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Teva Pharmaceutical Industries Ltd.

(TEVA)

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MANAGEMENT DISCUSSION SECTION

Chris Schott
Analyst, JPMorgan Securities LLC

Great. So I think we're ready to kick off the Teva breakout session. I'm going to start with just one on my end. Then we can have people throw out questions from there.

QUESTION AND ANSWER SECTION

Chris Schott
Analyst, JPMorgan Securities LLC

Q

But maybe just – I know you haven't given formal guidance, but as we just think about 2019, can you just walk us through some of the pushes and pulls we should think about for the Teva businesses we're thinking about this year?

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

A

Yeah. I can start and then Mike can maybe comment on some of the more financial specifics. We've said all along that we have two major factors, one moving down, one moving up, that affect the revenues and is no secret, of course, that the big one moving down is the constant reduction in CapEx and revenues. And then, of course you've got to bear in mind that they have been reducing this year from Q1 to Q3, and you'll see the same, of course, for a reduction in Q4. And you can always discuss the rate of this curve, but it is, of course, reducing and that means also in Q1 of this year it will be lower than it was in Q1 of last year. So that's an ongoing element. So that's a negative, of course, and that's one of the reasons why we did the restructuring.

Then there's a positive, which is, of course, the constant growth of the newly launched products, such as AUSTEDO, which is doing very well, growing very steadily, as we've also been sharing with you. It's – potentially once we see real revenue coming in from AJOVY. AJOVY is off to a real good start. But, of course, we have a lot of patient support right now, where we're basically paying quite a lot of the scripts right now before they start turning into normal commercial scripts. So those two movements there'll be a drag from COPAXONE and there will be something coming up.

Then there is the potential generic competition to ProAir, which we don't know about. That's always unknown on the timing. Then we have the whole thing about BENDEKA and the orphan drug status in TREANDA, how that's

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going to play out. There's nothing you need to take into consideration. And then on top of those two clearly – clear sort of patent expiry and growth of new products, you have the whole value scenario for U.S. generics and European generics overall. And I would say the new thing compared to like a quarter ago, after the third quarter, I'm more confident now that we're seeing this stabilization of U.S. generics and that we also continue to see a stable European outlook for generics. That's pretty clear to me.

I think it's difficult for anybody, including me, to in detail predict exactly the slowdown of COPAXONE and new generic competition to ProAir and bendamustine versus the growth of the other ones. So, I've been saying for the last year, and I still think so, that it's most likely that 2019 will be the trough year on revenue and earnings, simply due to the mathematics that the drag from COPAXONE is still relatively big. And then mathematically, of course, that will be reduced in absolute terms in 2020, whereas the benefit from the new products will, of course, be bigger in 2020.

But, Mike, maybe you want to add some color, too.

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

A

Yeah, let me add some color, and I'll focus mainly on the non-U.S. because I think that gets a little less attention. Some things to think about when you're looking at 2019 for us, and we'll crystallize a little bit more when we get guidance is the currency, the U.S. dollar, has continued to be strong. You've seen in our sales, they've been affected in Q3 and Q4 quite significantly both in Europe and in the international markets. If that continues, that is a continued drag on our performance because particularly in the international markets, we don't really have a natural hedge. We produce outside those markets. And when the currency goes down, it almost goes straight to the bottom line. We've also seen, of course, these API things like the valsartan we were getting from a Chinese manufacturing. That's probably not going to clear up in the short term, so it'll continue to have an effect on us.

So, some of those things will drag a little bit. And even COPAXONE in the Europe, you'll start to see more pricing competition. It's not substitutable like it is in the U.S., but more and more reference pricing and even some tendering of the class, and those kind of things are going to affect us in the 2019. So, think about those things when you're looking at 2019. We'll come back with, of course, very clear guidance when we give the earnings call in February.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

And just a follow-up on the generic commentary, seems like it is quite a shift in tone in a very short period of time. Maybe elaborate a little bit more what's giving you that confidence that you're seeing things stabilize, that that's sustainable?

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

A

Well, first of all, theoretically with the actions we've taken, you would argue that it would be happening. If you've had this death spiral of a market, which is partly a commodity market, and the market leader steps up and says, enough is enough, we're not going lower, then that will typically have a significant impact on the pricing dynamics of the marketplace. So, theoretically, it should happen. So that's a good thing, of course.

And then, how can you then judge whether it's happening or not? You can only just look at the value and look at what's actually happening in the marketplace. And if I look at Q2, Q3 for the total U.S. generics, then it is

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stabilizing. And if I look at early indications for Q4, it also looks like the total market is stabilizing. So, there's no more sophistication to it than that. And then the fact that the other participants in the market have been giving public statements where they've also been making it clear that they will not go with unsustainable profitability on their product portfolios.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

And when I think about the longer – I know in 2019 we're still dealing with some kind of businesses you got out, et cetera. Can you see a U.S. generic franchise that starts resuming in growth in 2020 and beyond if the market, in fact, is stable, or is it too early to be able to kind of predict that 2019 will be a bottom for that business?

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

A

I think for each competitor in the generic space, it will be a little random because, as you know, how many first-to-files you get first-to-launch varies from year-to-year, so you can't really say that there's a real steady prediction. It can vary. For the total market, I believe that it will be growing if you add in the biosimilars. But you have to think about the fact that biologics have taken a largest share of the total pharmaceutical marketplace, so you can only judge the generic business if you add in biosimilars. And I believe that in the coming years, you will see a gradual increase on biosimilars. So, if you take sort of the total market for pharmaceuticals that have gone off patent, then I think you'll see a modest single-digit growth of that market.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Okay. That includes biosimilars?

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

A

Yeah.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Maybe one more for me and I'll open up. Just on AJOVY, you shared some comments of launch going well, but just a little bit more color of just 30% share, is that what you would expect at this point and what are you seeing in terms of the shake out of the three players as the market's starting to evolve here?

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

A

Yeah. So, first of all, we should remind ourselves that it's a fantastic new therapy, where we have three competitors which have all shown actually quite comparable, very good clinical results. So, you have three products that are basically good products in the marketplace. Now, how will this pan out when you have three professional companies competing with really good drugs for a segment with a huge unmet need? Most likely it's going to be huge in volume because you have three big players with a good drug promoting it in a professional way, then you should expect to see big volumes. And I think that's what we're seeing. We're seeing bigger volumes than what we were predicting.

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Then in terms of the relative share, some would say, well, let's just use a generic order of entry model, or let's look at details on what margin parameters do one have versus another. I think we have a few parameters on ours. We have a simple way. We don't have two doses to get to the max. It's just once monthly dosing. We have the offer of quarterly dosing. And we have less constipation than one of the competitors. So, we have some hooks.

I was estimating that we would get between 20% and 30% from overall assessment. Right now we're seeing we're having 30% of NBRx and the TRx is, of course, climbing slowly towards that. So, it's probably half of that right now, the TRx. And I don't see in the marketplace, and what I hear anecdotally, any enormous differentiation apart from these smaller things I just touched on. And I will be saying that I think 30% seems to me like a fair and good share, which we should be able to keep on a sustainable basis.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

I know you made some comments on 3Q, but just any additional color in gross to net and how we should kind of think about that evolving and where that could shake out?

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

A

Yeah, I think it's a fact that the total value per patient is lower now than what we anticipated, let's say, two years ago. We were thinking that – maybe this therapy two years ago we were thinking maybe it will be $10,000 a year. Now it's more like a list price of something like $6,000. And the fact that there's been three competitors has probably meant that instead of going out with a minimum discount that you would normally do, if you're the only one to launch to the PBMs, there's already been competitive negotiations, which is taking the discount to a higher level.

So, you could say, our total projection is probably slightly better than we thought two years ago, but it's a lot more volume and it's a lower price. And I don't think that the first launch, where the list price went from $10,000 to $6,000. I don't think we got in the marketplace any benefit with the PBMs because of the starting point being lower because it's a relative game for them, they want the biggest possible cut and the biggest possible discounts so that they can make some money on that.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

So, I think because of the calls for maybe 25%, 30% discounts, is that seem to be a reasonable number or is it too early to say?

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

A

I think it's too early to say, but given the early indication, that's probably a reasonable total number to be looking at.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Okay. Great. So, we'll open up to folks.

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Q

Just curious if you have any timeline through auto injector there. And then secondly, curious if any Phase 4 clinical trial [indiscernible] (00:10:25) and things like cluster headaches, et cetera that you might be looking at.

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

A

Yeah. So, on the auto injector, we are working on it. We expect to have it. We don't have a firm date, but like, let's say, around a year from now, it does not seem to be holding back our scripts. So, actually, I don't think it's going to be a major factor in the marketplace for us which basically also means that once we get it, you shouldn't expect our script numbers to really radically change.

The prefilled syringe is relatively simple to use. All doctors know how to use it, it's very intuitive. It's not as sophisticated as an auto injector but you also know that if you have an auto injector, you might have a wet shot. And if you have a wet shot with a product that's a once use, what are you going to do, then you got to go to the pharmacy to get a new product and so on. So, it's not that auto injectors are just a fantastic solution in all situations. So, we're working on it. We're making progress.

This idea that we would have any technical barriers to it is not true. I mean, there's nothing about that whatsoever. So, we'll see that come into the marketplace. We're also working on new Phase 4 programs, and we're also looking into cluster headaches. So there will be more news coming in the coming years from the clinics.

Q

[indiscernible] (00:11:47).

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

A

I don't have any specifics on the timing. I think we'll have some data, the first data on some on the new indications we'll have during a little late this year. So, we're coming as we move along.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

So, the $3 billion cost reduction numbers for 2019, just as you gotten further along in the process, can you talk about is there opportunities to beat a number like that, whether it's 2019 or over time, or just how do we think about where we are in that process, and what you've learned as you've gone through kind of the consolidated facilities, et cetera?

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

A

Yeah, I can give the first overall ends and then I'm sure Mike can give some more color, too. So, the overall plan is for two-year restructuring where we want to hit $3 billion. And I've made the plan out of the total cost pool because I think it's always frustrating when people say, we want to do this cost saving and then they have 10 explanations afterwards why they didn't do it because of currencies and this change and this change. So, I thought, okay, why don't we take the absolute number? And we say, we're just going to reduce by $3 billion then

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there's not so much discussion about whether we did it or not. So that's what we are driving for. And we are completely on plan or slightly ahead of plan, so I have no doubt that we'll hit that.

Then as you move into the coming years, you could say, it's maybe not so much about the absolute number, it's more about the margin because, of course, if we do well and we grow revenue then, of course, some part of the cost picture will also grow. So, the absolute number might be growing. So really what you should look at there is the 27% operating margin target we have, which is better than where we are right now and which we are fully committed to reaching that target. But maybe, Mike, you want to add something?

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

Yeah. Of course, the $3 billion is a net number. So that also is offset partially by investments we're putting into some of the new products, but we didn't want to play this game of gross versus net savings. So, the $3 billion is there. Now, there is a portion of that $3 billion related to cost of goods for sales that have declined. So, it's not like all $3 billion fell directly to the bottom line from two years ago, but it is helping us overall. So, those are some parameters to think about.

And can we go further? There may be additional cost savings we can do in the future as we get into 2021, those kind of years. But there's also going to be pressure to continue to invest in new products. So, we're not committing to further net savings at this point. But, of course, we'll look at every opportunity we can to make efficiencies whether it's in manufacturing or other parts of the business.

Chris Schott
Analyst, JPMorgan Securities LLC
Q

And you mentioned that reinvestment on the new products. Do we think about that as mostly SG&A, or is there also an R&D component we should be thinking about?

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

I think you should primarily think it as SG&A for the products that are moving well in the marketplace. So, if we see for instance that AJOVY is moving even better than we estimate right now then, of course, we might put even more push behind it. But it would, of course, not, in any way, be hurting our overall profitability. That's why if you look at the total profitability in terms of percentage operating margin or in absolute terms then, of course, we would not be doing it in such a way that it would hurt the profitability.

Q

[indiscernible] (00:15:06).

Chris Schott
Analyst, JPMorgan Securities LLC
Q

The question was, for webcast to repeat, for a biosimilar market, are you interested in entering into the diabetes market?

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

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Yeah. So, I mean, I guess pretty much disclosure on where we have filed NDAs and so on. And of course, we are filing basically all big products. And since we're going for biosimilars, we're also filing basically all the big GLP-1s. We've not been going for the insulins. I would say with my experience in the field, then the per milligram price, if you want to look at it that way, per milligram price of insulin is extremely low, whereas the per milligram price for GLP-1s, whereas GLP-1s is extremely high. It has to do with the potency and so on, but that also means that the possibility of doing competitive biosimilars in the GLP-1 space is really good. The possibility of doing it in the insulin space is not there, I would say. So, you should expect us to actively pursue the whole GLP-1 space.

Q

Would you approach it as a brand or as a generic [indiscernible] (00:16:23)?

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

A

We would approach it as a biosimilar. And there's this thing about biosimilars that I also try to explain in my presentation that they are kind of in-between products, because you cannot launch them without the credibility with the key opinion leaders, with the pharmacist, with the hospital buying groups and so on, that you're making a quality product, and you have quality device and so on, which is why I believe we do have a good chance in those kind of areas, because we do know how to make devices for injectables, for inhalers and so on. We do know how to make sophisticated biologics.

So, it is kind of a hybrid, but you're not talking sales force in a normal way, you're just talking into action with key customers, key opinion leaders, to build credibility for the product that you're launching, which is by the same thing in oncology as well. So, the launches we're looking at with biosimilar Rituxan and biosimilar Herceptin has some of the same elements to it.

Q

In terms of your product rationalization in the U.S., can you give us some metrics when you look at how many products that you find that we're losing money, how many did you exit and so on so you have a senses?

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

A

Yeah. So, I'll give you the rough numbers, right? Not the detailed. But the rough numbers, we were looking at a gross North American, so U.S. and Canada business of some $4 billion in generics for last year. And then we looked at some $400 million roughly that were not profitable. So, we said in our – and that's how we communicated to the market.

Look, we're probably going to move out of these $400 million as fast as possible because we don't want to be there because we're not making any profits. But then, of course, we took careful discussions, constructive discussion with all our customers explained to them, explained why and how and, of course, gave them the option that if they wanted to pay us more for the product, we would keep the products. And I would say roughly, these are just rough numbers but out of the $400 million which is roughly 10% of our portfolio, we would say two-thirds of that we lost, which was fine because then we were out of the loss-making portfolio. One third of it we saw price increases, so we still had that. So, that's roughly how it's worked out.

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And we still have interesting discussions on parts of the portfolio with key customers where they, of course, also see a benefit of us being in the marketplace because if we leave as the biggest manufacturer in some cases of complex products then, of course, there's less competition and then it might just be that it looks fine if we leave and they get it cheaper. But one year later, there's a big risk that get much more expensive. So, I think we're seeing the right pricing dynamics compared to what I was expecting.

Q

Can you give us an update on your 4 times net leverage target? How much debt [indiscernible] (00:19:13) this year and in 2020? And when do you think this will shift from pure debt reduction to others?

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

A

Yeah. So, I'll give you big ends on this sort of strategy for debt reduction and then Mike can give you the details. So, I think we will continue to see debt reductions as the primary target for quite a number of years. We have a long-term financial target that we want net debt to be below 3 times EBITDA. And if you ask me right now, I would not be in favor of doing any kind of transaction that stop us in that progression until we hit that target. So that's, of course, some years out. But, Mike, a comment to the...

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

A

Yeah. So, our plan is to be able to meet the maturities that are coming up without refinancing, I think we're on track for that. We have 1.7 in 2019, another 2.1 in 2020. We will be looking at our revolving credit facility as well. It expires in 2020. So, we'll be looking in the course of 2019 at reshaping that. So, we're still trying to target the 4 times by end of 2020. There are, of course, swing factors in that. It assumes that the trough year is in 2019, as Kåre had mentioned. Currency can play a factor into that and the performance, of course, of the new launches and erosion of potential products facing generic competition.

So, we're still aiming for that. We'll be able to give more updates as we go along. The guidance for 2019, of course, will come in February. But very clear that we want to use all of our capital allocation to pay down debt until we reach that less than 3 times longer-term target that Kåre presented in the presentation.

After that, then we'll start looking at things. I think he also mentioned in his presentation that if we do have small targeted investments we can do to license projects and look at minor product things, we'll do that but nothing on a large scale until we get the leverage under control.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Back there.

Q

[indiscernible] (00:21:25-00:21:32) How does it blend together?

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

A

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So, in generics, you could say our strategy is really to be the market leader. So, we go for all big products no matter whether they are simple chemicals or complex proteins or devices whatever. So, there, we basically go for everything of significant value. Where there's a link to the CNS and respiratory and neurology is more in the biopharmaceutical and biosimilar field where you need some credibility in order to penetrate in the market. So, that's where you should see the therapeutic focus, so to speak.

And in our R&D pipeline, we have more than 20 biologics projects which we don't talk about because we really don't want to talk about them before they're quite late stage. But, of course, they are focused on the therapeutic categories where we know what we're talking about. So, we've done a big trimming of the pipeline and got rid of everything which we don't see as being core to what we know about it.

Q

Just one on COPAXONE, I know it's a tiny piece of the business, but just help us with Mylan's price cut and just what expectations into 2019. Just how should we be thinking about the erosion curve and pricing in that franchise?

Kåre Schultz

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

A

Well, of course, it's anybody's guess, right, because we don't know. I would say that if you look at the numbers, they didn't get much out of the move they made. So, if they do it again, it's just going to hurt them from a mathematical point of view. We still have more than 70%, as I said, volume. And we are not seeing any significant drop in that. And that also indicates that a further dramatic price reduction, I think, is not to be expected.

But on the other hand, you do see a constant price erosion based on the fact that there will probably also be potentially one more competitor coming into this space. It's not as dramatic. I mean, the first is the most dramatic. The second, it's slightly less. The third, slightly less. But we do expect, of course, to see a continued decline of COPAXONE in the U.S. in the coming year. We also have a European business which has been declining a lot less and in international business. So, in total, I would say, we think we have a sustainable, but declining business if that's the way to put it.

Chris Schott

Analyst, JPMorgan Securities LLC

Thanks. So, I think the rest of our time, I wish we had more minute or so, but thanks everyone for joining us and thank you guys.

Michael McClellan

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

Thank you.

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