for this year now, you could say for the first time, not only are the growth drivers bigger than the detractor, so to speak, so the combined sales of AJOVY and AUSTEDO are now bigger than the declining sales of COPAXONE. They've actually reached the level where they're twice as big.

So, that means that the [ph] simple math you could say if (00:40:18) both have a delta of 20% per year or 25%, then of course now the specialty portfolio in that sense will contribute to growth by AJOVY and AUSTEDO growing and continuing to grow for the next many years. You saw for instance on AUSTEDO that the IP situation looks like it's very safe until the early 2030s. So, there's a long growth path for AUSTEDO going forward. And so, that whole combination means that we're confident that we can achieve single-digit growth. Thanks for the questions.

Operator: Thank you. We will now take the next question. And the next question comes from the line of Nathan Rich from Goldman Sachs. Please go ahead. Your line is open.

Nathan Rich
Analyst, Goldman Sachs & Co. LLC

Q

Great. Thanks and good morning. I wanted to follow up on the long-term targets. A similar question, Kåre, to what you just were speaking to. But I was wondering if you could help us think about the main building blocks underlying the guidance for a mid single-digit constant currency revenue growth. And you put revenue growth as sort of the last factor on those – that long-term targets slide. So, I guess how important is achieving that to reaching the other targets on the slide? And if I could maybe ask a follow-up on your assumptions on the R&D and pipeline, it looks like you narrowed your focus on the specialty pipeline and reduced some of the programs that you had ongoing. Could you maybe just talk about the areas of focus going forward and any new run rate for R&D spending as a percent of revenue as we think about the long-term targets? Thank you.

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

A

Thank you for those questions. If we take the long-term targets first and let's say the dynamics between the different targets, then the three targets for margin, cash earnings and debt are not linked to achieving the fourth target. So, we will achieve the three targets even if we fail on the fourth target. But we don't plan to fail on any of the targets. We plan to reach all four targets. But the simple answer is we do not need revenue growth in order to reach the three other targets. But of course, we'd like to have revenue growth, because that means that the

absolute profit pool and the absolute earnings will be growing more than they would be growing if we just achieve the first three targets.

So, we are strongly committed to achieving all four targets. And the building blocks are quite simple in a way and what I tried to illustrate that there will be growth coming from biosimilars, which will be contributing. There will be growth coming from specialty, not just from AUSTEDO and AJOVY, but also Schizophrenia [indiscernible] (00:43:18), which is the brand name for risperidone LAI, which we still expect to launch first half of next year. So, there's a portfolio of specialty products which will be driving growth, not just in the US, but also in Europe. Continued growth of AJOVY in Europe, as AJOVY is doing very well in Europe, as you've seen, and will continue to do so for many years. So, there's a number of growth drivers, which all together combined with a stable position in traditional generics means that the overall revenue will be growing.

Your other question is about R&D, and you're absolutely right. We are focusing in our neuroscience and immunology. These are the areas where we have the most expertise historically and also the area where we have the best quality projects. And you're also right that we have closed a couple of projects because we didn't see the, you could say, scientific values being high enough – the value we could give to patients was not high enough, and therefore, we have stopped these projects. The ones we have that showed you, they all meet very essential unmet medical needs, which basically means if they succeed, then they have a higher chance of being successful. And we will continue to invest in R&D both in generics, in biosimilars and in specialty. We do not plan to increase the percentage of revenue that we invest in R&D, but we do not plan to reduce it either, which basically means with growing revenue, you will see that we will be spending a little bit more, but nothing dramatic. Thanks for the questions.

Operator: Thank you. We will now take the next question. And the next question comes from the line of Umer Raffat from Evercore. Please go ahead. Your line is open.

Umer Raffat
Analyst, Evercore ISI

Q

Hi, guys. Thanks for taking my question. So, look, the announced settlement framework is about $3.5 billion of sort of cash value, and I'm sort of adjusting the drug for the – cost of the drug, so $3.5 billion. Separately, we know that on your P&L, you had a $2.6 billion charge on an NPV basis, which was implying – and this is as of last quarter – which was implying the equivalent of $3.5 billion to $4 billion in cumulative payments over time. So, I guess I'm just a little confused why there's an additional $700 million accounting charge. That implies the value – the NPV value higher than sort of [indiscernible] (00:45:59). So, I just want to clarify and square that. The other one is the Allergan indemnification, I guess why hasn't it happened already and where do you stand on that? Thank you very much.

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

A

So, I'll just give an overall explanation for the accrual we have, and then Eli can give you some of the details, and then I'll get back to the [ph] Allergan thing (00:46:20). The overall accrual includes everything. So – and we won't comment on all the details on the agreement in principle. But you can imagine there's tons of details about the already settled cases, the product volume there, the fees in the different cases for the attorneys, the tribes, the different ways of the payment schedules, the 13 years, the discount rate, all kind of stuff goes into it. But the only thing I can reassure you, and maybe Eli will give you some more color to it, is that it's very, very comprehensive. It's very, very detailed. It's of course done extraordinarily well also together with our external accountants. So, the

$3.2 billion is a very good picture of the net present value of all obligations including product and everything else being involved here. But Eli, maybe you want to give some color to it.

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

Yeah. So, Umer, just at the high level, the $4.2 billion that we announced is including what we call the cash element there, and that's around $3.6 billion, and then we have the [indiscernible] (00:47:40) product element of 240 and then some element related to fees. And then, on top of this, there is some other elements which we cannot actually comment again related to Allergan and few other elements that we are considering [indiscernible] (00:47:56). But one thing to understand this is a not really evenly straight line 13 years, the same amount each year. We have some amount that's kind of front-loaded on the six, seven years and the start of the assessment period. And you know we already have some prior settlements that we commit that need to actually have their own schedule already that we commit. So, it's not like kind of a straight line [indiscernible] (00:48:21) NPV. And as Kåre mentioned, because it's a lot of [ph] players and very sophisticated, the $3.2 billion accrual (00:48:28) NPV base is actually considering all the elements considering the sort of full participation on the nationwide execution.

Umer Raffat
Analyst, Evercore ISI
Q

And Eli, if I may just...

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

Yeah. And with regards to your question on...

Umer Raffat
Analyst, Evercore ISI
Q

Apologies. Go ahead.

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

Yes?

Umer Raffat
Analyst, Evercore ISI
Q

Eli, if I may just clarify then, the announced – the announced amount is $3.6 billion, which is the cash element, if I may. The NPV of what's on the P&L is $3.4 billion. So, does that mean that the announced cash amount $3.6 million is actually higher than $3.6 billion, it's closer to $4 billion of cash based on some of these "other elements" that you just mentioned?

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

[ph] We announced it's (00:49:13) $4.2 billion – up to $4.2 billion in cash, which considering the cash element $3.6 billion, plus the potential convert from product to cash on to 240, that's 20%, and then additional [ph] fees element impact, right. So, if actually no one in theory is (00:49:28) getting the product, we actually took it to up to $4.2 billion. Now, there are a few other elements that we consider from what we call risk assessment and estimation in our growth, and it's actually on top of it, right. And we already considered what we paid. And what

I'm trying to tell you is that because it's not a straight line, the NPV is really getting different than straight line NPV, because if you have upfront payment, you actually get kind of more cash on the NPV [indiscernible] (00:50:04). So, that's what I tried to [ph] demonstrate (00:50:07).

Umer Raffat
Analyst, Evercore ISI

Q

Thank you for that.

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

A

Okay. Thanks for the question. With regard to Allergan, then we don't have any further comments to that. But we expect to see them as part of the final settlement.

Operator: Thank you.

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

A

Thanks for the questions

Operator: We'll now take the next question. Please stand by. And the next question comes from the line of Jason Gerberry from Bank of America. Please go ahead. Your line is open.

Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

Hey, guys. Good morning. Thanks for taking my questions. So, my question has to do with sort of the comprehensiveness of the deal as we know it today. When the J&J deal – I think it got announced in second half 2021, and then like 120 days later, I think it was finalized. 90% of litigants had agreed. All the allocations were sorted out. So, should we think about this deal as like on a similar trajectory and that most of the states and subdivisions have already sort of sorted out the allocations via the J&J deal? So, I'd almost think this could happen sooner. And then, can you give any color on how many states have agreed to this – for this working group dynamic? Just curious if you can shed any more light on that. Thanks.

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

A

Yeah. So, the short answer is, I think, the situation is very similar. So, all the details of course have been worked out. There's a ton of details on percentages and states and subdivisions and all that stuff, as I'm sure you know, and all those details have basically been worked out, because it doesn't make sense to agree on a number if you haven't agreed on all the other details. So, that's all been done. And in terms of timing, we are estimating that the timing will again be similar. So, we're estimating that within the coming weeks, we'll finalize, I'd say, the wording of the settlement.

But then, as you rightly alluded to, you have the process where people opt in, the states and subdivisions. And the understanding between the parties is of course that by far, the majority of states and subdivisions will opt in. That's the whole point of all the negotiations [indiscernible] (00:52:24) that you have a nationwide settlement in principle. So, we are very optimistic that we will see a very high participation rate, probably similar to what you saw with J&J. And some of the states that were hold-outs on the J&J and the three distributors, we have actually

already settled. As you know, we have settled West Virginia. We have settled Rhode Island. We have settled Florida, so – Texas. So, we're quite optimistic that we will, at the end of the day, see relatively few opt-outs.

Jason M. Gerberry
Analyst, BofA Securities, Inc.

Q

Got it. Thank you.

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

A

Thanks. Thanks for the question.

Operator: Thank you. We will take the next question, and it's coming from the line of Ashwani Verma from UBS. Please go ahead. Your line is open.

Ashwani Verma
Analyst, UBS Securities LLC

Q

Hi. Thanks for taking my question. So, on the opioid side, so just to follow up on Jason's question here, we saw in the media news that there are like 12 AGs that actively participated in the negotiation for this in principle agreement. I'm just curious to understand the level motivation for the remaining 35 or so AGs, like what gives you the confidence that they can join hands in the coming weeks and why did they not participate in the negotiations in the first place? So, that's the first question.

And just second, so Kåre, just wanted to ask you, now that we are presumably nearing the closing of a chapter on opioids and embarking on the next phase of the story, can we assume that you'd be part of that at Teva? We know that your current contract expires in November 2023, and we still haven't seen anything on the extension front. I remember the last one year extension was granted like two year prior to the expiration. But this time, the window is closing. So, anything that you can comment on there will be really helpful. Thanks.

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

A

Thank you. So, with regard to the participation, again, I would compare to what happened with the distributors and with J&J. It's quite normal that the, you could say, negotiation group is a subset of the total number of states. So, there is no indication in that number of states being directly involved. There's no indication that the other states would not end up participating. It's very, very likely, like I said before, that we will end up with a very high participation rate, just as it happened to distributors and J&J. And some of the hold-out states that they saw, as I said before, we have already settled with those. So, we are quite optimistic that this will be a settlement where nearly everybody will join in. With regard to my situation, it's actually correct. As you say that the contract I have expires end of 2023. And with regards to the future, I don't really have any comments to that right now as of today. But thanks for the question.

Operator: Thank you. We'll now take the next question. And the next question comes from the line of Elliot Wilbur from Raymond James. Please go ahead. Your line is open.

Elliot Wilbur
Analyst, Raymond James & Associates, Inc.

Q

Thanks. Good morning. I just want to shift gears here and focus on a couple of the key revenue drivers in the North American business. First, specifically AUSTEDO and thinking about trends in terms of new patient activation or new patient starts have been relatively strong, implying a fairly good return on your DTC investment earlier this year. [ph] We're also seeing a competitor (00:56:11) put more money into the market, which seems to be expanding overall patient volume. Curious how you're thinking about incremental investment behind AUSTEDO over the next 12 to 18 months, either DTC or possibly even an expansion of your sales force.

And then, as a follow-up, I want to focus specifically on North American generics, maybe just get your latest read in terms of key trends such as price erosion, volume trends, what we're seeing in terms of new product approval flow. It still seems to be relatively difficult to get complex generics out of the FDA, but wondering if you're getting any indications that we may be approaching an inflection point in terms of starting to see approval flow pick up, but just general outlook on North American generics for the second half of the year. Thanks.

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

A

Yeah. Thank you for those two questions. I'll give a very brief answer, and then I'll hand it over to Sven to give the detailed answers. We're very happy about the progress on scripts with AUSTEDO and patient. So, that looks good. And we're also happy about the performance of generics in North America here in the second quarter, hitting in North America combined with the biosimilars around €1 billion. So, that looks good. But for more details, over to Sven.

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

A

Yes. Thank you, Elliot. So, for AUSTEDO, we had strong TRx growth of 27% in the first half of this year versus last year. And also, the new patients are developing strongly. Generics grew 32% in the same period. So, we are definitely achieving our goal in terms of patient activation, and that was one of the key objectives for this year. For that reason, we are also confident that we'd achieve our sales target that we set for ourselves in the second half of the year.

As to your question about our marketing investments, we have achieved our goals of patient activation in the first half of this year, and we've also seen that we significantly increased the prescriber base, which speaks to the fact that the TV campaign was actually effective. We're now focusing our investments on downstream activities, on sales, on the titration management, on patient adherence, and we believe we have a significant potential in that area. And we already did these investments in terms of sales force expansion and other activities. So, we are fully on top of the AUSTEDO development.

On generics, our expectation is that the level of generic price erosion is trending back towards historic rates. We expect to see an incremental stabilization, especially for the segment of base generics in the second half of this year. It does not mean that we don't have price erosion. We just have stable price erosion, and we do not expect an additional acceleration for our portfolio. So, concerning our own development, of course the most significant factor for business stability is the rate of new product launches and the gradual shift to high barrier generics, which have a more sustainable pricing profile. And these are products like EpiPen, the patches we have, the inhaler we launched and long-term – other long-term injectables. They are more durable than the base generics business.

What we see here is that, of course, you're right. The FDA is currently seeing significant barriers for complex generic approvals. For that reason, some of our approvals that we expected for this year are now happening next year. But overall, we believe that especially in 2023, we see [indiscernible] (01:00:06) get to a higher rate of

product approvals, and we will also have with the HUMIRA biosimilar launch, I think for our generics business, an inflection point for the future, because we have other biosimilars lined up after that, so that we are optimistic about the outlook of our North American generics business. Thank you.

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

Thanks for the questions.

Operator: Thank you. We will now take the next question. And the next question comes from the line of Gary Nachman from BMO Capital Markets. Please go ahead. Your line is open.

Gary Nachman
Analyst, BMO Capital Markets Corp.
Q

Okay. Thanks. Good morning. So, back to the proposed settlement, how much are the payments front end-loaded over the first six years that you highlighted in answering Umer's question and how much is spread out over the next seven years? Just want to have a better idea on how to model that, even if you could give us order of magnitude if you don't want to give us the specifics there. And then, on the long-term revenue objective, at what stage would you be able to do business development again? You mentioned as part of revenue growth, that'll be one element. Where does leverage need to be in order to start doing that? And then, just give us any catalyst anytime soon from the specialty pipeline that you can highlight. I know you'll have an R&D Day, but just give us some of the key catalysts if you can. Thank you.

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

Thank you very much. So, if we take the settlement first, then what Eli was alluding to was that there are some current settlements that we have already done with individual states, where we're actually paying cash already this year – we have actually already paid cash in the first and the second quarter.

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

Yes.

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

If you look from next year and going forward, then the variations per year are actually marginal. So, you should imagine, you take the total amount and divide it by 13, and then the swing factors up and down are marginal. It's not dramatic. So, it's somewhere between, you could say, $300 million and $400 million a year in net cash for all the different elements. So, it's not front end- loaded in that extent. It's just the fact that we have some settlements we already did, where we have already paid some money this year, a couple of hundred million so far.

So, that's really it on the settlement. Then, on you could say the business development side, we already do small business development deals, where we do bolt-ons of individual products. For instance, it's a business development deal that's behind the HUMIRA launch that we're planning – or the biosimilar HUMIRA launch we're planning for next year, a deal we did with Alvotech. The biosimilar we just launched in UK, the biosimilar to LUCENTIS in the UK, that's also a business development deal. So, we do do business development deals and we will continue to do so.

If you think about when is there more room – significantly more room in the balance sheet to do something slightly bigger than this, that will be at the end of the five-year period, because since we're aiming for a net debt to EBITDA below 2, then if you do sort of the math on a marginally growing EBITDA, and therefore, the [ph] net EBITDA (01:03:38) will be growing over that period, a constant declining net debt, then of course you hit that around 2 times net debt to EBITDA, you hit that before the end of 2027. And that means when you get close to that or when you get below that, then of course you have some room within these targets to do a little bit more BD.

But you're still at the size where it's, I would call it, smaller bolt-on things you can do. And there's a lot of opportunities there. There's a lot of companies who develop products, and then they don't really have a commercial set-up. So, they need a partner. And we have a good traditional partnering with many different companies. So, we think we can continue to do so, and that will be one small element in continuing the growth of our revenues.

With regard to the pipeline, I think there's a lot of exciting things there, and I won't go into the details now, but just say that of course next year, the long-acting risperidone looks extremely good from a clinical point of view, both efficacy and safety. And it will be a major improvement of long-acting antipsychotics that you can do subcutaneously, and it works for one or two months. So, that's going to be really nice to get that finally approved and launched next year. Thanks for the questions.

Operator: Thank you. We will now take the next question. Please stand by. And the next question comes from the line of David Amsellem from Piper Sandler. Please go ahead. Your line is open.

David Amsellem

Analyst, Piper Sandler & Co.

Q

Thanks. So, a couple of questions. So, one, just thinking at a high level about the business, one of your US major peers, Viatris, has talked openly about divestitures. And I just wanted to pick your brain, Kåre, on how you're thinking about divestitures, particularly as a means to generate proceeds and perhaps then be able to more aggressively pivot towards the acquisition of brand assets, brand assets being a question and a topic that comes up quite frequently. So, how are you thinking about that, particularly now that you've gotten the opioid settlement largely behind you? And then secondly, just switching gears to the HUMIRA biosimilar, just latest thoughts on how you're thinking about that, not just in terms of timeline, but also how are you thinking about the ramp and adoption here, just your general thoughts there. Thank you.

Kåre Schultz

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

A

Thanks for the questions. I'll take the first one, and then Sven can take the second one. So, with regards to divestments, what we've done in the last five years is we've really analyzed the entire value chain, the entire business, and we have sold off those elements that we thought had no strategic synergy with the rest of the business and we've kept all the elements that indeed gives us a strong synergist effect. So, we have no plans of divesting any parts of our business. We basically had the plan to integrate and optimize the business we have elected to keep, because we believe it all fits very well together.

So, we will be working, like I explained earlier on in the strategy, to further optimize, further increase the gross margin, the operating margin, and building a stronger and stronger foundation. And then, we will, as a consequence of the debt reduction and the margin improvement, free up more and more cash to do what you

said, acquisitions of branded products either in one or another area. [ph] But it will happen (01:07:44) organically, you could say that we generate more and more flexibility to do so with the debt reduction and the margin improvement. And then, on HUMIRA, Sven?

Sven Dethlefs

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

A

Yes. Thank you. I think the question was about the expectation for uptake of HUMIRA next year. Just as a reminder, Amgen comes in January with their biosimilar and then a whole range of other companies including us in July 2023. I believe the uptake will be largely defined by the contracting strategies of PBMs and our customers, how they think they would like to build the biosimilar market versus the offer that they get from AbbVie. And that will be a two-step approach, one that will happen in 2023, primarily in the summer of 2023, and then you will see a second phase in 2024 when the whole book of contracting will be opened again. I believe we are in a good position. We have the best product profile of all companies coming to the market in 2023, and we're already in discussions with all our customers about the access approach for next year, yeah. And I think we'd know more about that at the end of this year when all the contracting has been done. Thank you.

Kåre Schultz

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

So, thank you very much for all your questions and thank you for listening in, and have a nice day. Bye-bye.

Operator: That does conclude our conference for today. Thank you for participating. You may all disconnect. Speakers, please stand by.