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TEVA.TA - Q2 2017 Teva Pharmaceutical Industries Ltd Earnings Call

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OVERVIEW:

Co. reported 2Q17 revenues of $5.7b, non-GAAP net income of $1.1b and GAAP net EPS loss of $5.94. Expects 2017 EPS to be $4.30-4.50.

CORPORATE PARTICIPANTS

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

Kevin Mannix

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

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

Dr. Rob Koremans *Teva Pharmaceutical Industries Limited - President and CEO, Global Specialty Medicines*

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

CONFERENCE CALL PARTICIPANTS

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

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

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

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

Liav Abraham *Citigroup Inc, Research Division - Director*

Louise Alesandra Chen *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

Randall S. Stanicky *RBC Capital Markets, LLC, Research Division - MD of Global Equity Research and Lead Analyst*

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

PRESENTATION

Operator

Welcome to today's Second Quarter 2017 Financial Results Conference Call. (Operator Instructions) I must advise you that this conference is being recorded today, Thursday, the 3rd of August 2017. I would now like to hand the conference over to your first speaker today, Kevin Mannix, Senior Vice President, Head of Investor Relations. Thank you, sir, please go ahead.

Kevin Mannix

Thank you, Rose. And thank you, everyone, for joining us today to discuss Teva's Second 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; 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; and David Stark, Chief Legal Officer. We will start the call, which will last approximately 1 hour, with a review of the quarter and revised 2017 outlook by Dr. Peterburg and Mike, followed by remarks from our Chairman, Dr. Barer. We will then open the call 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 will now turn the call over to our Interim CEO, Dr. Peterburg. Yitzhak?

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

Hello, everyone, and thank you for joining us today. I'm sure you all have had the chance to review the press release we issued this morning. We reported today lower-than-expected Q2 results. Revenues in this quarter were $5.7 billion, resulting in a non-GAAP net income of $1.1 billion and non-GAAP EPS of $1.02. Cash flow from operation was soft, amounting to $741 million. We have also lowered our 2017 revenue outlook to $22.8 billion to $23.2 billion and our non-GAAP EPS outlook to $4.30 to $4.50.

All of us at Teva understand the frustration and disappointment our shareholders are feeling. This morning we are going to outline what has changed over in the last 3 months, the actions we are taking and some of the positive development this quarter.

In the last 3 months, our results were greatly impacted by the performance in the U.S. Generics business and continued deterioration in Venezuela. In our U.S. Generics business, we experienced accelerated price erosion and decreased volume, mainly due to customer consolidation, greater competition as a result of an increase in generic drug approval by the FDA and some new product launches that were either delayed this quarter or got subjected to more competition.

Let me explain. One of the most notable challenges we have faced was price erosion and the decreasing volume as well as ongoing consolidation of our customers and their ability to negotiate lower prices for generic drugs. Specifically, in Q2, we finalized both prices and volumes of our in-line products with one of our largest customer, Claris One, the Walmart and McKesson RFP. This development and other new contracts has a greater-than-expected negative impact on our Q2 result and especially on the outlook for the remainder of the year. Given new insight we have into the business dynamic, we have updated our methodology for measuring and focusing price erosion, and Michael will review it in detail.

We've seen acceleration in generic drug approval by the FDA, which we expect will persist. This results in additional competition in our existing portfolio, further increasing price erosion and decreasing volume and negatively impacting our overall business performance and outlook for the remainder of the year.

In addition, some new product launches in the U.S. experienced delays, while other got subjected to more competition. However, we continue to stand by what we said in Q1 and expect to generate approximately $500 million from new products will lift confidence in our ability to launch stronger position for legal, regulatory and operational readiness. Our ability to exceed this number in 2017 has significantly declined over the last 3 months because some notable opportunities were delayed.

Regarding Venezuela, as we told you last quarter, our projection for 2017 included approximately $0.11 of earnings generated in Venezuela over the last 3 quarters of the year. During the second quarter, the situation in Venezuela greatly deteriorated and the Venezuelan currency has been significantly devalued. As a result, we expect to have no contribution from our businesses in Venezuela to earning in the last 2 quarters of 2017.

The collective impact of these headwinds resulted in the lower-than-expected second quarter financial results and lower guidance I mentioned at the outset. The revised guidance ranges assumes no generic competition to COPAXONE 40 milligram in 2017, which we believe is a reasonable assumption based on publicly available information. If there were one or more generic competitors to COPAXONE 40 milligrams in the U.S. for the full quarter in 2017, the result would be $0.20 to $0.25 impact to EPS.

On a GAAP basis, we are reporting today an EPS loss for the second quarter of $5.94. This loss is primarily the result of a $6.1 billion impairment charge to reduce goodwill associated with our U.S. Generics business unit, which includes both the Teva legacy business and the Actavis Generics business. This impairment reflects our revised outlook for the business given the trends we are seeing in the market, as I have just articulated.

While we are impairing some of the goodwill associated with the Actavis Generics business, we believe in the long-term value of the transaction for Teva, particularly as it relates to the best-in-class pipeline, R&D capabilities and global commercial deployment it provides us. Mike will provide further details on our results and revised outlook shortly.

Although I am an interim -- at interim position as CEO, given the current environment dynamics, I have had to take decisive actions, together with the Board and the leadership team, to move swiftly. We needed to make significant business decisions that were not easy to make and that heavily impacted all of our stakeholders, but they are decisions that are critical to supporting the business and Teva's future. Significant change is required at an accelerated pace. To this end, the Board and management team are continuing to take action to aggressively confront our challenges, invest in our core assets and strengthen our leadership position across global markets to deliver long-term shareholders value. First, we are focusing on streamlining our businesses to meaningfully reduce our cost base. Since the closing of the Actavis Generics acquisition, we have delivered on a pro forma basis over $800 million in cost saving, which is ahead of what we had originally planned. By the end of 2017, we expect to realize cumulative net synergies and cost reduction of approximately $1.6 billion, which is a further reduction of $100 million, compared to what communicated previously.

As part of the cost base reduction, by the end of 2017, we will have reduced our headcount by approximately 7,000 people since the closing of the Actavis Generics deal, which is approximately 2,000 above our initial plan.

We are continuing to optimize our operational network. As part of it, we anticipate closing or divesting 6 plants in 2017 and 9 plants in 2018. We are also reducing or optimizing our geographical footprint in markets where we are significantly subscale. By the end of 2017, we expect to exit 45 markets globally.

We recently concluded a full review of our specialty R&D pipeline, with assistance of an experienced outside adviser in order to rationalize and focus our pipeline assets and maximize return on investment. We are also in the final stages of engaging world-class consulting firm to support our U.S. Generics business to realize the full potential of its assets in light of the evolving environment.

To update you on the divestiture I discussed last quarter, I am encouraged by the progress that we continue to make on the sales of our global Women's Health business and our Oncology and Pain business in Europe. Given strong composition for multiple business, we are happy with where we are, and we expect to announce agreement in the coming months. We anticipate proceeds from the sale of both businesses as well as additional asset sales to be at least $2 billion, which is significantly in excess of our previously identified target of $1 billion. We anticipate closing these deals in 2017, subject to necessary approvals. The proceeds raised from divestitures will be used primarily to pay down debt.

Further, while we are solely focused on our core businesses, we continue to review our noncore activities to determine the potential for additional divestitures in 2018. This review will assure that Teva business is much more focused and efficient in this rapidly changing and highly competitive environment.

We are announcing today that our Board has authorized a reduction in our cash dividend by 75% to $0.085. This reduction represents approximately $250 million of cash per quarter. We are committed to striking the right balance and maximal importance in completing goals, including paying down debt, returning capital to shareholders, investing in our business and shedding noncore businesses to enhance focus and generate cash.

While we are tackling our challenges, I do want to highlight that the majority of our global businesses, with exception of the generics business in the U.S. and our business in Venezuela, have been performing well and in line with our expectation.

In the second quarter, we have seen some very significant milestones achieved in our specialty business. This includes a positive Phase III result for our anti-CGRP asset fremanezumab in both chronic and episodic migraine and the approval and subsequent launch of AUSTEDO in Huntington's Disease and its pending approval in tardive dyskinesia.

We also received, along with our partner Celltrion, confirmation that the FDA has accepted for review the BLA for CT-P10, our proposed biosimilar to Rituxan and more recently the BLA for CT-P6, our proposed biosimilar to Herceptin. We believe these exciting new assets, together with our established franchises in CNS and Respi, positions Teva Specialty business very well for the era for the potential entry of generic version of COPAXONE.

Even though the generics business in the U.S. faces challenges today, our deep R&D capabilities in generics give us a strong pipeline of new products in the U.S., where we have more than 300 ANDAs under review at the FDA, of which more than 100 are first-to-file. In addition, our geographical diversity provides a level of stability to balance the business environment in the U.S. And in 2017, we expect to generate more than 50% of our generic revenues outside the U.S.

Before turning the call over to Mike, I want to stress that our team is committed to take decisive action quickly. We recognize that the results we are reporting today are disappointing, and we are focused on executing and doing everything we can to strengthen Teva position, improve our financial performance and reposition the company operationally and financially to sustain and enhance our global leadership. We are also committing to continue being fully transparent. We look forward to updating you as our teams continue to work tirelessly to progress on the actions we are taking.

I will now turn the call over to Mike to provide more insight into the numbers.

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

Thank you, Yitzhak. Good morning, everyone. Please join me in reviewing our Q2 2017 results.

This quarter, revenues were $5.7 billion, up from $5.0 billion a year ago, mainly due to the inclusion of the Actavis Generics business, including Anda. Our GAAP results for the quarter were significantly impacted by a goodwill impairment of $6.1 billion booked this quarter, leading to a loss of $6.0 billion in the quarter, and I will expand on that later in the presentation.

On a non-GAAP basis, net income was $1.1 billion, compared to $1.2 billion a year ago.

Similar to last quarter, the effect of the mandatory convertible preferred shares was antidilutive, so the number of shares remains at 1,017,000,000. The EPS associated with the mandatory convertible preferred shares is $1.09 per quarter. So when EPS is lower than $1.09, we do not add the potential new ordinary shares to the number of shares.

Looking more deeply at our non-GAAP results. You can see the revenues increased by 13%, with a corresponding increase of only 4% in our operating expenses, despite increasing our investment in R&D by more than 20%.

Operating income increased by 1%.

This quarter had a lower gross profit margin, 56.8%, compared to 62.5% in the second quarter of 2016, which was a standalone Teva business only. This is the result of the addition of a low-margin Anda business, which is a distribution business in the U.S. as well as lower margins in our generics medicine business and a mix effect, as post the Actavis acquisition, the generics business has a higher weight than in the past.

The lower profitability of the generics business is mostly due to limited launches this quarter as well as price erosion in our in-line products, as described by Yitzhak.

In addition, R&D expenses for the quarter were up 30%, while S&M expenses were almost flat despite the fact that we have Actavis in our 2017 numbers and not in our 2016.

Cash flow from operations this quarter was softer than last year at $741 million. Since we paid out over $100 million related to the ciprofloxacin settlement and, in addition, Q2 2016 saw some positive impact of inventory reduction, while this year, we had no significant movements.

Looking at the non-GAAP adjustments made this quarter, I draw your attention to the largest item at the top, which is our impairment of $6.1 billion related to our U.S. Generics business unit.

As mentioned by Yitzhak, during the second quarter of 2017, management identified certain developments in the U.S. market, which we feel negatively impact Teva's outlook for the U.S. Generics business. And this has led us to review the value of this business at the half year, though we have typically done our goodwill impairment analysis at the end of the year.

First in Q2, we renegotiated both prices and volumes of our in-line products with some of our largest customers. These developments had a much greater impact than expected, negatively impacting not only our Q2 results, but our results through the rest of the year and our outlook going forward in the near term. This manifests itself as an accelerated rate of price erosion on our base generic portfolio as well as some reduced volumes sold into the marketplace.

In addition, since the end of the year, we have seen an increase in generics drug approvals by the FDA. This has resulted in additional competition on our existing portfolio, which is further accelerating price and volume erosion and negatively impacting our overall business and performance outlook.

Finally, we had some launches for the year in the U.S. that experienced delays and some did not materialize.

All of this led management to revisit its long-term forecast for the U.S. Generics unit, as we see these pressures persisting into the near future, leading to lower revenue and profit most likely in the U.S. Generics in 2018 and potentially 2019. All of these factors, which became strongly evident during Q2, triggered us to review and impair our goodwill to align our revised expectations for the performance of this business in our balance sheet.

The goodwill impairment was the main driver of the changes in our balance sheet, and you can see the goodwill went down by $5 billion. This is the $6.1 billion impairment, offset by $1 billion, which was reallocated to goodwill in the final Actavis purchase price allocation, as we closed the purchase price allocation as of June 30. There was also a corresponding reduction in our shareholders' equity for the charge of the goodwill impairment.

Our total debt increased by $0.4 billion, as foreign exchange fluctuations increased the U.S. dollar value of our debt, which is denominated in other currencies, such as a large portion in the euro and the Japanese yen by $0.6 billion. This more than offset a repayment of $0.3 billion during the quarter of our revolving credit facility and other short-term loans. At the end of the quarter, 4% of our debt is classified as short-term.

For foreign exchange impact, other than the bolivar, FX impact on our results was relatively minor, mainly driven by the euro, the pound and the shekel. We adjusted exchange rate used for Venezuela twice during 2016 and twice again in 2017. In May, we have adjusted the exchange rate used to 640 bolivar per dollar. This had a negative impact of $183 million on revenues and $47 million on non-GAAP operating income when we compare to the similar quarter in the previous year. So there is relatively no contribution from Venezuela to EPS in this quarter.

In light of the political and economic conditions in Venezuela, we exclude the quarterly changes in revenues and operating profit in any discussion of currency effects in our business. We also continue to assess the effectiveness of our control over our operations in Venezuela, and we will monitor our ability to manage this business. If at some point in the future we deem that we have lost effective control of this business, we may consider deconsolidating it from our financial statements.

Q2 EBITDA was $1.75 billion and EBITDA over the last 4 quarters amounts to $7.5 billion on the MAT.

Cash flow, looking at our cash flow over the past 5 quarters, this year has been off to a slow start as we've had almost $900 million of one-time payments in Q1 and additional $100 million in Q2.

Looking at the rest of the year, we expect cash flow to improve to a quarterly run rate of $1.1 billion to $1.3 billion. And as you know, we are in a dispute resolution process with Allergan, which is expected to conclude in November, and we believe we will be entitled to a crash recovery as true-up to our working capital based on the agreement that we have with the closing of the purchase.

Liquidity. As you've seen before, this quarter, our debt increased slightly, mainly due to foreign exchange fluctuations, while our shareholders' equity has decreased following a goodwill impairment. This has resulted in an increase of our leverage to 54%.

The increase in debt, mainly due to FX, has further increased our debt-to-EBITDA ratio to 4.65, compared to 4.63 last quarter, despite an improvement in EBITDA.

Net EBITDA, which -- net debt-to-EBITDA, which is used in calculating our covenants related to certain of our loans is 4.65 compared to 4.49 in Q1. We are currently on track to meet our covenants for the end of the year, which will require a net-debt-to-EBITDA ratio of 4.25. However, if we have lower cash flow in the remainder of the year, for example, if we have lower proceeds from the potential divestments or we have a crossover into the early 2018, we may face the risk in breaching these covenants, which will require us to renegotiate and amend the perspective financial covenants with our debtors.

Quarterly revenues. Looking at our quarterly revenues. They're up 13% from Q2 of 2016. U.S. Generics is up by $410 million, while the other generic markets have grown by $316 million. Most of the growth in the generics business is due to the integration of the Actavis business globally, offset by price erosion and volume loss in the U.S.

Regarding the key topic of price erosion, as mentioned by Yitzhak, if we look at Q2 '17 compared to Q2 '16, rather than a 12-month moving average that we have used in the past, price erosion of our base products was slightly over 6%. We believe this methodology better captures the rapid changes in the market, which we've been seeing recently. Had we used the previous MAT methodology, Q2 erosion would have been near 8%. We do not -- or we do expect price erosion to accelerate in the remainder of the year, and we will be using the quarterly comparison going forward as it better reflects the dynamic nature of our business.

COPAXONE is down $111 million year-on-year, mainly due to lower volumes of COPAXONE 20 milligram in the U.S. as well as some negative pricing effects.

Our other specialty products were $77 million lower. This is mainly due to the loss of exclusivity of the products AZILECT and NUVIGIL in the U.S. as well as some lower sales of our oncology products, mainly due to the stocking impact of the BENDEKA launch, which was at the end of Q2 2016.

We have also recognized $75 million of revenues this quarter related to the sale of the NINLARO royalty stream. There will be no additional income from this transaction going forward.

Other revenues have also increased dramatically, mainly due to the integration of Anda business in October 2016.

Venezuela, as I said previously, reduced revenues by $183 million, while other foreign currency fluctuations have reduced revenues by $35 million.

The changes in revenue described above in this slide have resulted in the following breakdown of revenues: generics revenues now comprise 54% of our revenues; COPAXONE is at 18%, down from 23% last year; our other specialty products account for 18% of the revenues; and the other items, mainly our distribution businesses, including Anda, account for 10% of the revenues.

In terms of profit, we are up 1%, compared to 2018 -- Q2 2016, sorry. Our generics segment has generated $136 million of additional profits, driven mainly by the higher sales as a result of the Actavis acquisition.

Specialty is down $91 million due mainly to the decline in revenue mentioned earlier, which was partially offset by lower sales and marketing expenses and the finalization of an ongoing vendor dispute, which together improved segment profit this quarter by $100 million.

The improvement in G&A you see here contributed $20 million to profit, which reflects both the ongoing effort to reduce expenses in the corporate functions as well as some minor income from the sale of assets.

Other items, including Venezuela and FX, reduced profit by $51 million, compared to the previous quarter -- last year.

The reduction in profitability we see in this slide in the first half of 2017 is the result of factors previously mentioned, mainly the price erosion and relatively low launches in our U.S. Generics business in 2017 as well as the Venezuela currency impact.

Looking forward, we expect profitability of the generics business to improve in correlation with the new launches in the U.S. market.

COPAXONE performance remains solid with both prescriptions and sales relatively stable. Over 85% of U.S. -- we are -- over 85% of U.S. prescriptions and 75% in Europe are now on our 40-milligram version.

Now we'll move to the financial outlook for the year. Our updated expectations for the annual revenues is down approximately 5% from our previous expectations, reflecting both the challenging environment in the U.S. Generics and the Venezuela devaluation. All of our other businesses are on track to deliver their forecasted targets. The same elements and specifically the U.S. price erosion and lower number of product launches also drove the majority of the reduction in our gross profit margin that you see here. We are tightly managing our expenses, as indicated by the savings that Yitzhak mentioned in his speech, and we are able to keep them on track with our savings target despite FX headwinds that we see in the shekel, euro and yen and lower-than-expected other income in the full year, which has negatively affected our G&A forecast.

This brings us to a new range of EPS from $4.30 a share to $4.50 a share. Our cash flow expectation is significantly down, due mostly to the reduction of net income as well as adjustments to our working capital assumptions, the most significant of which is the difference in timing of the cash rebate payments as well as the timing of sales in the U.S. due to delay in launches.

In addition, we plan up the $200 million of other asset purchases, mainly in the R&D space. Even with a lower cash flow from operations, we are on track for debt repayments of up to $5 billion in 2017, subject to the completion of planned divestments in 2017, the timely conclusion of the working capital dispute with Actavis and the risk of further FX effects.

Similar to our previous provided guidance, the revised guidance ranges assume no generic competition to COPAXONE 40 milligram in the U.S. Such generic competition for a full quarter in 2017 would result in a $0.20 to $0.25 reduction of EPS.

That is it for the financial review. I will now turn it over to our Chairman, Sol Barer, for his remarks.

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

Thanks, Mike. First and foremost, I want to echo Yitzhak's remarks and stress that the Board understands our shareholders' disappointment with today's results. I also want to reinforce the support of the entire Board, including our 4 new independent directors, for the actions Teva is taking to improve our performance. We understand that significant change is required, and we all have a sense of urgency. The executive team under the leadership of Yitzhak has the full backing of the Board as it navigates this difficult environment to deliver the results we know our shareholders expect from us.

It's never easy to take action to reduce the dividend. However, we will continue to make the tough decisions when necessary. After carefully reviewing our dividend policy, we determined that the cash generated from this reduction, combined with other measures, will help us pay down debt, invest in our business and great array of assets that Teva has within its portfolio and operate successfully in the current environment.

We are also mindful that Teva is an important company to patients and health care systems around the world. As I've said before, we also take this responsibility of being a responsible corporate citizen very seriously, and we are committed to doing things in the right way.

Before turning the call back over to the management team for Q&A, I want to briefly touch on our ongoing search for a permanent CEO. This is a process we are not going to rush, and we will not compromise on quality and on finding the best individual possible to lead Teva. Let's now turn to the Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of Randall Stanicky of RBC Capital Markets.

Randall S. Stanicky - *RBC Capital Markets, LLC, Research Division - MD of Global Equity Research and Lead Analyst*

I just have a question and a quick follow-up. When you first provided guidance late last year, you had implied a roughly $1 step-up in the back half. That's now $0.70 lower on the implied midpoint of your guidance currently. So can you just quantify for us where that $0.70 change has come from? And then my follow-up is, I just want to front this, you're going to get the question probably on this call about breaking up the business. But is that even a realistic given the $35 billion in debt and what would be likely significant dis-synergies, is that effectively off the table?

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

So to answer your first question on the guidance, as you've seen our guidance range has come down to $4.30 to $4.50. There's a couple of things driving that, mainly the price erosion in the U.S. business, the additional competition and the effect of Venezuela. Those are the things that are driving the majority of that $0.70 difference. And because we had a back-loaded year, we were expecting to ramp up significantly in the second half. We originally had guided to a 40-60 split. The way we see it now, we see Q3 more relatively in line with what we've seen up to now. And we will see a tick up in Q4, as the U.S. Generics launches take into more effect. I will now turn it to Sol for the second part of the question.

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

Okay, thank you for the question. Look, the Board and the management team are right now focused on doing what is best for our shareholders and that is concentrated on delivering our business goals to continue to take action to aggressively confront our challenges, invest in our core assets and strengthen our leadership position across all our markets. We believe by doing this, we are delivering long-term shareholder value. Having said all of that, we continually evaluate what the best things are for our shareholders. So again, just to be clear, we are focusing on our business and financial priorities very aggressively right now.

Operator

Your next question comes from the line of Andrew Finkelstein of Susquehanna Finance.

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

I was hoping you could talk a bit more about how the phasing from some of these consortium bids are coming in for the rest of the year and how that relates to your commentary around the accelerating price erosion in the back half of the year. And then you mentioned some work with outside groups to look at the strategy in U.S. Generics. Could you maybe talk conceptually about what kinds of initiatives you and probably others need to take to put the business on better footing for the longer-term?

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

Yes, so thank you, Andrew. First, let me address the question that you have around the consolidation of the buyers. As you know that, now at this point in time, approximately 80% or a little higher than that, of generics purchases are concentrated in 4 GPOs. Specifically in quarter 2, we saw the impact coming from finalization of ClarusONE, which is the RFP that was from a combination of McKesson and Walmart. We saw some impact of that due to price adjustment in the latter part of the quarter as well as some shelf stock adjustments that we had to do. It has negatively impacted our prices. And we also largely secured most of the volumes that we have seen. Earlier in the year, we had a similar RFP from another GPO, which

is ECONDISC. And at this point in time, we have no further news as to whether there will be further RFPs or not. In terms of the effect of these RFPs on the remainder of the year, it will lead to a higher price erosion and that is built into our forecast. Coming now to the second question.

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

When you say higher, higher than what?

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

So Mike mentioned earlier that using our new methodology, in quarter 2 we saw the price erosion to be around 6%. In the remainder of the year, we expect the price erosion to increase to high single digits. Now coming now to the next part of the question that you asked, which is around the strategy of the generics business, as was mentioned earlier, we are -- we have engaged or we are in the process of engaging some external consulting help to look at our overall strategy for the U.S. Generics business. We feel very encouraged by the fact that we have an extremely strong pipeline coming out of our R&D. We have slightly over 300 ANDAs, of which more than 100 which have been filed and of which we have in excess of 100 which are first-to-file. In addition to that, we also have about 300 products in development which we haven't filed as yet. As the combination of these 2, we are targeting close to $200 billion of brand sales. So as far as the future is concerned, I think we need to put it in perspective, not just in the context of the price erosion that we see, but also the value that is going to come through our new products pipeline.

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

So where is the area for improvement to -- I mean I think the rationale for the Actavis deal was certainly to get access to that pipeline. What's the key to making sure that you are able to get the value that those products are providing to the health care system and patients?

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

Yes. So the shift in the pipeline that we have accomplished through the Actavis acquisition is the products in our pipeline now, we believe the greater value will come through more complex products. We have products in development, which are in the respiratory area, they will be AB-rated products. We have products in development, which are long-acting injectable products, they are difficult to make, they are difficult to get regulatory approval, and we believe that the value that we will see out of these products will be far more durable than some of the blockbusters that we have seen in the past.

Operator

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

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

A couple of questions. First on buying groups. If we imagine they are like bullies and with the bully you kind of have a few different choices, either punch them in the face and hope they stop or you have a choice to keep getting beaten up or move. So when it comes to Teva, since you're generics and you can't really move out of the neighborhood, do you have -- and this quarter kind of shows that you don't really have the ability to stop the beating, why should we think this is a 1 year phenomena rather than something that we're just going to keep seeing happen year-after-year given the pricing power that the buying groups have? And then secondly, just a clarification, on generic COPAXONE, I want to make sure I heard it correctly that you said the impact of a generic COPAXONE 40 milligram you estimate would be $0.25 per quarter. Is that with one competitor assumed? Or is that multiple competitors? And is it fair to assume that 2018 guidance will include an impact of a generic COPAXONE so that roughly we should imagine all things being equal, a dollar lower EPS?

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

So David, first, let me take the question that you asked around the consolidation of buyers. So on the buyers, first, we see ourselves strategically aligned to the 3 or 4 large customers that we have in the U.S., okay? The relationship that we have is we try and find situations where there is a win on both sides. So while through these RFPs we have seen price erosion, we have also been able to secure additional business. So I think that to see them as simply a transfer of value from one place to another is not how we look at our partnership with them. Regarding as to what is the future outlook in terms of pricing, the formation of these GPOs has resulted in a degree of harmonization of prices among the different members of the GPUs. And as you are aware that in the GPOs, you've retailers, you've wholesalers, you have people who are different positions in the value chain. So over a period of time, as these prices are harmonized among the different trade classes, we do believe that there will be a degree of stabilization that will come.

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

Let me take the generic COPAXONE question. Based on what we see in the market and the public information that we have, we still feel confident that we will not see a generic COPAXONE 40 milligram in 2017. If we were to see one or multiple competitors in Q4, the numbers we have given you of $0.20 to $0.25 is a reasonable range for us. It's too early now to comment on 2018, we are just starting our annual operating plan. We will, of course, come back to you in early 2018 with our guidance for the year. But we still hope not to see a generic entry in 2018, though the numbers you have there for a quarter are probably not a bad rough estimate based on what we've seen up to now.

Operator

Your next question comes from the line of Ronny Gal of Bernstein.

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

If you don't mind, I'm going to ask 3. The first is to Sol. Sol, you had mentioned needing to do things the correct way on cost cuts. But we hear a lot of noise coming from Israel and the question is doing the right way is important but you're also resolute enough to actually go through with some of the cost cuts within Israel, which is obviously a place where a lot of your costs are based. And I know I am touching a tough point, but I think it's got to be addressed. Second on the U.S. Generics, I'm not going to join David's flowery language in terms of bullying and such, but I think the core argument is still there. I mean, are you actually making money in dealing with a large group purchasing organization on a commodity business? And given where you are today, should this business not shift to a differentiated generic business only cutting out of the commodity products that are not making you money in the United States? Are you not in a position to start thinking about exiting this? If we look at what happened with the injectable generic business when the group purchasing organizations have been founded, as the product pricing went down all the way down to the point where there was no supply in the market. We might be heading that way with the oral solid products. Is this not the time to potentially just step away from this business? And third, just not to be a complete downer for this call, AUSTEDO, you launched the product this year, can you give us a little bit about the update about the launch of that product?

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

So Ronny, it's Yitzhak speaking. I'll take Sol's question. I think questions about our notification of cutting 350 employees in Israel. So decisions like this are never easy, but we really firmly believe that this is the right thing to do, first of all, for our businesses in Israel and you know that even for the employees in Israel. And for sure for all of our stakeholders for the long term. We value the dedication and the hard work of all the employees, and we are committing to treating the affected employees with dignity and respect.

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

Second question, Dipankar?

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

Yes, Ronny, let me address it in the following way. We have a large portfolio of products. And a part of that portfolio is relatively more commoditized products. And the example that you gave are many of these are instant relief oral solid dose products. Overall, first, what we have is an active tail management process where we find that whenever a product within our portfolio which is highly commoditized with many competitors, where we are not cost-competitive enough, we usually remove them from our portfolio. We have an active portfolio review process through which we address that. Nevertheless, if when we look at the combined commoditized part of our portfolio, it still continues to be quite attractive. And one of the most significant contributors to that, the 2 reasons are, first is, many of these products are where we are vertically integrated and we have an extremely cost-competitive supply chain. The second part of it is the breadth of our portfolio by itself allows us to get a relatively attractive price even within the context of the overall commoditization. So I don't think that we have reached a point, and we are far from reaching the point, where this portfolio ceases to be attractive to us. Answering the second part of your question is, should we not move to complex generics, more difficult to make products? Yes, we have, and that is where our R&D investment is principally focused.

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

Net of COPAXONE, are you making money in the U.S. commodity Generics business?

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

Yes.

Dr. Rob Koremans - *Teva Pharmaceutical Industries Limited - President and CEO, Global Specialty Medicines*

And Ronny, let me take your third question on AUSTEDO. We are extremely happy with progress so far. The product is doing well, the feedback from patients, doctors is very positive. And also on the payer side, we really don't see any major hurdles. We now have about 800 patients being treated. As you know, you don't pick it up in IMS because about the largest part is actually going through Specialty pharmacy. We expect that you will only see about 10% or so eventually in IMS. And also, we started this launch with giving patients the option of titration free of charge, which will take about 2 months on average for patients. But so far, we are extremely happy and looking forward now to the launch in PD, which we expect to be able to do in September. We are in active negotiations with the FDA on the label. And also that looks good. It's too early to comment on anything because you always have to wait for it, but so far so good for AUSTEDO and I'm extremely pleased with the progress we're making there.

Operator

Your next question comes from the line of Louise Chen of Cantor Fitzgerald.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

I had a few. So first question here is just following up on some of the earlier questions on consolidation of these consortiums, it seems like they are pretty consolidated. So if they can't get any larger, shouldn't generic drug pricing stabilize from here? And when could we see that? And then the second question is, if a breakup of the company is achievable, does the result of this quarter in the generics business push you closer to doing something like that, just because it seems like the brand business probably isn't getting the attention and the valuation that it deserves given some of your advancements there. And then last question here is just despite the setback this quarter, do you think there is still room left to grow the

U.S. Generics business? And if so, could you give us specific examples where you see this, could it be biosimilars? You mentioned the complex generics. But what's still out there that's interesting?

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

So thanks for the question. Let me start with where you -- the first question where you are asking where is the effect of the GPU consolidations, how will it play out and at what point of time we will see the stabilization? So the GPU consolidation started a couple of years ago and accelerated since then. The more recent phenomena that we have seen in the last 6 to 9 months is the frequency and the scope with which the RFPs have been sent out by these GPUs. And to a certain extent, that was to bring about a degree of price harmonization among the different members from the different trade classes within the GPUs, as I mentioned earlier. And the most recent and the most significant RFP was the one that was with ClarusONE that closed at the end of the second quarter. Now the effect of these RFPs will take time to clear, and which is why I mentioned that we will see an increase in price erosion in the second half of the year. We have to see as to how long it takes. I expect that some of it will advance into 2018 as well. And so over a period of time, as the prices among the members become similar and the prices across the GPUs become similar, we will begin to see a degree of stability in the price erosion itself, but it's not that the price erosion will not be there, but the erosion in itself. The second is, in order to understand the dynamics of price erosion, there are 2 contributors to price erosion. One is the erosion that happens on the base business. And the second is the erosion that arises out of transition products. And let me explain to you what are transition products. Transition products are by their nature products that had enjoyed a certain degree of market exclusivity, enjoyed higher prices and volumes. And with the inception of additional competition, they see very radical decreases in prices and volumes. The second are transition products, which are currently enjoying higher prices and volumes, but they are likely to lose that in the foreseeable future because of additional competition coming. Now depending on the company and depending on the portfolio of the company and how much of the business comes from transition products, that is also a significant contributor to price erosion when you look at all-in portfolio of the company. So it changes from year-to-year, it changes from company to company depending on the products in the portfolio.

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

On your second question, it's Yitzhak, you know Louise, coming back to what's happening on generic, I think we spent some time about the challenges and what we're doing now, management and board, is really concentrating on really taking the right action items to aggressively confront those challenges. Things that -- Questions that are coming all the time about splitting the company, the only way I can answer is that our board and our management team are committed to acting in the best interest of our shareholders. We evaluate all the time the situation. And I think we are doing the right thing now.

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

So let me also address the question that you asked around is it possible for the U.S. Generics business to grow? In the U.S. Generics, our ability to grow is dependent on 3 factors. The first is the flow of new product launches that we have in any particular year. The second is the price erosion and the one that I explained in my earlier response, both on the base business as well as on transition products. And the third is net changes that we may see on our market share on some of our key products. Now the most important contributor to this is -- are the new product launches. And there, as I mentioned earlier, in our pipeline, we have 300-plus pending ANDAs, of which 100 are first to files. There are, in addition, another 300 products in development which we haven't filed as yet. Overall, this targets about $200 billion of brand sales. And even within our portfolio, the R&D dollars are now directed towards developing more complex products which are more difficult to get approval for and, hence, the intensity of competition around those products are likely to be less than what we see in either oral solid or instant relief or even extended relief product. Often these are medicines and device combinations, they are difficult to get approval for. So we do believe that there will be some years where we can grow, there will be other years it will be very difficult to predict, depending on the flow of new products.

Operator

Your next question comes from the line of Greg Gilbert of Deutsche Bank.

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

First, Mike, can you clarify your cash flow guidance and expound and give us free cash flow guidance for the year? Second for Yitzhak, you sounded confident in getting $2 billion or more from divestitures and getting the money by year-end. It sounds like it's important for covenants to get it. What supports your confidence in the more than the $2 billion or more comment as well as getting the money that quickly, given no announcements yet? So please be specific if you can. And third, I think it's for Dipankar, you're cutting your U.S. forecast on factors that many other companies and industry followers have highlighted months or quarters ago. So given that, how can we be confident that the new forecast is conservative enough? And what changes have you made to any processes or forecasting or personnel or you're simply just using a lower number in the model?

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

Let me address your first question on cash flow guidance. You've seen that our guidance on cash flow from operations is 4.4 to 4.7. When we look at free cash flow, we use a definition that includes the proceeds from the divestitures. Assuming that we are able to complete the divestitures as mentioned by Yitzhak, we feel that we will still be in the range that we originally had published of over $6 billion. Of course, that will be subject to the timing of all the necessary approvals. And does face a little bit of crossover risk between the end of Q4 and beginning of 2018. In any case, we feel, it will help us on our path towards deleveraging and help us to pay down the $5 billion of debt that we've promised in the past.

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

Regarding the divestitures, first of all, as I update you in the call, the situation is that we are continuing to make very good progress on the sales of those assets. We see strong competition from multiple bidders, and we are happy where we are and expect as I said to announce agreement in the really coming months. Saying all of it, we anticipate closing these deals in 2017, but this is subject to necessary approvals, and that's exactly where we are. We think we will get the number I showed you.

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

So let me answer the last part around the generics forecast. So in the remainder of the year, the way we have looked at our forecast is the following: that there are really 2 key elements. The first element is the degree of price erosion that we expect in our base and transition products. And what we have done is we have looked at the impact of the RFPs, the impact of the shelf stop adjustments that we have done. We have modeled them on the basis of volumes that we expect out of these for the remainder of the year. And that is based on information that we have, that is based on our anticipation of what further changes that can happen. And we feel good about that forecast for now. As we -- as I explained earlier also, that it does lead to a higher level of price erosion in the remainder of the year than what Mike reported for the second quarter. The second significant element is the new product forecast, which, for the year, we have said we feel good about the $500 million. And let me expand on that. So as we described at the beginning of the year, we were targeting more than 80 different product opportunities that are expected to yield from 40 -- yield about 40 to 50 launches in 2017. And let me give you some more color on that. As of July, we have launched around 30 products that we expect will yield approximately $270 million in annual revenue this year. Some of our notable launches year-to-date are the generics of GLUMETZA, Pataday and Epiduo. As you're aware, Pataday and Epiduo are 2 products on which we enjoy 180-day exclusivity. In the second half of the year, the way we have looked at our new product launch revenue is we have a number of launches where we have a stronger position from a legal, regulatory and operational readiness, and I'll give you some more examples of that. These are launches of the generics of Viagra, Viread and a combination of these, we feel quite good about the fact that we will get to the $500 million that Yitzhak spoke about earlier in his opening remarks.

Operator

Your final question comes from the line of Liav Abraham of Citi.

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

So just on the CEO search. Can you provide just a bit more of a detailed update, something going on now for 6 months. How close are you in terms of time lines? And to what extent is this any kind of limiting factor on making any kind of strategic decisions at the company? And then secondly on the debt. Can you confirm that you are still on target to pay down, I think you mentioned earlier this year about 5 billion --

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

You're breaking up. Okay. So let me provide I will answer your first question in terms of the CEO search. As I've said several times, and you're right, it's been approximately 6 months, we are looking -- this is a global search. We are looking for the right person to lead Teva. I've gone through the qualifications of that person, including significant very senior level, CEO level experience at major global pharmaceutical companies. The ability to manage in a changing environment, cultural fit, et cetera, all these things. To me, this is a very critical hire for us as we are determining in many ways the leadership for a long time and setting a course for Teva in doing this. So this is my primary sort of personal objective at Teva. I live, eat and sleep this. And while it is always great to do this in a rapid time, et cetera, 6 months is not a long time for -- to look for a CEO. We have (technical difficulty) .

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

Can you expand on your second question, we kind of got cut?

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

You're still on target to pay down $5 billion in debt this year and any comments on how much you anticipate that you'll be able to pay next year, any target going forward, that would be helpful as well.

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

Okay. As I mentioned earlier, with the proceeds of the divestment sales, we feel we are on track to pay down the $5 billion. The one fact that we just don't have control over is currency, if the euro and the yen continue to appreciate against the dollar, we could, of course, miss that target a little bit. But we are on track to pay the $5 billion. As we go into 2018, we are still early in the process of looking at that. We are committed to repaying our debts as they mature. And we're also on track for all the commitments that we have. We will come back to you of course early in 2018 with further color on that as we get into the annual planning process.

Operator

We would now take a question from the line of Umer Raffat of Evercore.

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

So I wanted to focus on 3 topics if I may. First on the free cash flow guidance, just wanted to understand why the free cash flow guidance drop was more than the EBITDA guidance revision down. Just wanted to understand the dynamic there, number one? Secondly, if you could comment a bit on the pricing pressure on COPAXONE, why that is, I noticed a bunch of your MS competitors didn't have that, but I just wanted to understand the dynamic. And then finally, just wanted to spend a minute on debt. So the latest debt is about $35 billion and probably drops and what I'm trying to get us is the covenant. So the debt is $35 billion, probably drops to about $33.5 billion organically by Q4. And if you get another couple of billion divestitures, that's $31.5 billion debt by year-end. So that $31.5 billion debt balance divided by 4.25x, which is your covenant, would get you an implied EBITDA of $7.4 billion is where you should be for the trailing 12 months, which is effectively 2017. Your first half of the year is tracking at

$3.6 billion, which would imply that a full year $7.2 billion or under. So isn't that below what the covenant requires? I just wanted to understand how you're thinking about that and what you have to do.

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

Yes, thank you for your suite of questions. I'll try to get through them. First of all, the gap that you're seeing between the net income and the cash flow from operations free cash flow are due to 2 things. One is some working capital timing as some of these launches and other items shift later in the balance sheet, the collections are more likely to be in 2018 than 2017. And in addition, in my slides I mentioned that we are purchasing some minor assets, mainly in the R&D space, of up to $200 million. So that kind of bridges the gap between the EBITDA that you see and the cash flow. In terms of COPAXONE, when we say net pricing adjustment, this isn't necessarily our pricing in the market. If you remember, we have a 20-milligram generic in the U.S., which is putting a little bit of pressure on us. We also saw in 2016 in Q2, if you remember from our presentation there, that we had a little bit of a favorable gross-to-net adjustments in 2016, which was a follow-on of the 2015 launch of the U.S. generic for the 20-milligram, which had some, of course, we weren't able to predict what channels all of that was going to be in. So we had a little bit of a one-time positive in 2016 that did not repeat. In terms of the debt, of course, doing the math, we are on track for the 4.25x based on our cash flow. Of course, it's going to be that we have to hit the EBITDA within the guidance that we've put out. We, of course will monitor the situation and be in close collaboration with our creditors to make sure that we take prudent steps and if necessary to talk about adjustments or refinancing if we feel that we need to do that sometime in the future.

Kevin Mannix

Okay Rose, we're going to close the call now.

Operator

I would now like to turn the conference back over to Kevin Mannix. Thank you sir, please go ahead.

Kevin Mannix

Thank you, everybody, for joining this call this morning, which started earlier than we normally do. We know it's a busy day for all of you. We apologize to the folks who we were unable to get to in terms of asking questions. And the management team will make itself available throughout the day, tomorrow and next week to answer any questions you might have. Thank you very much.

Operator

Thank you. Ladies and gentlemen, that does conclude our conference for today. Thank you all for participating. You may now disconnect.
