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TEVA.TA - Q1 2017 Teva Pharmaceutical Industries Ltd Earnings Call

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OVERVIEW:

Co. reported 1Q17 revenues of $5.6b, non-GAAP net income of $1.1b and GAAP EPS of $0.57.

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PRESENTATION

Operator

Good afternoon. Thank you for standing by and welcome to the first quarter 2017 results call. (Operator Instructions) I must advise you this conference is being recorded today on Thursday, the 11th of May 2017. I would now like to hand the conference over to your speaker today, Kevin Mannix, Senior Vice President, Head of Investor Relations. Please go ahead, sir.

Kevin Mannix - *Teva Pharmaceutical Industries Limited - Senior Vice President, Head of Investor Relations*

Thank you, Vivienne. And thank you, everyone, for joining us today to discuss Teva's First Quarter 2017 Financial Results. On the call with us today are: Dr. Sol Barer, Chairman of the Board; Dr. Yitzhak Peterburg, Interim President and CEO; Eyal Desheh, Chief Financial Officer; Dipankar Bhattacharjee, Global Generic Medicines; Dr. Rob Koremans, Global Specialty Medicines; Dr. Michael Hayden, 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'll start the call with opening remarks from Sol and Dr. Peterburg, followed by a representation from Eyal. We'll then open the call up for questions and answers. A copy of the slides can be found on our website at www.tevapharm.com as well as on 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 presented by Teva are used by Teva's management and Board of Directors to evaluate the operational performance of the company to compare against the company's work plans and budgets and ultimately to evaluate the performance of management. Teva provides such non-GAAP data to investors as a supplement of data and not in substitution or replacement for GAAP results because management believes such data provides useful information to investors.

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

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

Thank you, Kevin, and thank you all for joining us today. Before we get into the details of our first quarter 2017 results, I want to take a few minutes to discuss the board's ongoing search to identify a permanent CEO. As I've indicated previously, this is my highest priority.

We are looking for a world-class individual with deep and broad pharmaceutical experience, an individual with experience dealing with global and complex companies with a strong sense of corporate responsibility and proven strategic and operational capabilities. The process is moving along very well. We have interviewed a number of excellent candidates from all over the world. We are extremely encouraged by the talent and the overall quality of the pharmaceutical executives we are meeting with. The board will continue to take the time it needs to find the best candidate. But I am pleased with the progress we have made and the speed at which we are moving.

While the CEO search process continues, the work of Teva to stabilize the business and deliver for shareholders has been significant. I said it last quarter and I will say it again, as interim CEO, Yitzhak has the full support of the board to drive forward on Teva's strategies and key priorities. Execution remains the focus. The industry is facing turbulent times and there remain challenges in the business. But I am confident that while the board and I focus on finding the right individual to lead Teva forward, we are taking the actions we need to take today to put the company on the right footing, to continue to succeed in the future. Teva is doing everything in its power to deliver on its promise to shareholders.

With that, let me turn the call over to Yitzhak.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Limited - Interim CEO, Interim President and Director*

Thank you, Sol. Hello, everyone. Thank you for joining us today. Since I took over 3 months ago, my focus, together with the management team and with the support of the board has been to execute on our previously discussed priorities for the year, which are extracting synergies related to the Actavis Generics transaction, driving additional efficiencies throughout the organization, supporting cash generation and paying down our debt and delivering on our promises of the specialty pipeline and key generic launches.

First, let me take you through a quick review of our quarterly results. Q1 started off 2017 generally as expected and as we guided, which has been the lowest quarter of a back-end loaded year. Revenues this quarter amounted to $5.6 billion, resulting in a non-GAAP net income of $1.1 billion and a non-GAAP EPS of $1.06. However, cash flow from operations was relatively soft, amounting to $500 million, negatively impacted by multiple one-time payments that were previously disclosed, including a settlement with the U.S. Department of Justice.

Compared to Q4 2016, which marks the first full quarter consolidation of Actavis into our overall group results, revenues declined 30% primarily due to impacts resulting from a devaluation of the Venezuelan currency, which totaled $400 million, losses of exclusivity in the specialty segment during Q1 and divestment in the U.K. related to the Actavis Generics acquisition. We were able to mitigate approximately half of the decrease in the operating profit through a reduction in operating expenses.

Now let me elaborate on some of the progress and challenges we experienced with our key priorities. As it relates to our first priority, I'm pleased to report the synergies related to the Actavis Generics acquisition and additional cost reduction, which the company has identified, is now on track to realize cumulative net synergies and cost reduction of approximately $1.5 billion by the end of 2017. This is compared to our spend base in the full year of 2016 combined company pro forma. This is almost $200 million more than what we guided to in January and is the result of an extensive review.

Our second priority was to extract additional efficiencies in our organization. This was achieved during the quarter through various cost-saving measures, including initiation of site closures in R&D, restructuring in our global operation and additional initiatives, primarily consisting of headcount reduction and expense cuts. In most instances, we have witnessed an acceleration of planned cost savings. Since the close of the Actavis Generics transaction, we have reduced our headcount by approximately 5,000 people and expect further reductions through the end of 2017.

Moving to our third priority of supporting cash generation and paying down $5 billion of debt in 2017, we are pleased that we reduced our gross debt by $1.2 billion from $35.8 billion at year-end 2016 to $34.6 billion at the end of the first quarter. As discussed at a high level in January, part of the funds that we assume will help pay down the $5 billion are expected to come from divestiture proceeds. Since taking over in February, I've worked extensively with the board and management team to identify the relevant non-core assets to be divested.

Teva has elected to pursue the sale of its global Women's Health business. And we have engaged Morgan Stanley to serve as our financial adviser. In addition, we have elected to sell our Oncology and Pain business in Europe, where Bank of America will serve as our financial adviser. We expect the sale process for both businesses to commence in the coming weeks with the distribution of marketing materials to interested buyers. We believe we will be able to complete this transaction by the end of the year, subject to evaluation of pricing proposals and board approvals. We believe that the proceeds from the sale of both businesses as well as additional asset sales will be significantly in excess of our previously identified target of $1 billion.

Our fourth priority, delivering on the promise of the specialty pipeline and key generic launches: During the quarter, we received 8 approvals in our specialty business including AirDuo RespiClick and ArmonAir RespiClick in the U.S., and 5 in our growth markets. Furthermore, AUSTEDO or SD-809 for Huntington's disease was approved in the U.S. on April 3 and was launched less than 2 weeks later with revenues expected beginning in July. It is still very early in the launch, but the initial data we have from a small dataset is encouraging.

AUSTEDO for tardive dyskinesia was granted priority review by the FDA and provided a PDUFA date of August 30. Assuming we are successful in obtaining final approval, that would put us in a position for a launch in September. We are also quickly approaching a very important readout for our anti-CGRP Fremanezumab with pivotal Phase III results for both chronic and episodic migraine expected next month. As we all know, there are always risks when it comes R&D. And we were reminded of that just a week ago when we announced that the CONCERTO trial of Laquinimod in relapsing-remitting multiple sclerosis did not meet its primary endpoint. While we are disappointed for MS patients around the world, we have no further plans to pursue Laquinimod in relapsing-remitting multiple sclerosis.

Turning to generics. It has been 2 full quarters since the completion of our acquisition of Actavis Generics. The acquisition has provided us with many benefits, especially much stronger and broader R&D capabilities, which we believe are the engine for any substantial generic business. This is essential in today's world when we are operating across such an evolving competitive landscape and ongoing consolidation across our customer base. We are very confident that the global business we have built will allow Teva to thrive in the long-term future as a leader in the generics industry.

Our generic business is not immune to the challenges other companies in our industry are currently facing with increased competition and consolidation. This is reflected in the most recent analysis we completed that looks at net price erosion in our U.S.-based business, which came in at 7% versus the approximately 5% that we communicated previously. The 2 biggest contributing factors to this change are the ongoing consolidation of our key customers and the increase in generic drug approval by the FDA, which has created additional competition.

The situation in Venezuela continues to deteriorate, which has led to greater instability that could negatively impact our business in the country, including our ability to produce more drugs. This could have an impact on our projections, which include approximately $0.11 of earnings generated by Venezuela over the last 3 quarters of 2017. In 2016, we adjusted the exchange rate twice. And in February 2017, we further updated the exchange

rate to its current rate of VEF 380 per $1. Just to put it in perspective, in Q1 2017, revenues of generic and OTC medicine in Venezuela amounted to $21 million compared to $238 million in Q1 2016 and more than $435 million in Q4 2016.

As we stated in our press release from this morning, we are reaffirming our 2017 outlook. We are committing to being transparent. And therefore, we wanted to provide more clarity into our business and the moving parts of our projections, specifically regarding the challenges in the U.S. generic market and Venezuela. We will continue to keep you informed throughout the year as our team works extremely hard to execute on all of our promises and priorities for 2017.

Finally, I would like to take this opportunity to say a few words about the Eyal Desheh, our CFO, whose planned departure we announced a few weeks ago. Eyal has contributed significantly to Teva's growth and success throughout his tenure. I'm pleased to announce that Michael McClellan will serve as an interim CFO effective July 1. Prior to joining Teva, Mike was the U.S. CFO at Sanofi, where his career spanned over 20 years in roles of increasing responsibility in global finance and health care. For the last 2 years, Mike has served as a CFO of our Global Specialty Medicines division. I'm confident he will be an excellent addition to our team. Eyal and Mike will work closely together to ensure a smooth transition. As we have stated previously, we expect our new CEO to have a significant role in identifying a permanent successor.

Thank you. And I now turn the call over to Eyal to provide more insight into the numbers.

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

Thank you very much, Yitzhak. Good morning, and good afternoon, everyone. Before I dive into the Q1 numbers, let me say a few personal words.

As you read in our press release this morning and heard from Yitzhak just now, I will retire from my CFO role in Teva on June 30 this year. So this is the last quarter I report as the CFO of this amazing company. I shared my views with you -- with all of you for 37 quarters in a row. And I hope that I have served you well, enabling all of you to better understand Teva and its developing business model. I worked with Teva for over 16 years in 2 periods. I worked with outstanding people. And together, we faced challenges and successes. I'm ready and looking forward to the next chapter in my professional career, which will commence soon. And there is no question that I will miss Teva, the excitement, and I will miss the interaction with all of you. I'm sure that I will cross paths with many of you going forward.

With Mike taking over as Interim CFO, I am convinced that Teva finance is in very good hands. Mike is an experienced finance executive and will be a great leader to the excellent finance team we have in Teva and will do that during his transition period. So good luck to you, Mike.

Now let's take a few minutes to review the results of the first quarter of 2017. As always, I will take you through both GAAP and non-GAAP results. Our highlights for the quarter include revenues of $5.6 billion and earnings per share of $1.06 on a non-GAAP basis and $0.57 on a full GAAP basis. Our GAAP results were impacted by several items in the quarter. And I'll take you through the list of exclusions in a few slides.

Compared to the first quarter of 2016 we were up on operating revenues, operating income and EBITDA as a result of the inorganic moves we made, including both the Actavis Generics acquisition and the joint venture with Takeda in Japan. As this is our second quarter, full quarter with Actavis, I will also take you through a comparison with Q4 2016 in a few slides.

Our cash flow from operations this quarter was unusually low as we had a number of large irregular items. And I will share the details shortly. We did receive approximately $700 million in January for the divestment of portions of the Actavis business in the U.K. and Ireland. But this is not part of our cash flow from operations. However, we'll use it to pay down debt.

Non-GAAP adjustments for the quarter amounted to $0.5 billion. The largest line item is amortization reflecting the run rate of the combined company. We had relatively high restructuring expenses, which are related to the efficiency measures we are taking throughout the company both related to our integration with Actavis and to the additional measures being taken. We also excluded $52 million, which are related to the decrease in the British pound, which affected the value of the assets sold in the U.K. and Ireland, which were already divested.

We adjusted the exchange rate I used for Venezuela bolivar twice during 2016 as you already heard from Yitzhak, and once again, in February 2017 to VEF 380 per $1. This is a blended rate. This has a negative impact of $217 million in revenues and $67 million in operating income as compared to Q1 in 2016. So there was no contribution for Venezuela to our earnings per share this quarter, 0. In light of the economic condition in Venezuela, we excluded the quarterly changes in revenues and operating profit in any discussion of currency effect as you can see in the table. Other than the bolivar, foreign exchange impact on our results in the quarter was relatively minor.

As to EBITDA, Q1 EBITDA was $1.8 billion and EBITDA for the last 4 quarters totaled $7.5 billion. Cash flow, cash flow from operations in the quarter was $0.5 billion compared to $1.4 billion in the first quarter of 2016, reflecting several unusual payments made during the quarter. These were FCPA settlements with the SEC and DOJ for more than $0.5 billion, 111 -- $110 million related to a ciprofloxacin settlement and $250 million for the final settlement of our forward starting interest rate swap and treasury lock agreements that matured during the first half of 2017 which was settled and paid in first quarter of 2016 -- of 2017. Proceeds from divestiture related to Actavis Generics of $700 million or a bit more in Q1 '17 are not included in this chart.

Looking at the rest of the year. Just as our revenues and earnings are back-end loaded, we expect the same pattern for our cash flow from operations. We also are planning on a significant recovery in the second half of the year from Allergan as a true-up to our working capital. Cash management remains a top priority for the company and the finance team.

Liquidity. At the end of Q1 2017, we had total debt, excluding minority shares, of $34.6 billion and debt to EBITDA stood at 4.63x and the net debt to EBITDA, which is used for complying with the bank debt covenant, stood at 4.49, way below the threshold required.

Compared to the first quarter of 2016, you can see the growth of our generic business both in the U.S. and globally. COPAXONE revenues declined slightly and our other specialty products declined mostly as a result of the loss of exclusivity for NUVIGIL and AZILECT. However, these declines were offset by a payment of $75 million related to the NINLARO deal, which is included in this quarter. You can also see the impact of the Venezuela devaluation, which reduced revenue by over $200 million year-over-year.

Looking at where we made our sales. U.S. continues to be the largest market with 56% of revenues. European revenues accounted for 27% of total. And our Rest of the World markets are 17%, down from 19% of total last year. Following the inorganic moves of the past year, generics now accounts for 54% of total revenues with COPAXONE down to 17%. Other revenues are up significantly following the acquisition of Anda, which contributed almost $300 million for the quarter to our top line.

The increase in our operating profit was driven mainly by our generic business, following the closing of the Actavis transaction. Our specialty business contributed less following the loss of exclusivity of NUVIGIL and AZILECT as well as the lower profit coming from COPAXONE this quarter. All the moving parts resulted in a similar level of profit, though from somewhat different sources. Generics is now 42% of our operating profit without G&A while COPAXONE is down to 40% of total.

The profitability of generic business was very stable -- of our U.S. generic business was very stable this quarter. But there were some movements in other parts of the business. The lower gross profit compared to Q4 is driven by the devaluation in Venezuela, which reduced revenues by about $400 million from Q4. In addition, compared to Q4, operating profit was impacted by the divestment of certain of the U.K. and Ireland assets that were included in Q4 and with very nice profitability. And this was divested, as mentioned, in January this year, and in addition, by somewhat lower revenues in Japan.

COPAXONE. COPAXONE performance is in line with ex-U.S. sales maintaining a level of approximately $190 million. This reflects the penetration of COPAXONE 40 milligram globally and now also outside of U.S., which is over 70% of the units in Europe. In the U.S., the quarter was relatively soft from lower volume of COPAXONE 20, partially offset by a price increase of 7.9% in January '17 for both 20- and 40-milligram versions.

Now I'd like to take you through 2 additional slides, bridging Q4 2016 and Q1. This is the first time we can look at 2 quarters, 2 sequential quarters of the new Teva, which are comparable. On revenues, you can see that U.S. generic business was stable compared to Q4, a bit higher, while ex U.S. we saw lower generic revenues in Japan and in Europe following the divestiture of the U.K. and Irish business in January. In Specialty, we saw lower revenues of COPAXONE as well as the impact of loss of exclusivity of AZILECT and NUVIGIL also compared to Q4. We also had lower payment

received in connection with NINLARO, which were $75 million this quarter and $150 million in Q4. Obviously, the biggest piece is Venezuela devaluation, which reduced revenues compared to Q4 by $400 million.

Our operating income from Q4 to Q1 declined by 17%. While gross profit margin of our U.S. generic business remained stable, overall gross profit and gross margin was impacted by the Venezuela devaluation, our business in Japan and the divestment in the U.K. Lower NINLARO income was also a contributor to lower profit and profitability. On the other hand, you could see our efficiency initiatives, which reduced our operating expenses across the board and mitigated some of the decline in the gross profit. And we expect this trend to continue throughout the year. On our balance sheet compared to December 31, 2016, our balance sheet amounted to total assets of $91.3 billion and total equity of $34 billion.

Let me discuss the share count as we have made a change. It doesn't have an impact. It's fully offset this quarter, but I want to clarify that. The number of shares this quarter on both GAAP and non-GAAP is 1,017,000,000 shares. And it's non-GAAP and GAAP, which is exactly the same. This number is equal to the 1,076,000,000 shares, so let me explain how. As of December 31, 2016, the number of shares on a non-GAAP basis was 1,076,000,000. This has not changed. However, this quarter, the effect of the MCPS, which is the mandatory convertible shares, was anti-dilutive. So we did not add back $66 million of special dividend to MCPS holders. We didn't add it back to the net income attributable to ordinary shareholders nor did we increase the number of shares by 59.4 million shares. This has no impact on our earnings per share, which would have remained $1.06 in either treatment as these 2 entries offset each other.

And last, dividends. Our board approved dividend of $0.34 per share for the first quarter of 2017. As a reminder, Teva's board approves dividend payments every quarter after considering the financial condition of the company.

Thank you all for listening to us this morning. And I would now like to open the call for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We have a question from the line of Gregg Gilbert.

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

I'll ask one multipart question upfront. First, for Sol, what have you learned so far from the CEO search in what candidates see as pros and cons? Second, are the Women's Health and European Oncology, Pain businesses the only businesses for which you're exploring options? And last, generics in the U.S., are you still as confident as you were before in the flow and size of new product sales from launches in 2017? And can you provide any specific color on some of those key launches?

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

So this is Sol Barer. I'll take the first question in terms of the CEO search. I have to say that we are looking, as everyone knows, for the best person to lead Teva. And we're looking around the world for this individual who has strong pharmaceutical experience, is a leader, understands the complex situations, has a great deal of integrity, corporate responsibility, et cetera. And the one thing that I'm surprised about, to be very honest about it, is the quality of people that we are talking with. The senior leaders, the ones with experience, I'm very happy with. So again, this takes some time. But I am very encouraged in terms of who we are talking to.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Limited - Interim CEO, Interim President and Director*

So regarding -- . So regarding your second question. Those are the main, exactly as we said, including some other assets. Some of them are really financial assets and real estate assets and very small other assets. I don't think we need to go through it. The main 2 assets were identified really

undergoing, as we speak. And as I said, we hope to finalize it during this year. On the third question about generics, I'll ask Dipankar if he can comment.

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

Regarding the U.S. new product launches, as we described before, we are targeting more than 80 different product opportunities that are expected to yield between 40 and 50 launches this year. When we look at the breakdown of all these opportunities, the products where we have a high level of confidence in our ability to launch them this year due to a clear position from legal, regulatory and operational readiness, these are expected to generate approximately $500 million. Our ability to generate additional sales beyond the $500 million is the degree of success we achieve from the basket where there is a higher level of risk related to legal, regulatory and operational readiness as well as the competitive environment. It is the breadth and the depth of our generics pipeline that provides us with these numerous opportunities or as we have said in the past, more shots at goal every year. As regarding the timing of launches, as you know, most of our 2017 launches are in the second half of the year.

Operator

Your next question comes from the line of Jami Rubin.

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

Just a couple. Sol, just back to the CEO search, I think I asked this question before, I don't know that I got an answer. But would you be willing to waive the requirement for a CEO to live in Israel? And the second question is you said that $1 billion of the $5 billion of debt repayment this year would come from divestitures. Would incremental asset sales proceeds beyond the $1 billion accelerate debt repayment? Or will there be other uses of proceeds? And just my final question, Eyal, to you, just didn't completely understand the explanation of the drivers of gross margin deterioration this quarter. Can you explain that again?

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

Okay, so this is Sol Barer. I'll answer the first question with respect to the CEO. As I indicated, Jami, we are looking around the world for the absolute best candidate for Teva. We are committed once we find that candidate to bring that candidate to Teva. And we will do what it takes to make that happen, okay, to be very clear about that.

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

Okay. So first of all, regarding the asset acceleration, yes, we would like to pay down debt faster and delever the balance sheet. Regarding the drivers of our gross margin, compared to Q1 last year, this is a different company. We have the Anda business, which comes -- it's a distribution business naturally with a much lower margin than our other businesses, both the Generic and the Specialty. And we have divested the U.K. piece. That has a small impact, but it came with very nice profitability. And of course, we've talked a lot about the impact of Venezuela, which basically the profit completely disappeared and there's 0 profit on $21 million of sales in the results of Q1. So the impact of all these drivers has reduced the gross margin to where we are today. It could improve a little bit later on this year with new launches of generic products. But this is the area that could be a bit better.

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

Can you just -- kind of a quick follow-up. We thought you had said about $900 million of new product sales this year. Did you bring that down? I just want to make sure I heard that right. And I guess to what extent has pricing pressure in the business played or had an impact on your gross margins?

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

Dipankar, new product sales?

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

Yes, our new product sales, we had, even in earlier conversations, spoke about 80 different product opportunities. That basket still remains the same.

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

Did you give us a total number? I may have misheard you. But I thought you had given us as a total number of $900 million, just want to square that with what you're saying today.

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

No, I don't believe so.

Kevin Mannix - *Teva Pharmaceutical Industries Limited - Senior Vice President, Head of Investor Relations*

No, it was not $900 million.

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

And then the second one, Jami, on the pricing pressure, it did not have an impact on our gross margin. I think that we said it in the prepared remarks, the gross profit margin of our U.S. business or U.S. generic business remains exactly the same. It's around 55% or a bit higher and did not suffer -- was not impacted by pricing pressure in generics in Q1.

Operator

Your next question comes from the line of Andrew Finkelstein.

Andrew Finkelstein - *Susquehanna Financial Group, LLLP, Research Division - Research Analyst*

First off, just in fourth quarter, there were some one-time income from a deal with Takeda in Japan. Just curious if there were any proceeds from transactions like that in the current quarter. And then if you could talk at all just about what you're seeing from the FDA in terms of improving the predictability of reviews for complex generics since there's a number of them that are a potentially meaningful swing factor in your second half results.

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

Yes. So in Q4, we included $150 million of sales from NINLARO product to Takeda. And this quarter, we included $75 million from the same source.

Andrew Finkelstein - *Susquehanna Financial Group, LLLP, Research Division - Research Analyst*

But no other transactions like that?

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

No.

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

This is Hafrun speaking. So with regards to working with the FDA and seeing some improvement in the time lines there specific for complex generics, we are clearly seeing much more activity from FDA than we saw in the past. And we had been working very closely with them on some of the complex generics, which we have filed over the last few years. So clearly, we are seeing improvements there.

Operator

Your next question comes from the line of Douglas Tsao.

Morgan G. Williams - *Barclays PLC, Research Division - Research Analyst*

This is Morgan Williams on for Doug. So I was just hoping, I have a few questions. Number one, number of competitors said that the consolidation in the customer base is beneficial to a large manufacturer of generics. Are you seeing the same dynamics? Just asking for some more color around your commentary on generic performance this quarter. And then secondly, just hoping you could maybe provide a little bit more background on the AUSTEDO launch strategy and more on your rationale for pricing the product at a discount to competitors.

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

Yes. So first, let me take the question that you raised on customer consolidation. So while customer consolidation does raise some pressure on some of our generic manufacturers, we also see opportunities to increase our strategic partnership with our key customers. So our unique global reach, our broad portfolio and our deep R&D capability to bring a pipeline of new products will create strategic value for both us as well as our customers.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Limited - Interim CEO, Interim President and Director*

Rob?

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

And on the question on AUSTEDO, so you heard from Yitzhak, we're really pleased with the initial feedback from the market. It was a very good reaction from both patients, physicians and also payers. As you also know, we are developing this product and are awaiting approval into tardive dyskinesia. And so we've priced it to really meet with both ends of the spectrum in Huntington's and in tardive dyskinesia. And we really believe that with this, we have an incredibly good value for all stakeholders, and initial feedback really confirms it.

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

Also just to add one, Michael here. Why this is being so well received by both patients as well as physicians is the impact of this drug. Chorea really incapacitates these patients. This has major effects on chorea, also impacts swallowing and improves nutrition. And these are well recognized as major impacts without the side effects that you see with tetrabenazine. So overall, an excellent safety and efficacy profile for this product.

Operator

Your next question comes from the line of David Amsellem.

David A. Amsellem - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

So just first, on divestitures, just expanding on some of the earlier questions. So what's the rationale of your keeping the U.S. Oncology business but just divesting the European Oncology business, only bearing in mind that you don't really have a pipeline in Oncology? So that's number one. And then second, anything new to say on the EpiPen generic? And what are your expectations there?

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

This is Rob. I'm happy to talk about the U.S. Oncology business. It's very important business for us. BENDEKA is really doing extremely well with almost a 98% conversion and doing extremely well there. We have an important deal with Celltrion, where we will be launching in '18 and '19 2 biosimilars. So this really is a very important business and it fits perfectly with us. For Europe, what we see is it's different. We have a different portfolio in Europe than in the U.S. and we just don't have enough of a pipeline to be able to feed neither the Oncology products itself and also the Pain products in there. And we believe that someone else could be a better owner. And it would definitely help to decrease our debts there. So we've taken the decision to try and divest this. But the onco for us, with the opportunity for the Celltrion products, is really important going forward.

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

So a comment on EpiPen. So this probably remains to be a top priority for Teva. And this is one of the products which we are working very closely with the FDA on. We still see a meaningful opportunity for a true AB-rated generic here. And as a reminder, we have a settlement agreement with Mylan, which allows us to launch upon approval of our ANDA. The outlook for this drug has not changed from prior statements, so we are targeting a launch in early 2018.

Operator

Your next question comes from the line of Ronny Gal.

Aaron Gal - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Research Analyst*

Actually, I'm going to try to sneak in 3. The first one is about cost reduction. Eyal, how should we expect the cost -- the operating line to progress during the year? You had a one-time benefit on SG&A this quarter. But if we kind of think about quarters 2, 3 or 4, should we just, from the outside, see ongoing reduction on those operating lines? Or should they be, in absolute numbers, roughly flat? Second, the issue of selling respiratory. You seem to have a little bit of air to breathe here with Advair true generics being delayed. This looks like it's a contractual sales to the PBMs, or the big buyers. Can you tell us where you stand on this? And essentially, when should we see -- begin to see contribution for this product? Is it this year or only the 2018 contract? And last, to Sol, I guess, as a representative of the board, some of the discussions we're having on here on the investment side is whether the dividend should be suspended for a couple of years to bring down the debt level. And obviously, you guys had to struggle with this question as well. Is it something that is -- that you'll consider under any circumstances? Or is it something that you've essentially rejected in an absolute sense?

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

So on cost reduction, we're progressing very well. A little better than our already pretty ambitious plan. So we are seeing the results. The company has reduced headcount by almost 5,000 employees since we closed the transaction with Actavis on August 2 and about 1,700 from the beginning of this year. And the impact of that will be seen later on this year, it never happens on Q1, our people leave. We are also reducing expenses in the areas which are not headcount. Of course, it's labor-related, more efficiencies of cost of goods sold. So all this is going to be seen as the plan progresses throughout the year and will improve our operating margin. We said, and I'll repeat it again, this is not a linear year. The second half is expected also to benefit from more launches of new product, mostly coming from the U.S. generic. And a combination of both will improve the margin.

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

Ronny, on your second question, we've actually started being active in the market just recently with the sales forces. Key would be, as you indicated, the payers, right, and to really get on the right formulary access will take some time. The recent news, today's news on -- or actually yesterday's news on Hikma will help, I think, also payers to see that what we have is a very effective offering. But we will only start to see real sales early quarter 3 for AirDuo RespiClick. And it's an experiment we're doing. I think it's a good, new innovative strategy. But it will not have an immediate ramp-up as we need to really make sure that we get formulary access.

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

In terms of the dividend, as indicated, our policy hasn't changed. And as Eyal had mentioned, every quarter, we, as a board, evaluate paying the dividend. And obviously, this year, this quarter, we have said that we will pay the dividend. I can't speculate under any circumstances what would happen. I think it's just suffice that at this point that our policy is the same and that we have met and we have paid a dividend. And in the future, every quarter we will do the same.

Operator

Your next question comes from the line of Umer Raffat.

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

I have a few today, if I may. First, Dipankar, on generics, so you're tracking at guidance-like numbers but at lower margin. So I want to understand how you're thinking about the strategy in generics. Is it a revenue number you're working towards or an operating profit number? On specialty maybe, maybe for Michael. Michael, are you expecting the quarterly CGRP to work? And if so, can you deliver it in a way which doesn't involve 3

separate injections every 3 months? And then finally, for Eyal and Michael, I noticed your slides said your net debt-to-EBITDA this quarter was 4.49x. And I also recall that your covenant requires you to be at 4.25x. So I just wanted to reconcile those 2. And finally, I just also want to push back a bit on counting NINLARO as revenues.

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

Yes, thanks, Umer. So as regarding the generics question that you asked, we do look at a combination of both revenues and our margins and not one or the other. As regarding the revenues, it's obviously a combination of what we see happening in our base business in the U.S., our new product launches that our strong R&D capabilities bring. And also we look at a combination of how our business moves within the U.S. and the non-U.S. because from a revenue standpoint, you do have to recall and remember that about 55% of our generics revenue comes from outside the U.S. As regarding -- in terms of what we would expect and how we will track for the rest of the year, we would expect the current levels of price erosion that we have spoken about will remain for the rest of the year. It is embedded in our forecast. And our new product launch revenues, as I mentioned earlier in one of the questions, is we continue to look at that basket and we continue to look at the 40 to 50 launch opportunities that we have.

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

Thank you, Umer, for the question on Fremanezumab. We're obviously optimistic about quarterly injection. We're the only company that actually is looking at both monthly and quarterly. And the reason we're having some optimism is the long half-life of this particular product that we've seen before with very low immunogenicity. So we're exploring this. We expect to have the results of this before the end of June. And we will be able to see whether a quarterly dose injected just quarterly would be sufficient to have the impact. We also note that our efficacy in the Phase II was the best in the class. And so that also, together with the long half-life and low immunogenicity, gives us some optimism. But data will be available for us to really assess this in the very near future.

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

Umer, regarding the covenant, the requirement right now is 5.25. So at 4.49, we are way below that. By year-end, it will go to 4.25 and we see no problems or issues to comply with that.

Operator

Your next question comes from the line of David Risinger.

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

And congrats, Eyal, and best of luck to you. I have a couple of questions. First, with respect to the $200 million in additional cost savings this year, is that a full year benefit to 2017 guidance? Second, with respect to the new product launches in 2017, I wasn't quite clear on that. Could you restate what amount of new product launch revenue you expect in 2017 in the U.S. and globally? And then finally, with respect to the CGRP, Michael, could you just update us on the Phase III readout timing and the timing of filing in the U.S. and EU?

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

Thank you, David, for your kind words. The additional $200 million in cost savings are included in our guidance. They are not addition to the guidance. We reiterated the guidance, we reiterated the range. This will help us to be within the range in face of some challenges that Yitzhak has mentioned in his introduction. So we can't just take that and add it.

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

Thanks for the question, David. With regard to results, so as I said, we're expecting the results for CGRP for both chronic and episodic migraine before the end of June. We plan to file for the FDA before the end of '17. So this is a little earlier than we had stated previously. This reflects the fact that the trial is ending a little early because of the very rapid recruitment that occurred both for chronic as well as for episodic. Just to remind you, of course, also this program also is using -- this is using CGRP antagonist as add-on therapy. So we're getting a lot of the real-world scenario evidence, which will provide a very unique piece of information that will yield great value to doctors. And this will be important. And so we're expecting to be, depending on when Amgen files, second in episodic and potentially first for chronic, depending on Amgen's submission date.

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

And you'll press release this in June, the data?

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

The moment we have top line results, this will be press released before the end of June.

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

So I'll take the question on the new product launch revenues for generics. And I will repeat what I had said earlier is that the number that I said was specific to our U.S. new product launches. And we continue to look at our basket of 80 different product opportunities. This should yield between what we expect as 40 to 50 launches, products where we have a high certainty because of clearance on legal, regulatory and our operational readiness. Will we expect to bring approximately $500 million of revenue? We do have a higher risk basket, which has higher risks around legal and regulatory. And our ability to go beyond the $500 million, and to the extent we can, will depend on how we overcome these regulatory and legal and operational readiness barriers. But these are revenues of new product launches that are specific to the U.S. We also have a substantial business outside of the U.S., which also has the product revenues which I did not allude to. But they will add to the $500 million that we have.

Operator

Your next question comes from the line of Liav Abraham.

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

Just a couple of questions here. Firstly, for Eyal, given the cash flow in the first quarter, I know you had made comments on the trajectory of cash flow throughout the remainder of the year. But can you just confirm that you are also reaffirming your cash flow guidance for the year of $5.7 billion to $6.1 billion. And secondly, and apologies for flogging a dead horse here, I know the question has been asked a few times. But my understanding is that in the past, you guided to $850 million of new product launches in the U.S. Are you no longer guiding to that number? Is it $500 million plus the option for an additional $350 million more? I just want to make sure on that, and again apologies, I know it's been asked. And then lastly, just a follow-on question on your covenants. There continues to be concern from investors on meeting your covenants and the covenant progression over the next couple of years. Would you consider renegotiating these in order to provide yourselves and perhaps the investment community with some more confidence and breathing room?

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

Yes. So maybe I'll take the first and the third question, and then Dipankar will address the second one. So yes, we are reaffirming the cash flow guidance. And as I mentioned on the call, Q1 has a very unusual large number of one-time cash-related events that we don't expect to repeat later on this year. But I also said, and I repeat that, that the year is not linear on business performance and cash flow alike in the second half, where we will be stronger than the first. Regarding covenants, we see no need to renegotiate or negotiate the covenants. So we believe that we'll meet them in the near and the long term.

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

And apologies from my end just on the second question I asked on the generics, I think you guided to $750 million in the U.S. earlier at the Q4 earnings, not $850 million. So I just wanted to clarify that.

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

Yes. So thank you, Liav. So again, I will reiterate what I have said and how it relates to the number that you mentioned is that in the basket of products that we have, the ones that we have a very high certainty of launching because of clearances that we have from a legal and IP standpoint in the U.S. amounts to $500 million, right? Beyond that, there are a number of opportunities that we continue to look at, okay, which has higher risk around legal and regulatory barriers. And our ability to get closer to the number that you're speaking about is the degree of success that we have in overcoming those.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Limited - Interim CEO, Interim President and Director*

And I want to make sure that we never said $850 million.

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

Correct. I said $750 million, I corrected myself. Apologies for that.

Operator

Your next question comes from the line of Vamil Divan.

Vamil Kishore Divan - *Credit Suisse AG, Research Division - Senior Analyst*

Just one on the pipeline, and then one back on the financials. You mentioned Laquinimod and the disappointing data there for RRMS. But you're continuing still on PPMS and also Huntington's. I'm just curious if you have any updated thoughts in those 2 indications, and if your expectations are now lower for the products succeeding there? And then I've just got a couple of e-mails here, so I just want to clarify also. You mentioned the added synergies you think you'll get from Actavis this year. And presumably, that's a boost to your full year outlook. What is sort of the offsets that's kind of keeping your full year outlook the same? Is it more of the FX in Venezuela? Is there any other factors? Is it the margins? What's sort of leading to the outlook to remain the same despite that added synergies?

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

Thank you, Vamil, Michael here. Just to give a quick update on Laquinimod. Of course, we were disappointed with the failure to achieve the primary endpoint, which is confirmed disease progression. But we were interested in the secondary results, which showed a 40% decrease in brain atrophy,

a 28% decrease in time to first relapse and also a 25% decrease in relapse rate. So this confirmed the neuroprotective effect of Laquinimod. And as such, the study on progressive MS, which is a disease much more progressive to brain atrophy, we're expecting those results in the third quarter. And the Huntington's study, which is ongoing, will continue to a readout next year. The reason we're continuing is that certainly we've seen the neuroprotective effect. There's data from other studies. We understand the mechanism. And these studies are in full progress, fully recruited. And so these will be continued to their endpoint. Of course, progressive MS, I think, we have lower expectations based on the results in relapsing-remitting.

Operator

Your final question comes from the line of Chris Schott.

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

Just one coming back on generic gross margins. I think the earlier comments you said that we could think about some modest improvements from these Q1 levels as the year progressed. Can you elaborate a bit about longer-term trends on margins? Basically, where do you see generic gross margins moving longer term, given some of the adjustments we had with the Venezuela business, et cetera? My second question was on the 3 businesses that you're looking to divest. Can you just help us a little bit in terms of the size and the profitability of those business? I know you break out the Women's Health sales. Can you give us the sales on the EU Oncology and Pain franchises? And how do we think about margins for those businesses? I guess should we think about margins in line with your overall Specialty franchise? Should we think about just what could happen with the P&L as those potentially go away?

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

So gross margin on Generic, we expect that to go back to the level that we've seen in the past few quarters, 48%, 49% later on this year. This is based on both higher margin products that we intend to sell, launching new products that always come with higher margins and of course, cost reduction improvement from the other side. Both of them are going to improve gross margin and operating profit margins that we expect it will be around 29%, 30% for the year to complement the higher gross margin that we will experience later on.

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

And just as a quick follow-up, is that 29% to 30%, is that a good run rate going forward? Or can you give us a little bit of thoughts about just as we think about the longer-term progression of generics? Is that a good run rate? Or should that continue to improve over time?

Eyal Desheh - *Teva Pharmaceutical Industries Limited - CFO and Group EVP*

Yes, I don't want to talk to the much longer term. But when we're talking about 2017, these are the run rates that we assume.

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

And Chris, this is Rob. On your question to the Women's Health business, it's about $560 million in revenues and has a very good and healthy contribution. And the same is true for the onco, pain in Europe. It's about $360 million in revenues in '16 and again very, very contribution margins. So should be very attractive assets to divest and not only on the Women's Health. These are businesses that doesn't strongly depend on R&D impact and it's very sustainable products. And I think a new buyer will really also benefit from them.

Yitzhak Peterburg - *Teva Pharmaceutical Industries Limited - Interim CEO, Interim President and Director*

Okay. So I want to thank all of you for your participation, see you most probably in the next quarter. Good luck, everybody. Good morning.

Operator

Thank you. This does conclude our conference for today. Thank you for participating. You may all now disconnect.
