THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

TEVA.TA - Q3 2017 Teva Pharmaceutical Industries Ltd Earnings Call

EVENT DATE/TIME: NOVEMBER 02, 2017 / 12:00PM GMT

OVERVIEW:

Co. reported 3Q17 revenue of $5.6b, GAAP operating income of $0.4b and GAAP EPS of $0.52. Expects 2017 revenue to be $22.2-22.3b and EPS to be $3.77-3.87.

CORPORATE PARTICIPANTS

David M. Stark *Teva Pharmaceutical Industries Limited - Group Executive VP & Chief Legal Officer*

Dipankar Bhattacharjee *Teva Pharmaceutical Industries Limited - President & CEO of Global Generic Medicines Group*

Hafrun Fridriksdottir *Teva Pharmaceutical Industries Limited - EVP & President of Global Generics R&D*

Kåre Schultz *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Kevin C. Mannix *Teva Pharmaceutical Industries Limited - Head of Global IR*

Michael McClellan *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

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

Robert Koremans *Teva Pharmaceutical Industries Limited - President & CEO of Global Specialty Medicines Group*

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

Yitzhak Peterburg

CONFERENCE CALL PARTICIPANTS

Christopher Thomas Schott *JP Morgan Chase & Co, Research Division - Senior Analyst*

David Reed Risinger *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

David William Maris *Wells Fargo Securities, LLC, Research Division - Senior Analyst*

Gregory B. Gilbert *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Jamilu E. Rubin *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Kenneth Charles Cacciatore *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Liav Abraham *Citigroup Inc, Research Division - Director*

Marc Harold Goodman *UBS Investment Bank, Research Division - MD and United States Healthcare Analyst*

Timothy Chiang *BTIG, LLC, Research Division - MD and Specialty Pharmaceutical Research Analyst*

Umer Raffat *Evercore ISI, Research Division - Senior MD and Fundamental Research Analyst*

PRESENTATION

Operator

Thank you for standing by, and welcome to the Teva Pharmaceuticals Third Quarter 2017 Financial Results Webcast. (Operator Instructions) I must advise you the webcast is being recorded today, Thursday, the 2nd of November 2017. I would now like to hand the webcast over to your first speaker today, Kevin Mannix, Senior Vice President of Investor Relations. Please go ahead, sir.

Kevin C. Mannix - *Teva Pharmaceutical Industries Limited - Head of Global IR*

Thank you, Kalem. And thank you, everyone, for joining us today to discuss Teva's Third Quarter 2017 Financial Results. On the call with us today are Dr. Sol Barer, Chairman of the Board; Kåre Schultz, our President and CEO; Dr. Yitzhak Peterburg, our outgoing CEO; Mike McClellan, Interim Chief Financial Officer; Dipankar Bhattacharjee, Global Generic Medicines; Dr. Rob Koremans, Global Specialty Medicines; Dr. Michael Hayden, Global R&D Chief Scientific Officer; Hafrun Fridriksdottir, Global Generics R&D; Dr. Carlo De Notaristefani, Global Operations; and David Stark, Chief Legal Officer. We will start the call, which will last approximately one hour, with a review of the quarter and revised 2017 outlook by Yitzhak and Mike followed by remarks from Kåre and Sol. We'll then open the call up for questions and answers. Please note that Kåre will not be participating

in today's question-and-answer session. A copy of the slides of the presentation can be found on our website at www.tevapharm.com as well as on our Teva Investor Relations app. 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 represented 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 will now turn the call over to Yitzhak. Yitzhak, please.

Yitzhak Peterburg

Thank you, Kevin, and hello, everyone. I would like to start by offering a very warm welcome to Kåre. In just a few minutes, Mike will provide a thorough overview of our third quarter results and outlook for the remainder of the year. Over the past 9 months, it has been an honor to serve as Teva interim CEO, especially, during such a challenging period. I am -- very much appreciated having the full support of Sol, my fellow Board directors and the entire management team to take the necessary, important, and in some cases, very tough measures to help bring Teva back on track. I'm pleased with the progress we have made to date on key assets in our specialty pipeline, which included the approvals and launches of AUSTEDO for the treatment of chorea associated with Huntington's disease and tardive dyskinesia in adults. We also took measures to expedite the review of our recently submitted BLA for fremanezumab in anti-CGRP monoclonal antibody. During the quarter, we acquired a U.S. FDA priority review voucher to allow us to accelerate the review time for fremanezumab, which, if approved, will be among one of the very first to enter the market in a new class of drugs for the preventive treatment of migraine. We are thrilled about the potential to make this therapy available to the millions of people around the world who live with the debilitating effects of migraine. These achievements also represent an important part of the company's ongoing efforts to address the erosion of our largest product COPAXONE due to generic filers. This erosion accelerated significantly last month following a competitor's approval and the launch of a generic COPAXONE 40-milligram in the U.S. We have been preparing for this transition through our investment in geographical products and pipeline diversification and this investment will certainly take time to bear fruit and to begin to contribute steadily to our cash flow. We've also moved forward with the divestitures of several products and businesses, including yesterday's completed sale of PARAGARD and soon to follow Plan B One-Step to allow us to progress the repayment of our debt. We have now signed contract to divest noncore assets that will generate approximately $2.3 billion in net proceeds with the majority expected to be collected in 2017. I truly believe that Teva possesses unique capabilities and strengths that can serve as tremendous assets, while it looks to meet the demands of an evolving global health care industry. I believe that the company will be able to step out of this situation as a better and stronger company, and it will do that under the leadership of Kåre, who I wish every success in the future. I'm looking forward to working with Kåre as a member of our Board, where I now return to. Thank you all. It has been a privilege. I will now turn the call over to Mike to provide more insight into the numbers. Mike?

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

Thank you, Yitzhak. Good morning, everyone, and please join me as we review the results of the third quarter. So revenues this quarter were $5.6 billion, up 1% compared to Q3 of 2016. While we had another month of Actavis quarter as well as the revenues of ANDA, which was consolidated in Q4 2016. There have been continued headwinds in the generic business, while our specialty business was impacted by the loss of exclusivity of several products. We'll dive into the revenue trends in the coming slides. On a non-GAAP basis, operating income was $1.5 billion, resulting in $1 EPS; while on a GAAP basis, operating income was $0.4 billion and EPS was $0.52. As in Q1 and Q2 of this year, the effect of our mandatory convertible preferred shares was anti-dilutive. So the number of shares remains at $1,017,000,000. Now focusing on our non-GAAP P&L for the quarter. Operating income is down 18% and EPS is down 24%. The profitability of the company was down to 26.2% from 32.2% in 2016 Q3. This reflects a lower gross profit of 53% in the quarter compared to 61% in the same quarter of the previous year. This is driven by several factors. The inclusion of ANDA distribution business as well as lower margins in the generics, specifically, in our U.S. generic market. This was partially offset by reductions in expenses, mainly in our R&D and sales and marketing. Our cash flow from operations was over $1 billion, landing at $1.1 billion in Q3 2017. And this quarter had no significant one-time payments as we had seen in the first half of the year. For non-GAAP adjustments for the quarter, they were just under $0.5 billion net. We had impairments of over $400 million, mostly relating to assets acquired as part of Actavis. Amortization expenses

were $357 million, which is in line with our current run rate. During the quarter, we also acquired an FDA priority review voucher as mentioned by Yitzhak, which will allow us to accelerate the review time of fremanezumab, one of our key specialty assets for the treatment of migraine. You can see it here as an R&D expense. Finally, this quarter, we utilized historic capital losses related to the Actavis acquisition, resulting in a large -- unusually large tax effect in our non-GAAP adjustments. Starting with the balance sheet. Total assets at September 30 were $86.1 million, a slight reduction from June 30. The largest move was an increase in other current assets, reflecting the transfer of the assets related to our Women's Health business into a held-for-sale position. This includes an allocation of goodwill following the announcement of the upcoming divestments of these assets. As you may have seen yesterday, we closed on the first of these divestments with PARAGARD. On the liability side, as of September 30, 2017, our debt was $34.7 billion compared to $35.1 billion at June 30, 2017. The decrease was mainly due to $600 million of debt repayments on our 5-year term loan, our revolving credit facility and other short-term loans, partially offset by foreign exchange fluctuations on our euro-based bonds, which raise the debt by $200 million. 8% of our debt is now classified as short-term compared to 4% at June 30, 2017, mainly due to changes in the current portion of our long-term debt. Foreign exchange impacts -- impacted our results with the exception of the Venezuela bolivar were positive on the top line and negligible on operating income. In the third quarter of 2017, we continue to update the exchange rate we used to translate results in Venezuela and decided to use the DICOM rate of 3,345 bolivar per dollar, which is not materially different from the blended rate we calculated internally. This resulted in the decrease of $243 million in revenues and $25 million in GAAP operating income and $15 million in non-GAAP operating income compared to the previous quarter of 2016. In light of political and economic conditions in Venezuela, we exclude these changes in revenues and operating profit from any discussion of local currency results. Our Q3 EBITDA was $1.63 billion and EBITDA for the last 4 quarters now amounts to $7.3 billion. Cash flow: As mentioned previously, this quarter cash flow amounted to $1.1 billion as we had no exceptional payments in this quarter. In the first half of the year, I remind you that we had approximately $1 billion of payments, including $0.5 billion for our FCPA settlements, $250 million for the final settlement of certain hedging transactions and $225 million related to the ciprofloxacin settlement. Looking at our liquidity measures. While debt is reducing slowly, offset by some headwinds in the currency impact, this quarter's EBITDA is lower than that of Q3 2016, resulting in a net debt-to-EBITDA ratio of 4.7, up slightly from the 4.57 last quarter. Leverage, however, decreased slightly to 53%. Now getting into the quarterly revenues. We saw an increase of 1% quarter-over-quarter, made up of a number of movements. First of all, U.S. generics revenues were down $102 million, despite the increase of an additional month of the Actavis generics compared to the same quarter in 2016. The U.S. business was impacted from continued price erosion, which was 10% in Q3 2017 on the base business as compared to the same quarter of last year as well as accelerated FDA approvals of additional generic versions of competitors in our base business as well as lower volumes of the Concerta-authorized generic following additional competition. Our EU and Rest of the World's generics, excluding Venezuela, were up slightly due to organic growth and an extra month of the Actavis acquisition compared to 2016 Q3. I'll address COPAXONE separately in a minute. But our other specialty products increased $47 million due to strong performance in our respiratory and oncology franchises, partially offset by the loss of exclusivity of AZILECT. Other revenues were up $300 million, mainly reflecting the inclusion of ANDA business, which was consolidated first in Q4 of 2016. Currency fluctuations, particularly, the euro, resulted in the slight increase in sales, which was more than offset by the devaluation in Venezuela that I just discussed, resulting in a net decrease of revenues by $169 million. So for COPAXONE, revenues were almost $1 billion in Q3 2017, which is a decrease of 7% compared to the third quarter of 2016. The revenues were down 7%, mainly due to lower sales in the U.S., impacted by a $55 million increase in managed care rebate accruals for the inventory in the channel at September 30, following the FDA approval of a generic competition to COPAXONE 40-milligram, and in addition, we had lower volumes of COPAXONE 20-milligram compared to 2016. In terms of geographies, in which we generate our income, The United States generates slightly more than 50% of our revenues, in line with the results of last year. Europe was up slightly to 27%, while the Rest of the World markets generated 20% of our revenues, down from 23% influenced heavily by the Venezuela devaluation. Compared to this quarter of Q3 2016, the share of other revenues has increased from 4% to 10%, following the inclusion of ANDA. Specialty accounted for 36% and generics was down to 54%. For the quarterly non-GAAP operating profit, we are down overall 18%. The largest decrease was in the profit of our generics business, mainly due to lower revenues and margins in the U.S. COPAXONE revenues and profit were down slightly based on the discussion I just had. And the profit of our other specialty products increased by $109 million due to higher revenues and significant cost-savings. Financial outlook: Today, we are updating our full year guidance, expecting revenues of $22.2 billion to $22.3 billion, EPS between $3.77 and $3.87 and cash flow of $3.15 billion to $3.3 billion. Our 2017 financial outlook was lower to reflect the following events. An earlier-than-expected at-risk launch of a generic competitor to COPAXONE 40-milligram with an expected impact on EPS of approximately $0.30. In addition, we have lower-than-expected contribution from new generic launches in the U.S. We now project approximately $400 million of revenues from new product launches this year compared to a previous projection of $500 million. In addition, we have increased price erosion and volume declines in our U.S. generic business, including increased competition to our largest product, the Concerta-authorized generic. In addition, we have a lower cash flow from operations due to the reduction in net income as well as a delay in our resolution of our working capital dispute with Allergan, which is now scheduled to conclude in 2018 instead of Q4 2017. At this point, I'd like to turn it back over to Kevin Mannix.

Kevin C. Mannix - *Teva Pharmaceutical Industries Limited - Head of Global IR*

Thanks, Mike. We're just going to have some remarks from our CEO, Kåre Schultz, followed by remarks from our Chairman, Sol Barer. Kåre, please.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Thank you, Kevin. I'm pleased to be here and I would like to start by saying, I look forward to getting to know Teva shareholders and analysts so that we can have an open dialogue about Teva's progress in future. I have long admired Teva as a leader in the pharmaceutical industry. What drew me to this company and what makes Teva unique amongst its peers is its relentless commitment to developing medicines that help millions of people around the world lead better, healthier lives every day. Teva has achieved an extensive global footprint while continuing to build on the Israeli culture that has served as its foundation for over a century. I'm confident that the promise of Teva's specialty pipeline covered with the disciplined focus on executing key generic launches and the strength and scale of operations will allow Teva to compete successfully as the global pharmaceutical industry continues to evolve. I've spent most of my 30-year career overseeing both generic and specialty product portfolios. I am familiar with the ins and outs of the manufacturing footprint and development pipeline this entails. But, of course, will need to study Teva's operation closely at first hand. We need to build on the company's ongoing efforts to strengthen operations, improve financial performance and reposition Teva operationally and financially. I recognize the significant debt burden that Teva is currently under. And it will be an absolute priority for me that we stabilize the company's operating profit and cash flow in order to improve our financial profile. Although I'm not participating in the Q&A today, I do look forward to speaking with you and answering your questions at the appropriate time. With that, I will now pass the call to Sol.

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

Thank you, Kåre, and thank you to everyone for joining us today. Before we move to Q&A, I wanted to share some personal reflections accumulated over the 10 months that I have had since my appointment as Chairman of Teva. I've shared with you my deep commitment to the company and the measures we would carry out to transform Teva. Since then we have taken steps, including, strengthening our Board by welcoming 4 world-class directors, whose wisdom and expertise are already adding great value. We also conducted a thorough search, did not compromise, and ultimately, we found the right CEO for Teva, today marks the beginning of the next chapter for our company. I would like to emphasize how pleased we are to welcome Kåre to Teva as our new CEO. Kåre is a seasoned veteran in the health care industry. Over the course of his 30-year career, he has developed a unique perspective, overseeing generic and specialty drug portfolios, while managing complex business operations around the world. He brings a strong sense of corporate citizenship and his disciplined commitment to excellence makes him a clear professional and cultural fit with our company. This is a particularly demanding time for Teva. And we may continue to face significant headwinds. But I want you to know that the Board and I remain deeply committed and confident in the strength of the company, our people and in the future of Teva, and even more so that Kåre is the best person to lead Teva now and well into the future. Let me assure you that Kåre will take a fresh perspective as he begins evaluating the opportunities in the near and long-term to improve our performance, build on the company's strengths and position Teva for the future. The reemergence of a successful Teva is important to all of us, for the benefit of patients and shareholders alike. Before I close, I would like to take this opportunity to thank Dr. Yitzhak Peterburg on behalf of myself and Teva's Board of Directors for taking on the interim leadership role at a particularly challenging time, enabling a smooth transition, while remaining focused on our priorities. Throughout our history, we have never shied away from change or challenges. That's why Teva and our employees will continue to do whatever is needed to improve our performance. I know Kåre shares this commitment and has the background and proven experience to deliver the results that will reestablish Teva as a leader in the industry. So with that, we will start the Q&A session. Operator, first question, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from Liav Abraham from Citi.

Liav Abraham - *Citigroup Inc, Research Division - Director*

A couple of questions. Firstly, can you talk a little bit about your -- the pricing trends in the generics base business. I think last quarter, you talked about pricing declines of -- or prices in the high single-digit range. Is that what you are seeing at the moment as well? And then, can you talk a little bit about your credit rating, just given some of the operating cash flow trends, is investment grade, you didn't allude to that in your remarks. So, is investment grade still a priority for the company? How do you plan on -- if so how do you plan on maintaining that over the next 12 months? And would you consider some kind of equity raise or hybrid structure as a means of paying down debt in order to maintain investment-grade rating?

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Limited - President & CEO of Global Generic Medicines Group*

This is Dipankar. I will take the question on price erosion. As you may recall, last quarter, we explained the methodology that we adopt for our price erosion for the base business, which excludes our new products, which are products that have been launched in the past 12 months; and transition products, which are products, which, for one reason or another, have either enjoyed exclusivity or are enjoying some kind of a market exclusivity, for which, they have had higher prices and volumes and are now going through a transition of lower prices and volumes. So in the second quarter, we reported a price erosion of a little over 6% for our base business compared to the comparable quarter of the prior year. Since then, in our third quarter, we have seen an increase in price erosion. And as Mike explained that we have now seen, in the third quarter, the price erosion to be 10%. This is primarily driven by 2 factors. The first is that the increasing FDA approvals that are happening for products, for which, already generics players exist in the market. So the new players try and drive some gains in market share based on volumes -- based on lower prices. And the second is that the consolidation of the 3 -- of the customers into 3 GPOs, which now account for more than 85% of generics, which is in the U.S. market has also, while their RFPs have created additional pricing pressure. In terms of the rest of the year, we expect that these price erosions will remain at these elevated levels.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

This is Mike. I'll take the second part of the question. Since the beginning of the year, we've really been focused our efforts on extracting our deal synergies, reducing our cost base and divesting our noncore assets. This is really been with the goal of reducing our leverage. We continue these efforts, especially, facing all of the headwinds that we have. And we also -- we enjoy an active and open dialogue with our credit agencies. And we'll continue to work with them as we consider and prepare for all foreseeable scenarios. We have some important decisions to make in order to stay investment-grade. But we feel we'll be in a better position to really address that in our future calls. We'll be working on our 2018 plan together with our new CEO, and evaluating all options to make sure we do what's in the best interest of all stakeholders. Currently, we do not have a plan to raise equity. But these are some of the things that we will be considering together with new management and the Board as we move into the future.

Operator

And your next question comes from the line from Tim Chiang from BTIG.

Timothy Chiang - *BTIG, LLC, Research Division - MD and Specialty Pharmaceutical Research Analyst*

I know, Kåre, you can't really make any comments. But maybe the rest of the management team can sort of prioritize what you think 2018 -- the key items, that you will need to address in 2018 to, one, strengthen the balance sheet. Two, also shore up the generic business. Are there any items that you think -- that you're seeing that are actually somewhat encouraging down the road for you?

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

Yes. So, Tim, this is Mike. I'll take the first part and then I'll let Dipankar comment a little bit on the generic business. So we will continue to see strengthening our balance sheet as a priority. We are facing headwinds in the generic business. And we're facing headwinds now in our COPAXONE business with the launch of a 40-milligram generic. But we will continue to take all the levers, continue to look at our cost base. We will be doing a review to see if there is additional noncore assets that it would make sense to monetize, and do everything possible to strengthen our balance sheet. But we will be coming back to you with a more drawn-out plan in the coming quarters. After we've had time to really discuss it with new management, take into consideration, all of these evolving events and come back with a very solid plan. Dipankar, you want to talk a little bit about generics?

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Limited - President & CEO of Global Generic Medicines Group*

Yes. Thank you, Mike. So regarding the generics business, I'd like -- I like to remind you that the way our generics revenues are structured is approximately 55% of our generics revenue comes from outside the United States and 45% of our revenues come from the U.S. So as far as the business outside of the U.S. is concerned, it has a very different complexion. The price erosion is not really a factor in the European business that we see, very low single-digit price erosions, in the Rest of the World those businesses see very little price erosions. In fact, often, we have opportunities to raise prices. Because they're largely branded generics market. These markets are less volatile. And our prognosis, as far as these markets are concerned, continues to remain fairly optimistic. As far as the U.S. generics business is concerned, there are really 2 areas of focus, both for this year as well as going into next year and all of next year. The first is executing our launches. Now in terms of the generics business, it is not a recent development. It has been there for a while, which is, that the base business erodes as new and additional competitors come into the market. And this, in recent times, has been exacerbated by the increase in the FDA approvals. But the real driver of growth and value creation in our generics business is in the execution of our launches. We have over 300 ANDAs filed in terms of our pipeline. And we have, in addition, another 300 developments that we are evaluating and remain yet to be filed. So we are quite optimistic about our pipeline. We are targeting approximately $200 billion of brands. So overall, as far as 2018 is concerned, our focus, in terms of value creation, will continue to remain around new product launches. Regarding the commodity business of the United States generics, I think, that we have about 2/3 of our business, in what we classify as base business, we continue to remain very disciplined and focused on those parts of the base business that creates value. And then in the remaining tail of the commodity-type base business that we have, we look at products, where we can change the profitability profile of those products, and if that is not possible, we discontinue the product. So those would be the key elements and ingredients for 2018 and beyond for improving the profile and value of our generics business.

Timothy Chiang - *BTIG, LLC, Research Division - MD and Specialty Pharmaceutical Research Analyst*

I just had a one quick follow up, if I may. Are you guys still reiterating your debt paydown target of $5 billion? I didn't see that in the press release?

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

No, Tim. Due to the lower cash flow in Q4, particularly, the Actavis working capital disputes that's moved out. And due to the potential timing of the receipt of the divestments, we are looking more at a range of $3.5 billion to $4 billion. This is partially impacted by currency rates. We've seen the euro strengthen over the year, and we have over $8 billion in bonds denominated in euros. So the overall impact of the paydown is being partially offset by currency impacts. But we're not going to quite get to $5 billion this year as we'd originally planned, mainly due to some of the slippage of the cash flow from Q4 into Q1. But we are aiming to pay down the debt as quickly as possible. We are using the proceeds yesterday that came in from the PARAGARD sale, have already been used to pay down term loans. And we plan to do the same with other divestment cash as well as the cash flow generated in Q4.

Operator

Your next question is from the line of David Maris from Wells Fargo.

David William Maris - *Wells Fargo Securities, LLC, Research Division - Senior Analyst*

So, Dipankar, you said that you'd have $500 million to $750 million of generics in 2017, that were kind of pushed out from '16 and then that came down to $500 million, now it's $400 million and the same thing happened with the price erosion expectations. So I have a couple of questions. First, is this just the -- how less predictable the business has become or is there something with the -- with either the finance or the forecasting ability of Teva, given all the turnover to predict the business? And then separately, on -- if we assume that the debt is downgraded, as we think is likely, can you walk us through what the debt maturities are in the next couple of years? And what you think the added cost would be under, say, if you wanted to refinance that -- the near-term debt, maybe in the next few years versus the current blended rate, what that difference would be? And also, is there anything, I think, we've spoken about this before. But the -- in a debt downgrade, is there any debt that automatically becomes at a higher rate? And can you just walk us through or reconfirm the debts about $6 billion and 12.5 basis points?

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Limited - President & CEO of Global Generic Medicines Group*

David, this is Dipankar. I will take the first part of your question regarding the new product forecast. So first is, we always spoke about $500 million right from February onwards, as what we felt good about and anything beyond that had significant uncertainties associated with that. So for the $500 million, also, we spoke that about launches, which were date certain and there were certain launches where of the 4 stage gates that we had to go through, which is clearing the way through legal, getting a regulatory approval, operational readiness and then our ability to launch the product. We, in most of those instances, we had at least 3 of those bases covered. Now, why did the number go down from $500 million to $400 million to what we are forecasting at this point in time? The most significant contributors to that were really a handful of products. And let me give you some examples. So we had anticipated getting an approval for the generics of Lialda in the second half of the year. In working together with FDA, our understanding is, most, if not almost all of the approval processes and the reviews are close to completion, nevertheless, we are still awaiting approval. The second example I can give you is the generics of NuvaRing, which we had planned. And we had -- we thought it was a relatively strong position that we had in the appeal that was carried out. But the court decision went against us. So those are the kind of things that contributed significantly to the change in the number. Now I don't think the nature of the business has changed. Our new product forecast has built-in date-certain launches. And where we feel relatively good about because most of the clearing of the way has been done. But this has been the nature of the generics business for a very, very long time.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

Hi, David. This is Mike. I'll try to address the second 2 questions, mainly, around the debt. Of course, we're going to be working with our rating agencies and other partners on this. But in the case that there was a potential downgrade, it's really just the $6 billion of term loans that would be impacted immediately. We have over 80% of our debt in fixed rates at this point. The term loans would be subject to a 25-basis point-increase upon a notch downgrade in their interest rates. In terms of maturities in the coming years, in 2018, we have $5.5 billion. And in '19, '20, '21, roughly $4 billion in maturities each year. At some point, we may look to refinance that. And if we are looking at refinancing and we would get a theoretical downgrade, you're probably looking at 100 to 150 basis points increase on the interest rate of those maturities, depending, of course, on the tenors -- the time frame we put them out. So there's lots of variabilities there. But that, hopefully, will give you basically a picture of the overall debt.

Of course, in the term loans of $6 billion, we do plan to pay those down. We've already put $1.1 billion against it from the asset sales that we did yesterday. We will plan to do that with future. So take that into consideration, when you're calculating the amount of debt that could be subject to higher interest rates.

Operator

Your next question is from the line of Marc Goodman from UBS.

Marc Harold Goodman - *UBS Investment Bank, Research Division - MD and United States Healthcare Analyst*

Two questions. First, COPAXONE. Can you give us a flavor of what's going on right now in the channel? How much pricing did Mylan take versus how much pricing you've taken, you decided not to launch or authorize generic suit, maybe whatever details you are willing to give us from that situation? And why has guidance continuously come down on COPAXONE, when I would have thought that it's pretty straightforward what was going to happen. That's why I'm asking the question. And then second question, Dipankar, you've talked about 2018 U.S. generics being below '17; 2019, being below 2018. I was wondering if that's still how you see it, the operating margins you've talked about once we get through all the synergies moving into the mid-20s, is that still realistic and how soon do we get there?

Robert Koremans - *Teva Pharmaceutical Industries Limited - President & CEO of Global Specialty Medicines Group*

Hi, Mark, this is Rob. I'll take your COPAXONE question. Of course, we've been waiting and ready for a generic to launch. But when Mylan came, and we've really had a very good position with most of the payers and PBMs securing just over 60% of our units through contracts. And we've really been executing on that extremely fast, what we, however, did see is for the -- Mylan came in with a lower price and net price or higher discount than any analogue or any previous experience would suggest. So this was higher than expected. And that's what you see reflected in the figures that Mike shared with you. So in terms of volumes, we are doing exactly as we expected, in fact, slightly better, but they are at a lower net price.

Marc Harold Goodman - *UBS Investment Bank, Research Division - MD and United States Healthcare Analyst*

Can you share with us what you're expecting and what they came in at?

Robert Koremans - *Teva Pharmaceutical Industries Limited - President & CEO of Global Specialty Medicines Group*

No, I don't think that would be wise.

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Limited - President & CEO of Global Generic Medicines Group*

Marc, let me take the second part of your question. We are right now focused on executing the rest of 2017. We have our own budget process to go through. And it's a little premature to talk about 2018 at this point in time.

Operator

Your next question is from the line of Chris Schott from JP Morgan.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Just coming back on generic gross margins. I know you are not going to give us formal commentary about '18. But it seems like you had very severe erosion these last few quarters, so can you just give us a little bit of color on -- should we expect these margins to remain in these very low levels as we look out to 4Q? And beyond just new product launches, is there anything you can think about that should lead to improving gross margin performance on the generic business? Just trying to get my hands around, directionally, where that margin is going. The second question is also on COPAXONE. I know you talked about the $0.30 of impact. Can you just give us, again, just some sense of the percent erosion you're factoring in there on the COPAXONE revenue and just again, so we're thinking about run rates into '18, does that reflect a pretty high level of erosion at this point or should we think about further step downs in the COPAXONE franchise, again, from that 4Q run rate as we think out to next year?

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

I'll take a little bit of the gross margin on generics and then we can maybe give you a little bit more flavor from Dipankar and Rob. So the overall gross margin, the net margin on generics has been declining. We do -- it's driven by a couple of things. One is the level of price erosion we've seen in the U.S. generic business. We've seen lower contribution from our business in Venezuela over the quarters and compared to last year. We've also seen some unfavorable FX and other variance in our costs of goods sold. So all of those things have been pressuring margins, especially, in our U.S. generic business. We would expect Q4 to tick up a little bit because of the new launches. We've had relatively lower levels of new launches in Q3. And that should pick up with some date-certain launches in Q4. When it comes to COPAXONE, you will see a normal erosion curve on that. I don't think we want to get into too much detail for confidentiality reasons on pricing and impact. But a normal erosion where it accelerates slightly and then it flattens out over the course of time would make sense to us. So Rob, maybe you can add a little to that.

Robert Koremans - *Teva Pharmaceutical Industries Limited - President & CEO of Global Specialty Medicines Group*

Happy to do. So I think, what you're seeing now is the erosion as the result of Mylan launching into the 40-milligram space and also in 20-milligram, right. So we also see an impact from 20-milligram. And -- if there were to be additional generics on 40-milligram or if one of the players changes their game dramatically, obviously, this would impact also what we would have to do. Like I said before, we have secured in contracts over 60% of the units. And that's at the moment, what you see in '17's forecast. We're working on '18, a lot of the cost of COPAXONE we have been refocusing on launching AUSTEDO there is a fairly large overlap of about 2/3 of the customer base between Huntington's and tardive dyskinesia. And also next year, we are very much planning to launch our fremanezumab, which is a very exciting opportunity. The 2 opportunities there on AUSTEDO and fremanezumab, obviously, require all our investments and focus and energy and brings down the investment we do in COPAXONE, which is a natural effect anyway there. So that improves the margin in that sense on COPAXONE and helps us to do something very important for 2018, continue the launch of AUSTEDO and prepare for the launch and execute the launch of fremanezumab in migraine.

Kevin C. Mannix - *Teva Pharmaceutical Industries Limited - Head of Global IR*

Thank you. Next question.

Operator

Next question is from Umer Raffat from Evercore.

Umer Raffat - *Evercore ISI, Research Division - Senior MD and Fundamental Research Analyst*

I wanted to focus on debt and then on the branded side, if I may. On the debt side, so if I'm doing my math correctly, your 4Q guidance implies an EBITDA of $1.3 billion in the fourth quarter or effectively about a $5 billion run rate going into 2018 and that includes COPAXONE. Your year-end '17, net debt is $30 billion. So that's about 6x and again, the EBITDA number includes COPAXONE. So my question is this, what's the track on the debt side. Just to understand at a high level, what would be the track, the $5 billion EBITDA versus $30 billion debt going into 2018, first? And on the branded side, I was curious, what's the breakeven on CGRP sales from an EBITDA perspective. What's the sale threshold in which the CGRP launch starts to become a breakeven on EBITDA. Because I understand that might involve investment? And finally, I noticed no mention on AUSTEDO on the call or in the press release, certainly, not in the press release despite a huge beep that Neurocrine put up in their press release last night. So I was trying to understand the dynamic there?

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

So I'll take the first question. Of course, we are still in the process of developing 2018. So I can't really give you a hard figure on EBITDA. But we will be closely monitoring our debt situation. We will be paying down as much as we can with these asset divestments and the other things, including the working capital dispute that we expect to resolve in Q1. We'll be coming back to you -- in our year-end, giving you a layout of exactly what's

going to happen with 2018. But, of course, we'll be making all of our plans to address it. We will be working together with our lending partners and the rating agencies, as we layout that plan. But we do see, we're going to have to urgently address our 2018 situation. But until we've worked out our plan, including additional cost savings, additional asset divestments, it's too early to comment too fully on that. And in terms of the CGRP, in terms of margins, you've got to expect, since we are launching late 2018 that '18 and '19 are not going to be accretive to income. As we get into the '20 and beyond, we will start to see a real profitability coming from that product. AUSTEDO, I think, we did mention somewhere in our press release. We had 6 million sales booked in the quarter. I'll let Rob comment a little bit on how we're approaching that product. Because we are having some period where we are giving product to the patients as they titrate up. But, Rob, maybe you want to comment on that?

Robert Koremans - *Teva Pharmaceutical Industries Limited - President & CEO of Global Specialty Medicines Group*

Yes. Pleasure, Mike. With AUSTEDO we're doing really well. We are tracking in line with our plan in terms of patients. I need to remind you probably that we initiate patients on a titration, which is not charged, so there is no sales, no revenues generated there. But in terms of patients captured, both on Huntington's and on tardive dyskinesia and that's where Neurocrine is our competitor. I am very encouraged also when I see the Neurocrine figures, it shows clearly that there is a market. And I think there was some skepticism among some of the analysts before that would payers be blocking this. We see none of that. So there is a real good acceptance. Clearly, this is a new treatment paradigm for psychiatry, from psychiatrists towards something -- there is a lot of education to be done. But we are, in terms of patient recruiting, tracking, in line or even slightly ahead of what Neurocrine is doing. They report different sales, right. The sales that they have is everything that goes to wholesalers and retail and the specialty pharmacies immediately reported as sales. And we only do that when data confirm the pull-through to patients. So you look at different numbers from us. But we are really happy with progress, both on Huntington's and on tardive dyskinesia. And going forward, also, this is an important opportunity. A lot of education to be done. We always cautioned that this would not be a fast ramp up sales, but an important opportunity going forward.

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

And let me just add on. And this is Michael. AUSTEDO, of course, we are also beginning our studies on the third indication that we're developing AUSTEDO for Tourette syndrome. This is going to be a Phase III study, aligned with the FDA. And this will be starting in the next few months with our development partner Nuvelution.

Kevin C. Mannix - *Teva Pharmaceutical Industries Limited - Head of Global IR*

Kalem, next question, please.

Operator

That comes from the line of Jami Rubin from Goldman Sachs.

Jamilu E. Rubin - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Kåre, just want to offer my congratulations, looking forward to meeting you, and you certainly do have your work cut out for you. Sol, maybe if I could ask you a question since we are not going to hear yet from the new CEO. Is there anything that the Board would stand in the way of what Kåre might want to do in repositioning the company going forward, anything off the table. And secondly, just we've had this study cadence of earnings downgrades and I can't even keep track of the number of quarters. But it seems that some of the problem relates to the company's internal information systems, planning, et cetera, et cetera. How fixable do you think that is? Because it's just, it's kind of uncanny that just the number of downgrades, but it seems that some of this might just be -- may also be due to the fact that the internal systems are not where they should be, not where the rest of the industry is. So I'm just wondering how fixable that might be? And just last question, curious to know if you filed an ANDA for levothyroxine?

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

I'll take the first question and then I will turn it over to Mike regarding the internal systems and things of that sort. As you know, we performed a long, extremely thorough search around the world for the best person to lead Teva. And I promised that in a couple of calls, and we found that individual. I and the Board have great confidence in Kåre. And we are looking to Kåre to lead this company, obviously, in partnership with the Board. But he will develop the strategy, the plans, et cetera. So you can't give any guarantees whatsoever. But Kåre will be the leader of this company. And I'm very confident in terms of what he is going to do. And I'm not worried about any sort of dynamics, political or whatever that will stand in the way.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

Jami, this is Mike. Clearly, we're working on all our internal systems and processes. We did a large merger recently. So we're coming together on that. But I would put the difficulty in guidance more down to the lack of visibility in this incredibly changing environment. We are facing, now, 2 headwinds, continued pressure in the U.S. generics and in our COPAXONE. We've made estimates on that. But clearly, we need to take a look at our internal valuations and our approach to how we're looking at the future and try to get sharper. That's very clear. We will be focusing on that. We will be focusing on continuing to improve our systems and processes. It is a key priority, not only of mine, but I'm sure it will be of the new management.

Operator

Your next question is from Greg Gilbert from Deutsche Bank.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Sticking with the U.S. generics, sort of lack of predictability of your business. You've talked about the amount of new products to come this year. I assume those are all date-certains and you're not betting anything anymore in (inaudible) . So hopefully, can you confirm that. You've spoken to the amount of new products, you spoken of 10% erosion, but you have not commented on what your assumptions are for volume loss across the business or on sort of volume or price for those transition or unique products. So hopefully, you can give us a fuller picture of all those elements because it appears you've missed on several of those elements, not just the $400 million from $500 million, and not just the 10% versus the 6%. So can you walk us through all elements of that process? On COPAXONE, can you give us your thoughts on generic COPAXONE exposure outside the U.S. in as much detail as you can? And lastly, how much did you spend in the quarter on COPAXONE sales and marketing and infrastructure? And how much of that is needed to support the other products? It sounds from Rob's comments that you need of all it, but hoping you can provide some more granularity on specifically what was spent and whether you need all of that going forward for the other products?

Robert Koremans - *Teva Pharmaceutical Industries Limited - President & CEO of Global Specialty Medicines Group*

Should I take COPAXONE first, it's probably good. As you know, we sell COPAXONE also outside of the U.S. on the $1 billion that we had in the quarter. This is just shy of $200 million. The European market situation is going to be very different. There is one 20-milligram COPAXONE generic already on the market in Europe. The authorities have asked for data to show efficacy and safety. And these generics are not substitution generics, the so-called follow-on generics, and they will have to compete in the doctor's office. Synthon, who developed this product and it's marketed by Mylan in most markets that was a fairly expensive development for them as well, doing full clinical development or almost full clinical development. So what we've seen so far is very, very, very modest erosion, less than 1%. What could happen going forward in certain countries, some Nordic countries, for instance, you can be pulled into tendering and that would definitely impact some of our pricing. But I don't think that our volumes are going to be impacted all that dramatically. The second dynamic that happens in Europe standard, where the product that is over 15 years on the market is, authorities, and again, country-by-country review pricing, and there are sometimes automatic price changes, right. The -- and the third thing is the legal component. We still have a patent covering all of the molecule and production in Europe going forward for a long time. And we will continue to fight country-by-country. And again, Europe, this is very much a country-by-country fight. So the durability, if you like, of

COPAXONE in Europe is much, much better because of all those 3 reasons that I just mentioned. And in '17, we definitely do not foresee a big impact of any generic. In '18, there will be some pricing impact, not related to the generics, but more related to the measures that authorities take in Europe as a standard thing. In terms of your expenses, obviously, we'll bring down some of the expenses as they are sales force-related. A lot of that will go to AUSTEDO and the preparation of the launch for fremanezumab. Some of the direct expenditure for COPAXONE, we are reviewing and we've already brought down some. And going forward, we'll continue to really look at what is the right investment level. At the moment, we really look at very good return, still for the COPAXONE, but will make those decisions very prudently and not with a long-term defense of COPAXONE, but really much more on maximizing profitability and keeping COPAXONE as a brand available to patients in the U.S.

Kevin C. Mannix - *Teva Pharmaceutical Industries Limited - Head of Global IR*

Before we take the next question, Kalem, I think, we had a question for Hafrun regarding levo and an application for that.

Hafrun Fridriksdottir - *Teva Pharmaceutical Industries Limited - EVP & President of Global Generics R&D*

Yes, so levothyroxine is, of course, aproduct with no patent blocks,so we don't really see any information about it. We do not comment on ANDAs against products with no patent blocks.

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Limited - President & CEO of Global Generic Medicines Group*

I think the question was around, whether the revenues that we are forecasting for the new products, for the rest of the year, are they based on date-certain? Yes, the answer is to that question. The key launches that we have in quarter 4, that are going to materialize are primarily in December. And these are the generics of Viagra, generics of Reyataz, and generics of Viread. So that is where the predominant part of our quarter 4 new product launch revenues are concentrated.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

When it comes to the price and volume erosion on the other parts of the business, we are seeing a volume erosion, hitting pretty hard on the Concerta-authorized generic. And the price erosion that we see on the transition products is slightly higher than that we see on the base, just by the nature of the products because they're going from exclusivity to a non-exclusivity situation. Next question.

Operator

Your next question is from the line of Ken Cacciatore from Cowen & Co.

Kenneth Charles Cacciatore - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Just have 2 quick questions. I know you're all going to be talking about setting the stage for 2018 a little bit later. But can you just remind us in where we stand with your previously discussed R&D and SG&A kind of cost reductions? Just where we are in that plan and maybe just reframe that for us. And then on AUSTEDO just wondering if there is anything you can do in the marketplace, kind of willingness to be flexible with managed care to make sure that you're able to properly participate in what does look to be an interesting TD market given Neurocrine's report. So can you just give us a little bit of the pushes and pulls on how, maybe, from a managed care pricing perspective, you can ensure that you're there in a meaningful way?

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

Ken, I'll address, first, the cost-savings. So we laid out plans for synergies in cost savings for the year. At the Q2 results, we mentioned we would be at $1.6 billion by the end of this year in terms of synergies and cost savings versus the pro forma. We are on track to meet that. Some of that will carry over to next year. But we will -- when we build our 2018 plan, have to look at further efficiencies and things we can do to sharpen up the business. I'll remind you of that $1.6 billion of savings, there have been some reinvestments on the other side of the business in terms of some R&D expenses and other things. So we will see the majority of that coming through to the bottom line versus a pro forma. And we will continue the cost-saving efforts as we go into next year, focusing on the priorities of the business that we will be building together in the 2018 plan with Kåre.

Robert Koremans - *Teva Pharmaceutical Industries Limited - President & CEO of Global Specialty Medicines Group*

And Ken, on your question on AUSTEDO. Yes, I fully agree, it's an exciting opportunity, the TD and also Huntington's look good, like I said before, performing well. One of the key things will be to get psychiatrists, who've not been used to prescribe products like this to educate them. And if there is not enough, say, prescription, it is also difficult for payers to really take it and list it high. And we do everything. And obviously, are open also for more innovative approaches. And actually, we have been talking to many of our payers on programs like that. So far, like I said before, we're really encouraged by the feedback from all stakeholders, patients, physicians and doctors alike both in Huntington's. But we are alone, as you know, tetrabenazine doesn't have an indication there and on tardive dyskinesia. But education is going to be really important to really make sure that we get to the full potential there.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Senior VP & Interim CFO*

Kalem, we'll take 1 last question.

Operator

Last question is from the line of David Risinger from Morgan Stanley.

David Reed Risinger - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

I have 3 questions, please. The first is, with respect to the ex-U. S. generic pricing comment, it struck me that pricing has improved, so the comment was low single-digit price erosion ex-U. S. And I know that years ago, Teva used to talk about mid to high single-digit price erosion ex-U. S. So if you could just provide some more color on that and the improvement in pricing ex-U. S.? Second, with respect to U.S. pricing, could you just help us understand whether the ECONDISC partnership with WBAD to squeeze generic prices is already in the numbers or when those new contracts are going to be finalized, if not yet reflected? And then third, the CGRP patent estate that Teva has may be underappreciated by the market. Could you just speak about that, and your asserting of those patents against Lilly and potentially against other CGRP players in the future?

Dipankar Bhattacharjee - *Teva Pharmaceutical Industries Limited - President & CEO of Global Generic Medicines Group*

David, this is Dipankar. I will take the first 2 parts of your question. So the first is regarding the price erosion environment in the Rest of the World. We really should look at the Rest of the World in 2 parts. One is the business that we have in Europe and the business that we have in, what would be outside of U.S. and outside of Europe. Okay, which is, the key markets there would be Japan, other key markets would be Russia, and then we have a nice business in Latin America. As far as the European business is concerned, the prices in Europe -- the generics prices in Europe are already much lower than those in the U.S. Because the price erosion and the compression of prices in Europe started much earlier and they are further down in the cycle. So as far as the price erosion is concerned, not just for 2017, for the past, at least, 2 to 3 years, we have seen this stabilize at low single digits. And the savings for the payers primarily comes through the savings that happen on the loss of exclusivity of the brand. Regarding the business that we have outside of Europe, what I can comment on is that we see price erosion in Japan, in mid-single digits, but in the rest of the countries, we do see stabilization of prices, they are branded generics. And then in some markets, we even see small price increases. As far as

your second question is concerned, regarding the pricing and the harmonization and alignment because of ECONDISC and WBAD trying to bring their prices at similar levels. The answer for that, whether it's in our numbers or not is, yes, it is. And what we have forecasted as revenues for the rest of the year takes that into account.

David M. Stark - *Teva Pharmaceutical Industries Limited - Group Executive VP & Chief Legal Officer*

This is David. I'm taking the question on the CGRP patent estate. So first thing is, we're very pleased with the result that we got in Europe. So I'd like to talk about results. There was a challenge to the patent estate in Europe. And our main claims came out of that very nicely. And we're pleased with that result. There will be more to come there. But it's I would say a very positive sign. I'm not going to comment on our legal strategy in the U.S. You saw that we filed a complaint recently against Lilly in Boston. And I won't comment on the legal strategy there. And, of course, there'll be more to come on that. And we'll keep you updated as matters proceed. I think Michael wanted to add something on the science end.

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

Thank you, David. Just to also reemphasize that the claims issued are not just to the ligand, but also to the receptor. So we do believe we have issued claims that really cover CGRP for the ligand and the receptor, which gives us very broad coverage.

Kevin C. Mannix - *Teva Pharmaceutical Industries Limited - Head of Global IR*

Okay. Well, thank you, everybody for joining us today for the call. As always, we'll be available throughout today and coming weeks. We look forward to seeing you and speaking with you. Take care.

Operator

Thank you. That does conclude the webcast for today. Thank you all for participating. And you may now disconnect.
