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Teva Pharmaceutical Industries Ltd.

(TEVA)

JP Morgan Health Care Conference - Q&A

CORPORATE PARTICIPANTS

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OTHER PARTICIPANTS

Chris Schott
Analyst, JPMorgan Securities LLC

MANAGEMENT DISCUSSION SECTION

Chris Schott

Analyst, JPMorgan Securities LLC

Okay. I think we are live here. So, we're going to kick off the Teva breakout session here. I'm Chris Schott. I'm going to just kick off with a few questions for Kåre and the team and then we can open up to the audience.

QUESTION AND ANSWER SECTION

Chris Schott
Analyst, JPMorgan Securities LLC

Q

I think you mentioned in the presentation, I think it was two years ago you were at the conference talking about the restructuring and kind of repositioning of Teva. Just reflecting on those two years, maybe just talk through what were some of the bigger surprises as you went through that, both positive and negative as you've kind of repositioned the business, took down the expenses, et cetera?

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

A

Yeah. So, one of the interesting elements over the last two years is that if you look at the operational restructuring process, then we've actually had a very few surprises. So, the assumption from the beginning was that we had ended up in a unfortunate financial situation taking on too much debt compared to the value of the acquisition of Actavis, but that the company and its employees had all the needed competences to be successful both, you could say, in the R&D side both on generics and specialty, in the commercialization, manufacturing, reach and so on.

And getting started on the restructuring and working with the board and with management, it was very clear that both facts were correct. The debt was definitely too big given the strategic outlook for the company and the organization definitely had the right competences to manage the situation, which is also why it's been possible to have more than 12,000 people leave, shutting down 20 factories and still have, you could say, the complete operational capacity to do very sophisticated things, both in specialty and in generics. So, if you then want to say what has been surprising, then I would say the only thing that's been surprising, which I'm sure people will ask about today as well, has been the legal environment in the US.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Sure. Yeah.

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

A

That's the only real surprise, I would say, in those two years. And that's not even on the ordinary legal front such as normal cases on patents and...

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Yeah. Sure.

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

A

...Paragraph IVs and so on. It's basically the opioid political situation that has been a surprise.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Yeah. Yeah. And on that point, I know it's [indiscernible] (00:02:23) maybe just update relative to – I think the last time you heard from me was in the third quarter, what's happening in terms of negotiations and the background, et cetera, just an update of how you're feeling with regards to the framework you've put together and the ability to get that to go live.

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

A

Yeah. So, I'm sure most of you are aware that we reached a framework agreement with the AGs. So, the attorney generals of US states represented by four state AGs, and the work is still ongoing on turning the framework into an actual settlement. I'm cautiously optimistic that this will work its way through in a positive way. There is kind of a deadline coming up because it would be advantageous for everybody to get the actual settlement done before the next state trial, which is a trial in New York mid-March. So, like I said, I'm cautiously optimistic that we'll find a way to get the actual signing done before that, but it remains to be seen.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Okay. Talk a little bit – in terms of the ability to get – it seems like there's different objectives of the different parties, what do you see as kind of the rate-limiting factor in terms of – is it going to be the counties and the cities that are going to be the biggest challenge or is the other AGs or...

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

A

No, I think the way you should think about it is that the framework is a deal between the three big distributors, Johnson & Johnson and Teva, which has a lot of components that are very positive for the states in the sense that there is a cash payment over many years, which is substantial, and there's a product donation which is very substantial from us which will help wean people off opioids.

So, I think there's a lot of political momentum behind this because it's actually doing something really to try and improve the situation despite the fact that I think both we, J&J, and the three distributors do not actually feel that we did anything wrong or that we actually contributed negatively to this situation, but we would all like to help improve the situation and we'd like to not spend the next 20 years litigating this.

Now, the framework is, like I said, with the state AGs, being optimistic and assuming that works, then there might be some residual litigation with some counties, some cities who decide not to go into it. But because this is a political situation much more than a legal situation, then the fact that the AGs are either Republicans or Democrats, if they all come together and we make this framework into a real settlement, then I think there's going to be a lot of political pressure on the cities and the counties to get on with improving life and reducing the risk of drug abuse rather than fighting to get the extra million dollars for the attorneys.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

And again, on the timing, you think kind of washing around this kind of New York case is probably a good place to...

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

At least that's a natural occasion for wrapping things up because, otherwise, you need to go through one more trial similar to the one we had in Cleveland.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Yeah. Pivoting a little bit, just on the CGRP side of things, just an update as we head into this year, maybe timing on the auto-injector and just in general how are you seeing market dynamics shaking out now that we've had a little bit of time with everyone kind of...

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

Yeah.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

...feeling each other out in the space.

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

Yeah. So, the dynamics right now are that, as you know, Amgen launched first and they had a good launch in terms of volume, but they've had declining shares since. Lilly and I launched about the same time, both had good launches. Lilly have kept the momentum. They have an auto-injector which is a fine product. We have a really nice auto-injector as well. Unfortunately, due to some very minor technical discussions, we've had a delay of that approval. We still hope to get it within the next few months.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Okay.

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

And then we think the competitive situation will be leveling. And what I was referring to on the clinical profile is basically that our product is having excellent efficacy result. Also, in the extended phase 3 trials – actually we had a extension of a phase 3 trial where we saw even better efficacy, more than 50% reduction in migraine in this extension. And normally, when you extend the phase 3 trials, you get lower efficacy in the extension phase. So, we're very optimistic about the clinical profile. We don't have any safety concerns. One of the competitors have an issue with constipation that's gone into the label. So, we think we are well-positioned. Our aim is to have around 25% share longer term also in Europe and we are moving nicely with launches in Europe. So, we're very optimistic about the class going forward.

Unfortunate, compared to our original assumptions three, four years ago, the pricing has moved lower. It was initiated by Amgen who went for pricing below specialty. So, not the $10,000-plus, but more like $7,000. And then the contracting dynamics with three players led to slightly higher rebates than you would normally see, and that basically means that the value per patient is probably maybe half of what we thought it would be in that three, four

years ago, but on the other hand, the volume is significantly higher. So, in today's environment, I think that's maybe not a bad place to be in. So, we don't have this threat. You could say that other specialty products that are very high priced at.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Okay. And as we think about the dynamics kind of – it's hard to think longer term at 2020, should we expect another kind of step-down in price, or was that kind of 2019 where that gross to net dynamic played out?

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

Of course, you never know. But the way I look at it, it probably has settled pretty much by now.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Okay.

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

That's the way I look at it. And, of course, we don't expect to see any major turbulence in the market. Of course, there might be plans to switch from one to another, but we've not seen this – typically at the beginning of the year is where you see big changes. We've not seen any big changes. We've slightly improved our coverage, but nothing dramatic. We're happy with the coverage we have. So, I think it's probably a situation that has stabilized. We know from the PBMs that really have about the situation as well. So, we think it's a real stable situation.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Okay. And maybe just last one from me, and as I think about the auto-injector approval and kind of bridging to that 25% share target, help us get our hands around how quickly you think you can improve the share position once you have that product in the market?

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

So, the way it would normally work is that once you get to the market with the auto-injector, you start to launch that specific product into the marketplace and then you see your capture rate weekly, capture rate of new scripts move up in that level of 25%, and then of course, it takes probably 12, 18 months before that works all the way through to your TRx, so your total scripts.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Okay. Okay. Okay. So, a little of time [indiscernible] (00:09:18)?

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

Yeah.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

We'll open it here just for some questions. Go ahead.

Q

Yeah. Just in terms of the opioid litigation, just going back to some of your comments, just two questions, the number that people have talked about is a global settlement in the $50 million to $75 million range. Is that consistent with your thinking? And then the reports are that you will provide a lot of your payment in the form of [indiscernible] (00:09:42) product as opposed to actual cash payments. Is that the right way to look at it?

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

A

I'm repeating the question just for the case of the people who are listening in. So, the question is about the opioid framework settlement in the US, what are the components and how does it look. So, it's a pretty firm thing, so it's not what we think about it, it is what it is, it's an agreement between, like I said, the three distributors, J&J and Teva, and the state AGs. And it has basically $18 billion in cash from the distributors, $3 billion in value of distribution, $4 billion in cash from J&J, and $250 million from us over a 10-year period. In total, $250 million, and $23 billion worth of product, Suboxone, which is used to wean people off opioids. And that $23 billion is at the list price. And as you know, that's the only official price in the US, and that's the only price nobody ever pays for a product.

So, the actual pricing is probably around half of that. So, the actual street value, you could say, or Medicaid, Medicare value of it is probably around $11.5 billion. And then, of course, there's been a lot of debate, for those who follow this in detail, what is our manufacturing cost of that and so on, we don't comment on that. But we have made an accrual in the accounts for nine months of just shy of $1 billion for the framework settlement, inclusive of all the uncertainty that we have right now.

Q

So, will you update that at the end of the year or...

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

A

So, there's a follow-on question here, will that be updated? Yes, it works this way from an accounting point of view that, with these kind of ongoing litigations, in every quarter, you will update with what you think is the most likely. If you don't have a fixed point exactly, then you have a range and then you report the lowest number in the range of what's likely.

Q

Sorry, just a follow-up on that. So, the settlement is with the state AGs. Obviously, there's still tens of thousands of [indiscernible] (00:11:50) cities, but if I understood your comments correctly, that settlement, it's not so much a legal enforcement for those, but for the political pressure that those entities would be under to then work with us [indiscernible] (00:12:08)...

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

A

So, the question is, how will it work if the framework with the state AGs gets signed and gets done, how does it then work for counties and cities? And that's, you could say, is very much, like I said, a political thing in the sense that imagine you're a mayor in a city in Wyoming and some years ago, a lawyer visited you and said, if you sign here, I might get you some money and you signed and then you're part of this litigation. And then, this overall settlement is done and money is also allocated to cities and counties and so on. And then, your lawyer comes, say, well, you shouldn't accept this settlement, don't do it, we'll do a trial on our own. And let's say you're a Republican mayor in that town and the Republican state AG for Wyoming's part of the state AG big framework settlement, then my take on it is the likelihood that this mayor will say, okay, I'll fight it alone to make some more money for also the plaintiff lawyer that's doing this specific case. That likelihood I think is very low because the whole country will have decided to settle this issue. And you have to think about – the whole reason for doing this is to make life better for people who misuse drugs and who have a miserable life and a miserable situation. So, deciding to stay out of it just because you think you can get a bit more money out of it, I think politically, that will not be a very good way to go for most people.

Q

On FORTEO, do you have a new [indiscernible] (00:13:35-00:13:46)?

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

A

So, the question is on generic FORTEO, if we have a new action date. We don't have a firm date on that. So, we'll just have to wait and see when we get the approval, and that also means it's too early for us to say what will the exact effect be on the value. But, of course, in general terms, the more you get delayed, then often the value goes down, but then you have the whole complexity that you never know how many competitors you will have. So, we can't say anything specific on it.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Maybe just a broader question on the US generic market, it seems like we've hit this kind of stability in the business. First of all, do you see 2020 as – it seems like there could be a number of kind of interesting launches teeing up, how do you think about 2020 in the context of what we've been seeing for the business? And then maybe a second question, longer term is this kind of stability is that – is it reasonable when you think of the longer term US generic business as a kind of a flattish business over time?

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

A

Yeah, I'll give the long-term comment, then Brendan you can talk about the 2020. So, when we model long term what we have in terms of filings, what we have in terms of products going off patent, be it both biologics where it's biosimilars and normal pharmaceuticals where it's normal generics, then we see that there's a huge value up for grabs in the coming years. We think we're very competitive. We have by far the biggest portfolio of ANDAs finings. So, we think that on a long-term basis, they'll definitely be a very sustainable and stable combined generic and biosimilar business. More of the products in the future will be technically challenging to do which is what we know how to, which is our benefit. So, we foresee a stable positive outlook for US generics and biosimilars.

With regard to 2020, maybe, Brendan, you can comment on some of the products that we're hoping for.

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

Sure. So, if you look at 2020 – I mean, I'll comment on 2019 first.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Sure.

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

So, we had 80 potential launches in 2019, and I think we did 46 or 47 of those. So, in any particular year, you have a number of products that are in there and you're not sure from a legal, technical risk and so forth what you'll actually launch. But I think this year, we have a smaller basket, but we also have some potential high-value launches: FORTEO was mentioned as one; and, of course, NuvaRing's been...

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Sure. Yeah.

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

...out there and RESTASIS and some others. We just launched rituximab, and we'll update again in February as to – during the earnings as to how that is going, but we're very pleased with how that's gone so far. We'll have HERZUMA later this year.

So, all in all, I think that, when you look at 2020 from a generic business, Kåre has made the comment that the North American generic business is around a $4 billion business, and I think what you typically see is you see anywhere from – North America can be anywhere from $850 million a quarter to over $1 billion a quarter depending upon what happens. So, we do see it as around a $4 billion business in North America. We see that we'll continue to – after it's stabilized here, we'll have some slow growth in the business and we think it's very sustainable. And if you just kind of look at the – what's happening in the market is the focus continues to be on low-cost products and the demographics favor the generic market, so we're optimistic, yeah.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

Okay. And just two quick follow-ups there, and not to get too product specific, but any update on where NuvaRing and how that's coming along?

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

So, we continue to have discussions with the FDA and we'll see. We're hoping that we'll launch it in 2019 and hopefully sooner rather than later, but those discussions with the FDA are ongoing.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Okay. And then just on the rituximab launch, help – just infrastructure to actually launch that, was – were you able to leverage the existing Teva infrastructure or did you have to bring in additional cost to get that off the ground?

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

A

Yeah. So, if you think about Teva and you think about biosimilars, so biosimilars are really a combination between a specialty and a generic launch. And Kåre made the comment earlier that, given the diversity of our portfolio, both on the generics side and on the brand side, we know those customers very well, whether they're payer, whether they're wholesaler, GPO or whatever they are. So we're able to kind of optimize that in a strategy that we think bodes well for us not only with this biosimilar launch, but with others.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Okay. Open it up to the audience.

Q

Just a question on the – can you talk about the generic environment and [indiscernible] (00:18:21) stable, would you say the same about operating margins and gross margins [indiscernible] (00:18:27) generics? And also, could you comment on both the more traditional generics and the biosimilars in terms of operating margin?

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

A

Yeah. So, the question here is about operating margins in generics and biosimilars in the US, how that's developing. We see a stabilization of the margins in US generics, and we see biosimilars having, you could say, a slightly higher margin, but it has to be qualified due to the dynamics. So, if you launch first with a chemical compound, you have a very good margin in the beginning and then it slows down pretty fast if you get a lot of competition.

On biosimilars, you typically get less competition, your launch margin is probably little less than you could have on a traditional generic, but it stays longer because the pricing is much more stable due to less competition in that field and the fact that the barriers of entry to biosimilars are a lot higher.

Now, looking sort of into the future, we think that the basic supply and demand in US generics and biosimilars are favorable and are stable. That doesn't mean that we'll see a dramatic increase in margins, but we do believe that the plans we have for our whole manufacturing footprint will result in some improvements on the gross margin, and we will comment more specifically on that 12th of February in connection with our full year accounts.

Q

A couple of years ago, you said you were going to rationalize certain products in your business which were not profitable, and then perhaps other companies were going to do the same thing. Can you update us on what you did? Is that over, are you still in the process of doing it?

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

A

So, the question is about the portfolio of generics in the US where, two years ago, we made it very clear that we were going to optimize our portfolio and get out of products that were not having a positive contribution. Now, the action we took there I think is directly linked to the stabilization of the US generics space because the competitors were in, what I call, this death spiral of price decreases where everybody wants to hang on to market share, so everybody's cutting the price more and more and more until you start losing money on products. That kind of spiral you can only change if the market leader, being us, goes out and say, enough is enough, we're just moving out of these segments and we won't feel any commitment to stay there unless the price gets back to a level where it's profitable.

Now, we had that discussion starting two years ago with all our three big customers and it was a really good constructive discussion. We made sure that the products we did phase out, we did it without harming customers or patients and we probably looked at 10% of our portfolio as something we would potentially move out of, and we probably ended up moving out of two-thirds of that. In the last third, we got the prices up. But the most important was that this inspired other companies, of course, to do the same analysis and it's not rocket science to analyze your gross margin, right, and figure out that it's not a good business model to sell products at a loss, and that whole dynamic has been part of the stabilization of the US generic business And you can see that in total value that US generics in total value have now stabilized, which was not the case two years ago. So, I think that has been very successful.

Q

Just on your last quarter earnings call you made some comments on the 2020 earnings outlook that there are many moving parts, can you please comment on how do you see the earnings [ph] trending in (00:22:11) 2020? I understand you can't give exact numbers, but just [indiscernible] (00:22:15)?

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

A

Yeah. So, of course, here again due to the timing of this conference, I'll have to say that we'll give guidance on the 12th of February, but I've said and I'll repeat that that the whole strategy is based on these dynamics of COPAXONE, AUSTEDO, AJOVY and so on stabilizing the business, improving the margins. And based on that, I've said from the beginning, 2019 will be the trough year in terms of earnings, which basically means that we are expecting to see improvement in our earnings in 2020, not dramatic because we still have the drag from COPAXONE, but of course, once that gets even less in 2021, then the improvement gets even bigger because the absolute – we sort of add in, this is same roughly and what gets subtracted was more in 2019 than it is in 2020, and it's even less in than 021. So, that's why we have a positive expectation for the development in our earnings in 2020.

Q

Can I just ask on – you had brought up the debt balance and you took some steps to address that with the guaranteed debt issues. So, I'm just curious, sort of over the medium term because you still have a fair amount of debt [indiscernible] (00:23:25) the next few years, how are you thinking about it.

Kåre Schultz

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

A

Yeah. So, there's a question here, actually I need to correct you, we did not do any secured debt at all. We only have standard unsecured bonds, they're all the same, and the last issue we did was the same straight-out bonds. And we think we'll have absolutely no problems. We were heavily overprescribed this time and we only do it as, you could say, maturity management that we push out some maturity. So, the $2 billion we borrowed we used immediately to pay down some other debt. And we don't see any operational challenges in doing that again. We will not have to do it until – and we will not do it probably until three years from now, which is when we again have a debt stack that's a bit too big, and that will probably be the same size, couple of billion, and it's pretty clear that we won't have any troubles with that.

Kåre Schultz

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

We are running out of time now, and I would just like to thank you all very much for coming and asking good questions, and have a nice day. Thank you.

Chris Schott

Analyst, JPMorgan Securities LLC

Thank you.