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TEVA.TA - Q4 2016 Teva Pharmaceutical Industries Ltd Earnings Call

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OVERVIEW:

Co. reported 4Q16 revenues of $6.5b, GAAP loss of $973m and non-GAAP EPS of $1.38. Expects 2017 non-GAAP EPS to be $4.90-5.30.

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Teva fourth-quarter 2016 financial results conference call.

(Operator Instructions)

This conference is being recorded today, Monday, February 13, 2017.

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

Kevin Mannix - *Teva Pharmaceutical Industries Ltd. - SVP & Head of IR*

Thank you, Lawrence, and thank you, everyone, for joining us today to discuss Teva's fourth-quarter and full-year 2016 financial results. On the call with us today are Dr. Sol Barer, Chairman of the Board; Dr. Yitzhak Peterburg, Interim President and CEO; Eyal Desheh, Chief Financial Officer;

Dipankar Bhattacharjee, Global Generic Medicines; Dr. Rob Koremans, Global Specialty Medicines; Dr. Michael Hayden, Head of R&D, Chief Scientific Officer; Dr. Carlo de Notaristefani, Global Operations; and David Stark, Chief Legal Officer.

We'll start the call with opening remarks from Dr. Barer, and Dr. Peterburg, followed by a presentation from Eyal. We'll then open the call up for questions and answers. A copy of the slides can be found on our website at www.TevaPharm.com, as well as on the Teva Investor Relations App.

During this call we will be making forward-looking statements which are predictions, projections or other statements about future events. These estimates reflect management's current expectations for Teva's performance. Actual results may vary, whether as a result of exchange rate differences, market conditions, or other factors.

In addition, the non GAAP figures exclude amortization of purchased intangible assets, costs related to certain regulatory actions, inventory step up, legal settlements and reserves, impairments, and related tax effects. The non-GAAP data presented by Teva are used by Teva's management and Board of Directors to evaluate the operational performance of the Company, to compare against the Company's work plans and budgets, and ultimately to evaluate the performance of management. Teva provides such non GAAP data to investors as a supplement of data, and not in substitution or replacement for GAAP results, because management believes such data provides useful information to investors.

And with that, I'll now turn the call over to our Chairman, Dr. Sol Barer. Sol, if you would?

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

Thank you, Kevin, and thank you all for joining us today. Before we get into the details of our full-year 2016 and fourth quarter results, I want to take a few minutes to discuss last week's leadership announcement. As you know, we announced that I have been appointed Chairman of the Board of Directors. Dr. Yitzhak Peterburg, who had served as Chairman since January 2015, was appointed Interim President and CEO.

In addition to my new role as Chairman of the Board of Teva, I have significant Board experience, including serving as Chairman of Celgene Corporation, where I was a Founder. Since joining Teva, I've been impressed by the depth and variety of experience and knowledge of the Teva team.

We are fortunate to have someone with us, with as much experience as Yitzhak, to lead the Company during this transition period. During his years of service as a member of the Teva management team and Board of Directors, most recently as Chairman, Yitzhak has gained unique insight into the business, strategy and operations. I believe we are both ready to hit the ground running, and to continue working to the benefit of our shareholders and all other stakeholders.

As Interim President and CEO, Yitzhak has the full support of the Board to drive forward on Teva's strategies and key priorities. While the title may be interim, the job is important and major for Teva.

The Company cannot stand still. There is too much at stake. We are looking to Yitzhak until a permanent CEO is found to execute and deliver on Teva's promise to shareholders.

The Board has already begun a comprehensive search to identify a permanent CEO with significant pharmaceutical experience. We will take the time we need, with the assistance of a leading search firm, to identify the best leader to take Teva into the future.

Before handling the call over to Yitzhak, I want to reinforce my confidence in the future of Teva. I would not have undertaken the Chairman of the Board if that was not the case, and Teva is a personal priority for me. I am fully committed to do everything I can to position Teva for success, and I look forward to working alongside Yitzhak, the rest of the board, and the management team.

I know the board, management team and all employees of Teva share my passion about providing the highest-quality medicines for our patients all over the world, and recognize the responsibility of that role. In addition, the Board continues to recognize the importance of Teva being a good

corporate citizen. This is critical for us, and everything we do needs to be looked at within that context. Simply said, we are committed to doing business the right way.

Lastly, I want to thank all of our employees for their commitment and dedication to Teva, and for providing solutions to patients. We look forward to earning the trust of all our shareholders, and significantly intensifying our efforts towards execution, and enhancing value for all our stakeholders. I will now turn the call over to Yitzhak.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Ltd. - Interim President and CEO*

Thank you, Sol, and hello, everyone. I know that the Board has put their trust in me, and I hope that over the next few months, I will earn your trust as well, while the Board is conducting the comprehensive search for a new CEO.

Let's start by quickly reviewing what has not changed, so that we can move the discussion to what is going to change. The Company's priorities continue to be extracting all synergies related to the Actavis generic acquisition, successfully launching the key generic and specialty products we have planned for 2017, and generating significant cash flow to rapidly pay down our existing debt to maintain a strong balance sheet.

We are reiterating our guidance for 2017, including our earnings per share of $4.90 to $5.30. We are very committed to this EPS range, and the management team and I will do what it takes to protect it, including additional cost reduction if necessary.

When I accepted this position, I stated that we would conduct a total review of the business, and this process is already under way. We will be looking at every part of our business, including our current global manufacturing footprint, key therapeutic areas, pipeline assets in both specialty and generics, and existing business lines and markets.

As we have previously stated, 2017 is an important year for Copaxone. Since our January 6 guidance call, we have received a decision from the District Court invalidating four of our five Orange Book patents. Based on the court decision and further analysis, we have revisited our assumptions for Copaxone, and are now providing the following update.

While we are appealing the court decision, the following remains uncertain. The outcome of the appeals decision and other patent enforcement efforts, if and when we may see approval of competitors purported generic products, and if they will launch at risk. With the introduction of generics, we would anticipate continued sales erosion, due to the increased competition.

Based on our most current insights and the future anticipated growth in the neurology space, we now plan to have larger than anticipated sales and marketing expenses. The situation is extremely dynamic. In case of generic competition, as of February 2017, for the 40-milligram we would expect a reduction to our base case of $1 billion to $1.3 billion of revenues, and of $0.75 to $0.95 in EPS.

As you very well know, 2016 was an extremely challenging year for Teva, on many different fronts. I would like to personally thank the employees of Teva. We want to recognize their hard work and commitment to realizing the full potential of Teva, and their drive to help improve the lives of millions of patients around the world. And with that, I will now turn the call over to Eyal, who will provide an in-depth review of our fourth-quarter and full-year 2016 results, and then we will be happy to take your questions.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd. - CFO*

Thank you, Yitzhak and I wish you and all of us a lot of success. Good morning, and good afternoon, everyone. I would like to review the financial and business highlights of Q4 and 2016, and I will start with the quarter.

We present both GAAP and non-GAAP results. On a GAAP basis, the quarter resulted in a loss of $973 million, due to a significant number of one-time charges, which I will review in a few slides.

Our highlights for the quarter include revenues of $6.5 billion, and earnings per share of $1.38 on a non-GAAP basis. As you can see, on a non-GAAP basis, our profit and EBITDA were up about 30% compared to Q4 last year, all driven by inorganic growth, related mostly to the Actavis acquisition, and also to the joint venture with Takeda in Japan.

Let's look at the major charges and adjustments that we had to non-GAAP in our financial statements. In our non-GAAP P&L, we reported a loss of $973 million this quarter. This loss was driven mainly by the following one item charges which we adjusted in our non-GAAP report.

One, a $900 million impairment of the Rimsa goodwill. Following the acquisition of Rimsa, we discovered a significant fraud related mostly to product registration, testing and manufacturing processes, and we are working diligently with the local health authorities to remediate it.

We recently received an approval to activate the plant, and we will soon begin ramping up production. We strongly believe in this opportunity in the Mexican market; however the time to market we lost and the costs of remediation led us to impair the acquired goodwill by $900 million.

In Venezuela, we made changes to the exchange rates we used in our accounting, and this drove a financial expense charge of $500 million. We also reduced the inventory value by $133 million for the same reason.

Number three, this is a place to update that to date we sold approximately 75% of the Mylan shares we held, the majority since the beginning of this year. Adjusting current market price to the book value resulted in a finance expense of $43 million. Number four, in January, we settled a legacy Barr antitrust case for $225 million, and the outcome is included in the Q4 results.

And five, amortization of intangible assets this quarter were $182 million. This number does not represent our future run rate, and was driven by the progress made on the Actavis purchase price allocation. Future run rate is expected to be about $360 million per quarter.

Exchange rate impact. Exchange rate differences between the first quarter of 2016 and the fourth quarter of 2015 decreased revenues by $41 million, decreased GAAP operating income by $14 million, and decreased non-GAAP operating income by $9 million.

In addition, the Venezuela bolivar exchange rate that we use, and inflation-driven price increases in Venezuela increased revenues by $184 million, decreased GAAP operating income by $34 million, and increased non-GAAP operating income, by $75 million. In light of the economic condition in Venezuela, we exclude the 2016 changes in revenue and operating profit in any discussion of the currency effect.

We saw similar effects on our non GAAP operating income, while both impacts were negative on operating income on a GAAP basis, also. As reported before, as of December 1, 2016, we are no longer using an exchange rate of VEF10 which is the preferred exchange rate, but a blended rate, which was VEF273 per $1. The new rate had a significant adverse impact on the value of our working capital assets in Venezuela.

EBITDA. Our Q4 EBITDA was $2.1 billion, the last four quarters totaled $7.3 billion. And our cash flow from operations stood at $1.4 billion this quarter.

Net Capital Expenditures were $319 million. This number did not include any cash from divestiture related to the Actavis acquisition.

At the end of 2016, our total debt was $35.8 billion. Our debt to EBITDA stood at 4.87 times, and net debt to EBITDA, which is used for complying with the bank debt covenant, stood at 4.72 times for the past four quarters.

We are updating our segmentation reporting. As a result of an analysis following the acquisition of Actavis generics, we have revised our reporting segment and we now have two segments. Generics and OTC, and specialty.

Our distribution and other activities, including Anda, are reported separately. This has made minimal effect on the profitability of our generics segment, as you will see in a few more slides.

Starting with the first quarter of 2017, we will not provide Actavis Generics contribution on a standalone basis, as a result of the integration between Actavis Generics and our existing generics business, such figures are no longer meaningful. Actavis contribution to the generic revenues after divestitures is $600 million in the US, and $360 million in Europe, $150 million in the rest of the world.

In Q4 2016, our US business accounted for 53% of our sales, Europe was 24%, and the rest of the world was 23% of our total sales. Generic sales accounted for 57% of our total, an increase compared to last year. Copaxone sales up $55 million compared to Q4 2015, were 16% of our total sales, compared to 20% last year.

The increase in our operating profit was driven mainly by our generic business, following the closing of the Actavis transaction. We also saw improvement from the specialty business. Generic profits were 48% of our operating profit before G&A. Copaxone profit increased by $100 million compared to last year, but were down to 36% of total operating profit from the Company, as compared to being 40% last year.

On this slide, generics includes OTC, but those of you who are familiar with Teva's results, we know that the differences in profitability are minor, as the profitability of generics and OTC at Teva are very similar. Gross profit was 49.4%, and operating profit was 28.9%.

In Q4, our sales and marketing expenses are usually seasonally higher than in other quarters. Copaxone continued to perform well, exceeding Q4 2015 sales results by $55 million, and totaling $1.015 billion for the quarter.

Now, let's look at the year-to-date results. In our 2016 GAAP results, we generated a net income of $329 million, due mostly to the Q4 one-time charges which I described earlier. 2016 net revenues were up 11% year over year. Our non GAAP net income in 2016 was $5.2 billion, 12% higher than in 2015.

The full-year non-GAAP adjustment, which is represented on this slide, were mostly influenced by the decision made in the fourth quarter as I described earlier. Notable adjustments in the first three quarters of the year were the FCPA settlement, investment in Regeneron, and income generated from the divestitures driven by Actavis deal, which were also adjusted in our results.

Exchange rate differences between 2016 and 2015 for the whole year, decreased revenue by $174 million, decreased GAAP operating income by $81 million, and decreased non GAAP operating income by $55 million. Generic sales in 2016 accounted for 55% of our total sales, and Copaxone was 19% of sales, and specialties accounted for 20%.

Looking at profit, operating profit before G&A and our generic business were 41% of total, and Copaxone accounted for 43% for the total year. Our balance sheet reflects the impact of the Actavis acquisition. Total sales were $93 billion, with significant growth in goodwill and intangible assets, resulting from the progress made on the Actavis acquisition versus price allocation.

2017 guidance, as you have heard from Yitzhak, we are reaffirming our guidance today. Our guidance is based on the assumption that we will not see generic competition to Copaxone this year; however, these possibilities do exist, and in my next slide will indicate what could be the impact of a generic launch.

So potential impact of one to two generic competitors to Copaxone 40 milligrams launching in February 2017 in the United States could reduce revenues by $1 billion to $1.3 billion. We are maintaining a higher level of expenses to support sales, compared to what we had in the January guidance, and we estimate earnings per share decrease of $0.75 to $0.95 if this happens immediately.

On the quarterly progression for the year, Q1 is expected to be the lowest of the four quarters. We estimate that 40% of our 2017 EPS will be generated in the first half, Q1 and Q2, and 60% in the second half. This is due to the fact that a majority of the US generic launches are expected only in the second half of 2017, and the progression of cost savings and synergies throughout the year will result in lower cost base in the second half.

And last but not least, dividend. Our Board approved a quarterly dividend of $0.34 for ordinary shares or ADS, the same as in the past fourth quarter.

So that concludes my comments and remarks. Thank you very much, and then, we would like to open the call for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Your first question comes from the line of Gregg Gilbert.

Gregg Gilbert - *Deutsche Bank - Analyst*

My first question is about the CEO search. How comprehensive will that search be? You described it as comprehensive. Are there any strings attached, such as requirement for the CEO to live in Israel?

And Dr. Barer, you've been associated with a very successful Company, that's created a lot of shareholder value over time. Other than switching the person at the top at Teva, what is Teva lacking? What does it really need in your view? You were complimentary of Teva in your prepared comments, but perhaps you could be more critical about what's missing, and what needs to be done, other than finding the right CEO.

And my follow-up is on the exploring options for your assets. Will any of that happen before a new CEO is identified, and can you be more specific about what you are considering, along the lines of things that could be done sooner than later? Thank you.

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

Okay so there's a bunch of questions there. Let me personally focus on the first one, in terms of the CEO search. As I indicated, our objective and actually my highest priority, is to find the best candidate for Teva, literally in the world.

So we have a global search going on, and without enumerating all of the qualities and so on in light of what is self-evident, and I think it's important to people to recognize we want somebody with deep and broad pharmaceutical experience that can lead Teva, and take us to the next level as a Company. So that's the most important thing.

Everything else can be worked out, but just to recognize that I am personally involved, I am personally leading this, and that I am committed to bringing the absolute best person from anywhere to head Teva. That was question number one.

Question number two is, I've been fortunate to have led Celgene, which has had tremendous success, significant success, and it didn't used to do so, with my colleagues who are still running the Company. As I look at Teva, I see really significant assets. The number of people, the millions and millions and millions of people touched every day by Teva and Teva prescriptions are actually a real asset, a strategic asset. There are a number of strategic assets.

I just think we have to get the right leadership, who will then institute the right strategy, to harness the very good people at Teva. I have to tell you, I've been extremely impressed in terms of the caliber of the people.

I think we just need to focus, get our strategy right, and move forward. But that's the secret of managing a lot of large companies and the last point was--

Gregg Gilbert - *Deutsche Bank - Analyst*

Exploring options.

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

So before I turn it over to Yitzhak, did I answer your questions?

Gregg Gilbert - *Deutsche Bank - Analyst*

Yes, thank you.

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

Okay, thank you.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Ltd. - Interim President and CEO*

Gregg, so regarding your last question, I said it and I reiterated that we are committed to a thorough review of the business. This is a critical time for Teva, and we are here to fix what is not working, and as I have said, we will leave no stone unturned.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thank you, gentlemen.

Operator

Thank you. Your next question comes from the line of Elliott Wilbur.

Elliot Wilbur - *Needham & Company - Analyst*

I didn't catch it in your prepared commentary if you detailed or not, but could you talk about some of the factors specifically underlying the change in the potential bottom line impact, from the assumption of generic competition around Copaxone? I think roughly $0.10 to $0.15.

You mentioned something about higher expenses being maintained with that franchise. Just curious what is driving that specifically?

And then just as a follow-up to that, outside of the US can you just remind us if there's any key LOE or loss of exclusivity or potential generic competition in any of the key markets in either 2017 or 2018 we should be thinking about? Thanks.

Rob Koremans - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Specialty Medicines*

Elliot, it's Rob. Happy to answer. So what we have had recent insights coming from patients and physicians, research and payer research suggests very clearly that when forced to use a generic of Copaxone, about 70% of patients and doctors would opt to an oral therapy, rather than to a generic.

We believe and as you well know, Copaxone is the number one in new patients, not only in the US, but also in some of the key European markets. It's in our best interest, given the fact that we will appeal, to continue to protect both the Copaxone but also the Glatiramer market, to make sure that when successful in an appeal, actually, there is a switch back.

So looking at all of the options, it just financially made more sense to continue to really protect the prescription and continue to drive this. We've done this very thorough analysis, and this is what the result is, right? So we are optimistic about potential outcome, and as long as there is a fair chance, this is really financially the best option going forward.

As to Europe, Copaxone 40 three times a week is doing extremely well. Also in countries like Germany, this is the number-one product in new patients. We continue to see an uptick very much like what you have in the US, in the switch from the 20 to the 40-milligram.

The situation in Europe is very different, in terms of legal and regulatory. There is one so-called generic on the market. They had to do their own clinical trials showing some sort of efficacy and safety, and it's not an A-B rated, it's not a substitution generic, so it's a follow on generic. It's on the market already and we've seen minor impacts, and frankly we expect to see minor impacts going forward.

So Copaxone is actually developing really well in Europe, and continues to do so. We just recently launched in France. Also significant market and everything is well on track, the team is really motivated.

Generics will be there, but they aren't going to impact the business as we expect. Any other, Azilect has already come off patent, so actually in the foreseeable future in Europe, we don't expect any other loss of exclusivities.

Operator

Thank you. Your next question comes from the line of Randall Stanicky.

Randall Stanicky - *RBC Capital Markets - Analyst*

Just a question on the strategic review that you're running now. Why run that now, as opposed to waiting for a new CEO to come on board?

And then just how bold in terms of changes would Teva be willing to make, with respect to changes in the strategy? Would you be willing to look at breaking up pieces of the Company, or should we view this review as more of a tweaking of the existing strategy?

And then the follow-up, I just noticed that you're talking with respect to Copaxone competition now in terms of one to two generic competitors, versus two. Is there any significance behind that clarification? Thanks.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Ltd. - Interim President and CEO*

So I want to make clear that we are very focused on execution, and we are committed, that is what I said, that we are committed to a thorough review of all the business. It has been seven days since I became CEO, and as you know, I can not give you specifics at this time. As I mentioned I'm going to dig deep into the business, meet with our businesses, and determine our path to move forward. Rob?

Rob Koremans - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Specialty Medicines*

With relation to the Copaxone, there's no new, this is a very dynamic market, right? And it's a bit of a crystal ball. We always planned for one or two, which if at all would be the most likely thing to happen, and that's the range. What has changed is our insight into what we want to do, in order to protect Copaxone in 2017 pending the appeal.

Randall Stanicky - *RBC Capital Markets - Analyst*

Could I ask a follow-up? With a new CEO coming on Board, would it be expected that CEO would take a Board seat as well with Teva?

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

Yes, it would be. He or she would.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay, thank you.

Operator

Thank you. Your next question comes from the line of Chris Schott.

Chris Schott - *JPMorgan - Analyst*

Just two quick questions. Just on the topic of potentially splitting Teva into a branded and generic Company, there's been a lot of discussion about this around the street, just your view here. Does that one, structurally make any sense? Could you split the business into two if you wanted to?

And second, strategically, I know you're just starting this process, but do you see any merit of looking at the businesses separately, to allow maybe a more focused approach to each of the franchises?

My second question was just about leverage in 2017. To the extent we see generic competition to Copaxone, does that change any of your strategic priorities or commitment to the dividend, in the event that we do see EBITDA under pressure with competition? Thanks so much.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Ltd. - Interim President and CEO*

So again I'm not going to speculate, and I want to make sure that we are now focusing on execution, we are focusing on really doing the best we can now. And while doing the thorough reviews that I promised we will make sure that we are going to fix what's needed, and I think by that, it's enough.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd. - CFO*

Hi, Chris, good morning. First of all, regarding your question of impact of potential generic competition to Copaxone on leverage, yes of course, we will see an increase in our financial leverage, but we do not see a risk to our bank loan, debt facility covenants, even with the generic competition to Copaxone. As we already said, we will do whatever it takes to maintain our rating, maintain the right leverage, and management has a number of tools to do that.

Operator

Thank you. Your next question comes from the line of Liav Abraham.

Liav Abraham - *Citigroup - Analyst*

Just in the Copaxone bear case scenario, could you remind us what the downside would be to cash flows in this scenario? In the past, Eyal, you've mentioned, in a two generic Copaxone scenario, you've talked about $800 million downside to cash flows. Is that number being updated as well, following your updated bear case guidance range?

And then secondly, on your generics performance for Q4, it seems as though, and correct me if I'm wrong, there was a lower monthly run rate for the Actavis component of the US business in Q4 2016, versus Q3. Can you just, first can you just let me know if I'm understanding this correctly? And if so, can you just provide an explanation as to why, and how you see this business performing in 2017, based on your current insights into the US generics market, Thank you.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd. - CFO*

Liav, it's Eyal. So I'll take the cash flow question, and Dipankar will take the generic. So the cash flow downside, in case of immediate generic competition is up to $800 million impact of cash flow for the year.

And of course every day that goes by, this number goes down, but we will be we are waiting to see, I don't want to speculate on the entire amount, but this is calculated the maximum possible. Dipankar?

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Generic Medicines*

Yes, so actually, the only difference that was there between quarter three and quarter four in the Actavis business, was just that the launches that carry through into Q3 had some effect, but basically, we did not see any fundamental difference in the way the business performed.

As far as 2017 is concerned, we have our basis for our assumptions, in terms of launches that will come out of Actavis pipeline, the way the performance of the base business will be, so there's nothing that leads us to change our assumptions at this point in time. We are quite confident about the way we are projecting the numbers.

Liav Abraham - *Citigroup - Analyst*

Great, thank you.

Operator

Your next question comes from the line of Marc Goodman.

Ami Fadia - *UBS - Analyst*

This is Ami Fadia on behalf of Marc. A quick question on just your outlook on the generics business, as you think about the next couple of years, based on your review so far. Does Teva still think about its commitment to the generics space the same way as before? And how do you see the margins evolving in the next couple of years? Thanks.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Ltd. - Interim President and CEO*

So Dipankar will take it.

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Generic Medicines*

So in terms of the performance of the generics business, as to how we look at it, the growth of generics business will be dependent on three factors, especially in relation to the US business. The first is the flow of new product launches. The second is the impact of transition products, which are products that have recently lost exclusivity, and the third is price erosion of our base business.

As I have described in past discussions, in the US we expect net price erosion in our base business to be around 5%; however, there are additional price erosion factors at work, which will depend upon the amount of transition products in our portfolio for that specific year. And finally, all this has to be offset by new product launches provided by our industry-leading pipeline.

So for our forecasting, I believe the growth in the US can be around low single-digits on a go-forward basis. There will be some years we can generate mid single-digit annual growth, but that will depend on the mix, as I just described.

You also have to remember that you have 55% of our business, approximately generic revenues that comes from outside of the United States in Europe and other non-US markets. In these markets, we expect mid single-digit growth, and this is consistent with the past behavior of the market.

Ami Fadia - *UBS - Analyst*

Could you talk about the margins itself please?

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Generic Medicines*

Yes, so what we expect, is as far as margins are concerned, our pipeline that we see coming through in the US has a very healthy mix of complex generics products. We expect these products to be more durable in margins. So overall, we see relatively stable performance in margins, as we go forward.

Ami Fadia - *UBS - Analyst*

Thank you.

Operator

Your next question comes from the line of Ken Cacciatore.

Ken Cacciatore - *Cowen and Company - Analyst*

Just wondering, you mentioned that there could be additional cost savings, if you had the generic Copaxone. I guess the corollary to that, if maybe you could discuss a little bit more specifically, a corollary to that would be how do you justify this type of R&D spending, given what we've seen yielding from this portfolio, both generic and brand?

Just the run rate of around $2 billion. I know it's coming down next year, but maybe just discuss how you possibly justify that much spending there?

And then also just on Copaxone, is there any reason why we haven't seen an approval yet? Is there anything holding -- that would be holding in terms of exclusivity or 30 month stay? Just wondering why we haven't yet seen an approval issued. Thank you.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Ltd. - Interim President and CEO*

Okay, so on your first question, I'm sorry if I'm saying it one time after the other, but I've been the CEO for one week. I think it's not even seven days, now, so I cannot get into specifics. And I say again, including your specific question about R&D, I'm looking on every part of the business, on every part of the business, and I'm sure that when I have something to say about it, I will come back to you. And the second question about Copaxone, Eyal?

Rob Koremans - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Specialty Medicines*

I can take that. It would all be speculation, right? We really don't know, so really, what you see it's a crystal ball. You know as much as we do in this respect. Don't want to speculate.

Michael Hayden - *Teva Pharmaceutical Industries Ltd. - Head of R&D*

Yes, I would like to say something, Ken, thank you so much for the question. It gives me an opportunity just to remind our investors that Teva's specialty R&D budget in 2017 is $950 million. It's amongst the lowest in the industry.

And then when you look at what's happening, in fact this is a landmark year for specialty R&D, of course I've been in this job just over four years, and so when you look at this and you see what's happening this year, we have already had three approvals, we are looking at major clinical results this year. We also are looking forward to, although we of course await the FDA decision about SD-809, both for Huntington's and tardive dyskinesia.

And this year, we'll have very important five clinical results. Our anti-CGRP results both in episodic migraine and chronic migraine, our NAV 1.7 antagonist, and Laquinimod both for relapsing and progressive MS. And so the spend is actually on the low side compared to our peers, and I think you'll see today, you'll see further about the productivity this year, but it's an important year for specialty R&D.

Ken Cacciatore - *Cowen and Company - Analyst*

Thank you.

Operator

Thank you. Your next question comes from the line of Umer Raffat.

Umer Raffat - *Evercore ISI - Analyst*

I have a couple, if I may. Perhaps first, should we be expecting any additional announcements of departures from management and/or senior management team, first? And secondly I wanted to come back to something Eyal said.

Eyal, you mentioned you do not see a risk to bank loan covenants, even with the generic competition to Copaxone, and that you'll do whatever it takes to maintain the ratings and leverage. So my question is as an organization, can you cut $1 billion plus in OpEx, if that's what was needed to maintain rating and leverage, and do you think you'll be revisiting dividends as part of the broader reorg, in case there were to be cuts needed? Thank you.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Ltd. - Interim President and CEO*

So we are focused on delivering on our commitments, and I'm very pleased with how the team has come together. And on the second question on Copaxone, Eyal?

Eyal Desheh - *Teva Pharmaceutical Industries Ltd. - CFO*

So first, it's very hard to speculate on the real impact. We gave you the boundaries, and we stand behind them, where we mentioned before, and Yitzhak referred to it in so many words, we aren't going to leave any unturned stone, in terms of our ability to become more efficient, to create the right tools in order to mitigate any changes, any possible changes in leverage in order to maintain rating. And of course maintain debts covenant and we believe that we're there. And regarding dividend, our Board is approving dividends every quarter, and that's the policy.

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

Yes, and if I can just say a word about dividends is, there are no plans to do any changes with respect to dividends, and I'll just leave it at that I think.

Umer Raffat - *Evercore ISI - Analyst*

Thank you very much.

Operator

Thank you. Your next question comes from the line of Jami Rubin.

Jami Rubin - *Goldman Sachs - Analyst*

Sol, just was wondering if you could take a step back. You've been on the Board now for a couple years, you're now Chairman, ran a successful Company, and I'm just be curious to know what your vision is for Teva over the next few years? I think it's pretty abundantly clear to most of us that the Company has not been successful, and when you go back three, five years under the previous CEO, Jeremy Levin, who was more focused on pharma, that didn't work. Erez was more focused on generics, that didn't work.

What do you see as the right structure for this Company? Can the two businesses, generics and specialty brands, co-exist together and unlock value? Or is this an opportunity to really rethink that? I know a couple of other people have been trying to ask the question. But doesn't that also depend on what kind of CEO you choose?

And then I think the question was asked earlier, I don't know that I heard the answer, but would you consider changing some of Teva's corporate governance rules such as requiring that a new CEO live in Israel, where most of the expense base is? I'm just wondering how, now we've had a long year period of underperformance. Isn't this an opportunity to really rethink the future of the Company, the future strategic direction of the Company? Thanks.

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

Yes, so that is a long and very, that's a long and very good -- that's a long-answered question. It's a question that has a long answer, but is a very good question obviously.

And just let me take the last one is, I will repeat what I said before in terms of the CEO. When we find the right CEO, which again, as I say Jami, is my highest priority, is then we will do what it takes to bring that CEO to Teva. And so I'll just leave it at that for now, but we will bring that CEO to Teva.

And in terms of the strategic vision, I have my own obviously prejudices and so on. What I can tell you is when I came to Teva, and especially since I've been Chair, where I've seen things even more closer, I am really impressed with a lot of the assets that this Company has. Without going into detail, the generic assets are spectacular in terms of the logistics, the reach, the touching the lives of so many patients, et cetera.

And on specialty, there are some exciting things going on there as well. And as you know, the line between specialty and generics isn't what it once was. Biosimilars are in between, and 505(b)(2)s are in between, so it's a bit of a continuum.

So you can make arguments in either case. My personal vision is that we have a Company that serves with existing drugs, and we have a Company that develops new ones.

But again, this is part of a more in-depth strategic view in terms of what will be best to unlock value for shareholders, and that's something that will be done by the incoming CEO to a significant extent. Did I answer the question, Jami?

Jami Rubin - *Goldman Sachs - Analyst*

Yes, well this is a very long question, as you said, but yes.

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

We can take it offline.

Jami Rubin - *Goldman Sachs - Analyst*

We'll take this offline. But Eyal, can I ask a follow-up on the question regarding the commitment to the dividend? You don't have a ton of room under your covenants, and both Moody's and S&P both put Teva's credit rating on negative outlook.

In this environment, where you don't have a ton of levers to pull, you have said you are not going to do M&A, you are not going to do buybacks. Not sure why I understand why you're still committed to the $1.6 billion dividend. Would you prefer to face a ratings downgrade than cutting your dividend, is that how you look at it?

Eyal Desheh - *Teva Pharmaceutical Industries Ltd. - CFO*

Well first of all, no. Of course there is a balance, and as we said throughout this call so far, we'll need more clarity. We don't know if there will be generic competition to Copaxone, when and what would be the order of magnitude.

So we do have the tools ready and will implement them as necessary. But as you heard before there are no changes currently. Sol, do you want to add anything to the dividend question?

Sol Barer - *Teva Pharmaceutical Industries Ltd. - Chairman of the Board*

In terms of the dividend, just to reiterate the fact there are no plans to change anything.

Jami Rubin - *Goldman Sachs - Analyst*

Okay, thank you.

Operator

Thank you. Your next question comes from the line of David Maris.

David Maris - *Wells Fargo Securities - Analyst*

Two questions. First Eyal, history lesson. A couple years ago, or a few years ago, Teva went through the same process of reviewing the -- deciding whether to split up the Company, and you explained at the time that it was very clear not to do that because of dis-synergies. So just respecting that times change and administrations change and the rest, but can you go through, at the time what were those dis-synergies, how clear was that decision, or was it border line?

And then lastly, Eyal, I think you also, last week we did a call with your folks about debt and there may be some confusion about this. Our understanding is that you have to lose two notches in order to lose investment grade, and the first notch down is only about a 12.5 basis point impact to about $8 billion of debt, so a very small impact. Is that correct, and can you confirm that?

Eyal Desheh - *Teva Pharmaceutical Industries Ltd. - CFO*

So with the last one, to go out of investment grade requires two notches, and not one notch from where we are today. And I just want to refer you to the press releases of the rating agencies, how to view it, how to view Teva. And I think that it's not just the simple math, but our commitment to maintain ratings, to delever our balance sheet, and to avoid any other uses of cash and capital allocation, as long as our debt to EBITDA ratio is about the desired targeted 3.5 times.

Regarding your first question on splitting up, yes, we have reviewed this a number of times before, and when it will come to a strategic evaluation, of course all of the possibilities to create maximum shareholders for our investors will be on the table. The last time we did review that, you are correct. Your memory is correct.

Our conclusion was that dis-synergies and the Company, and it's more than expenses and synergies. I think Sol talked about it in a previous answer. It's about how the new pharma companies are going to look like.

David Maris - *Wells Fargo Securities - Analyst*

Thank you.

Operator

Your next question comes from the line of Louise Chen.

Louise Chen - *Guggenheim Securities LLC - Analyst*

I have two here. First one is on some of your key generic opportunities. I was wondering if you could give us an update there. Those would be like Restasis Acthar, Premarin, Advair, and EpiPen.

And second question, is are you still interested getting bigger in OTC drugs? You'd mentioned that before at your Investor Day. And then just curious how confident you are, you're going to get exclusivity for Nexium this year? Thanks.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Ltd. - Interim President and CEO*

Dipankar?

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Generic Medicines*

So let me take them one by one. Thank you, Louise. So regarding generics new product opportunities, as I described last month, we are targeting more than 80 different product opportunities that I expect to yield approximately 40 to 50 launches in 2017.

For the products, we have a high confidence in terms of executing. We have clearly outlined them. Now specifically for the products that you mentioned we have developments in our pipeline, but I think the time to update as to where those developments are, at what level of maturity they are progressing, I can simply say as for plan. All the products that you mentioned are in our development, and they are progressing as they should be, and as for the milestones that we have set for them.

Now regarding the point that you mentioned, around what we have for launches, we have a process where we look at the three conditions that have to be met for the launch of a product, the legal positions, the regulatory approval of the product, and operational readiness.

So I feel that we have addressed those. As regarding specific updates as and when we have an update to give on any of the specific products you mentioned whether it is Restasis, or whether it is Premarin, or whether it is EpiPen, we will do it at that time. But I think it is relatively premature at this point in time.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd. - SVP & Head of IR*

Lawrence, we'll take one final question.

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Generic Medicines*

There was one point around the OTC business. As you're aware, as far as our OTC business is concerned, it is a joint venture that we have with Procter & Gamble.

In addition to that, we have also received as a part of our Actavis acquisition, a very nice standalone OTC business. The OTC business in the past, the one that we have with the joint venture, has at least in the last three years, always exceeded the growth rates of the market by a factor of two to three, and we see a very healthy growth continuing in that business.

Louise Chen - *Guggenheim Securities LLC - Analyst*

I'm sorry, I meant to say the store brand drugs, not the branded products, in terms of if you plan on getting larger, or something that you want to expand on.

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Generic Medicines*

The store brand business is only in the US, and at this point in time, there is no plans to expand that business.

Louise Chen - *Guggenheim Securities LLC - Analyst*

Okay, thanks.

Operator

Thank you. Your final question today comes from the line of Ronny Gal.

Ronny Gal - *Sanford C. Bernstein & Co. - Analyst*

First I want to wish the new Board and new CEO good luck ahead. Obviously, you'll have a lot of work in front of you, and I wish you great success. Second, I've got two questions.

First, Eyal, I'm struggling a little bit with the math of losing $800 million in case of the generic entry. You have done a ton of generic businesses. I just look at $3.2 billion business with 80% operating margin. I tell myself you lose 20% of volume, 25% on price, or something like that, and the impact looked to be twice as much. So if you can help me a little bit understanding there the assumptions here around the cash flow, just because, even if it's not a typical generic launch, your estimate seems to be low for the impact here.

And second for Dipankar, the three big products that we're facing near-term generic erosion you referred to those as transition products, Concerta, Pulmicort, and Adderall XR, if we think about the impact moving on from 2016 to 2017, are those products now stabilized? Should we assume they will another step down on the revenue profitability of those products? Or are we more or less in a position where the damage from new entrants has been done, and we are like on a new stable basis?

Eyal Desheh - *Teva Pharmaceutical Industries Ltd. - CFO*

So I'll start on the financial implication and Rob can add some of the assumptions behind what you see in case of a generic launch. You're correct, this is not a regular generic launch. And when we ran all of the possibilities and all the scenarios, and of course nobody has a crystal ball on that, we are also looking back at what happened with the 20-milligram launch. It's a different situation of course, but something to learn from, both on price and volume, that's the worst case scenario we currently see, and we believe it makes sense. Rob, do you want to add?

Rob Koremans - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Specialty Medicines*

Ronny, we have a very solid contracting strategy in place already, and based on what we've seen with the 20-milligram, we've modeled also on the 40. It remains very dynamic, and there's a lot of crystal ball in it, but what we do know is the loyalty to Copaxone of patients and doctors alike. What we do know is that payers are going to be reluctant to force anyone to a generic version of the 40, if they know that the patients are going to switch, in 70% of cases to more expensive oral therapies.

And then also, the uncertainty around the appeal, payers are not going to be forcing anyone to switch if there's a likelihood of having to switch back, after winning the appeal. So all of these things we factored in, and it's also why we really opted to continue to be present with selective marketing and medical spend, and contracting in place. So this is really not a standard generic in any way, and you were correct in stating it.

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Generic Medicines*

Yes, Ronny, so thanks for the question. The products that you mentioned, the answer to that is as far as Pulmicort is concerned yes, it has stabilized. As far as Concerta is concerned, our assumption regarding the competition and pricing is pretty much holding up, and that is in our forecast for this number.

Ronny Gal - *Sanford C. Bernstein & Co. - Analyst*

And Adderall XR?

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Ltd. - President & CEO Global Generic Medicines*

Yes, so as far as our assumptions are concerned there, these prices are stabilized.

Ronny Gal - *Sanford C. Bernstein & Co. - Analyst*

Thank you very much.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd. - SVP & Head of IR*

Okay, thank you, everybody for joining us for the call today. We appreciate your questions. We'll be available throughout today and the rest of the week to take additional questions. Have a great week, and thank you.

Operator

Thank you very much. That does conclude our conference for today. For those of you wishing to review this conference, the replay facility can be accessed by dialing within the UK on 0845 2455205 or from outside the UK on +44 1452 550000, and quoting the reservation number 62969090. Thank you for your participation. You may all disconnect.