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TEVA.TA - Q1 2016 Teva Pharmaceutical Industries Ltd Earnings Call

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OVERVIEW:

Co. reported 1Q16 EPS of $1.20. Expects 2Q16 revenue to be $4.7-4.9b and EPS to be $1.16-1.20.

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Teva reports first-quarter 2016 financial results conference call. I would now like to turn the conference over to the Head of Investor Relations, Kevin Mannix. Please go ahead.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - Head of IR*

Thank you, Operator. Good morning, and good afternoon, everyone. Thank you for joining us today to discuss Teva's first-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, Senior Vice President and Deputy General Counsel.

We will start the call with presentations from Erez, Siggi, and Eyal before opening up the call up for questions and answers. A copy of this slides, as well as this morning's earnings press release 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 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 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. We, as Management, believe 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. Good morning, good afternoon, and thank you for joining us today.

Our results for the first quarter of 2016 manifests a good start to the year on all the parameters. Despite a tough comparable quarter in Q1 2015, with the launch of generic Nexium, and the exclusivity we had on generic Pulmicort.

EPS for Q1 2016 is $1.20, at the top end of our quarterly guidance. We have improved our profitability, profit margin by 144 basis points, and operating margin by 101 basis points. Cash flow from operations in the quarter was a robust $1.38 billion. Our solid performance was driven by continual improvement of our core business, with a strong focus on profitability, cost control, and portfolio optimization. Additionally, our performance was driven by our operational network transformation, which creates value by driving efficiencies further, and through the assimilation of new technologies including in biologics. Finally, we enhanced our performance of all our business units, including Europe, Tapi, and OTC in our global generic business, and respiratory in our global specialty business.

Copaxone 40 milligram continued to gain market share, leading the MS market with 24.5% TRx share at the end of March, versus 20.3% at the end of March 2015, and 82% share of the overall Copaxone family TRx. We also launched BENDEKA at the end of January, and have achieved a patient adoption rate of 71% as of May 5, 2016.

Our global generics business generated 26.9% operating margin in the quarter, without major new launches in the US and other key markets. We also saw significant progress in our global respiratory business, net revenues and operating profits, and 21% higher operating profits of our global specialty business quarter over quarter.

During Q1, we continued to strengthen our specialty business through the launch of CINQAIR. We also achieved successful results in three important Phase 3 trials including RespiClick FS and FP, which utilize our core breath-actuated multi-dose dry powder inhaler and QVAR BAI. Additionally, we are on track with our TV-84125 Phase 3 trials on both episodic and chronic migraine.

We also achieved significant milestones on the deals we announced in 2015. We closed the acquisition of Rimsa in Mexico. On April 1, we closed the business venture with Takeda in Japan, and we have made significant progress towards closing the Actavis Generics deal, and we are on track for a June 2016 close. Siggi will provide an additional update on this shortly.

Everything we are doing in 2016 will enable us to fundamentally change the Company, and complete the creation of a new Teva. Before the end of 2016, which is a transition year for us, Teva will be an even stronger company with a solidified foundation, a significantly enhanced financial profile, more diversified revenue sources and profit streams, strong product development engines in both generics and specialty, and positioned

to continue the transformation of our business model. Post the Actavis Generics acquisition, Teva will serve approximately 250 million people every day. And as the world's largest medicine cabinet with more than 1,000 molecules, we will have one of the most competitive fully integrated operational platforms in the industry that cover the full spectrum of products, from volume generics to complex generics, and all the way to specialty medicine and biologics.

Both the US and global generic markets present huge opportunities in the coming years. The platform we are creating is ideally positioned to enter in the evolving generic pricing landscape by leveraging our global infrastructure and deployment, go-to-market platform, leading product portfolio, and industry-leading pipeline and R&D capabilities. By the same time, we are well-positioned to realize the opportunities that our global and US generic markets offer, especially given the challenges and the changes we are witnessing in the various competitive landscapes for the benefit of patients, healthcare systems, and our investors. We'll address that with more details later on.

And last but not least, the Company's strong combined free cash flow would allow for rapid deleveraging. And as we have previously stated, give us the ability to pursue acquisitions of attractive branded and pipeline assets, as well as ones that would expand our footprint in key growth markets. The platform we are building offers top and bottom line growth opportunities, even if we were to face generic competition to Copaxone 40 milligrams, also driven by the expected launches of our major specialty products in 2017, 2018, and beyond.

All of us at Teva are fully aligned around our key priorities for 2016, which are a combination of maintaining business continuity, fully achieving our short-term operational and financial goals, and moving ahead on longer-term strategic moves that ultimately creates the new Teva. To sum it up, we are focused on defending Copaxone and BENDEKA, on the continued transformation of our operation and network, around cost controls, efficiency measures, and 2016 operational and financial targets. We also continue to focus on our integration and synergies. We commenced the integration of Rimsa and the new business venture in Japan. We are prepared for the Actavis Generics integration, and we are working hard to close the deal in June.

2016 is another important year for our specialty pipeline, with important pending approvals in key clinical milestones. We are awaiting FDA approval for our abuse-deterrent extended-release hydrocodone, our abuse-deterrent technology is a platform for us and we are focusing our efforts in this field on the development and growth of a responsible pain care franchise to help address the challenges of opioid abuse and misuse. TV-46763 is the immediate release abuse deterrent hydrocodone product, which is generated from our novel abuse deterrent technology. Phase 3 top-line results are expected in Q2 and our application submission in 2016. We are awaiting FDA approval for our SD-809 in Huntington's disease, and expect results in 2016 from Phase 3 of our SD-809 in Tardive dyskinesia, and from Phase 2 of Pridopidine in Huntingtons.

In addition we are focused on strengthening our biologics capabilities, and targeting potential partners within advanced biosimilar programs, in order to bolster our biosimilar portfolio. We are active in identifying specific specialty branded deals that complement and enhance our core TAs, and deals that expand our footprint in key growth markets. Finally, we continue to gradually transform our business model in a way that enables us to benefit from the ongoing changes in the pharmaceutical industry and the global health care space.

That's the way we see our business outlook during the next few months, in the context of the upcoming Actavis Generics deal close. We continue to expect and work towards the June closing with Actavis Generics, and in August as part of our Q2 earnings, we'll provide the combined outlook for 2016. Then in September, we'll provide you with our business and financial outlook for full year 2017 and full year 2018.

With that, I would like to thank you again, and turn the call over to Siggi.

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

Thanks, Erez. Good morning, and good afternoon, everyone.

The global generic drug market has no shortage of manufacturers supplying vital medicines to patients in the US and around the world. As a result, there is endless commentary and interpretation of the operating conditions that we, as an industry, are operating under. This can make it extremely difficult to identify and understand the specific opportunities and risks for each company in the sector, and for the industry as a whole. As you know, in February, during the fourth-quarter reporting season, several industry participants referenced a tougher pricing environment than what

they have experienced in previous years, as a reason for the softness in their respective generic businesses. Now, we fast-forward to April and May, to a new reporting season, and we find the number of companies citing a tougher pricing environment or price deflation seems to have grown at an almost incredible rate. The referencing of generic drug price deflation has not been limited to the manufacturers, but is also being cited by those on the purchasing and distribution side, leaving many to wonder about what is the real opportunity in generics.

As always, I will do my best to provide you with as much color as possible on what Teva is experiencing, in regards to pricing and volume; and more importantly, where we are headed. Throughout the ongoing debate this year about the level of generic price erosion in the United States, Teva has been very consistent and clear with investors. Teva has not seen any fundamental change or worsening in the pricing environment -- something we have been consistent about telling investors all year. Teva experienced approximately 4% price erosion in the United States last year, and our guidance for this year is that it will remain the same. In fact, Allergan, and Mylan, two other companies with broad and diversified portfolios and high quality products, have also reported similar trends. From where I sit today, there is nothing that changes my mind about that. Nothing has happened in the last two quarters that has changed the pricing environment. What this boils down to is each individual company's business model, and I'll explain that further in a few minutes.

Additionally, we have heard from many of the companies in this sector that consolidation of the customers is having an impact on the pricing environment. Of course, this consolidation creates pressure on generic manufacturers, but there has been no meaningful change in the last two quarters. We believe we have already reached a new status quo with the big customers; the fees and charges resulting from the customer consolidations are more or less already built into the pricing of the products when most of the consolidation took effect 24 months ago.

Overall, Teva's generic business in the first quarter 2016 performed extremely well. The operating profit compared to last quarter improved by 140 basis points from 25.5% in the fourth quarter 2015, to 26.9% in the first quarter 2016. When compared to first quarter 2015, the operating profit declined by 360 basis points, fully explained by the exclusive launch of generic Nexium, esomeprazole, in the first quarter 2016. Excluding the exclusivity period of esomeprazole in first quarter, the profit margin of the generic segment was 24.4%.

So why is Teva different? Why is our performance better than most generic companies? Why are other companies continuing to say, there is a pricing pressure greater than what we at Teva are seeing? I see three reasons: first, the companies with older portfolio seemed to complain much more loudly. What I mean by that is, that if you look carefully at some companies with older portfolios, they will tell you that the pricing environment is worsening. But this is not an environment. This is purely a reflection of their portfolios, some of which are concentrated in one, or very few, therapeutic classes that are experiencing normal competition. This takes me to the second factor, new product launches. When companies don't have new product launches, and the business is declining, they tend to talk about the market more than anything else. This is not a reflection of the environment, but rather again, a reflection on a company's portfolio.

The third factor is companies that are trying to grow their market share. Some companies are aggressive in going after market share for a variety of reasons, including to utilize excess capacity with relatively cheap volume. But in order to do that, you'll have to drive down price. Buying new market share in price will cost you on the bottom line. We, on the other hand, are seeing our volumes go down, deliberately, net-net approximately 1% a year, because we think that is better for our business, and we would rather reduce capacity, than fill it with less profitable products. So if you look at this slide, you'll see that over the past few years, we discontinued 70 products. At the same time, we introduced 68 new ones in the US.

So how does the growth formula work? Our simplified business model formula is as follows: approximately 10% growth from new products, minus approximately 5% erosion, which includes price erosion of approximately 3% to 4%, and volume decline of approximately 1% to 2%. This equals mid-single-digit of 5% growth in Teva generic business. It could be 7% in a specific year, and 4% in another year, but this is the basic formula in trying to understand our business. The business model may seem simple, but not easy to duplicate. Teva needs to grow by 10% every year with new product launches, and this is the key. This is the basis of any good generic business model.

How do you do that? It comes down to the right portfolio selection, and smart investment. Teva and Actavis Generics are the leaders in this field. Each company invests approximately $425 million in generic R&D and regulatory affairs. While we won't maintain an annual generic R&D budget of $850 million after combining the two companies, the spend level will still be both significant and industry-leading, enabling us to achieve 10% growth a year. We intend to maintain the leadership position here. At the end of the day, the key to growth in generics has been, and always will be new product launches, which are the only true live source for successful companies. Teva had approximately 450 global launches in 2015. For

2016, on a full-year pro forma basis with Actavis Generics, we see over 1,000 new product launches growing to approximately 1,500 new launches in 2017.

Both Allergan and Teva are performing well since the announcement of the transaction in July of last year. The pipeline was estimated to be 320 ANDAs at the announcement in July; has grown to 326 ANDAs after taking into account divestiture of approximately 20 pipeline products. The number of combined first-to-file has grown from 110 to 123. And in the first quarter 2016 combined, the two companies had over 200 new product launches. This alone has a tremendous impact on our future portfolio and product mix, as well as our long-term growth.

So what do we have to do to close the Actavis Generics transaction? Well, as you know, we have received regulatory clearance in Europe and other international territories. We are close to finalizing the divestiture list with the FTC, and agreeing on the remedies. We have identified the buyers for a majority of the product, and remain on track for closing in June. And rather than making you wait to the Q&A section, I'll reconfirm our commitment to achieve cost synergies and tax savings of approximately $1.4 billion annually, largely achievable by the third anniversary of the closing of the transaction. This assumes approximately $1.1 billion of net global revenue divested, which, while higher than anticipated, as you can see has no impact on our commitment to delivering on our promise.

We have taken a significant step to transform our generic business, solidify our foundation, increase our profitability, and to better position us to generate sustainable long-term growth. These many steps have included portfolio optimization, strengthening our capabilities in R&D, and manufacturing of complex products, regaining a leading position in submission on first-to-files, enhancing our go-to-market, and sales force effectiveness capabilities, and much, much more. These are the very capabilities that companies must possess in order to thrive at the global level. We have created a unique and differentiated platform, positioned to extract significant value in the global growing generic space.

Now I turn the call over to Eyal.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

Thank you very much, Siggi, and hello, everyone.

I'm pleased to review the financial section of the Q1 2016 results. As you can see from the highlights presented here, this was another strong quarter for Teva. Sales declined by 3%, mostly due to exchange rates impact. However, operating income, EBITDA, net income, and earning per share were at the same level of last year, due to improved efficiency, and profitability -- and Q1 last year was a very strong quarter as well. This is one a notable exception here. We'll continue to increase our investment in R&D, both in generics and specialty. Total R&D spend was $375 million for the quarter, 14% higher than last year.

So let's talk about exchange rates. Exchange rates had a negative influence of $107 million on revenues, but only $30 million on operating income, which was 2% up in real terms. We continued to generate a lot of cash this quarter, with cash flow from operation at $1.4 billion, and free cash flow at $1.2 billion. Our total debt was $10 billion at the end of March, and financial [leverage] as well as debt to EBITDA ratio were down year over year, and we are well-positioned to raise the debt for the financing of the Allergan generic business. And also we continued the trend of strong EBITDA at $1.6 billion to $1.7 billion per quarter.

The sales decrease in the United States, as you can see from the geographical mix, was driven by the generic segment, mostly due to loss of exclusivity of esomeprazole and budesonide -- and Siggi referred to that before -- partially offset by increase in specialty medicine, mostly Copaxone and respiratory products. Net of FX, revenues were down by 1% as the loss of exclusivity of the US generic products was almost fully compensated by the strong performance of our specialty and OTC business, and the growth in our other generic businesses.

Generic sales accounted for 45% of total sale, as a result of the loss of exclusivity in the US. Copaxone sales were 21% of total, 1% higher than in full-year 2015. The specialty business without Copaxone was 24% of sales, an improvement, compared to the 2015 average, of 2%. Global generics accounted for 32% of our operating profit. This compares with 37% in 2015 full year. The reason is loss of exclusivity, as we mentioned before, with few new launches this quarter. Copaxone contributed 44% of total profit, compared to 42% for the whole year of 2015. Speaking about Copaxone -- when we look at results quarter over quarter, total scripts were the same level as last year, with an increased proportion of 40-milligram, which

contributes to our profit, where the small increase in units sold as well as the positive price effect leading to 9% sale growth mainly in the United States market.

So this concludes the financial review, and now let's look at the dividend distribution. As you can see, our Board approved a dividend payment, in line with the $0.34 per share distributed in the 2015 quarters. Total payout increased, as a result of the equity offering last year, so we continued with the $0.34 per share dividend.

So now let me take you through our guidance. Some background: pending the closing of the Actavis Generics acquisition, we are providing revenue and non-GAAP earnings per share guidance for the second quarter of 2016 only. This includes the results of the Rimsa acquisition and the Teva-Takeda business venture, but not the Actavis Generics acquisition. We continue to work towards satisfying all conditions for the closing. And based on our estimate of the timing to obtain clearance from the US FTC, we currently expect to close in June 2016. Assuming a June closing, and as you already heard from Erez, we expect to provide additional guidance as follows: full-year 2016 guidance including Actavis Generics during the Q2 2016 earnings call in August; and 2017, 2018 business and financial outlook in September 2016 after Labor Day. So our guidance for the second quarter here is $4.7 billion to $4.9 billion for revenues, and $1.16 to $1.20 for earning per share.

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

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - Head of IR*

Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Your first question comes from David Risinger.

David Risinger - *Morgan Stanley - Analyst*

Thank you for all of the detailed prepared remarks, including Siggi's commentary on the pricing outlook. I have a couple questions. First of all, I guess, first of all, Siggi, could you please comment on your expectations for longer term pricing? Obviously, you just reiterated that you expect mid single-digit US price declines in 2016, but I was hoping that you could comment potentially longer term. And then second, you mentioned $1.1 billion in net global revenue to be divested, which is above expectations. Could you discuss that, the impact of that on the expected accretion from the Allergan generics acquisition longer term? Thank you very much.

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

Yes, thanks, David. First of all, on long term pricing, it's difficult to comment on the long term pricing. But maybe we can think about, what are the factors that play into pricing. So it's obviously, it has to do with competition in the market. We know, if we look at the US market, there's 230 generic companies that are competing, so the competition is fierce.

Secondly, its impacted by the new approvals by the FDA. The FDA has been approving more products, and it's impacted obviously by consolidation of the customers. I think overall, the consolidation of the customers hasn't changed that much in the last 24 months, as I said in my prepared remarks on, the change in the competition hasn't been that much. So at this point in time, I don't see foresee any big changes in the pricing environment in the US or globally. There's nothing on the horizon that changes my mind.

Over the last 10 years, I've been operating a US generic business now for 10 years in a row. The cycle has been from approximately minus 1% deflation, to maybe minus 7%. It goes a little bit back and fourth. It's a cycle, it's a process, but we are approximately mid single-digit price erosion. And there's nothing that we see now, that changes that, at least in the medium term, but very difficult to talk about the long term view on pricing.

With regards to the $1.1 billion divestiture, you have to keep in mind, this is the global revenue impact. Where we were about expectations, just so we are clear, was in the UK. We highlighted that, there was a larger divestiture in the UK than we expected so. But we highlighted also, we are committing fully to our net synergy number of $1.4 billion in cost and tax synergies as before. So there is no impact on the accretion of the deal, due to the divestiture we are talking about. And on the timing of the synergies, is as before, we estimate that we get most of the synergies in the first 36 months after closing.

David Risinger - *Morgan Stanley - Analyst*

Thank you.

Operator

(Operator Instructions)

Our next question comes from Tim Chiang.

Tim Chiang - *BTIG - Analyst*

Hi, thanks. Siggi, there's certainly been a lot that's happened in the generic space over the last 9 to12 months, and certainly one thing that's happened is a resetting of valuations. Now, I know that you guys announced this deal back in July of last year. What can you comment about, in terms of the price you're putting on the table for Allergan? You think that's still a fair price in today's environment?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

Hi, Tim. The answer is absolutely yes. The strategic value of the deal, is at least they[re one, that was when we announced the deal. We have the opportunities in that US generic market, and in the global generic space are huge. And we strongly believe, that with everything that we are witnessing now, our opportunities for Teva are even bigger, compared to basically where when we announced the deal. So for us, what we're creating in here, is a very unique platform, with the same at least the same strategic value that we alluded to when we announced the deal. And at the end of the day, it is also about the economics. And from all of the messages that we are conveying in here, we strongly believe that we will be able to generate the economics that we promised.

Operator

Your next question comes from Jami Rubin.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. I just have a couple questions. Siggi, again I appreciated your explanation, but I think part of the confusion too, is that we're hearing about worsening generic drug price deflation, not just from other generic drug makers like Endo and Perigo, but also from some of the distributors. And in fact, AmerisourceBergen said last week, that they were citing a worsening deflationary market, worse than they had expected, and they expected it to grow to high single-digits by the end of 2016, and stay there, in that range for the entire 2017.

So if you could just explain the interrelationship between the manufacturers, the distributors? Why are the distributors citing something different, and citing something worse? What needs to happen out there, for your guidance of sort of minus 4% or so, price deflation go to minus 6%, minus 7%, minus 8%? Give us some confidence that we are not going down this slippery slope? And then Erez to you, clearly you are doubling down on a sector that has faced major headwinds, or clearly has been reset in terms of valuation.

Can you remind us all, what is the investment thesis, what is the attractive investment thesis for being the largest generic drug company in the world? And then just lastly, you have cited your interest in continuing together do specialty pharma deals, once the Allergan deal is done. But given where your valuation is, and given where your stock is sitting, and your confidence in the generic drug business, how do you balance the desire to do deals, with a significant stock buyback program that I think investors would really appreciate in this environment? Thanks very much.

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

So thanks, Jami on the -- this clearly is the hot topic, no question about it, and that's why I went in some details in my prepared remarks around the pricing. So first of all, I think what I laid out in my prepared remarks was, why we are saying the 4%. It's basically due to our portfolio, because we are not operating -- we have approximately 375 products on the US market. We have a good understanding. We also walk away when the competition is too fierce on a product. We are not trying to grow our market share, which affects the 4% market share.

I can't obviously comment on why ABC is seeing a high single-digit price erosion when we are talking about 4%. But I would remind you both Cardinal and McKesson are seeing the similar numbers that we are quoting, that Mylan is talking about, and also what Allergan is talking about. So it's not all that bad. That's number one. Number two, in terms of the -- not all companies are created equal, and one investor asked me is, are you the only good house, in a really bad neighborhood?

And I don't think that's it, because I think the other houses are blaming the neighborhood for their maintenance issues. They are working with leaking houses, and it has to do with renewal of the portfolio, of lack of investment in generic R&D. That keeps you growing the business, because that is the key at the end of the day. So I don't think you can look at companies, different companies, and say if company A is experiencing 7% price erosion, that should be the market norm. You have to look at it differently for a company that has a big portfolio, strong new product launches, a differentiated portfolio, and a high quality portfolio.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

Hi, Jami. Thank you for the questions, and I'll try to address all of them one by one. So first, in general, what we do in here, we build a diversified growth platform, a balanced portfolio of durable products that offers top line and bottom line gross profit. And that's something which is important, in general to understand. And now, to address the additional questions, I think it's important to just put the context here, which is imperative. Now, I believe that Teva has demonstrated an ability to allocate capital in a disciplined and strategic manner, and we'll continue to do that, to support our strategy first and foremost, which we believe ultimately will reward our shareholders.

We continue to see very attractive opportunities to grow our business through business development, and continue to explore them. Furthermore, the combined Company of Teva and Allergan generics will generate significant amounts of cash. We mentioned numbers like $20 billion to $25 billion during the first three years following the closing.

Today we believe that the best use of our capital will be to rapidly de-lever in the coming years to 2 to 2.5 debt to EBITDA, as well as invest in the business development to secure additional growth opportunities, around the globe and in our different businesses. Of course, in any event, our Company is no stranger to share repurchases. Over the years we have shown a willingness to employ them, in an effort to further reward shareholders. We will continue to take a balanced approach to capital allocation.

And number three, we are -- the global generic industry is a $1 trillion industry, which is very profitable. At the end of the day, when you look at it, very profitable industry, and there are not too many industries out there like the global generic space. We think, that when we look at the competitive

-- the global competitive landscape, and what we are building here, it's a very, very unique set up. We believe that this global space possesses huge opportunities.

And we believe that the challenges that folks face nowadays, just reinforce even further the opportunities for Teva, given the changes that we have been undergoing, and given the way we have been transforming the business, and given what we are building in there. So for us, the challenges around us, just even reinforces further the opportunities that we see. And last but not least, we do not plan to use equity in acquisitions that we might entertain in the course of 2016. So in any event, basically we said it and reiterated it, we plan to use the $3 billion to $5 billion capacity that we have modeled, in entertaining potential branded drug deals in the course of 2016.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you.

Operator

Next question comes from Louise Chen.

Louise Chen - *Guggenheim Securities LLC - Analyst*

Hi, thanks for taking my questions. First question, I had here was on your CGRP program. I was wondering if you could give us an update on how enrollment for this trial is progressing, and when is the earliest we could see data here? And can you remind us also your $11.6 billion also -- I know this an older number on EBITDA in 2018 -- does that include CGRP or not? And second thing here, is just on your guidance, post close of generics deal. Just curious, in the past you've talked about potential upside to your synergy guidance from sourcing? Is that still on the table? Thanks.

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

Well, thank you, Louise, for that question on CGRP. I'm pleased to say that both the chronic and episodic migraine trials have begun. We primarily are recruiting in the US. Recruitment is going exceedingly well, and of course, this talks to the tremendous need for novel therapies in this particular space.

We're looking forward to getting top line results by the end of 2017, with full exposure to results in 2018, and launching by early 2019, but we will keep obviously the Street informed. We're delighted our recruitment is ahead of schedule, and we're making terrific progress associated with this. Also just to mention, and reiterate is, that we will be starting our trial in cluster headaches in the second half of this year, a very important unmet need, the suicidal headache for which CGRP may offer significant hope and benefit.

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

Maybe quickly on the synergies, as we said we reconfirmed, the $1.4 billion number, taking into account the new number, in terms of the divestiture of $1.1 billion. We, that is our statement now, but we obviously will give a full guidance on the combined Company in August.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

And Louise, On your question about 2018 EBITDA and does it include CGRP, the answer is probably nothing, the product, even if launched sometimes in 2018, is not expected to generate any profit during the first year of launch.

Louise Chen - *Guggenheim Securities LLC - Analyst*

Okay, thanks.

Operator

The next question comes from the line of Ronny Gal.

Ronny Gal - *Bernstein - Analyst*

Hi, good morning, everybody, and thank you for taking the questions. First, Siggi, would you help us understand the Paragraph IV launches during the year? It seems you're now sitting at a point where you've got very few Paragraph IV revenue generating, or high margin products right now in your portfolio? Can you take us through how this will change during the year? And you could also comment on your cost position for conversion cost overall, now that you are looking at your combined business with Actavis. Where would you be in terms of cost structure? And last, this is more for the branded side, the ProAir conversion to the second generation, it seems to be going a bit sluggishly. Can you help us at all think about this franchise going forward, how much you think we can keep Teva can keep at the time of generic entry, and is there any way you can accelerate this conversion?

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

So let me start, Ronny. So first of all, we have been very clear on that in the guidance for 2016. There's no, in the Teva portfolio, there's no significant Paragraph IV that we have pointed out. There are quite a few smaller launches that we have in 2016. None of those that we have been talking about in the public domain, but obviously for the combined Company the picture looks better for sure.

Just to highlight, and I'm not here to talk about the Actavis Generics business. I think they will have their results tomorrow. But to highlight for them, is in as far as last week, they have launched 30 new products in the US as of this year. So I think overall 2016 has a fewer Paragraph IV launches than before, Straightaway in 2017, we're going to show you that when we get together after closing of the deal, what to look for in the pipeline. But I don't want to point out any Paragraph IVs in the Teva portfolio for the remainder of the year. These are relatively small launches that we are doing for the remainder of the year.

With regards to the conversion cost of the combined Company, that will be part of our guidance when we get together in August. We also don't think it's the right time to talk about the conversion cost guidance of a combined Company where we haven't closed the deal.

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

Yes, Ronny, with the conversion of ProAir to ProAir HFA, it's doing extremely well. If I look at ProAir in terms of volume, it's more or less at 5% of the HFA. When it's in RespiClick, it's about 5% of the overall ProAir. And the last part of it, really comes from new patients and if we compare to the conversions or the change to new inhalers also from Boehringer or GSK, we actually outperformed them.

But you're absolutely right, in terms of really moving the entire ProAir franchise towards the RespiClick, we need to further accelerate, and we are very committed to that. Going forward, for the entire Respi franchise, we just launched Cinqair, the reslizumab, and we just also achieved very positive, as Erez said data on the FS RespiClick and FP RespiClick. So we're strengthening the entire Respi Click franchise there. And having one and fairly unique advantage intuitive inhaler available for patients with multiple fixed combination products would be really an advantage. And we continue to drive that forward, and bring that forward. And at the same time, defend our HFA as good as we can.

Ronny Gal - *Bernstein - Analyst*

Thank you.

Operator

The next question comes from the line of David Amsellem.

David Amsellem - *Piper Jaffray & Company - Analyst*

Thanks. Joined late, so apologize if I missed this. But on Bendeka, so assuming that there are generics on the lyophilized product, I guess, with the product not having a -J-Code, can you talk about how it's viable, if you do go to multi-source? And talk about your latest thoughts on, where your share would go in that kind of scenario, assuming that the case doesn't go your way? Thanks.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

Hi, David. I'll start, Rob or Michael can reinforce. So I think the next important milestone and the inflection point is, basically a decision on the ANDA case, so that's what we need to expect, and that's an inflection point and tipping point in the market. And I think all of us need to wait, and see what you basically got coming out in the course of the next few weeks. And just then, a comment on potential ramifications. And Rob, would you would like to add something?

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

Yes, Erez, I think you're fully right. And then also on the J-codes, there's a preliminary decision by the CMS. Eagle, with our support, definitely we'll try and fight that and try to address it in a public hearing, later this month, and the final decision is out in November of this year. So even if the initial decision wasn't positive, the fight on the J-code itself is also not over. Clearly, if --and I think we need to really wait for these results. If the J-code would not come, there would be generics for the lyophilized products, then we really are facing a difficult situation, where we believe that Bendeka will become a relatively small product going forward, but we still have many options to try and intervene and present it.

David Amsellem - *Piper Jaffray & Company - Analyst*

Thank you.

Operator

The next question comes from the line of Ken Cacciatore.

Ken Cacciatore - *Cowen and Company - Analyst*

Hi, good morning. Just wondering on that $1.1 billion of revenue, just could you give us a sense maybe in advance of the value that you're going to be capturing as you assign that? And then, maybe discuss how that value may have some impact on your ability to, either increase the size of your business development that you're looking at? And then in terms of business development, can you talk about the environment asset values have come down to a certain extent? But can you discuss maybe the other side of the fence, the folks you may be negotiating with, their reason ability in terms of where valuations are now? Thank you.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

Hi Ken. First, I think that's an opportunity again, just to underscore the implication of 1.1b (in divestitures) is basically embedded into the $1.4 billion of net synergies. That's something I think that message is in a very important message. And so, when we say that we are committed to generate $1.4 billion of net synergies, it means that it includes the higher divestitures, versus initial expectations. And that's basically a clear important message that we are conveying here. So that's number one. Number two, yes, we will get higher value. It might increase the optionality on potential BD deals during 2016, but we prefer to discuss details when we close the deal.

Operator

Next question comes from the line of Chris Schott.

Chris Schott - *JPMorgan - Analyst*

Great. Thanks very much for the questions. Just heading back to the competitive landscape on the generics side, it clearly seems like some of your competitors are having some challenges here. I guess, just two part question here. A, what do you see happening to these smaller players, given these challenging market dynamics? And B, are you concerned that these companies become increasingly less rational competitors as they try to defend their business, and that could have spillover effect into Teva's business?

The second question I had is on that $1.1 billion divestiture, what was expectation? So how much more are you offsetting with the synergies in the business, to keep that net number the same? And then, finally on generic gross margins, some very healthy trends year-over-year. How much more opportunity is there to improve margins on the current standalone business, as we think about the next year or so before, Allergan gets into the mix? Thanks so much.

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

Thanks, Chris. First of all, on the competitive environment, and on that you're right. The smaller companies are probably having a tougher time. And it goes back to what I mentioned as the first reason on why they're seeing a tougher price erosion is. There was, It think, a market where it was good for the business to be in a niche environment, where you had one or two products, where you could take price increases and thus allowed your overall market to grow.

I think in the current environment, maybe there isn't the same opportunity for that. You basically benefit from having a much larger portfolio, where some of the portfolio is clearly under threat, but other parts of the portfolio you can grow with new product launches. Am I concerned that they might take up irrational behavior? I don't know. I have said to you Chris, many times before, we are only as good as our most stupid competitor in the market. So we have to see. But so far, I think there's no sign of that in the market per se.

What was the original number? I'm not going to go down to that, because we never gave that in our guidance. But as I highlighted around the $1.1 billion. Where we ended up with a higher divestiture, was around the UK. We basically we have to divest as it's in the public domain from the European Commission. We have to divest more than 50% of the Actavis UK business, and we haven't assumed that. But that is the key difference in the divestiture. But also we have to keep in mind, that it is approximately $1.1 billion we are talking about because we haven't had the sign off -- the final sign off from the FTC. So it's not right at this point in time, to talk about the final number. But although, we feel that we have agreed to the products that need to be divested.

With regards to how we would look standalone, and that's a little bit like a fairy tale. I said that when we talked about last year, where we were at last year, that I thought we could do about 200 basis points more, if we would be a standalone. I think we still can do that. We went half way in this quarter. There's still an opportunity.

I'm optimistic about the business. We are really running a good business, even in the US business where we experience that year-over-year comparison is difficult, due to the exclusivity of esomeprazole a year ago, really the underlying business is doing well. And I have to say, that our European business is performing better than ever before. So I'm optimistic, but there is a limit how much you can improve the operating profit of a business. And I stand by my previous statement of around 200 basis points from last year.

Operator

The next question comes from the line of Gregg Gilbert.

Gregg Gilbert - *Deutsche Bank - Analyst*

Yes, hi, good morning and good afternoon. Sorry if you covered this, I don't think you did. But is the EBITDA contribution from Allergan in 2016, the same that you already projected, other than the change in the closing timing? And Siggi, what type of info are you getting from Allergan, and how frequently do you get it? And then my follow-up is on 809? Perhaps you could talk about commercial readiness, and how your interactions with the FDA are going so far? Thanks.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

So maybe I'll start with the EBITDA coming from the Allergan generic piece. They're moving pieces, we, in the original model, we assume the full year. Now it is becoming a half a year. Of course, the synergies are not linear, in six months, you can achieve less. But as you heard from Siggi, our three years from closing target, remains very well on target, and in place. So proportionately, it could be a little less, but keep in mind, it is a six-month period, and not a full year period. So look at 2016 as a transition year, and the real year to measure will be 2017. And that's why we will provide some outlook earlier than what we normally do.

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

On the, Gregg, around the information we get from Allergan. First of all, we have -- we are competitors in the market. We have to be very careful. We cannot exchange any information. We are competing very forcefully in the market until closing. So for example, we have no access to financial information that we have in the quarter, that they haven't reported. But the information that we have is what's in the public domain.

So we know how many first-to-files they have had. We know what number of launches they're doing in the market, because we are competing with them in the market. And with all of the indicators that we are seeing, and most of them -- all of them are in the public domain, they are running a very good business.

With regards to the integration, we're doing well. We have announced the first four layers of the organization, obviously pending closing of the deal. And all, we have 31 integration team in place, which are now prepared to launch for day one. So we are ready, whenever we get the final approval from the Federal Trade Commission, and we can close this transaction.

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

Thanks, Gregg, on the question of the SD-809, the NDA is under active review, and we are working very closely with the agency to address the final questions that have arisen during the review process. I must say, there's tremendous enthusiasm in the community, the Huntington community about this particular product. Of course, there's been only one product ever approved for Huntington disease in the United States in 2008. And this product has improved efficacy and in particular an improved safety profile. And Rob, if you just wanted to talk about the preparations for launch?

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

Yes, Gregg, Michael, with pleasure. The commercial, is in great shape. We're taking a very patience and also caregiver type of approach, where this is really, really important. Like Michael said the excitement is big, not only in the Huntington's community. But also for us internally having the opportunity to bring a real meaningful improvement to people that so badly need it, is really exciting. And in terms of medical, commercial and also payer preparation, everything is in place, and we are ready to do this, and bring these products to patients, as soon as the FDA would approve it.

Operator

The next question comes from the line of Liav Abraham.

Liav Abraham - *Citigroup - Analyst*

Good morning. Siggi, you spoke about 10% volume growth from the combined product pipeline over the next few years. What visibility do you have for this growth, and what makes you confident that you can maintain this volume growth over a period of time, beyond the next couple of years? And then, secondly, can you comment on the increased pace of ANDA approvals by the FDA? One could argue that this will increased the competitive environment for generic companies including the combined Teva Allergan generic business? I'd be interested on your thoughts on these dynamics, and the potential net impact on Teva, if any? Thank you.

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

Yes, thanks, Liav. So in terms of the formula, I talked about the 10% growth, we're talking about obviously value growth, revenue and profit growth. It doesn't mean necessarily this is the volume growth, because usually the new product launches have a smaller volume, than the old portfolio so. But we have amazing network, obviously we have in the combined network, we have plenty of capacity for complex generics that we will be introducing. But overall, we are very confident with our current network we still have plenty of opportunity to grow going forward.

In terms, of how long we can maintain this, I feel we have it for the long run. What I know now is, what is pending at the FDA in the combined pipeline of Actavis Generics and Teva, from what I see, I'm very confident over the next two to three years, because of what has already been filed. So that gives me -- that's the beauty of the generic business, the risk around approval is much less than otherwise.

And the second reason is why I think it's long term is, that our current commitment to further invest in the generic R&D as I mentioned before, yes, we are not going to invest $850 million, which is the combined generic R&D budget, but it will be very significant investment we want to do. And also to be enablers to maintain the growth we are talking about. With regards to the increased pace of the FDA of approval you're right. They are picking up the pace.

And I think partly that has to do that they want to meet the GDUFA statistical guidelines where they need to be, because we have already started to negotiate GDUFA 2. But also you have to keep in mind, that for every approval that generics get, we get approximately two complete response letters. So yes, there is a lot of movement. They are having a targeted action day but the ratio is currently for one approval, there's two complete response letters. The good thing is the FDA is that the moving forward.

But when you think about it, the combined portfolio of 300 and nearly 30 ANDAs, is that if the FDA starts to accelerate for the whole industry, the combined company of Actavis Generics and Teva will have approximately 10% of all ANDA pending at the close of this transaction. And we will also benefit from the acceleration, so it's not only [net additive] on the pricing. I think this is net-net positive for the combined Company going forward, so I'm excited about it. I only see that as a good thing, if the FDA accelerates approval of generics.

Liav Abraham - *Citigroup - Analyst*

Okay. Thank you.

Operator

The next question comes from the line of Elliot Wilbur.

Elliot Wilbur - *Raymond James - Analyst*

Thank you, good morning. I also wanted to touch on the subject of pricing, but actually my question is directed at Rob, with respect to the specialty business. Specifically, in the press release you talk about Copaxone having a net positive impact in terms of year-over-year growth, driven by positive pricing dynamic? And I'm just curious how you're seeing that play out, or how you expect that to play out over the balance of the year?

Obviously, it seems like there's a lot of payer pressure on specialty products. And I think the expectation was that the pricing dynamics would be neutral to negative for Copaxone, but obviously not the case in the first quarter? Then maybe extend that question to some of the rest of the specialty portfolio, specifically in the US, maybe just generally comment on price volume dynamics there?

And then a follow-up question for Eyal. Given the expected immediacy of the close of the Allergan generics business, can you maybe talk to us a little bit about your expectations around the debt side of the balance sheet, in terms of the current bridge loan? How much of that needs to be refinanced and what you think about in terms of the terms structure there, and the associated interest rate with the final debt package?

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

First, the Copaxone is really doing well, and like you said, we see a lot of the impacts also from the net price increase of 7.9% that we -- that were on both strengths in the beginning of the year. But it's actually really a result of fantastic underlying demand. The products is keeping well, it's the number one product in new patients now, and Copaxone is really, actually a very good alternative and patients have access to it, right? So in no way has the price been a limitation in that sense. And I think that's the key going forward, is you'll always have to be able to demonstrate value to stakeholders, to patients, to payers and overall for your products in whatever we offer.

It's really important to be able to show the value of what you're doing. And it's not just about the price, but it's really incredibly important thing to just talk about the value you're offering. And clearly for Copaxone, we're having the right mix. The product is much appreciated, unparalleled in its track record of both efficacy and safety, and available to just about 96% of lives in the US. So pricing there, I see extremely good. Going forward, I think I just answered that. You cannot just look at price. You have to look at the value you're bringing to patients and the system. And for all of our products we're very much aware of this, and this is exactly the approach we're following at Teva.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

Okay, and on the final plan, it remains by and large the same, maybe improved a little. We continue to accumulate cash during first half of 2016, so we'll probably not need an entire $[27] billion of bridge loan which is available to us. The plan is to close on the bridge, and go to the market at September time frame or in Q4.

We see a very good market environment, and rates remained very favorably low, a bit lower than what we had in our original expectations, and hopefully we'll stay that way. And the bridge is just to remind everyone from two years from drawdown, so we have a lot of flexibility on selecting the time of go-to-market.

Operator

The next question comes from the line of Umer Raffat.

Umer Raffat - *Evercore ISI - Analyst*

Hi, thanks for taking my question, excuse me. Erez, maybe one for you, how do you intend to approach SD-809 pricing, considering your initial approval being Huntington's, but the bigger population will be tardive dyskinesia where your competitor might come in materially lower than Pridopidine pricing?

And Michael just wanted to clarify two things with you. First you said CGRP Phase 3 timing is late 2017, and I suspect that might put you 6 or 12 months behind competition? I just wanted to make sure I clarified that? And other thing you said was, on SD-809, Michael you said FDA had raised some final questions in the review process. So I wanted to confirm, are we still on track for late May PDUFA? And finally for Siggi, Siggi just wanted to ask what's your updated EBITDA number for Allergan generics standalone in 2017, given the divestitures? Thank you.

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

Okay. Thank you, Umer. Just to answer on CGRP. Of course, at the present time yes, we've always calculated for chronic migraine that we would be in all likelihood, first-to-market for episodic second.

But I would say that we're making great progress, and we'll have to see how these trials run out. The -- it's all about the timing of the recruitment, and also the strength of the results. But we believe that this particular product is --has a differentiated profile thus far, and is being -- the recruitment is ahead of schedule. So at the moment, we are talking about the end of 2017. But again, as the recruitment continues, we'll be able to update that during the course of the trial, and to be able to give you the latest information on that.

With regard to the FDA, at this point, we don't really comment, and we do not want to comment on active discussions with the FDA at this time. We're excited about SD-809, and certainly we will keep everyone informed of any actions when the review is complete.

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

And maybe Umer, of course, I can't update on the guidance on EBITDA for 2017. We are going to come out in September, as you heard from both Erez and Eyal in terms of guidance. The only thing I want to say is, obviously with a six-month delay or five month delay in closing, we are still committing to the synergies of $1.4 billion within the first 36 months, majority of them within the first 36 months. So they are moving out.

Clearly in 2016, you don't get the same synergies as you would have been getting if you get, for 12 months the same year. The synergies are not linear. S we need to look at it, when we get the business, when we close the transaction to give you an accurate number, what we see the EBITDA for 2017. And as we mentioned in our presentation, that would be in September.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

And Umer, on the first one, it's too early to comment on pricing of SD-809. I think it's just entertained all of the relevant milestones on a step by step basis. First the approval for HD, and then conduct successfully these clinical trials that relates to tardive dyskinesia, and the same (inaudible) competitive landscape. And then we will strike the right price, in order to generate value to patients and in order to be smart on the way we manage, basically given molecules from a different indication from the same molecule.

Umer Raffat - *Evercore ISI - Analyst*

Got it. But Erez, just to be clear, would you reprice it once Tardive is approved, or would you just go with one pricing for both, or is it something TBD?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

TBD.

Umer Raffat - *Evercore ISI - Analyst*

Got it.

Operator

The next question comes from the line of Jason Gerberry.

Jason Gerberry - *Leerink Partners - Analyst*

Hi, thank you for taking my questions. A question for Siggi. Just can you comment at all, for the pro forma entity as you look at it maybe for the last three to five years going backwards, what was the average annual new product sales contribution for the generics business? Just trying to get a sense, Teva used to provide this disclosure three or four years ago. And I think it's important because as we look forward to your math, it implies something like $600 million to $700 million in annual new generic product contribution. So just wanted to have a sense of where we've been coming from, to how we get to that number?

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

Yes, Jason, thanks for that. I think on the Actavis side, obviously, I have the benefit of knowing that internally. That was achieved every year, because there was a significant that was the key to the Actavis Generics business model, and I can confirm that in the Teva at least for the last year, because I know the numbers very well for 2015, we achieved more than 10% new product revenues from new product launches last year. So it can be achieved with the investment in the pipeline we are talking about for sure.

Jason Gerberry - *Leerink Partners - Analyst*

Great. And if I can just get my follow-up in so. There's a little bit of discussion on the CGR landscape around some of the IP that [Laboris] had, and I'm curious if there's any plan to try to enforce that IP, if that might create freedom to operate issues for any other CGRP players in the market? Thanks.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

We don't want to discuss it at this stage.

Jason Gerberry - *Leerink Partners - Analyst*

Okay, thank you.

Operator

Your next question comes from the line of Mark Goodman.

Marc Goodman - *UBS - Analyst*

Good morning, a few things. So first, I just want to confirm, so previously, we had divestitures that were supposed to be below $1 billion, now they're going to be little bit above $1 billion. We had a cost cutting plan before, of a certain amount. And now that cost cutting is going to be bigger, such that the net number which is the accretion to earnings from the deal, will basically be about the same as you thought before? That's question number one. I just want to confirm that.

Second, the specialty products, if you look across the board, the ones that you disclosed Azilect, ProAir, QVAR, I mean, they all seem to be pretty much above what everybody was expecting. So just curious, why was their inventory build? And then maybe Siggi, just give us color around the key countries outside of the United States, what's going on -- a little more color than what was in the press release? Thanks.

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

Yes, so on. Maybe I'll take one and three. So you're correct, on the first question, we are listed about $1 billion, and we are very confident to achieve the same net synergy number as before. So tour assumption is fully correct. With regards to the international market, we have a good performance in international. We were under a little bit of pressure. There is increased pricing pressure in UK.

We have seen that, and the same in France. But we also have a good performance. We saw a better performance than we expected in Italy, Germany, and in Spain, where the environment has changed. There's a new guidance in terms of discounts and things like that. So we are sitting at the same table, as the local producers in Spain which means a lot. I think our business in Russia has been performing extremely well, both on the generics side, but also on both the brand and OTC side. Obviously still challenging currency, the ruble but doing well.

And obviously, from first of April, the environment for Japan changed completely with the joint venture from Takeda in Japan, changes the business model. We are going to talk about that in more details in the second quarter results in August, explain a little bit of the impact of the joint venture, and how that is going. So overall, I was very pleased with the international. We are still under some pressure due to FX. But overall, there's a net growth in the business, we see both in the growth markets, but also in Europe.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

And on the specialty, just to maybe start, we guided by the market by January 14, on how we are going to see the next three years, in terms of our existing specialty portfolio, with strong focus on how we manage the life cycle, and we are just delivering on the promises.

In the respiratory, that's firstly and fore-mostly, the new business that we are growing, and that's the intention to continue doing it in the future, the strategy of Teva here is to put a strong focus basically on improving the adherence and compliance of patients, and growing new business basically, and to at least offset the consequences of our ProAir's loss of exclusivity. That's -on respiratory. On Azilect, we just again guided the market that we plan to launch the product in the key international markets. And at the end of the day, to be able to protect something in 50% of the franchise going forward. So we are just delivering on that on step by step basis. And on Copaxone, maybe I think maybe, Rob, you would like to comment on Copaxone.

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

Yes, Erez, thank you. So but just as a straightforward answer to the question, no there is no inventory build in the good results of specialty in this quarter. And then I think we addressed Copaxone before, the amount continues to be strong. We are number one in new patients in the US, and also number one Copaxone with 40-milligram in the US, and Copaxone is the number one in new patients in Germany.

We see incredibly strong conversion to the 40-milligram, which is a very nice and competitive product, and future in that sense, is really looking really good, as patients and doctors continue to really appreciate the products, and appreciate it so much, that it's the first choice in the two key countries. And overall performance of specialty has been good. And as I said already, that should be not driven by inventory build. Thank you.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So maybe just to maybe let you look at the fact, that by the end of 2014 or of 2015, inventory levels that related to Copaxone were very, very low. Today we are at normal basically inventory levels by the end of Q1 2015 -- Q1 2016.

Operator

Your next question comes from David Morris.

David Morris - *CLSA Limited - Analyst*

Good morning, Erez and Siggi. Today you mentioned biosimilars, that you're looking to expand the pipeline with some biosimilar further biosimilar exposure. So given that Teva rarely says that they are looking to do something, and then doesn't do it. So maybe you could describe what you're looking for? And then just remind us what the state of the current Teva biosimilar pipeline is? Thank you.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So maybe I'll start, so we promise that during 2016, we'll basically be able to address a Wave 2, and clear direction for Wave 3, in a pursuing potential collaboration and partnerships, with (inaudible) that might bolster, in a way that might bolster our biosimilar pipeline. We are basically, have every intention, and plan to deliver on that promise during 2016.

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

And David, where we are currently is, that we have one product in late stage development, we have biosimilars of Humira it's in the public domain. And then three, Wave 3 biosimilars in development, relatively early development. But we have the infrastructure basically to develop our own biosimilars. We have an outstanding biologic group around the world. We have the regulatory affairs and IP knowledge to do this, And really the reason why we are looking for a partnership here, especially around Wave 2 because we have a gap in our pipeline around Wave 2, and maybe some of the early Wave 3 products where we simply don't have the time to catch up.

In terms of where we are in the market today, we have a revenue of the Wave 1 biosimilars of approximately $300 million to $400 million on a yearly basis. These are the old versions, of course, [Epo, phil CAST stream PEGylated, phil CAST stream] et cetera are doing well. But we also have the infrastructure to sell these products. And I think maybe as the last point here is, we recognize that to sell biosimilars today and going forward, you need to be both a specialty company and generic company. Because I think that's the key to be able to market these products going forward. I think we are the ideal partner in this way. But as Erez mentioned focus on the partnership is on Wave 2, and maybe early Wave 3. But we're looking for ourselves, for development of other Wave 3 products.

David Morris - *CLSA Limited - Analyst*

Just as a follow-up though, based on your commentary, should we expect or is it your goal to have something, or a start of that augmentation policy or strategy put in place by the end of this year?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

The answer is yes.

David Morris - *CLSA Limited - Analyst*

Great. Thank you very much.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - Head of IR*

Operator?

Operator

The next question comes from the line of Sumant Kulkarni.

Sumant Kulkarni - *BofA Merrill Lynch - Analyst*

Hi, thanks for taking my questions. Siggi, actually both for you. On generic pricing erosion, we heard a lot, but especially on alternate dosage pharma like topicals, are those as attractive products as they used to be, given everything going on in the market place? And second, what are your latest thoughts on potential for getting generic an AB rating for your generic EpiPen?

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

Thanks, Sumant. I'm pleased we didn't have a call without an EpiPen question. I think first on pricing on different dosage forms. It depends a little bit of the situation in the market. You probably remember, Sumant, that in the year 2009, nobody wanted to be in the injectables. And then we obviously had that quality issue in the injectable space. And then two years later, everybody wanted to be in injectables. So on topicals now, I think there is some pricing pressure. You've seen that maybe in the companies that are more exposed to topicals like Perigo and Sando, to some extent they have been talking about more pricing pressure than we have been talking about, or Mylan or Allergan, so that could be a reason.

Overall, in topicals, the competition is a little bit less. We are talking about usually maybe three to five competitors in the market, where you have on commodities maybe 18,19 -- up to 18,19 competitors. But currently, we are not that exposed to topicals ourselves. We have some products, but we also a very interesting pipeline on topicals going forward, where it's -- where we when we combine with Actavis Generics, we will have a first-to-file opportunities on topicals.

But regarding the EpiPen, as we mentioned before, we got a Complete Response Letter from the FDA. We were seeking advice from the FDA. The FDA offered us to get further advice on the letter we are getting right now. We are building a strategy. We are till fully committed to this development, There will be a delay obviously due to the Complete Response Letter. We have not finalized our strategy. We are working with our partner Antares on the final strategy for this product. But I want to reemphasize, we are still fully committed to this product, but we don't know how much the delay will be until we can introduce an AB rated EpiPen.

Sumant Kulkarni - *BofA Merrill Lynch - Analyst*

Thank you.

Operator

That does conclude the question-and-answer session. I'll now hand the call back to Erez Vigodman, President and CEO for final comments.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So thank you, everyone for participating this morning, at the outset of a new week, and have a great week.

Operator

Thank you. That does conclude the conference for today. Thank you for participating, and you may all disconnect.
