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TEVA.TA - Q3 2016 Teva Pharmaceutical Industries Ltd Earnings Call

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OVERVIEW:

Co. reported 3Q16 total net revenues of $5.6b and non-GAAP EPS of $1.31. Expects 2016 net sales to be $21.6-21.9b and diluted non-GAAP EPS to be $5.10-5.20.

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Teva Pharmaceutical Industries third-quarter 2016 results call. I must advise you this conference is being recorded today, Tuesday, November 15, 2016. I would now like to hand over the conference to Kevin Mannix, Senior Vice President, Investor Relations. Thank you, please go ahead, sir.

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

Thank you, Lawrence. Thank you for joining us today to discuss Teva's third-quarter 2016 financial results. On the call with me today are Erez Vigodman, Chief Executive Officer; Eyal Desheh, Chief Financial Officer; Siggi Olafsson, President and CEO, Global Generic Medicines; Dr. Rob Koremans, President and CEO Global Specialty Medicines; Dr. Michael Hayden, Head of R&D Chief Scientific Officer; Dr. Carlo De Notaristefani, President and CEO Global Operations; and David Stark, Chief Legal Officer.

We will start the call with presentations from Erez, Siggi and Eyal before opening the call up for questions and answers. A copy of today's press release and slides can be found on our website, Tevapharm.com under the Investor Relations section, as well as on the Teva Investor Relations app.

During this call, we will be making forward-looking statement, 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 the results 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 supplemental data, and not in substitution or replacement for GAAP results, because management believes such data provides useful information to investors.

And with that, I'll now turn the call over to our CEO, Erez Vigodman. Erez?

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

Thank you, Kevin. Hello, everyone.

Thank you all for joining us today to discuss our financial results for the third quarter of 2016. Before I start, I would like to make a personal note. I want to acknowledge the passing of a dear friend and colleague, Richard Egosi. Rich was an integral part of Teva for over 21 years, serving most recently as our Chief Legal Officer. He was a pillar of strength and integrity, with passion, professionalism and innovative thinking, left a remarkable legacy. He will be greatly missed.

I've often noted on our quarterly calls, and in my discussions with all of you that 2016 is truly a year of transition for Teva. Throughout the year, we have completed key moves highlighted by the closing in August of our purchase of Actavis generics business.

I'm very proud of the role that the employees of Teva have done to get us to the finish line, of all of them and begin integrating them into Teva. This will serve us well in building our long-term future, and achieving our mission of providing the Company with a balanced and diversified portfolio of levers of growth, which we believe will create lasting shareholder value.

I want to start by briefly discussing our third-quarter results. Eyal will take you through a much deeper dive of the numbers in just a few minutes. This was an important quarter for Teva, with the first in time inclusion of Actavis generics. Our total net revenues of $5.6 billion for the quarter were up 15% compared to the third quarter of 2015. This includes two months of Actavis generics, which contributed approximately $890 million to the top line.

Our non-GAAP operating income for the quarter was up 16% compared to Q3 2015, while non-GAAP EBITDA and net income were up 16% and 17%, respectively. Our non-GAAP EPS declined 3% year-over-year as expected, due to the dilutive effect in the first year of the additional shares used to help finance the transaction.

Our cash flow from operations was also strong at $1.5 billion. In addition, we received approximately $1.7 billion from the proceeds of 79 divested products in the United States required by the FTC to satisfy the conditions for completing the Actavis acquisition.

The completion of the Actavis acquisition strengthens and broadens our R&D capabilities, and highly complements our product pipeline, product portfolio, geographical footprint and operational network. It enhances Teva's leadership in an evolving competitive landscape and massive consolidation across our customer base. In addition, our integration plans with the Actavis generics business are on track.

Looking at our specialty pipeline, in the third quarter, an important highlight was our Company's resubmission in response to the FDA's Complete Response Letter for SD-809 for Huntington Disease. In October, we were pleased to report that the FDA had accepted the resubmission and assigned

a PDUFA date of April 3, 2017. And by the end of this year, we plan to submit an application for SD-809 for the treatment of tardive dyskinesia, after having completed successfully the second pivotal Phase III study which met primary and secondary endpoints.

In September, we announced a collaboration with Regeneron to develop and commercialize fasinumab, an investigational NGF antibody for chronic pain. We believe fasinumab has the potential to provide treatment option for chronic pain without the concerns of abuse addiction and misuse of opioids.

The collaboration will result in incremental specialty R&D spend in the fourth quarter of 2016, and for the next few years. Lastly, soon after the quarter ended, in early October, we are pleased to announce an exclusive partnership with Celltrion to commercialize certain biosimilar products leveraging on Teva's unique cross-functional capabilities in specialty and generic medicine.

Before I discuss the focus for Teva moving forward, I would like to acknowledge that while 2016 is indeed the year of transition, it has also been a challenging one for Teva and the entire industry. I would like to address a few Teva-specific challenges now.

As mentioned in today's earnings release, we are in settlement discussions with the US Department of Justice and the Securities and Exchange Commission to fully resolve the previously disclosed FCPA investigation. The conduct under discussion relates to three countries, Russia, Mexico and Ukraine, during the time period covering 2007 to 2013. In light of the advanced stage of this discussion, we are now establishing a provision for approximately $520 million in the third quarter.

None of the conduct of question involved Teva's US business. We are looking forward to putting this matter fully behind us as soon as possible, and we have addressed in a robust way the issues that gave rise to it as follows. Upon learning of FCPA concern in 2012, we accelerated the pace of changes to address these issues by completely transforming our governance program and processes on every level. This resulted in actions including terminating problematic business relationships with third-parties, separating relevant employees from the Company, fully overhauling the management of several subsidiaries, ceasing operations in several countries, and even disbanding entire business units.

We have also restructured the Company through a new global organization structure and chain of command that reduces risk. In order to institute a culture of compliance throughout the organization, we have also trained tens of thousands of employees on compliance measures, protocols and best practices.

Since becoming Teva's CEO in 2014, I have made compliance a top priority in everything we do. The compliance program that Teva has in place is serious, rigorous and comprehensive, and is designed to protect the Company and its subsidiaries against future violations. Today, Teva has a compliance culture that begins with a strong tone at the top, including our executive regional and local management, a culture of compliance that underpins every single business decision that Teva makes.

Next, I'd like to turn to our acquisition of RIMSA in Mexico. In September, Teva filed a lawsuit again the sellers of RIMSA for fraud, as well as breached representation and warranties in the purchase agreement, after Teva uncovered evidence of systematic information manipulation regarding the drug development and manufacturing that were carried out over an extended period of time. These violations were concealed from us, during the due diligence process by presenting us with false records.

We did not disclose the situation in RIMSA earlier, as we attempted to address the situation with the local agencies, and then negotiate a settlement with the seller. We have put in place a full remediation plan to address the issues identified. We believe that over time, we will be able to realize the opportunities that the Mexican market provides for us.

Finally, I cannot conclude this part of my remarks without briefly addressing the US Department of Justice investigation into price collusion in the generic drug industry, which has been in the news this month. I would like to emphasize that based on all of our efforts to date, internal and external, we disclosed, and I'm reiterating it here today, that we are not aware of any fact that would give rise to an exposure to Teva with respect to the investigation.

Let me now turn, and provide you with an overview of the near-term focus for Teva. It is very clear to our management and Board what the priorities must be fulfilled. A significant amount of capital has been deployed over the last 12 months to acquire assets and partner with other companies, in order to enhance our existing levers of growth, as well as create new ones.

Now it is time for Teva to step away for the foreseeable future from executing material BD deals, and to focus all of its energy on organic growth, and extracting all of the deal-related synergies, and unlocking the maximum value from the deal. We are determined to use the deals as a catalyst to transform Teva even further, and drive even more efficiencies throughout the entire organization, with a focus on cash flow generation and paying down our debt.

For our generics business, this means capturing cost synergies while driving organic growth through new launches around the globe, especially in the United States, while constantly replenishing our pipeline through our industry-leading R&D. We leverage the combined portfolio infrastructure of Teva and Actavis generics and maximize value from our market-leading position.

For our specialty business, this means successful execution in the development and commercialization of our key pipeline assets, most notably our anti-CGRP product for migraine, SD-809, and fasinumab, and further expanding our pipeline through in-house development programs. By the same time, we continue to protect Copaxone in multiple ways. 2017 will be an important year for Copaxone, as we await the decision of the lower court on several patents protecting Copaxone 40 milligram.

It is our intention now to focus on using our cash flow to pay down our current level of debt. Today we benefit from an investment grade rating, and it is very important for Teva that we maintain it, and even make it stronger over time. And with that, I will now turn the call over to Siggi to review our generics business.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

Thanks, Erez, and good morning, everyone. This quarter was one of monumental change for Teva's global generic medicines business. On August 2, we completed the strategic acquisition of Actavis generics. The result is a much stronger, more competitive Teva that is best positioned to thrive in an evolving global generics marketplace.

We also announced the acquisition of Anda, the fourth largest distributer of generics in the US, which closed shortly after the end of the quarter. The acquisition of Anda reflects our belief that distribution capabilities are very complementary to our pharma business, and Anda provides an important service for many of our customers, as well as our competitors. The combination of these businesses expands our growth opportunities and the value we can bring to our customers and the US healthcare system.

Turning to the performance of our global generics business in the third quarter. Total revenues were $2.9 billion, an increase of 32% compared to third quarter of 2015, reflecting the results of operation of the Actavis generics business from August 2, 2016 or approximately two months contribution. The two months of Actavis contributed $887 million in revenues. No revenues from Anda were included in third quarter.

In the US, there was a small decline in the Teva legacy generics business, which mainly resulted from a loss of exclusivity, and intensified competition for generic versions of Pulmicort, Nexium and Xeloda. As I've stated before, new product launches are crucial for growth over any period of time, and there was a lack of significant new product launches during the third quarter.

This was attributable to delays in product approvals and the IP decisions, as well as quality challenges experienced by third-party suppliers. These delays will likely impact fourth quarter as well, pushing some of the larger launch opportunities into 2018 and 2017.

This quarter, the price erosion on our US-based business was approximately 7% versus a year ago. This is slightly higher than our expectation going into the quarter, with a key driver being increased price pressure on select products as we divested some of the Teva/Actavis overlaps, and they transitioned to the new owners.

This created some temporary market instability for these lower competition products. Despite this, we are very confident that the price erosion we experienced in the US will continue to be in the mid single-digits as we have guided throughout the year.

As we have shared in the past, our broad portfolio, strong pipeline of new launches, and the durability of our more differentiated products continues to set Teva apart from many in the industry. Compared to third quarter 2015 and adjusted for divestiture, Teva standalone global generics business is down approximately $30 million in revenue. With very few product launches in the quarter, that's a really good result, and shows the strength of our underlying business.

Turning to our profit margins, the generic business came in at 29.9%. By exercising strong focus on cost control, and driving the right business mix, we compensated for challenges on the top line.

The closing of the Actavis transaction has gone very smoothly since day one, with no operational disruption. While we were disappointed at the delay with the anti-trust review, the time allowed the integration teams of Teva and Actavis generics to work diligently to plan for integration of the two companies, in order to ensure that combined Company would be fully operational immediately upon closing of the transaction.

As a result, Teva was able to begin capitalizing immediately on the benefits offered by the acquisition of Actavis generics. This included optimizing our R&D activities, harmonizing our customer contracts and relationships, and realizing economies of scale with our purchasing.

We also continued with the integration of the joint venture in Japan. Full distribution integration was achieved by the end of the quarter, and we are very pleased with our partnership with Takeda. As Erez discussed, we continued the integration of RIMSA despite the challenges. We are committed to the Mexican market, and we are working hard to leverage the assets from RIMSA as the basis to drive our growth in the region.

Our global generics R&D effort continued to produce new files around the world. Most notably, we continue to lead the industry in the US. On first-to-files, which is still a significant value driver in the US generic market, this year Teva has received confirmation of 23 new first-to-files, which is approximately half of the total number posted by the FDA, and more than [80%] of the total first-to-file brand value posted in 2016.

10 of these 23 first-to-files occurred in third and fourth quarter, and we hope for several more by year-end. New launches are the life blood of any generics business, and are key to any company's ability to grow both the top and bottom lines. With the acquisition, Teva now has more than 2,000 product registrations pending approval around the world, and we have significant value in our more than 100 confirmed first-to-files for the US markets. These include potential opportunities to launch generic alternative products to Nuvaring, Viagra, Axiron and Byetta, and many others in the next 12 to 24 months.

In closing, we strongly believe in the generic industry for the long-term, despite the current volatility. With our recent investments, Teva is the best positioned Company in terms of market presence, manufacturing capabilities and pipeline, and I see this business growing mid single-digits going forward.

We bring tremendous value to our customers and savings to the global healthcare system, generics are part of the solution. As I've mentioned previously, short-term volatility will always show up in the generic business, but over the long-term, we see profitability and growth.

And with that, I will now turn the call over to Eyal.

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

Thank you very much, Siggi. Good morning, and good afternoon, everyone. I would now like to walk you through some of the highlights of our financial results for the third quarter and the first nine months of 2016.

This was a good quarter, the first to combine Teva and Actavis generics businesses. Our GAAP results that shows first, which include a number of one-time item which I will discuss in a few slides, showed net income and earnings per share improvement compared to Q3 2015. Looking at the non-GAAP results, all-in all it was a good quarter, with 15% inorganic growth in revenue, which was complemented by 16% growth in EBITDA and

17% growth in net income. Non-GAAP earnings per share was $1.31, $0.04 lower than last year, resulting from the increase in number of shares following the Actavis acquisition.

Cash flow from operations and free cash flow were up nicely compared to last year. We generated a strong $1.5 billion in cash flow from operations. It was up 34% compared to Q3 2015.

We had a number of one-time items this quarter, as well as costs associated with the acquisition of Actavis. Non-GAAP adjustment include the provision for the anticipated FCPA settlement with the government, the investment with Regeneron, which is classified as in-process R&D, a gain from divesting certain Teva products as part of the Actavis deal, and increasing amortization and dealer-related inventory step-up, and the corresponding tax impact of all of that.

Our financial leverage increased to 50% as a result of the borrowing needs to finance the Actavis acquisition, and debt to EBITDA is 5.4 times at the end of the quarter. We expect this ratio to improve to under 3.5 times 18 months following the close of the transaction, in order to protect our BBB rating. Following the transaction, EBITDA increased to over $1.9 billion this quarter.

Now let's look at what happened to revenues. In this view, we separated the products we had to divest as part of the Actavis deal. You can see that in the separate column of $105 million in divestitures. It was split approximately 50/50 between the legacy Teva and the Actavis business.

Without these divested products, Actavis two-month sales added about $940 million, and the legacy Teva generics business was in total $30 million down year-over-year. Important to note, however, that the Teva generic sales this quarter included additional $150 million in sales from the Teva/Takeda joint venture in Japan, which were not included last year.

Looking at the original breakdown, US is now 52% of our total sales, Europe is 25%, and the rest of the world is 23%. Generics accounted for 52% of our sales. Copaxone was 19% of our sales, and specialty products were 18% of our total sales.

Our non-GAAP operating profit, this measure excludes G&A, was up 16% year-over-year. Generics including Actavis contributed additional operating profit of more than $300 million to our operating profit, and our operating profit from our specialty business was down by $120 million year-over-year, all in all, a 16% increase.

And when we look at the contribution to total operating profits, generics accounted for 41% compared to 31% last year, and Copaxone was 42% as compared to 47% last year. So the profit contribution from our generic business and Copaxone is almost even this quarter. The margin of our generic business continued to be healthy, with 50.5% in gross margin and 29.9% in operating margin. In Copaxone, total Copaxone sales posted another over $1 billion quarter, of just 2% less than Q3 last year due to losing the tender in Russia. We experienced good sales in Europe, and a fast adoption of Copaxone 40 milligram.

Now let's take a quick look at the year-to-date results. Looking at our three quarters results, it is important to remember that they include only two months of the Actavis business. Net income for the period was 6% up year-over-year, and EPS was 9% down due to the higher number of shares.

For the first three quarters of 2016, our generic business was 48% of total sales, and it was 36% of our total operating income, with Copaxone was 45% of total operating income. The picture in Q3, of course, is very different. Dividend: in its meeting yesterday, our Board of Directors approved a $0.34 per share quarterly dividend, together with the preferred dividend of the MCPS total dividend is estimated be $410 million for the quarter.

I would like to update the guidance for the full year-ending December 31, 2016. We now expect net sales of $21.6 billion to $21.9 billion, and diluted non-GAAP earnings per share of $5.10 to $5.20, with an estimated fully diluted number of shares of 1.020 billion shares for the full year, and share count for Q4 exiting 2016 is expected to be 1.080 billion shares.

Regarding 2017, as always this time of the year, we are working on the 2017 AOP, annual operating plan. We will communicate our forecasted plans for 2017, together with the Q4 results in early February.

Thank you all for listening to our remarks and comments this morning. And now we will be -- we will like to open the call for questions.

QUESTIONS AND ANSWERS

Operator

Thank you.

(Operator Instructions)

Your first question comes from the line of Louise Chen.

Louise Chen - *Guggenheim Securities LLC - Analyst*

Hi, thanks for taking my two questions here. So first question I had was on your tax rate, and why it came in lower than expected? And then, secondly could you talk more on the magnitude of the OTC beat that was driven by the Venezuela FX? Thanks.

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

Okay, this is Eyal. Thank you for your question. Regarding the tax rate, you'll remember we guided it, as of the combination of Teva and Actavis, we expect our tax rate to be -- at the range of between 16% to 18%. This quarter, it was just below the low end of this range of 15.9%. Our expectation going forward is within that original range.

Regarding Venezuela, Venezuela, this quarter posted about $280 million in total sales. There was more OTC sales than generic Rx sales. In the mix this quarter, remember we share the profit of the OTC results with the PGT partnership with Proctor & Gamble, so Teva will only record half of that. Total results of Venezuela this quarter in the bottom line were lower than Q2 and Q1, represented just about $0.02 per share for the total result of the Company.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

And maybe Louise to add to the OTC, you'll also need to keep in mind, that there was an extra two months of Actavis business which contributed to the OTC line. There was a portfolio of Actavis OTC products which is solely sold by Teva, and that increased the revenue and the profitability of the OTC line also.

Louise Chen - *Guggenheim Securities LLC - Analyst*

Thank you.

Operator

Thank you. Your next question comes from the line of Vamil Divan.

Vamil Divan - *Credit Suisse - Analyst*

Great. Thanks so much for taking my questions. Just two if I could. One, I appreciate your comments regarding the guidance for this year. Can you just discuss -- you've obviously given longer term guidance as well before, and do you still stand by those numbers, or when might we get an update on your views for the outer years beyond 2016?

And then, second, just around your comments you made around generic drug pricing, you mentioned that 7% erosion this quarter, but you said you're confident it will still remain in the mid single-digits going forward. So can you just maybe provide a little bit more insight, there's obviously an area that there's a lot of investor focus, just what gives you the confidence that what's going to happen in the coming quarters will be different than what you saw this quarter? Thanks.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

Yes, so it's Siggi here. Let me start on the drug pricing, so overall, like previous quarters, there hasn't been any fundamental change in the US drug pricing. And what we saw in the difference between the 5% or mid single-digit we guided for going into it, versus exiting at 7%, was the impact of the pricing impact on the divested product. As we mentioned, to close the transaction and to fulfill the requirement of the FTC, we had to divest 79 products in the US. And these products have limited competition, and that's why we had to divest them. So our customer views the opportunity of the instability of the market, so there was more pricing pressure, during the time when the transaction happened on these 79 or a little bit less marketed products that were in the market.

So we saw that, we saw a little bit increase in pricing. But the underlying market itself, the competition in the market is in line with what we have seen for the first two quarters of the year, we saw the same in third quarter. And our expectation going into the fourth quarter is the same, or similar price erosion in the mid single-digit.

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

Vamil, we are working out now a bottom up assessment of the opportunities and challenges. We see as part of our comprehensive annual operating planning process for 2017, we plan to complete that process as in every other year, early next year, and to provide you with our 2017 guidance when we report our fourth quarter 2016 results in early February. This guidance will include the comprehensive review of our expectations for all of our businesses, including the scenario of generic competition to 40 milligram Copaxone.

Vamil Divan - *Credit Suisse - Analyst*

Okay, thank you.

Operator

Thank you. Your next question comes from the line of Tim Chiang.

Tim Chiang - *BTIG - Analyst*

Hi, thanks. Erez, Eyal, could you talk a little bit about just the revised guidance for operating cash flow? What's going into that? And also what do you expect for the fourth quarter in terms of new product launches? And also in the first half of 2017, do you expect a recovery on the new product launch cycle?

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

Should I start with the cash flow? Yes, so we revised our operating cash flow down by $300 million to $400 million, as a result of what we are seeing. Some payments that we inherited with the account payable of the Actavis transaction were a bit higher than what we had expected, and other than that, cash flow is very well intact as we have seen.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

So Tim, on the new launches, it's Siggi here. I think first of all, obviously we're very dependent on both the approval by the regulatory agencies. We have over 90 cases ongoing in Paragraph IV challenges in the US, so we're dependent obviously on IP decisions. And then on top of that, obviously, we are using API sometimes from a third-party manufacturer which could affect the approvability of our products.

In this quarter, even though I mentioned that we had no significant launch in the quarter, we still have the 11 launches in our US business. So there were 11 launches, we still maintain to be a launch machine to grow the business. The challenge was, these were relatively small launches in the overall scheme of things. And as I mentioned in my prepared remarks, in fourth quarter we don't see any significant large launch coming in fourth quarter.

In terms of 2017, we will take that much deeper when we guide for 2017. But keep in mind, that Teva now has over 300 ANDA pending at the FDA, and of those 300, there could be the possibility of over 60 of them coming to the market in 2017. But again, that depends very heavily on regulatory approvals, IP decisions, et cetera, et cetera. So I think we have the best portfolio to have a good launch here, but we are doing the work now, we are evaluating the IP situation, the regulatory situation, obviously of the Actavis portfolio. So in February when we guide you for 2017, we can give you a much better picture of the new launches. But clearly, we have the best pipeline in the industry and we will continue to grow the Teva generic business with new launches.

Tim Chiang - *BTIG - Analyst*

Okay, great. Thanks.

Operator

Thank you. Your next question comes from the line of Ken Cacciatore.

Ken Cacciatore - *Cowen and Company - Analyst*

Hi, thanks, guys. Just quick question here on the business development. Appreciate that you're taking a pause. Just trying to understand what you're going to do to change some of the decision-making process here? Zecuity, Rimsa, the Regeneron deal, these things seem to be going bad, and not just going bad, they seem to go bad quick.

And so, trying to understand internally besides pausing, what we're doing and what we're learning, to make sure these decisions improve or get better? And then also we're spending quite a bit of money, a $1 billion on branded R&D. Can you explain how it's at that level, given the pipeline as we observe it? It seems like a really high level for a portfolio that one would think would be better than a $1 billion in annual spend? Thank you.

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

Well, thank you. Let me just answer firstly about the pipeline. The pipeline is a very focused pipeline in our areas of particular interest, migraine and pain, movement disorders, neurodegeneration, respi. And when you look at this, as we look at the end of 2016, 29 programs. This is a year where we also had very significant results. We just think about the SD-809 for tardive dyskinesia, the Huntington successful resubmission, of course,

48125, our anti-CGRP which is a -- doing very well, recruitment going very well. We're looking to results in 2017. We've also initiated the same TEV-48125 for cluster headaches.

We're also continuing to develop abuse deterrent opioids, where the advisory board gave us the highest abuse deterrent claims that have thus far been supported. We are waiting for approval of that. So we also are -- starting in 2017, expect to see significant organic growth from both our small molecule development, early drug development, and biologic pipeline. So Teva has been in the process of transformation.

And in fact, our specialty pipeline R&D is among the lowest in the industry, highly productive. We also are using innovation, using existing molecules, deuterated molecules, other ways to reformulate to improve compliance, efficacy, and tolerability. And this is a very balanced portfolio, and you will be seeing additional results, 2017, a very important year for us as we look to the results of Laquinimod, a Nav1.7 antagonist for pain, the results of migraine. So this is a very active focused productive pipeline, which is expected to yield increasing value, as we go through this transformation into a balanced, both generic and specialty company.

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

I can just to add to that. First in any event, we are looking again in 2017 on priorities. And we might end up the year with a much more focus on less initiatives in general, and the specialty also in particular, in order to really make sure that every penny we spend, moves the needle for us and creates value for us. And if there are projects which don't generate value for us, I will terminate those projects. So that's again, we are in a process as I indicated before, of reevaluating everything we do, in order to use the transaction of the BD deals as a catalyst to transform Teva, and to take Teva to the next level, also in terms of comprehensive efficiency measure plan that is not confined just to extracting synergies from the deal.

On the third question, yes, Rimsa is a failure, and we are deeply investigating ourselves on that, in order to draw all of the conclusions from that failure. And it doesn't denigrate of course, from all of the efforts to build a business in Mexico. And we believe that over time, we'll be able to reach the targets that we've set for us. Needless to say, it will take us a number of years more than what was expected initially. But will lead to all the basically targets that we have set for ourselves in that important market. But that's something that of course, doesn't denigrate from the need to learn deeply what went wrong, and to draw all the conclusions from that. And that's something that we are, of course, we are doing.

I want to really distinguish Rimsa from the other examples as you had indicated. We acquired other very -- at least to date, a successful specialty asset that we're extracting the value from them, and we'll extract the value from them over time.

And Regeneron, that's a very different case compared to the Rimsa, on all relevant plans, we strongly believe in that project. It is just about time, we believe that it is just about time, until the partial hold will be basically lifted, a clinical hold will be lifted. And we strongly believe in that partnership and in the potential contribution of that asset to Teva and Regeneron over time. And the Zecuity, maybe I'll ask Rob to address?

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

Okay. First of all, Zecuity was a relatively small acquisition that we did. It was an interesting opportunity, and the opportunity would have been there, but the product showed a side effect that was very difficult to predict. And reviewing that, what we are doing at the moment, to see where we can bring down that side effect ratio, which is going to be very difficult, because it's relating to the [iontophoresis] per se, right?

So I think the lesson that we took there, is with a device like Zecuity, the technology behind that, and in an indication like acute migraine where there are quite a number of alternatives available, authorities and also patients do not tolerate any increase of side effects. And although we had quite a number of happy patients, people very committed to this product and the match with our pipeline with our TEV-48125 is really striking, we said we'd put the interest of the patients first here, and withdrawn the product from the market. I think the lesson learned there is, what we have learned. And as I described, to put it, it was really an extremely small deal in that respect, and would have been a very nice opportunity.

Ken Cacciatore - *Cowen and Company - Analyst*

Thank you.

Operator

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

David Risinger - *Morgan Stanley - Analyst*

Yes, hi. I just wanted to get a little bit more perspective on the generics business. The Company hosted a very bullish generics meeting in early September, yet generics are disappointing, and the guidance is coming down. And so, could you just talk us through a little bit more detail on what you weren't aware of in early September, and how we should think about the prospects for the generics business going forward? Thank you.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

Thanks, David. So first of all, I'm as bullish on the generic business today as I was on September 9 for sure. I think the volatility you see between months, between quarters, you -- I think we all recognize that, that the volatility of new launches between quarters and between years has a significant impact, especially on the US business. The price erosion in the US is similar to what we expected in September. The impact on the divested product was a little bit more.

I think the guidance on how we see the pricing environment is very similar as we guided to in our meeting, the difference being is basically the new launches. New launches as I mentioned in the September meeting, to maintain the mid single-digit growth in our business in the US, we need to launch new products every year of between $500 million and $600 million in revenue every year from our pipeline. On where I sit today, and I see the pipeline and the pending products, the first-to-files, we mentioned the 80%, the total brand value of the first-to-files that have been filed this year is $7.1 billion. We have approximately 80% of that, including some shared first-to-file. So there's a lot of value there in the overall business, but the volatility will come from quarter to quarter.

I think what we are saying here is, we didn't get the big approvals that we expected in third quarter. We don't foresee them in fourth quarter, and then we are building the plan for 2017. But I'm as bullish of seeing the mid single-digit growth as before. But to make -- be able to do that, we simply need to deliver between $500 million and $600 million in new product revenues every year going forward, and I really see that with the pipeline that's pending.

David Risinger - *Morgan Stanley - Analyst*

Thank you.

Operator

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

David Amsellem - *Piper Jaffray & Co. - Analyst*

Thanks. So first, just following up on the brand R&D, it's not lost on me that you called out in your programs, but do you think that there's significant efficiencies to be extracted, as you review the internal R&D pipeline, and maybe how should we think about the brand R&D spend longer term? And then secondly, I'm just trying to drill down on your pulling back from business development and M&A for the time being? I mean, should we expect that in the next one to two years, you're going to completely revamp the team, and then redouble your efforts to source brand assets,

particularly given that we should expect a little long-term pressure on Copaxone? How should we think about -- not really for the near-term, but more say, for 2018 or 2019? Thanks.

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

Thanks for the question. Just on the branded R&D, I think that it's important as I've stated before, this is a highly efficient and already effective organization, in the sense of the results in terms of -- and we judge that by the number of products coming in by organic growth, and the number of submissions, and the number of approvals that we see. But of course, and how we really moderate risk, and I think we've totally revamped is also understanding fundamental pathways, looking for other indications for drugs that have similar pathways. So for example, obviously SD-809 which depletes dopamine and depletes early presynaptic dopamine is useful for movement disorders, not only for Huntingtons but for also for tardive dyskinesia, where we've seen such stellar results, and also now we've embarked in Tourette's syndrome.

So I think the approach that we take is really understanding deeply how these drugs work, looking at additional indications, using some of the safety and the different approaches, the CMC we already, of course, know how to do. So we have synergies in terms of the understanding the biochemistry, the pathways that leads us to other disorders. 48125, for example, CGRP is not just useful for migraines, but also early evidence suggesting might be useful for cluster headaches. So as we go forward, of course, we are focusing more on brain and mind.

We also have a significant respi portfolio that is also developing the first biologic for Teva, developed for approval this year, IL-5 antagonist, and we're looking to also refine. But we constantly are looking for ways to improve efficiencies, improve time to market, inclusion of commercial perspectives very early in the R&D development. And you will expect to see -- 2017 will represent the maturity. This is, of course, as you understand, it takes awhile for building the capabilities, which we've done really over the last four to five years, 2017 we'll see a significant number of INDs that have all come organically growth through our biologic and small molecule development pipeline. These are molecules, of course, we know and that's why the need for BD is much less, as we go forward for big deals, as we're actually are growing our pipeline organically.

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

So just to underscore, maybe the most important message here. We firstly focused on a number of key molecules that we have been developing internally. Around that, we look for basically extending those molecules through additional conditions and indications. That's also a process which is underway. We will terminate all the projects that don't add value for us, or don't move the needle for us over time. We might pursue a tuck-in deal which are not significant ones in terms of financial results, which are required in order to complement further our core TAs.

Operator

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

Randall Stanicky - *RBC Capital Markets - Analyst*

Thanks, guys. Siggi, I just want to follow-up on the generics business. If we take the third quarter revenue, and add another $400 million for the extra month of Allergan, we're run rating at about $23.8 billion. That's a $1.4 billion short of the low end of guidance that was given in July for next year. So I guess, my question is that guidance realistic, can you grow towards that? And that's before any erosion around Copaxone, so can you help us calibrate that? And then I have one quick follow-up.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

Yes. So Randall, I think the overall, you see the run rate of Actavis, you can take the $800 million around what, $[880 million-some-odd] in revenue, divide it by two, and you see the run rate of Actavis as it is currently. It's between $4.8 billion and $5 billion, which I think is in line with our expectation going into the acquisition. We are very pleased with the asset, with the Actavis asset when it comes in.

I think the Teva business, as I mentioned we are a little bit under, and it's related to the hit we get on the exclusive products that we had a year ago, and not having a significant product launch, even though we have many small product launches. Remember last year, that the revenue from new product launches in Teva alone last year was over $800 million, which was very significant that year. This year it will be significantly less. And this variability, we see in the US product launches is the variability we see in the overall business.

We are doing our work now on the pipeline. It's a lot of work, with over 300 ANDAs pending, looking into the IP situation and regulatory situation, but the movement in the Actavis, in the generic revenue is very much dependent on revenue and opportunities from new launches.

We have plenty of shots on goal. I'm very pleased with the pipeline. But to be able to guide you in 2017, I really need to understand the overall pipeline better, so I can give you a number where we stand in 2017. But all of the indication in terms of the status of the Actavis business, in terms of number of first-to-files, in terms of number of ANDA pending, in terms of the price erosion. Even though we have a slightly higher pricing erosion in this quarter, there's no fundamental difference, are still intact, but you need to give us a time to validate the new launch assumptions for 2017, so we can guide you for that year.

Randall Stanicky - *RBC Capital Markets - Analyst*

That's fair. I'm just going to ask the question, that I think a lot of people on the call are trying to understand. Numbers have come down significantly since July. So if the environment and the outlook for Teva generics and rest of the business is relatively unchanged, what are we missing? What's changed since -- from July, when you looked at the business, and provided that three year guidance, whether it be on the generic side, or the brand side, what's changed that has brought numbers lower than we initially thought?

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

What has brought the numbers lower than we thought in July for 2016 are the revenue from new launches. That's very, very simple. We estimated a significantly higher -- there were about three or four key launches that we expected to get by the end of this year, which are not coming in, that would deliver the hundreds of millions in revenue which are not coming in. The good news, on this bad news is, they will come later.

They will come in 2017 and maybe into 2018. So they're not lost at all, but basically the simple situation is that there are hundreds of millions in new product launches that we expected before the end of this year, which will come later. And basically moves the growth curve a little bit later in the year. And that's why you see the impact of the revenue, both in third quarter and fourth quarter this year, but it doesn't mean -- it doesn't undermine at all the fundamental of the generic business, because these are not lost opportunities. These are opportunities that we are moving into next year and the year after.

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

And on the back of that volatility, we have been carrying out efficiency measures, beyond what was initially expected and planned. So that's something which is coming into play in 2016 already, and it will continue and gain more momentum in 2017.

Randall Stanicky - *RBC Capital Markets - Analyst*

Okay. Thanks, guys.

Operator

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

Umer Raffat - *Evercore ISI - Analyst*

Hi, thank you for taking my questions. Siggi, I want to focus on US generics for a minute, and maybe just do a very simple bridge. So US generics for Teva, so Teva business only, not Actavis, was $892 million in the second quarter. It's $755 million this quarter, if you basically take the overall reported and subtract Actavis, so $892 million went to $755 million. Can you make a bridge for us on, between Q2 versus Q3, sequentially what changed?

And also Siggi, what's your confidence in a 505(b)(2) Advair equivalent in February, and a possible EpiPen next year?

And Eyal, perhaps one for you real quick? So SG&A this quarter came in at about $1.2 billion, which is about the same as last quarter. So I'm just trying to understand, what did two months of Actavis contribute, and/or were there any certain non-GAAP adjustments that got us there?

And finally Michael, is SD-809 in Tourettes still ongoing? Thank you.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

So Umer, that was a great one question. So let me start on first part of your question. I think if you compare the $892 million versus $755 million, these are basically the main impact on -- about half of this is the added competition on Pulmicort that we saw between second quarter and third quarter. On top of that, we mentioned Xeloda, with competition, esomeprazole and Nexium, and the last one being aripiprazole. These four products more than explain the gap between second quarter and third quarter, and you can even see this pretty well when you look at the IMS data for product, where basically we had some semi or exclusive position, and we have an increased competition in the third quarter.

Against that, we had very low revenue from new launches, we had 11 new launches. So we didn't compensate for the competition we got on these products. And so, at the end of the day, the beauty of having a huge portfolio, it gives us more stable. But when you have a threatening or a basically competition to your key exclusive products, and you don't have the new launches to compensate for it, you will see a volatility in the revenue line. Just to come back to what Erez mentioned before, I think we have done better than anyone expected in terms of managing our cost, so we defended the bottom line more than the top line, with the product mix and control of the cost.

In terms of the EpiPen, we are working very closely with the FDA. I haven't changed my view, my expectation for EpiPen is still early 2018, there's nothing to change my view on that. We are still moving forward in good collaboration with the FDA. We had a meeting with the FDA. We understand the way forward, what needs to be done, we think pretty well, but it hasn't changed my best estimate on the EpiPen launch. Maybe Rob you want to take the 505(b)(2) Advair product which is in the specialty group?

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

Well, we are, the job is on plan, on track. We will be launching, hopefully depending on the FDA approval both forms, the mono and the combination mid next year is our planning.

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

And just to answer the Tourette's, yes, Umer, the Tourette's program is continuing. There's been significant discussion with the FDA initially based on the question of the metabolites that were asked for SD-809 in the HD program. We, of course, have submitted that and provided, hopefully provided reassurance, but certainly was accepted around SD-809. This will add impact also on the Tourette program, and so we are in discussion with the FDA, but our plan is to start the Phase III study for Tourette's in the near future.

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

Umer, regarding your question about SG&A, SG&A run rate, well that's an opportunity to say a word about synergy and the progress. We're making very good progress on cost synergy, and tracking extremely well. So expense run rate, as a result of the combination of our generics business is expected to further go down in Q4, and later on, as we have guided originally. This is the main reason why you see the addition of two month Actavis, but no significant increase in SG&A.

Umer Raffat - *Evercore ISI - Analyst*

Thank you very much.

Operator

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

David Maris - *Wells Fargo Securities - Analyst*

Good morning. I'd be interested in your comments about the US policy issues facing the Company, especially with a new administration, so if you could speak broadly about maybe three efforts? Specifically, efforts to reign in large price increases, the second to speed in more generics to market, and third the potential for reimportation, and how these might impact Teva and, more broadly speaking, pricing? Thank you.

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

So David, I think on the first two, we see opportunities, that's basically where we are today, we are well-positioned to I would say, strike the right balance between access and innovation in the US, and of course, also ex-US. We do it ex-US today. We had a business in Europe which was less, which was much less profitable a few years back, and that's a very profitable business today. We told them that it was conducted under huge pressure of pricing. And that's exactly what we are doing now here in the United States, look at all of the efficiency measures that we have been carrying out. And we'll accelerate by the way, the string of efficiency measures that are conducted. And I alluded to that before, and I'm underscoring it again.

For us, that's an opportunity to take the transformation of Teva to the next level, beyond just extracting the synergies. So it will be much leaner, and we'll focus on all of the things that really matter, all of the things that move the needle for us, all of the things that generate value for us. We'll basically get rid or terminate projects that don't meet that condition.

So in the US, with our infrastructure, with our portfolio of generics, we believe we are positioned to become part of the solution in the United States. And we'll continue to basically accelerate the pace of being able to basically contribute to the solution here in the United States, more access and the right balance between access and innovation. As far as the FDA approvals are concerned, maybe Siggi would address that?

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

Yes, so David, it's a valid question. I think first of all, on the generic approvals, we on balance, are very pleased if we get more generic approvals. Keep in mind is, we have just over 8% of all pending ANDAs at the FDA. And so, if there is an increase in approval speed, I think we on average get benefit from that versus, obviously there is increased competition on our product when our competitors get approval. So we are fully supportive of increase, and the new GDUFA too that will be in place soon, I think pushes for that, and we were a supporter of that. But with having the largest ANDA pending at the FDA, I think we will benefit from that.

I think maybe to add to the price increases, keep in mind, and we talk a lot about that, the overall prices in the US of generics always go down. I've been in the business for 23 years, and the prices, even though there are examples giving of a product going up significantly, maybe a single molecule, even one SKU, but overall, when you look at the 300 to 400 products we have on the market, our price erosion on average is about 5% per year. And our generic pricing is everything from a 30% discount from the brand pricing to about 98% discount from the brand pricing. And there is a great value, and I think that the US policy that will come in place, will probably hopefully recognize the value that the generic. Because as I mentioned in my prepared remarks, we are part of the solution, we are not part of the problem.

And maybe around the reimportation, let's see how that goes, that has been on the agenda for many years. But keep in mind that with the pricing we have on many of our generics, the pricing on generics in the US coming from the manufacturer is lower than many of the countries around us. We can take obviously examples of brand products where the differences are, but when you look at everyday generics, of big volume generics where the competition in the US is fierce, the discount from the brand value is maybe 97% to 98%. The pricing here is lower than in the neighboring countries. So I think being a global Company with a position around the world, we need to see how it's done. But overall, this doesn't scare us, and I think it puts Teva in a strong position going forward.

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

On the specialty side David, we are always -- we believe, of course, our point of view, that we're very responsible as far as pricing was concerned. And more than that, in all of the cases, we competed in areas where there were more than one alternative for patients. So basically, what we witness is competition, and strong competition on the specialty side.

So all in all, we believe that with everything that we possess as a Company today, we are positioned in a good manner to deal with challenges that might emanate from policies that pertain to pricing. Having said that, I think that at this stage, there are still questions, a big question mark about policy that is underway, and we need to wait and see whatever we shall basically be confronted with, and how we address that. But bottom line as a Company, we believe that we are positioned to address the challenges that might emanate from a new policy.

David Maris - *Wells Fargo Securities - Analyst*

Just as a follow-up, Siggi. So what you're saying is the acceleration in the price decreases that you've seen this past quarter aren't a result of increased competition on existing molecules, and it's not a result of having to tame previous price increases, or give back some of those?

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

No, basically, the main reason, David, was that we had to divest a very good portfolio of products that had limited competition, so we had to divest it. What our customers did, as they do, is that there is a new player in the market that took over those products, and that became a pricing pressure on roughly about 60 molecules of -- and these were one of our top -- the top molecules we had in our portfolio. So there was an instability that happened in the market during the month of August, when the new owners were taking market share.

It didn't change the fundamental of the market. It didn't change the structure of the market, or the chemistry of the market, but we saw the impact on the divested molecule significantly more than we saw for on the rest of the portfolio which gave us a 7% versus 5%, which we assumed going into the quarter.

David Maris - *Wells Fargo Securities - Analyst*

Great. Thank you very much.

Operator

Thank you. Your next question comes from the line of Marc Goodman.

Marc Goodman - *UBS - Analyst*

Siggi, in the past you've talked about the operating margins you believe you can get to, over the next couple years on the global generics business, now that you really do own the Allergan portfolio. Can you just talk -- talk again about those margins, just so we understand what you're thinking over the -- kind of the -- and the progression over the next couple years? And secondly, just in rest of the world generics, $782 million, you help us understand what was Rimsa, what was Allergan, what was Japan? I think you said $150 million. Just so we can understand what the apples-to-apples versus last year's Teva-only business was? Thank you.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

Yes, so Marc, first of all, on the operating profit, I was extremely pleased with the operating profit this quarter, 29.9[%]. I don't expect that to come through in fourth quarter, maybe a little bit lower, we need to see how it comes. Obviously, the mix of the portfolio when you have it for three months versus two months, the mix in terms of the new product launches, we don't foresee product launches in -- big product launches in fourth quarter.

But before the close of the transaction, I said that I was hoping to see in 2017 that we would stabilize around 30%. So I really didn't expect us to get to 29.9% at this point in time. I think, that highlighted with, I think, early synergies, a good work around those synergies, but also a very good cost control. But I'm still of the opinion that we can be in the 30%s in 2017 with the right mix of product launches.

I have to say, because maybe you didn't ask the question, but I was ready for it, Marc, around our European business. I was very pleased with our European business in third quarter. They had an outstanding quarter, they didn't miss a beat, there was a full integration in all of the Actavis market. And the profitability in the Europe really stabilized, they're really showing amazing results. There was no hiccup of new launches in Europe, and that was extremely pleased with the European business.

To the apples to compare it year-over-year, I think Eyal highlighted it, in terms of there was a $30 million difference in the net revenues from third quarter of 2015 to third quarter of 2016. Basically the additional revenue that the joint venture with Takeda contributed to the [2016] numbers was about $150 million. The impact of Rimsa was negligible, due to the recalls we had in the market. We had a cost in Rimsa, so really that didn't change the overall picture.

So if you do the comparison net to net, it's about $180 million. And still I think, that is a really, really good results, comparing third quarter last year, versus this year, because of the movement of new product launches as I mentioned to the question Randall asked, has such a significant volatility impact on the overall business.

Marc Goodman - *UBS - Analyst*

What was the Actavis contribution in rest of world versus Europe?

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

So we don't have the contribution, but you saw it on Eyal's revenue, there was about what, $349 million? I need to -- ?

Marc Goodman - *UBS - Analyst*

$349 million.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

$349 million was the contribution outside of the US, and really a good result.

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

(multiple speakers) more or less in line with that.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

Yes.

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

Next question, Lawrence?

Operator

Your next question comes from the line of Liav Abraham.

Liav Abraham - *Citigroup - Analyst*

Good morning. I just want to come back to your lower 2016 guidance, and apologies if I missed this, but can you walk us through exactly what has driven your change in revenue guidance for the year, how much do you expect in under contribution in Q4? And then, what offsets that, is it only performance in the generics business, or does it come from branded expectations as well?

And then quickly secondly, can you be more specific in the economic terms of your Celltrion partnership? I understand that it is a profit share, but if there are any more details you can provide, that would be helpful? Thank you.

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

Yes so, hi, Liav, this is Eyal. So without being too specific on splitting, we do expect the generic business to increase in contribution from Q3 to Q4 by between 7% to 8%, with similar increase in total sales, or basically a bit higher increase in total sales due to the inclusion of a fourth quarter of -- a full quarter of Activis business, and some growth in the business. We can see this in the US generic business, we can see this in the European business, mostly in these two parts. We can even see this in Canada. So there is some growth reflected, of course in the guidance, so that we have provided for the quarter, sequentially between 7% to 8% on the profit.

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

On the -- yes, and on Celltrion, while we are excited about the opportunity, obviously, it's -- we are in with both Herceptin and Rituxan, we have the opportunity to be in the first wave. It's a North America deal, so Canada and the US, where we work with Celltrion together in partnership, and we do split also the commercial profit there. We have a smaller down payment which we already did of $10 million, and there's a relative small

milestone payment upon registration on that. And it's a really nice opportunity for us to be partnering, with Celltrion. I'm not sure we disclosed the exact split there, so I'll have to check that, a bit reluctant to do that here.

Liav Abraham - *Citigroup - Analyst*

Okay, thank you.

Operator

Thank you. Your next question comes from the line of Gregg Gilbert.

Gregg Gilbert - *Deutsche Bank - Analyst*

Yes, Rob, can you comment on the potential for generic Copaxone in 2017, assuming generics are approved, and they don't wait for an appellate decision? I'm not looking for financial guidance here, just looking for a conceptual of what you think you can do to maintain a large chunk of the franchise, in the event that it occurs in the way I described? Thanks.

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

Yes, sure, with pleasure. First of all, we're extremely pleased with Copaxone at the moment, the way it's moving, Europe launching the 40, and a similar conversion route -- rate as you've seen for the US, now at over 60% already. And for instance, a country like France hasn't even launched yet. And in Europe, there is not going to be a substitution generic, and it's still a very substantial part of our business, right? So the business there is performing extremely well.

We also have Canada just recently approved. And if you look at the US, where we are still like in the key countries in Europe with Copaxone, they're number one, new two patients, so you'll see incredible enthusiasm for that product. And it's holding much better than I think anyone expected, both against the generics, and against oral competition there. Going into 2017, the market will be a little bit more dynamic. First of all, FDA hasn't approved any 40 generic, and I remain very skeptical that they will do that, because I think we have good scientific reasons for that.

If you look at today's Glatopa performance, they're about 11% of the overall Copaxone, and about just over 40% of the 20-milligram. If you take that as a model going forward, when the generic would head to the market, and that's exactly what we've been guiding in previous calls. That's not, no information to date to change my opinion on that, and wouldn't change that. And what we have seen though, in the last months is that Copaxone actually has been holding much better, and performance shows really good, and I'm extremely proud of all of the teams that do this.

Patient support programs will play an important role, and that's what we've seen people move into Glatopa in the US, often came back, actually the biggest source of new to brand comes from Glatopa changes in the US when they switch, because of the value they place on our support programs, amongst which are the shared solutions. So other than that, there's very little new information that we have, product is doing well, and we are optimistic about the future in that respect.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thank you.

Operator

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

Ronny Gal - *Bernstein - Analyst*

Good morning, and thank you for taking the questions. I guess, I'll start with a couple of the branded questions. On GF, Michael, what convinces you that we will not see osteoarthritis in patients who are currently not diagnosed with osteoarthritis? I guess, that's the critical question that product, given that you could have sub clinical osteoarthritis advancing?

And second, on Advair, in Europe I believe you were not approved for all dosages of the drug? Are you convinced you'll get all dosages of the drug in the United States, you'd obviously need all of them to get an alternative to Advair?

On the generic side, Siggi, just a quick housekeeping. I don't know if you break for us roughly the US versus OUS profit for generics post-Actavis, just so we understand the magnitude of the risk that comes from the US pressure? And then more specifically on the US pressure, I understand what you did in Q3, I understand there were a few products that you divested that had a more significant pressure. But we're hearing from both retailers and distributors, they're seeing pressures on that business from the MCLs, and that generally translates to further pressure on their suppliers, which means you.

How are you thinking about that, what tools do you have to do something about that? And as ANDA helps you, so if we think about the pressure on you in the next year, given the pressure on the entire value chain, where is your ability to compete?

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

Hi, Ronny, thank you for the question. It is important to clarify this issue. So of course, we have as part of the development of this anti-NGF with Regeneron, fasinumab, we have -- are planning to do both a Phase III(08)study, and we'll plan to also come back with chronic low back pain.

It's important to note that the patients who have had the rapidly progressive osteoarthritis have all been of a particular type, classified in osteoarthritic terms, KL -- these are KL3 and above. So as we continue for patients with early osteoarthritis, the risk at this moment is really not viewed as significantly higher. And so when you look at -- and Pfizer and Lilly have done the same thing, when they've continue with their Phase III programs, they continuing with OA and mild OA, and severe OA patients have been excluded from the study. And that's what we plan to do. So firstly, in the patient selection we'll go with patients with lower degrees of OA.

OA is a progressive illness over time but it's very slowly progressive, and obviously will have to be monitored. And then second thing, but there's a huge population of patients with early OA, and a KL less than 3 is very significant too. These are very significant proportion of patients. And then secondly, the dosage is important. And what we've seen when you start getting down to lower doses, and for us it's 3- and 6-milligram, there is no evidence for increase in OA of some of these severe population, of severe side effects in this population.

So the Phase III studies are going to have two important parameters, and this is already, this is going to be osteoarthritis of a milder degree, number one, number two, lower dose. The patients that were seen in the rapidly progressive with chronic low back pain had severe osteoarthritis, KL greater than 3, and were getting 9-milligram IV, which is even higher than 9-milligram oral and 9 milligram sub-Q. So we will be planning these studies appropriately, and patients with severe osteoarthritis won't be candidates in part of our clinical trials.

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

And Ronny, maybe as part of the respi question, the development strategy we've chosen in the US was very different from Europe, right, where basically in Europe they tried to show and had to show bio equivalence which led to only being able launch the high dose. In the US, we will have both doses. We have a different development, and we will be able to cover, if we get the registration, the entire spectrum.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

So if I take the housekeeping, Ronny, obviously we're not giving the profitability of the Actavis business, but if you look at the slides that Eyal showed, the overall revenue prior to divestiture of the Actavis business was $943 million. We had roughly around $50 million from the Actavis business as a divested business, and the breakup would be roughly that there would be $530 million from the US and roughly $350 million from the rest of the world. I think the divestiture is 50/50 Teva and Actavis overall. So that's what's coming from Actavis. We are very pleased with it, in terms of the total revenue.

In terms of the pricing pressure, I think we heard our customers talk a lot about increased competition between them. And I think that's right, but that's for -- I don't think that is for the whole market, because ABC obviously has strong ties with Walgreens, and the remaining of their business they're competing for. The same applies obviously to Cardinal. They have strong ties to CVS. The rest of their business, they're competing with the rest. And McKesson has maybe a little bit more fluid business, but they have currently the Rite-Aid business, they just took over Wal-Mart, and they have a strong support for many of the other businesses. So I think there clearly is a competition, but it's for a relatively small part of the overall business.

Clearly, we are impacted by it, but we being the largest supplier I think what we can say is; with our pipeline, with our service level which we have increased year on year, I think we will be impacted. But we will be impacted to a lesser degree than any of the other players in the market due to the size and the strength of the business we have. So I, we notice it, we know of the competition of our customers, but at the end of the day, it's not a majority of the market. It's a small portion of their overall business, where they're competing very fiercely at the moment.

Ronny Gal - *Bernstein - Analyst*

Thank you.

Operator

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

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. I just have a few. Siggi, recognizing that you're not ready yet to give 2017 guidance, and listening to your commentary about first-to-file opportunities, et cetera, are you standing by your mid single-digit growth projection for the combined Teva/Allergan generic businesses? And I only ask, because obviously, your standalone Teva business both in the US and total generics is way down. I can't really tell, and maybe you could help us to understand what the Actavis business is growing ex-divestitures?

It looks like that's also trending below that 5%, so your 5% would require a monumental turnaround going forward. I'm just wondering if you can comment on that? And then, I have a couple follow-ups for Eyal.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

So thanks, Jami. As I said in my prepared remarks, I believe in the mid single-digit growth going forward. I don't know if we achieve that in 2017. That will depend very heavily on how the launches hold up, but going forward, going over the next five years, I believe that the underlying business and the new products that we have pending, and that we believe this very, very strongly, Jami, we will be able to grow 5%.

Will we do that in every quarter? Of course, not. Due to the variability of new product launches, you will have quarters where you might go down, and you will have quarters where you do better. Just remember first quarter and second quarter last year, where we had the 15% growth on the Teva generic business versus the year before.

So we have the ups and downs, but when you take the long-term view, which you absolutely have to do when you look at the generic business, it's not nearly as stable as a specialty business. But when you take the long-term view, when you take the five year view of the business, I'm absolutely convinced with what we have in place, we have a 5% to mid single-digit growth in the overall business. But I really can't tell you from quarter to quarter, that we will always do 5%, because it's simply the volatility in the business doesn't allow you to do that.

Jami Rubin - *Goldman Sachs - Analyst*

I guess, I'm just asking because the guidance assumes 5% growth on an annual basis, I recognize we can't project quarter by quarter, so it sounds like you're sticking by that.

Eyal, just a couple questions for you. How much -- I mean, the OTC business is very strong, up 40%. What was the contribution from Venezuela, and how much of that can we expect going forward, just given that other companies have written down that business?

And then also what is the $155 million in other COGS related adjustments that helped your gross margin this quarter? Didn't notice that item in 2015, and just wondering what this is? Thanks very much.

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

Yes. All right, thank you. I'll start from the last thing, other cost adjustments, it's a long list of items, no one that stands out, so if we could take it offline, I can run you through the list. It's not very material.

Regarding Venezuela, I think I preempted that in one of my earlier answers. But just to repeat, sales in Venezuela, from Venezuela to this quarter were about $280 million, including the generic product, the Rx product, and the OTC operating profit was lower than in Q2, which was also lower than in Q1, represents about $0.02, or just under $0.02 per share to our overall EPS for the quarter. And there's no change in the accounting treatment and the exchange rate that we used since the beginning of the year.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you.

Operator

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

Chris Schott - *JPMorgan - Analyst*

Great, thanks very much. Just to make -- we talked a lot about this generic pricing environment. But you obviously saw a more difficult pricing dynamic this quarter with these 60 products. But a number of your smaller competitors also seemed to be really struggling throughout this year. And it seems like each subsequent quarter this year, we're seeing a different part of the generic market under pressure.

So I guess, I'm just trying to get how you separate out normal quarter to quarter volatility of generics, versus an overall more challenging generic pricing environment that could persist for an extended period of time? Because anyone that look at the industry as a whole, it feels like this a broader issue than one-off market disruptions. So any color you have on that, I know we've talked about some of this before, but any color would be great?

And the second question I had, is just with the stock in the $40 range, where does share repo factor into your capital allocation plans? And do you have the ability or the capacity to look at a share repo, given the leverage position right now? Thanks very much.

Siggi Olafsson - *Teva Pharmaceutical Industries Ltd. - President & CEO, Global Generic Medicines*

So Chris, a good question. I think Teva is ideally positioned probably to take the temperature of the pricing in the US. So let me maybe explain how we think about it. We market between 300 and 400 products on the market, when the smaller players are maybe dealing with 30 to 60 products. So any impact on one category, on one therapeutic area, on even their biggest product has significant impact on their Company, and the price erosion. Where even an impact on maybe 50 to 60 of our key products doesn't move the needle that much, in terms of price erosion in the quarter, even though obviously, we felt the extra 2% clearly in the business. But it shows the strength and the benefit of being large in the market.

We have a good service level. I think our operational colleagues here have done better than ever before, in being ready for the integration. We have serviced our customers well. We're offering all these products to the market. How I think about it is, I think about basically transition products, products where we are losing exclusivity, which always will hurt us. And that was the comparison I talked to Umer about as in terms of esomeprazole, Xeloda, aripiprazole, et cetera. Those are the transition products you will always see a little bit higher price erosion on these products. Then, obviously we could identify the transition product that we have to divest, the duplicates to our competitors, we saw more pricing pressure there.

And then, the base business, is very big base business, where it's the best [rating] I think in the overall pricing environment in the US. So maybe we have to take a view of what we will see in 2017, but where I sit here today, experiencing the market, there hasn't again been any fundamental change. Yes, our customers are talking about more fierce competition, but as I mentioned before, it's for a limited part of the market. And then on top of that, I think we are servicing our customers significantly better with Anda by our side, Anda being the fourth largest distributor of generics, which will help us to service the customers better in the long run as a plan. But the bottom line, Chris, there hasn't been a significant change in the business. But we will take a view on that, of course, before we guide for 2017.

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

On capital allocation, Chris I said it before, just reiterating what I've already said, our focus now is on unlocking the value from the integration, from our generic business, realizing the value from our specialty pipeline, with strong focus on internal programs, complementing core TAs with the deals which are tuck-in deals, not significant ones. And then focusing strongly on paying down debt, and with a quest to reach the level of 3.5 times debt to EBITDA as quickly as possible. And before we do that, we'll not consider other potential capital allocation initiatives.

Chris Schott - *JPMorgan - Analyst*

Great. Thank you.

Operator

Thank you, we have no further questions on the phone. I'll now hand the call over to Erez Vigodman. Please go ahead.

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

So on behalf of the entire team, I would like to thank you for participating in today's call. We look forward to speaking with you, seeing many of you in the coming months. Thank you again.

Operator

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