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TEVA.TA - Teva Pharmaceutical Industries Ltd Business Outlook Conference Call

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OVERVIEW:

Co. expects 2017 total revenues to be $23.8-24.5b and non-GAAP EPS to be $4.90-5.30.

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PRESENTATION

Operator

Good afternoon, ladies and gentlemen, thank your for standing by and welcome to Teva's 2017 business outlook conference call.

(Operator Instructions)

I must advise you this call is being recorded today, on Friday the 6th of January 2017.

Now I'd like to hand over to your host, Mr. Kevin Mannix, Senior Vice President and Head of Investor Relations. Please go ahead, sir.

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

Thank you, Sophie. Good morning and good afternoon everyone. Thank you for joining us today to discuss Teva's 2017 financial outlook. On the call with me today are Erez Vigodman, Chief Executive Officer; Eyal Desheh, Chief Financial Officer; Dipankar Bhattacharjee, President and CEO, Global Generic Medicines; Dr. Rob Koremans, President and CEO, Global Specialty Medicines; Dr. Michael Hayden, Head of R&D, Chief Scientific Officer; Dr. Carlo de Notaristefani, President and CEO, Global Operations; and David Stark, Senior Vice President and Deputy General Counsel -- excuse me, General Counsel.

We will start the call with presentations from Erez and Eyal before opening the call up for questions and answers. A copy of the slides can be found in our website at www.tevapharm.com.

During this call we'll 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 the 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 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 CEO, Erez Vigodman. Erez?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Thank you, Kevin. Good morning and good afternoon. Thank you for joining us today to discuss Teva's 2017 financial outlook, as well as our continued progress on the execution of our strategy. I will start by briefly discussing our 2017 financial outlook and then Eyal will take you through a deeper dive of the numbers.

For 2017, we estimated that Teva's total revenues will be between $23.8 billion and $24.5 billion. For non-GAAP EPS, we estimate a range of between $4.90 and $5.30 per share. EBITDA for 2017 is expected to be in a range of $8 billion to $8.4 billion. Our cash flow from operations is expected to be between $5.7 billion and $6.1 billion. Cash generated throughout 2017 will primarily be used for paying down debt while we continue to drive organic growth and realize savings from the Actavis Generics acquisition.

2016 was a transition year for Teva, and one filled with significant milestones, highlighted by the closing in August of our purchase of Actavis Generics. It is no surprise to you that the entire healthcare sector has faced significant headwinds, and we have not been immune. We also had some issues specific to Teva, which are not underestimated. We continue to face challenges as a company and as an industry and we expect some of these challenges to continue in 2017.

The 2017 guidance we provided today is significantly below what we provided in the July preliminary outlook. Besides FX headwinds ex-US, we have an EBITDA gap of $1.2 billion emanating from our US generics business.

First, it is important to note that the preliminary outlook for 2017 we presented in July of the combined business included our best judgement based on the available information we had at that time. The majority of the $1.2 billion gap is attributable to not being able to realize new launches in our Teva legacy business in a way that is consistent with our past track-record. As we communicated in November, this impacted the second half of 2016 and will have an impact on 2017 as well.

In addition, the long waiting period for the closing of the transaction had an adverse impact on our ability to fully exploit all opportunities from the business during this long transition period. In 2017, the combined US generic business is expected to generate approximately $6 billion in annual sales. This represents a strong base from which we will grow. It is also important to note that the contribution of Actavis generics in 2017 is expected to be $2.1 billion of EBITDA, which will also grow over time.

Our guidance and financial outlook reflect the current market environment and expectations for 2017. Teva remains well positioned to manage those competitive areas upon which the company can exert control. These will ultimately drive shareholder value. Looking ahead, Teva continues to have the strong foundation for an enhanced financial profile, and more diversified revenue sources and profit streams, backed by strong product development engines in both generics and specialty.

2016 was a transition year. 2017 will be a year of execution. If we take a look at the revenue by business line, you see the increasing significance of our global generics business following the completion of the Actavis Generics acquisition. As you can see, Teva is moving further away from our reliance on Copaxone.

If we look at our profit split, the generics business represents approximately 50% of our business while Copaxone represents approximately 35%, and other specialty products represent the remaining 15%. Now that the transaction has closed, we are seeing a 50-50 split in terms of generics and specialty.

As I mentioned before, our focus for 2017 is execution. We focus on 5 key priorities for 2017 and we are determined to deliver on them. First is the execution of key generics launches around the globe. We have a robust pipeline that is expected to produce more than 1,000 new generic product launches in 2017. Additionally, we plan to further expand this pipeline through our industry leading R&D organization. Second is achieving the synergies from the Actavis Generics transaction and driving additional efficiencies throughout the organization.

Third is delivering on the promise of the specialty pipeline. We have a very important year in 2017, with several anticipated key milestones as we continue to realize the potential of our specialty pipeline. Fourth is defending Copaxone in the face of an important pending legal milestone. Fifth is continuing to generate significant free cash flow in 2017, which we plan to use to pay down debt and maintain our strong balance sheet and investment grade credit rating.

Since the start of 2014, one of our greatest priorities has been to increase the profitability of our generics business. In the first three years of this great effort, we have been able to improve significantly the margins of Teva's standalone generics business. This has been accomplished with a strong emphasis on the cost of goods sold, product mix, and the overall cost structure. We have also prioritized the most important markets. These efforts will now be taken to the next level as we integrate the Actavis Generics business. In 2017, we expect to see the operating margin increase to approximately 30%, generating $4.1 billion to $4.3 billion in operating profit.

I want to take a minute to highlight the geographic diversification of our global generics business. We are structured into three regions and each region is a significant contributor to our net revenues and profit. Our generics business in the US represents approximately 43% to 45% of our generics revenue. Here our robust pipeline and the ability to launch new products are critical to our growth beyond the regular price erosion that occurs in the market. Europe, which represents approximately 26% to 28% of our revenues, is demonstrating stable profitable growth, and we realize benefits from our scale and strong market position.

In the last region, which we refer to as Growth Markets, we generate 28% to 30% of sales. We do that by focusing on key countries where we see significant long-term potential. We continue to expect this region to deliver high single digit increase in profit. Our profit split roughly mirrors what you see here in the sales chart, with approximately 55% of expected profit for the United States, and the remaining 45% from the other two regions.

Our broad generic pipeline from the combined business provides a robust pool of new product opportunities in 2017. We are planning for more than 1,000 launches across many different countries, and this will be one of the most important drivers of our performance this year. In the US we have more than 80 product opportunities comprised of date-certain launches and a large basket of additional potential opportunities. These are the shots on goal we are always talking about. We have carefully risk-adjusted this basket to reflect the uncertainties of litigation outcomes and FDA approval timelines.

Here we see the benefit of the combined Teva and Actavis Generics in having a large diverse pipeline. We are not reliant on any one new product and the risk is balanced. With these risk adjustments, we are projecting more than $750 million in sales from US product launches in 2017, and we believe we can continue to deliver this level of launches in the years ahead. Our US Generics pipeline now has greater than 90% coverage of all potential launches through 2020 in terms of brand value.

In the detail on this slide, you will also see that we are planning for many smaller launches that will add up to be meaningful contributors. They are also likely more durable than some of the short term larger wins we have had in the past. Finally, our leading market position allows us to maximize the value from each of these opportunities, and the many exclusive first-to-market products that bring significant value to our customers.

Let's now talk about synergies and additional cost reductions we are seeing in 2017. We have taken a deeper look into our cost structure to determine how to make the organization even more efficient, following the business combination with Actavis Generics. Again, in 2017 we expect to generate $1.3 billion in net operational synergies, additional cost reductions, and tax savings. To remind you, we said we would generate $1.4 billion in

deal-related synergies and tax savings by the end of 2019. We are making progress on our promise, and we have plans to continue driving additional operational efficiencies in 2018 and 2019.

Let's turn now to the Specialty business. We have a promising specialty franchise that we strongly believe will deliver significant value for the future. Our focus within Specialty is the successful execution in the development and commercialization of our key pipeline assets, most notably our anti-CGRP product for migraine and SD-809. We are also moving along with our exclusive partnership with Celltrion to commercialize certain biosimilar products leveraging Teva's unique cross-functional capabilities in specialty and generic medicine. We are excited about the anticipated results in 2017 of our Phase III asset in migraine, and the expected approval and launch of SD-809 for Huntington's Disease in the first half of the year, and for Tardive Dyskinesia in the second half of the year.

2017 will also be an important year for Copaxone. As you know in the first quarter we expect the district court to issue its decision on the recently completed trial on 4 of the 5 orange book patents protecting Copaxone in the US. We believe in the strength of our IP, but decided to present to investors our base case and our downside case as captured on Slide 12. Our base case does not include generic competition on the 40mg in 2017, but we do anticipate continued sales erosion due to the increased competition. In the downside case, assuming two generic entrants launch in February 2017, we'd expect a further reduction of $1 billion to $1.2 billion of revenues, and $0.65 to $0.80 in EPS, so $0.65 to $0.80 in EPS. We'll continue to manage the lifecycle of Copaxone to minimize the impact to the business over time. However, even in a downside case for Copaxone, Teva maintains today diversified franchises and a promising specialty pipeline that will enable us to weather a potential loss of exclusivity of Copaxone over time.

At the time we announced the Actavis Generics transaction, we told you that deleveraging and maintaining an investment grade rating is top priority for us. We expect our debt to EBITDA ratio to be 3 to 5 times 18 months following the close of the Actavis transaction, which is in Q1 2018. This will keep our balance sheet strong and allow us greater flexibility to continue to potentially allocate capital for the future. As we have stated on our Q3 2016 call, until we reach our target debt to EBITDA ratio of 3.5, the company does not intend to pursue material BD deals.

I will now turn it over to Eyal to discuss our 2017 financial outlook in more detail.

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

Thank you, Erez, and good morning everyone. I will review the financial part of our 2017 guidance and provide some more color on the numbers.

Here are some of the assumptions behind our plan for 2017. First, this is the first full year of Actavis Generic integration and a full inclusion of the results of the Actavis Generic business and Anda. Cost reduction and synergy acceleration are central to this plan. Copaxone 40mg exclusivity is assumed to be maintained throughout 2017 in the base plan. New specialty product launches expected in 2017: SD-809 for Huntington Disease in Q2; SD-809 for Tardive Dyskinesia in Q3; FS and FP Respiclick in Q3 of 2017. Specialty Loss of Exclusivity include Azilect in the US in Q1; ProAir in US in the third quarter of 2017; and Fentora in the US in Q4 of 2017

From Q4 2016, we will update our segment reporting to reflect the following. The generic segment will now also include our OTC activities. Our specialty segment will maintain as before. And a non-segment, other activities, mainly distribution services, including the first full year of Anda.

In 2017 we will deliver 11% top line growth, including FX headwind of $800 million, 11% growth in EBITDA, and strong cash flow from operations of $5.7 billion to $6.1 billion. Earnings per share development during the year will not be linear. We assume 40% to 45% of our EPS to be generated in the first half of the year, and 55% to 60% to be generated in the second half.

In light of the strengthening US dollar, exchange rates will continue to play a role and will have a negative impact of $800 million on sales and $200 million on operating profit. In Venezuela as of December 1, 2016 we will no longer use the Dipro official rate of 10 bolivars per dollar, but use a blended exchange rate which we expect to be approximately 300 bolivars per dollar from December 1, 2016 and on.

Looking at our full 2017 P&L compared to 2016, which only included five months of Actavis Generics and three months of Anda, our total SG&A and R&D are down year over year, to enable operating margin higher than 31%. Teva emerges in 2017 well balanced geographically, with US sales comprising approximately 55% of total sales, Europe sales at 23%, and the rest of the world at 22%.

Looking at business cycle position, generic accounts were 58% of our sales. MS Copaxone accounts for 16%, specialty sales accounts for 17%, and other sales, mostly distribution, are 9% of our total. Revenue increased by approximately $2.4 billion net of FX, driven mostly by Actavis Generic and Anda, while sales of Copaxone and specialty products are down $500 million year-over-year. And of course as we mentioned before we have a total headwind of $800 million impacting mostly the generic sales.

EBITDA grows by approximately 11% to a range of $8 billion to $8.4 billion, and looking at lines of business contribution before G&A allocation, Generic represents 49% of profit, Copaxone at 35%, and Specialty products approximately 14%.

Our key specialty products in 2017 are presented on this slide. Copaxone sales are expected to be between $3.8 billion to [$3.9 billion] (corrected by company after the call); Bendeka and Treanda $600 million to $660 million; the ProAir family at $440 million to $540 million; the Qvar family at $450 million to $490 million; and Azilect which will face generic competition in the US in Q1, between $110 million and $190 million.

Our cash flow from operations is expected to be approximately $5.9 billion of leverage, and free cash flow which includes the divestment of Actavis European business and other non-core assets will reach $6.3 billion to $6.7 billion.

So, in summary we see 11% revenue growth in the plan and they are affected by a full-year inclusion of Actavis and Anda. It includes foreign exchange headwinds of $800 million. We have a robust cost reduction program. We're focused on extracting synergies and expanding cost reduction activity, and we'll continue with this efficiency program in the future. It is not limited just to 2017. This is driving an improvement in profitability to over 30% of operating margin. Cash flow generation is one of our major focus areas for this year and is designed to enable rapid deleveraging to approximately $30.5 billion in debt at year end.

That concludes my part of the prepared remarks. Thank you all, and I would now like to give the call back to Erez for his closing remarks.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Thank you, Eyal. Before we take your questions, I recognize that the gap between the outlook we gave you in July versus our guidance presented today is disappointing. Let me assure you that our management team is fully committed to delivering for our shareholders. A key takeaway from today's call is that 2017 will be a year of execution and we know exactly what needs to be done. We'll focus all of our energy in 2017 on extracting the deal related synergies and unlocking the full potential of our differentiated pipeline and unique global platform.

We are determined to transform Teva even further, and drive efficiencies throughout the organization, with a focus on cash flow generation and paying down our debt. With the strength of our generics pipeline, unique R&D capabilities, and unparalleled footprint, coupled with our existing assets and growing pipeline in specialty medicines, we firmly believe in our long-term growth prospects.

Thank you for your time this morning. Let's now turn to Q&A.

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

Sophie, if you would?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

Yes, good morning. You mentioned that generics launch delays are a key part of the gap that you mentioned. Can you tell us what else you changed relative to pricing erosion assumptions or anything else to make us feel that you're being adequately conservative beyond simply the launch timing?

And sorry if I missed it, Eyal, on the free cash flow, what are you including in free cash flow that makes that number higher than the cash flow from operations? Thanks.

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

All right, Dipankar will take the first question on the price erosion and the assumptions that we've made.

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

Thank you, Gregg. On price erosion, as you know price erosion depends on the mix of products in the portfolio of a company and differs from company to company. We expect to see mid single digit price erosion to continue in our base business in the United States. However, if we include products that have unique market events, such as moving from an exclusive or semi-exclusive position, to seeing additional competition, this erosion could be higher. An example of this kind of a product would be the generics Concerta that we have been selling in the United States.

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

Yes, Gregg, hi. On the cash flow, so the free cash flow includes sale of our Actavis European asset that will be concluded very soon, this is next week, of close to $800 million; capital expenditures of our program of about $1 billion, which is reducing the numbers; and a divestiture program of non-core assets of close to $1 billion. Real estate assets, financial assets that we have accumulated over the years, [IPs] which are not in use of the Company and could be very [distinct too], some other companies and other assets that are very detailed and robust divestiture program.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thanks.

Operator

David Maris, Wells Fargo.

David Maris - *Wells Fargo - Analyst*

Good morning. On the forecast can you talk a little bit, Erez, about not what goes into the forecast, but specifically do you think that you have the team that you need to be able to forecast the business accurately? And when you mentioned that you're moving from a dependence on Copaxone

to generics, are you moving to less predictability? So what changes have you made to make sure that the forecasting process isn't a year from now we're going to be in the same spot explaining away some other things? And then separately what gets you from the high end to the low end of that range? What are the levers that might impact that? Thank you.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Thank you, David, good morning. Let me begin with the second question. So the range provides us with the right buffers, that pertain basically, firstly and foremostly, to risk-adjusted launches in the United States. That's basically the main buffer it provides us with. So we believe that we might have opportunities to launch products that go even beyond the numbers that was indicated here and if we are able to go beyond that we might then of course reach the top end of the range and maybe even more than that. We wanted to be careful of course in 2017, and we risk-adjusted the launches in a way that is supported by the range that is provided, that's on the second question

On the first question I'll ask maybe Dipankar to share the way with you the way we risk-adjust potential launches in the United States.

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

Thank you, Erez. And so the way we have looked at our launches in the United States to arrive at expected revenue from new product launches to be a little in excess of $750 million is the following.

The first is we have looked at our R&D and pipeline initiatives. This gives us, as you have seen, more than 80 product opportunities with a brand value of a little over $30 billion. So fundamentally the 2017 approach to launches is that we have many more shots at the goal.

In this basket of opportunities first we have in mix of date certain launches. We also have a large basket of additional potential launches.

We have carefully reviewed our positions on legal, on the regulatory situation, and our ability to make or source the product. And these have been the essential components of the risk adjustment. We think these combinations positions us very well to generate the revenues that we are talking about in the US of approximately a little over excess of $750 million.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

And maybe to add to that something which has to do the business model of Teva in generics in the United States which is evolving and changing, the dependency on big launches is basically is being replaced by a launch of 40 to 50 and sometimes even more smaller products, which are in many cases are more durable. They decrease the dependency on big launches in a way that enable us also to predict better the net revenues that we generate. And also it will enable us over time to enhance the differentiation and uniqueness of our product portfolio.

Operator

Sumant Kulkani, Bank of America.

Sumant Kulkani - *BofA Merrill Lynch - Analyst*

Good morning, thanks for taking my questions. The first one is on Copaxone. Does your downside scenario include the launch of an authorized generic? And if not, what would be downside be if it did?

Secondly, given this current environment do you still see the potential to take generic prices up on some products? We know those opportunities are few and far between, but if the opportunity does come up, do you still retain that ability?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Yes, so the second question the answer in a very selective fashion, yes. On the first question, I'm not sure we understood, can you repeat the question?

Sumant Kulkani - *BofA Merrill Lynch - Analyst*

Sure. On Copaxone in your downside scenario, if generics come in in 2017, do your assumptions include the launch of an authorized generic by Teva?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Basically our assumption at this stage includes measures that we shall carry out in order to mitigate the negative implications of that launch, and I don't want to dive into all the measures that we will carry out.

Sumant Kulkani - *BofA Merrill Lynch - Analyst*

Thanks.

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

Next question?

Operator

Tim Chiang, BTIG.

Tim Chiang - *BTIG - Analyst*

Hello, thanks. I know you guys mentioned a little earlier in the beginning of the call potential competition with Concerta, and I know Concerta is one of your largest generic products. Mylan just launched a product. What's your expectations in terms of what they're going to do in the markets, given the fact that you guys are the leading player there?

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

Thank you, Tim. Our assumption is in the course of 2017 there will be additional competition from two sources. One is the one that has already happened in January, and we expect an additional competitor to come in in the middle of the year.

Tim Chiang - *BTIG - Analyst*

And just a quick follow-up, how much share do you think you'll be able to maintain with two additional competitors in this market?

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

I think that the shares, the way we would look at it is we'd be evenly split for each of the additional competitors that would come in.

Tim Chiang - *BTIG - Analyst*

Okay. So basically you're going from around 80% market share right now, and so the two new entrants would probably, what, gain 40 to --

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

No, we don't want to dial in to that. Let me just say that we are fairly conservative in the way that we mounted the plan for 2017 in that context.

Tim Chiang - *BTIG - Analyst*

Okay, great, thanks.

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

Next question?

Operator

Ronny Gal, Bernstein.

Ronny Gal - *Bernstein - Analyst*

Good morning, everybody. I guess I've got three if you don't mind.

The first one is just a math question for Eyal. Eyal, it looks like your operating cash flow is about $5.9 billion. I take away from that about $0.9 billion in CapEx, I'm at about $5 billion of sustainable free cash flow. You pay $1.6 billion in dividends, leaving you with $3.4 billion in post dividend cash flows, and that includes Copaxone.

If you take Copaxone way, and I'm assuming Copaxone has at least $1.5 billion of free cash flow associated with it, I'm left with $2 billion of free cash flow, and your debt load is $33 billion as of the end of the third quarter. I'm just asking, are you not getting pretty close to the point where you have to think about cutting the dividend, or you'll have to think about slowing down the rate of paydown on the debt? I'm just kind of stuck with that.

Secondly as long as I got you, can you just quantify for us the combined impact of the Venezuelan change and the currency effect on your operating cash flow? Just because I'm trying to understand same to same how the numbers have changed?

And last but not least, you've mentioned $750 million in launches in 2017. Frankly it's a little bit lower than I thought it would. Can you just tell us how the assumptions around first to file generics have changed? That is, are you expecting to make less revenue versus the innovator in market sales in the exclusivity period? Essentially are early launches less profitable today than they were a year ago?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

(Multiple speakers). Maybe I'll start with the last one. So more than 10 first to files, and $750 million, that's a fairly conservative number that we decided to embed into the plan, and we can generate more than that. And as I indicated before, it is correlated with the range that was provided. And that's a base case for US only. We might generate more than that, and that's a number which might be fairly conservative at the end. Eyal?

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

On the cash flow -- first if I managed to follow your quick calculation, you counted Copaxone declined twice, but we're not losing the product so quickly, and I believe it will continue to generate cash flow for Teva. We give the downside plan or forecast -- but you took something beyond that.

We are, as I mentioned, we are going through a pretty robust program of asset sales, a lot of assets accumulated over the years that we don't need and we don't use. We'll continue to generate a lot of cash in 2017, a little bit will happen every year in the past few years, but in 2017 that's a robust program. We have no intention to change the dividend policy in light of our cash flow projection.

Regarding Venezuela, the impact on sales coming from Venezuela is about $400 million out of the $800 million that we have globally. Impact on profits between $120 million to $150 million which means that the contribution of Venezuela in 2017 is going to be very small, and we know that the exchange rate there is also subject to further changes that cannot be predicted.

Ronny Gal - *Bernstein - Analyst*

All right, thank you very much.

Operator

Umer Raffat, Evercore.

(Technical difficulty).

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

Okay, you can take the next question, Sophie, we'll come back to him.

Operator

Jami Rubin, Goldman Sachs.

(Technical difficulty).

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

Okay, next question, Sophie.

Operator

Douglas Tsao, Barclays.

Douglas Tsao - *Barclays Capital - Analyst*

Hello, good morning, can you hear me?

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

Yes.

Douglas Tsao - *Barclays Capital - Analyst*

Great. Thanks for taking the questions. Just quickly, Eyal, on the generics business the guidance for gross margin, the 48% to 49% looks to be sort of continued progress on that front as well as the overall profitability. Maybe if you could just speak to some of the key drivers there, given some of the dynamics especially on pricing, certainly sort of an encouraging outlook, and just trying to understand how we should think about that, and what opportunities there are for further improvement even close to 49% to 50% down the road.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

So maybe I'll take the question. I indicated that between the deal related synergies and additional cost efficiencies measures that we have been conducting 2017 will generate $1.3 billion of savings. And basically a big part of that pertains to the generic business, and it culminates with the improvement on the basic gross margin front, but especially on the operating margin front.

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

Maybe just to add, so that is correct. All of our cost of goods sold savings are impacting the generics business.

We are looking at a better mix in 2017 compared to the combined Company pro forma of 2016, there were some large products with low margin. This year a lot of the launches that will occur in 2017 are becoming relatively high margin. Margin improvement, ex improvement, ex US is happening also in Europe in the gross margin, and it's also very healthy, close to 50% gross margin of our generic business.

Douglas Tsao - *Barclays Capital - Analyst*

And then just maybe at a high level, Erez, you spoke to a transition of the generics business to sort of smaller products that you thought it would sort of enhance the differentiation of the portfolio. Maybe if you could just talk a little bit about how you see the biggest competitive differentiators for Teva's generics business in this sort of evolving landscape?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Yes, so maybe I'll take it first and Dipankar will then complement that.

So first maybe in the context of the evolving business model, in the past in order for us to generate $750 million sometimes we didn't need more than two products. Nexium, Abilify, Crestor are just an illustration of that.

In the future and already in 2017 in order to generate $750 million in new net revenues, we plan to launch between 50 to 60 products. There are smaller ones, at least apparently with less benefit during the first six months, but with more benefits over time, with more opportunities to differentiate and to make the portfolio more durable.

Just focusing on more complex generics like respiratory products, long acting injectables and others, it will evolve the portfolio, it will make the portfolio over time more differentiated. And that's basically the way we are evolving the business model in the United States. That's number one.

Number two, when we really look at the conjunction of our leading R&D capabilities, go to market platform, economy of scale that we have been employing, we believe that we are differentiated versus the competition in the United States and ex US. At the end of the day we put a lot of focus on the US, but ex US generates for us more than 50% of the revenue, and almost 50% of the operating proceeds. And the ability to capitalize on our unique competitive position in ex US would over time continue growing the business in a profitable fashion.

Dipankar?

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

Just to add to what Erez mentioned is that the nature of our pipeline doesn't mean that we will not have the larger opportunities. We will continue to have.

However, I think the important distinction here is-- and I go back to the statement I made on the larger number of shots at the goal, is that a larger number of products, opportunities that we have included may be smaller in revenue, but the profit from those products will be more durable. And if I could give you a couple examples, we have products which are date certain launches like the generics version of Butrans, which is a higher value product. All the products in the basket that we have of additional potential launches of products like NuvaRing, which are more difficult to make and higher value products, and consequently their value is retained over a much longer period of time.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

And last but not least we continue to transform and to elevate the competitiveness or our operation network. Network today is one of the most competitive networks in the industry, covering a full spectrum of products from volume generics to complex generics. And we believe that the way we have been elevating competitiveness of the network would enable us to compete also on volume generics in the US and in ex US.

Douglas Tsao - *Barclays Capital - Analyst*

Thank you. Finally can you give an update on your generic Advair program?

Dan Motto - *Teva Pharmaceutical Industries Ltd. - Head of Generics Portfolio Management & Business Development*

Hi, this is Dan Motto, I'm here joining the call. So Advair, we continue to work on it. It's a very appealing opportunity, I think everyone knows it's a high barrier product, a complicated product. We haven't filed yet, we'll be open on that, but we continue to work on it and confident that we'll get there eventually.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Yes, we'll believe we'll play an important role in that product.

Douglas Tsao - *Barclays Capital - Analyst*

Okay, great, thank you very much for taking the questions.

Operator

Umer Raffat, Evercore.

Umer Raffat - *Evercore ISI - Analyst*

Hello, can you hear me? Okay, thank you so much, sorry I'm having bad phone issues.

So three questions today, if I may. Eyal, there's a lot of inorganic moving parts into 2017, including Actavis, Anda contribution, incremental impact from Takeda. So if I tease all that out, and I also tease out your big brands, I'm estimating that your assumption on the underlying business excluding all these inorganic parts is about -- it's in a mid single digit decline. Is that in line with the way you model business? Because we're just trying to understand what are you assuming on the underlying business, if tease out all the inorganic stuff and the big brands? That's number one.

Second, perhaps on the branded side, I noticed the slide on key launches does not mention 505(b)(2) Advair. Are you still expecting an approval this quarter? And what type of contribution are you expecting?

And then finally, Erez, if I may, so if I compare the guidance given today on the top line and on EPS, versus the guidance given six months ago, or the expectation six months ago for 2017, how do you bridge that? How do think about what changed? What are the biggest things that changed? Thank you.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

So your first question, look at the Specialty contribution to net revenue. We see a decline in 2017, you are right. So between the loss of exclusivity, ion two products that we indicated already, Nuvigil and Azilect, and the erosion of Copaxone, we see basically top line that goes down by $600 million in Specialty.

By the way also operating profit that goes down by $600 million before efficiency measures. So part of the $1.3 billion, $250 million to $300 million related to Specialty business, and that's something that mitigates the negative ramifications of the net revenues drop that I have just indicated. That's on the Specialty side.

On the generic side, if you take into account the assets, in fact you are right. But part of that is driven by the FX effect. So that's where we are.

And to say something which is more general here, everything that we have done during the last three years was in a quest to diversify away from the moment we lose exclusivity on a number of important products. These important things on the Specialty side. It will take some more time to see the (inaudible) of that once the new products kick in, from SD-809 [TD HD], and then of course TEV-48125 and others. That's part of the process that we have been carrying out during the last three years.

And on the generic side we have a platform today that would enable us to grow the business in a profitable fashion, and that was exactly the notion behind that we did during 2016, also on that front. So that's on the first question. On the third question --

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

Yes, on the 505(b)(2) Advair, yes, Michael.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Michael, please?

Michael Hayden - *Teva Pharmaceutical Industries Ltd. - President of Global R&D and Chief Scientific Officer*

Erez, I was disconnected, can you repeat the question please?

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

Just the status of the 505(b)(2) for Advair in the United States.

Michael Hayden - *Teva Pharmaceutical Industries Ltd. - President of Global R&D and Chief Scientific Officer*

Yes. Our Advair, we're making great progress and we are expecting to submit this in 2018. In addition, we are looking at a total of seven approvals in 2017 for a whole host of products. And I think what you're seeing on our Specialty pipeline is really a maturation, and one way to judge the Specialty pipeline is not only the NDAs for approval but also clinical results and the number of new products entering the pipeline.

And for the first time in Teva's history, in 2017 we will have eight INDs all entering the pipeline from organic growth. So the capabilities, the crystallization of the capabilities and the hard work that's happened over the last four years leading to strengthening and deepening of the pipeline in crucial areas of unmet need including brain and mind, migraine and pain, and respi, and these products also will be utilizing different kinds of capabilities, for example in respi technology digital approaches to enhance differentiation of our products. So 2017 will be a year of crystallization and maturity of the pipeline, both in terms of the strength of early R&D activity and also the number of submissions and also the number of approvals that are expected.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Thank you, Michael.

Umer Raffat - *Evercore ISI - Analyst*

Sorry, I meant to ask about the 505(b)(2) Advair? The one that you guys submitted in 2016? I believe the PDUFA was this quarter, so I was more curious about that, your thoughts on approval, and what you expect from launch performance?

Michael Hayden - *Teva Pharmaceutical Industries Ltd. - President of Global R&D and Chief Scientific Officer*

Rob, do you want to take this?

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

Happy to do that, Michael. So we still expect that it's still planned, it's going to be -- our 505(b)(2) products there, we'll expect peak sales of about $200 million, it will have a slower uptake and expect it to start this year, which we'll see maybe small numbers in this year and that's the way we've modeled it. But it's still very much on track, Umer.

Umer Raffat - *Evercore ISI - Analyst*

Got it. And the one for Eyal.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

(Multiple speakers) I'll take your third question, Umer. So I indicated that when we look at the outlook that was provided in 2016 versus the guidance for 2017, I indicated before that all the parts of the business are in line with the guidance but US generics.

Ex US we have just FX headwind of somewhere in the neighborhood of $200 million, and the rest basically focuses on US generics with something in the neighborhood of $1.2 billion gap in terms of EBITDA. We use basically very reasonable assumptions in the model, we modeled, based on past performance in the US and pipeline assets of Teva. In retrospect a number of potential launches were not realized in the second half of 2016 as we indicated already would carry over, affect 2017, and we decided to lower expectations that pertain to the Teva's legacy business in 2017, and that explains the majority of the gap.

Umer Raffat - *Evercore ISI - Analyst*

Got it. Thank you.

Operator

Jami Rubin, Goldman Sachs.

(Technical difficulty).

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

Next question, Sophie.

Operator

Liav Abraham, Citi.

Liav Abraham - *Citigroup - Analyst*

Good morning. Just a quick question on SD 809 in Huntington's. Any thoughts regarding the launch trajectory of the drug and the contribution that you've assumed in your modeling for 2017?

And then the second question on by biosimilars. I appreciate the collaboration with Celltrion, but you guys are still somewhat subscale in this area, and it is a big opportunity over the next 5 to 7 years. So just any updated thoughts on bolstering your presence in that arena? Thank you.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

Hello, Liav, good morning. I'll start with the biosimilar question.

So today we are generating $300 million net revenue from biosimilars already. We expect with the partnership with Celltrion to almost double that during the next number of years. And we are in a very active fashion, we are exploring additional opportunities to collaborate with relevant players on the commercialization front and also on the development front.

And I believe that during the next year we'll see more collaboration potentially on both the commercial front and the development front, in order to bolster further our pipeline and product portfolio in biosimilars. That's the intention, that's the strategic intention, and we'll deliver on that.

On the first question we expect an approval for HD, SD-809 HD by the end of Q1. We are fully prepared for launch and our assumptions for 2017 are fairly conservative on that one, minimal effect in 2017 from that launch.

Michael Hayden - *Teva Pharmaceutical Industries Ltd. - President of Global R&D and Chief Scientific Officer*

If I could just add to that on the biosimilar front, of course in addition to these business development activities, there is significant activity in house for developing biosimilars that will reach the market 2020. Capabilities are fully in place and this will be complementing the biosimilar activities that will be derived from external activities. But the internal activities are significant, deep, and highly capable.

Liav Abraham - *Citigroup - Analyst*

Thank you.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Great, thanks very much. Just two quick ones here.

First, the longer term generic growth target of 5%, is that a target that still holds at this point? Or is that something that's under review? And thinking about longer term generic operating margins, is a mid-30% level still achievable, as we think about 2019, 2020 timeframe?

Final question, you've addressed some of these disappointments on the generic launch portfolios being part of the shortfall in the numbers, or much of the shortfall. I just need a little more color, was this an issue that the assumptions were too aggressive? Something in the model isn't delivering? Or is it really just about market dynamics and just getting unlucky on some of these risk-adjusted opportunities in the second half of last year? Thank you.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

So thanks, Chris. Maybe first with the last one. I think that these are things that which should not happen but might happen in the generic industry, and that's something that pertains to less market dynamics, more regulatory front, and IP basically, and it might happen.

We look at basically short-term goals and sometimes you are not able to reach all your short-term goals. You need to be able to do it in a balanced fashion, but sometimes you might face what we faced during the second half of 2016, something that we discussed already with the street in November.

But we are basically drawing all the conclusions from that in order to be even more conservative when we risk-adjust shots on goal. But having said that I believe that a more balanced portfolio of products and a bigger number of short-term goals that we are witnessing now will enable us to risk-adjust better going forward.

That's the third question. Dipankar?

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

Thank you, Erez. So on the growth prospect of the generics business, you have seen that the sources of revenue for us for the generics business is very well diversified. Now in terms of the individual components, in the US market we believe that our R&D efforts and our pipeline initiatives can

deliver more than $750 million of new product sales annually. And some years it might be a little more than that, some years it might be that, some years it might be less than that. But this will significantly offset the price erosion that we will see.

In addition to that, if you look at outside the United States, in Europe we believe that we are well positioned because of our leadership position as well as our pipeline, to deliver mid single digit growth. And in the growth markets we expect that we will be able to deliver longer-term, mid-and longer-term, mid to high single digit growth. So overall the prospect of the growth as a combination of these three is consistent with what our expectations in the past have been.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd. - President & CEO*

And maybe, Chris, just to underscore the 5% related to the US market [always], and the notion was that if we are able to launch products that generate more than 10% growth before erosion, we might beat the 5%, net 5% growth in the US. $750 million of new net revenues for launches basically represents more than 10%. And if we are able to launch at least $750 million of new net revenues on yearly basis, we believe that on average we are able to grow the business at around 5%.

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

Thank you, Sophie. Thank you everybody for joining us today for this call. We'll be available throughout the day for additional calls. Hope to see you all next week as well, and thank you again.

Operator

Thank you. Ladies and gentlemen, that does conclude your presentation for today. Thank you for participating. For those of you wishing to review this conference, the replay facility can be accessed by dialing within the UK on 08452455205 or alternatively on country code 00441452550000. The reservation number is 44010191. Once again, thank you for participating and you may now disconnect.
