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TEVA.TA - Q2 2016 Teva Pharmaceutical Industries Ltd Earnings Call

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OVERVIEW:

Co. reported 2Q16 sales of over $5b and non-GAAP EPS of $1.25. Expects FY16 revenues to be $22.0-22.5b and non-GAAP EPS to be $5.20-5.40.

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Teva Pharmaceutical Industries' second-quarter 2016 results call.

(Operator Instructions)

I must advise you this conference is being recorded today, Thursday, the 4th of August, 2016. I would now like to hand the conference over to your first speaker today, Kevin Mannix, Senior Vice President and Investor Relations. Thank you, and please go ahead, sir.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Thank you, Rose. Good morning and good afternoon, everyone. Thank you for joining us today to discuss Teva's second-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. Michael Hayden, Head of R&D, Chief Scientific Officer; Dr. Carlo De Notaristefani, President and CEO, Global Operations; David Stark, Senior Vice President, General Counsel, Global Markets and GSM; Mike McClellan, Senior Vice President, CFO, Global Specialty Medicines; Mike Derkacz, Senior Vice President and Head of Global CNS; and Sven Dethlefs, Head of Global Respiratory Medicines.

We will start the call with presentations from Erez 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, and under the Investor Relations section with the Teva Investor Relations app.

During this call, we will be making forward-looking statements which are predictions, projections, and 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. Good morning, good afternoon, and thank you for joining us today. 2016 is a transition year for us. We are focused on fully delivering on our short-term operational and financial goals, and at the same time moving ahead with our longer term strategic moves.

During the first half of the year, we closed the Actavis Generics deal, announced the acquisition of Anda, and completed a very successful global equity and debt (inaudible)financing. We closed the JV with Takeda in Japan, and the acquisition of Rimsa in Mexico. We are making progress in our specialty franchise, and we are able to successfully manage the life cycle of Treanda. And lastly, we continued the transformation and optimization of our operational network, and the deployment of cost controls and efficiency measures.

In the first six months of 2016, we were able to generate very similar results to the strong comparable first six months of 2016 without major new generic launches in the US, versus the exclusive Aripiprazole, Esomeprazole and Budesonide we had in 2015.

Non-GAAP EPS for the first six months of 2016 is $2.45, based on share count of 981 million shares. Adjusted to exclude the impact of the December 2015 equity offering, non-GAAP EPS in 2016 is similar to that in the first six months of 2015. Eyal Desheh will cover Q2 in detail.

Slide 6 provides you with a revenue bridge and tells the story of the first six months of the year. The loss of exclusivities of generic Aripiprazole, Esomeprazole and Budesonide were more than offset by the growth of our generic and OTC business in 2016, without having major new launches in the US, and by the growth of our specialty business versus 2015. Our global generics business generated 26.8% operating margin in first six months of the year.

Two days ago, we were very pleased to have report the closing of our deal to acquire the Actavis Generics business. The generics industry is one of the most attractive industries in the world in terms of growth rate, profitability, return to investors, and contribution to healthcare system and societies in the US and across the globe. The transaction between Teva and Actavis Generics transformed the generics space by combining two of the industry's best generic companies.

It cements 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 customer landscape and massive consolidation across our customer base. Finally, it strongly reinforces our strategy, opening a new set of possibilities for us in generics and specialty.

Financially, the transaction yields very compelling economics. It is highly synergistic with $1.4 billion in operational and tax synergies achievable by the end of 2019. It is significantly accretive to non-GAAP EPS with 14% accretion in 2017, and 19% accretion in 2019, and is expected to generate 9.3% ROIC by the end of 2019. The combined Company will generate more than $25 billion of free cash flow from the beginning of August 2016 until the end of 2019.

On July 21, we completed a very successful global bond offering, with total net order book of $100 billion, raising $20.4 billion in three currencies across 12 [trenches], ranging from 2 to 30 years with average duration of 8.65 years, one year longer than our original plan, and blended interest rate of 2.17%. The total cost of our borrowing for the deal including the term loan is 2.12%, and including the cost of the bond offering and cost of hedging 2.32%, versus 2.96% that we assumed in the financial outlook model we shared with the street before the bond offering, and 3.5% when we announced the Actavis Generics deal.

Anda is one of the leading distributors in the US of generic, brand, specialty and over-the-counter pharmaceutical products, and the fourth largest distributer of generic pharmaceuticals in the US for more than 350 manufacturers to more than 60,000 retail independent and chain pharmacies, nursing homes, mail order pharmacies, hospitals, clinics, and physicians offices across the US. Anda ships to more than 85% of the pharmacies in the United States, and it is the premier distributer of new-to-market launches to the chain.

Anda is a natural fit into Teva's business model, enhancing the offerings that Teva can provide, and improving patient access to generic medicine in the United States. Financially, the Anda transaction we announced yesterday yields compelling economy.

Post the close of the Actavis Generics deal, and with everything we have accomplished as a Company since the beginning of 2014, we have been creating a new Teva, with strong foundation, significantly enhanced financial profile, more diversified revenue sources and profit streams, promising specialty pipeline backed by strong product development engines in both generics and specialty. This is a platform that will generate multi-year top-line and bottom-line growth as well as significant cash flow.

There are many moving parts on our patent estate on Copaxone 40-milligram, and we thought it would be useful to describe to you the major pieces. First, the traditional court process under Paragraph IV of Hatch Waxman that we are all familiar with. We have five patents that are listed in the Orange Book. Orange Book listings are important because if we prevail in the court process, we are entitled to an automatic injunction.

Trial on the first four patents is scheduled to commence next month on September 26 in front of Judge Sleet in the District of Delaware. During the trial, the judge presumes the patent is valid, and the plaintiffs have the burden of showing otherwise by clear and convincing evidence. We have not yet brought any action on our fifth patent.

Judge Sleet has a lot of experience in pharmaceutical patent matters, and we expect a decision sometime in Q1 of next year. Appeals of lower court decisions are heard by the federal circuit, and generally take about a year, though en banc review can take longer. And as we all know, it is not unheard of for the Supreme Court to become interested these matters. There is a separate, but related process, where our patents are being challenged in the patent office which is relatively new under the America Invents Act, so I will get into a little more detail on this.

First off, Mylan and Amneal have challenged our first three patents in an inter partes review known as an IPR. Back in May, we participated in a hearing in front of a three-judge panel at the patent office, i.e. the Patent and Trademark Appeals Board, where we defended the validity of these patents, and we expect a decision at any time, but no later than August 25.

There is also a request for the patent office to commence a post-grant review or PGR on the fourth patent. The patent office has until August 24 to decide whether to commence this proceeding, and if it is declined, we expect an IPR will be sought on that one as well.

Generally speaking, the patent office has around six months from the request to decide whether to commence a proceeding, and then the process to decision takes another year from there. Each of the IPR and PGR decisions can be appealed by either side to the Federal Circuit, and although there is less experience here, that process should take about a year. Accordingly, both the Paragraph IV lawsuit and the IPR/PGR proceedings will need to be decided by the Federal Circuit.

These patent office proceedings are cancellation proceedings, which mean that they seek to have the patent revoked at the patent office. This would only occur, if at all, after the appeals process is exhausted. One more thing to look for, it is common for the Appeals Board to cancel some claims at issue, but not others. In the event that the patent office does so in this case, we would view that very favorably for Teva, because the claims are independent and expire in 2030.

Also in the event that we prevail on certain claims at the IPR, Mylan and Amneal would be prohibited for making these arguments in the Paragraph IV proceeding. And even, in the event that we lose all the claims in the IPR in August 2016, as far as the patent office is concerned, we still have the fourth and the fifth patents. And in addition to this, Judge Sleet is not bound by the IPR decision, and can reach a different conclusion. So finally to conclude, any generic launch prior to a final not-appealable court ruling on all five patents which is not expected before the second-half 2018, would be at risk.

Moving on to our specialty pipeline. We continue to make progress focusing on our four core therapeutic areas. These are the upcoming key milestones in the second half of 2016, in movement disorders and neuro-degeneration diseases, SD-809 for Huntington Disease, full response to the CRL we received from the FDA is targeted for the end of September 2016, with up to six months for FDA to review, and target approval by the end of March 2017.

SD-809 for Tardive Dyskinesia, we expect Phase III clinical results. Pridopidine for Huntington Disease, we expect Phase II clinical study results. In pain, we expect approval in the US for Vantrela Extended Release our Hydrocodone product, and Phase III clinical study results for immediate release Hydrocodone.

In respiratory, we expect two approvals in Europe for Reslizumab and for FS Spiromax. In migraine and headaches, we continue to be very excited about the prospects we see in the clinical development of TEV-84125 in episodic migraine, chronic migraine and cluster headaches. Recruitment for the Phase III clinical trials in the episodic and chronic headache programs is going very well, exceeding our earlier expectations.

And finally, these are our key priorities for the remainder of 2016. We'll put strong focus on the integration of Actavis Generics, and the extraction of synergies while we continue to deliver on our operational and financial targets. In addition, we'll put strong focus on achieving all 2016 key milestones in our specialty pipeline.

On the business-development front, we are targeting attractive pipeline and specialty assets in our core TAs, biosimilar assets and strategic platform in key growth markets. And lastly, we plan to provide you with a few business updates in the coming months. In September, we plan to hold combined global generics medicines business overview. Before the end of the year, we plan to hold a specialty medicine R&D Day. And in conjunction with 2016 full-year results, we plan to provide in early 2017, detailed 2017 financial outlook.

Thank you. And I would like to turn the call over to Eyal.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

Thank you, Erez. Good morning and good afternoon, everyone. Following a busy week of closing one major deal and signing on another one, I am pleased to review the financial results of the second quarter of 2016.

Revenues and non-GAAP profit came above our updated guidance, with over $5 billion in sales and $1.25 in earnings per share. On an apples-to-apples comparison, adjusting for the number of shares we raised last December, earnings per share was $1.43, same as in the second quarter in 2015. Our GAAP net income and earnings per share this quarter were lower than last year. This is due to expenses related to the voluntary withdrawal of Zecuity from the market, and the termination of our involvement in the development of Revascor. These two events amounted to $546 million of total adjustment.

During the past four quarters, we generated over $5 billion in cash flow from operation. Cash flow this quarter was light, due to large cash tax payment, which were $500 million higher compared to Q1 this year.

On our liquidity trends, liquidity ratios continued to be strong this quarter. However, following the Actavis closing early this week, our total debt increased by approximately $25 million. On EBITDA, we continued to generate strong EBITDA trends of $1.6 billion to $1.7 billion this quarter, and ended at $1.7 billion which is one of the highest in recent quarters.

Now let's take a look at the results of the business this quarter. Exchange rates reduced revenues by $141 million compared to Q2 2015. Revenues of our US generics business was impacted by competition to our Aripiprazole, Esomeprazole, and Budesonide which were the major drivers of our generic business in the US in the second quarter last year. This was compensated by the performance of our global generic and OTC business, strong sales of Copaxone, and our specialty-product portfolio.

When we look at revenue distribution by region, US was down, and accounted for 53% of total revenues. Europe and the rest of the world were up, and accounted for 25% and 22% of total sales, respectively. Revenues by business line showed $170 million decline in global generics, and (inaudible) growth coming from Copaxone, specialty products and our OTC business.

Operating profit for the quarter, which was similar to last year were influenced by the decline of our Aripiprazole, Esomeprazole, and Budesonide due to competition. While the rest of the global generic business improved nicely but not enough yet to compensate for the entire decline, Copaxone and specialty business generated $120 million improvement of operating profit over last year, and compensated for that.

So our global-generic business accounted for 33% of profit contribution this quarter, Copaxone was 49%, and specialty products 17%. Despite the year-over-year decline in major generic products, profit margins stayed healthy due to COGS reduction, and more profitable product mix. Copaxone continued its strong performance with exceptional sales of over $1.1 billion this quarter. Script level remains flat over the past four quarters.

Now let's look at the numbers for the first half of 2016. First half of 2016 revenues and non-GAAP profits were similar to the first half of 2015, while our GAAP net income was down $100 million due to the Q2 2016 impairment that I reported earlier. For the first six months, generics were down and accounted for 45% of total revenues, while Copaxone and specialty products were 23% and 22%, respectively.

Looking at profit contribution by lines of business, generic contributed 32% of our total profit contribution for the first six months of this year. Copaxone was 47%, and our specialty product contributed 19% of total contribution.

Dividend. So dividend payments for Q2 as approved and declared by our Board remain unchanged at $0.34 a regular share third quarter.

I would like to talk about our financial outlook. So I'd like to reiterate the 2016 financial outlook which we provided just a few weeks ago, of revenues of $22 billion to $22.5 billion and non-GAAP earnings per share at $5.20 to $5.40. The strong non-GAAP EPS which we generated in Q2, are included in this forecast.

So I would like to thank you all for listening to our remarks about the quarter. And I will now like to open the call for questions. Thank you very much.

QUESTIONS AND ANSWERS

Operator

Thank you

(Operator Instructions)

Your first question comes from the line of Liav Abraham.

Liav Abraham - *Citigroup - Analyst*

Good morning. First question, for Siggi on the generics business. US generics revenues were a little lower than expectations. Can you just talk to us again, about your conviction in pricing stability, on the dynamics in the industry, and was just this a case of us just not properly modeling the impact of Abilify and Nexium in the quarter?

And then secondly, Michael, on SD-809 in Huntington's perhaps you can give us an update on where you stand on addressing the FDA's request for additional data? And your confidence that no additional data in humans will be required by the FDA? Thank you very much.

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

Yes, thanks, Liav. I think, first of all, it's the old story in the generic business, and we have talked about it many times. It's the short-term volatility, but a long-term profitability that we are seeing in the generic business. I think on the US side, clearly the impact we highlighted, the impact of having a competition on Aripiprazole, Esomeprazole, and Budesonide was very, very significant. I think overall, the underlying business did well.

We had that one quality recall in the quarter, which affected our business a little bit, but overall, the impact was that we didn't have any significant new launches. This always happens quarter to quarter, when there's no significant launches. So I think, in terms of the revenue of the US business, we were in line with our expectation going into the quarter.

In terms of the pricing, the pricing is stable to the same degree as before. We saw approximately in the US, 4% price erosion in the business, in a way very stable from the first quarter And the global pricing impact we saw in the business, in the generic business was approximately 5%. So we are pleased with the environment. And I think we are coming now in line, with our other competitors that have been reporting. We are saying, seeing same price erosion in the market as others. So I think overall, a good quarter. There was a volatility due to the exclusive products we have a year ago, but overall, a very, very good quarter for the generic business of Teva.

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

Thank you, Liav. Just to come back to the SD-809 issue. So we have completed, essentially all of the experimental work. This is also non-human studies, no clinical trials, but measurement of various metabolites. The request for the Type A meeting has gone back for the FDA.

We expect this meeting within the next month, with full response to the CRO by the end of September. So we're totally on track. We've been able to, I think complete the results, the issues that the FDA has raised. Of course, it's impossible to totally predict what the FDA will say, but we're very confident that the integrity of the data, and the nature of the response will provide support for approval of this particular product shortly thereafter.

Liav Abraham - *Citigroup - Analyst*

Thank you.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Next question?

Operator

The next question comes from the line of [Manoj Garg].

Manoj Garg - *ABR-Healthco - Analyst*

Hi, thanks for taking the question. I have two, actually one for Eyal, and then one general one. Eyal, in your preliminary guidance issued last month, you included a cost of financing of about 2.8% to 2.9%. But by my math, at least in the initial years, I'm getting a cost of capital substantially lower of about 2.2%. Can you confirm that?

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

Yes, I think, Erez just in his comments [said] 2.32%.

Manoj Garg - *ABR-Healthco - Analyst*

Okay, Oh, great. Sorry, I apologize I must have missed it. And then, this morning, Momenta has a press release out saying they're expecting tentative approval on the 40 milligrams this year. So just wanted to see if you guys had any commentary on that?

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

I think, just to say on that, I think Momenta has said before that they have a targeted action day for the 40-milligram this year. So I don't think there's any new information.

Manoj Garg - *ABR-Healthco - Analyst*

Okay. Thank you.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Great. Next question?

Operator

The next question comes from the line of Vamil Divan.

Vamil Divan - *Credit Suisse - Analyst*

Great. Thanks so much for taking my questions. I'll just one, if I could on the Copaxone side, building off that last question. Maybe you can give a little bit more insight into what you're seeing in terms of share? And then, it seems like you've got a little bit of benefit on price, since the rebate

this quarter. Maybe if you can give us a little more detail there, on how that impacted the numbers, and what your expectations are for pricing going forward? Thanks.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Mike?

Mike Derkacz - *Teva Pharmaceutical Ltd - SVP and Head of Global CNS*

Hi, Vamil, thank you very much. So on the Copaxone share, I think we're very, very pleased with the fact that 40-milligram is about 83% of the US market. Of the number one product in the MS category now, of course is 40-milligram, and a 24.1 share. And I think of equal importance is the fact that the EU remains on track with the US. We're quickly approaching a 60% conversion. In Germany, we lead with new patients for Copaxone. And I think this just speaks to the support by payers, by patients, by physicians around the long-proven track record of the safety and efficacy of the product, and a tribute to the team's great work here.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Any additional questions, Vamil?

Vamil Divan - *Credit Suisse - Analyst*

Just maybe a little bit more on just expectations on pricing going forward, and just a little bit more, if you could break out the impact of the Medicaid rebate, versus the net pricing you're getting, given your price increase?

Mike McClellan - *Teva Pharmaceutical Industries Ltd - SVP & CFO, Global Specialty Medicines*

Yes, what we've seen in the quarter, if we compare to last year is that sales are relatively stable. We have pretty stable volumes, and a little bit of a favorable price impact. We did have a nice upside this quarter, because of a favorable mix. But overall, sales without that favorability would be relatively stable with last year.

Vamil Divan - *Credit Suisse - Analyst*

Okay, thank you.

Operator

The next question comes from the line of Elliot Wilbur.

Elliot Wilbur - *Raymond James - Analyst*

Thanks, good morning. A question around the recently acquired Anda business, both financial and then strategic. First, with respect to financial. Can we just take the run rate that Actavis talked about, or Allergan talked about in their press release, annualize that, and add that on top of the guidance you have recently provided? In other words, is that business purely additive? And maybe you can talk about sort of what you see kind of in terms of the trends in the -- within the framework that, or the guidance time line that you have previously talked about through 2019?

And then, just maybe perhaps for Siggi, strategically could you talk about, I mean, what does the business really do for Teva? I guess, the historical knock against it in terms of being owned by a generic company, was that it somehow worked against you, and you're competing with your customers. Obviously, that never hurt Actavis in the amount of time that they owned it. But just curious, how you view that historical perspective, and what that business really enables you to do, or sort of what the benefit is of owning it? Thanks.

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

Yes. Thanks, Elliott. So if we start on the finances, how you need to think about it is, we reported, obviously, the third-party revenue was the total revenue that Allergan reported in their PR. I think what you need to keep in mind, that obviously in the third-party revenue as we reported it, includes Teva revenue. So what we need to do, when we close the transaction is to see if there's an overlap of Actavis versus Teva products, because of the combination and things like that. But overall, the third-party revenue we gave for, estimated for 2016 was in the excess of $1 billion on the revenue.

In terms of contribution, I think that it's within the [margins] that we gave at guidance a few days back. The contribution to the overall business fits nicely within the guidance ranges that we gave you days back. With regards to strategically, I have to say, I'm extremely excited about this. Obviously, from my Actavis days, to two years ago, and I know this business extremely well.

It really gives us an opportunity to service our customers better, not only on the generic side, but also in terms of our specialty business. It's access to 60,000-plus pharmacies within 24 hours of service. It really is not a big threat to the Big 3 customers, because obviously, Anda is significantly smaller. But it relies as a service function to help also the Big 3 customers, and many of them use Anda as a primary/secondary as we call it, where they rely on Anda to step in, if there's shortage in the market. Also there's biosimilars coming to the market.

There's an opportunity of delivering straight to the clinics, to the doctors offices. They have a cool chamber, they have the warehouses in Mississippi next to the FedEx site. And really, overall, I think that it's the next best for Teva, in getting closer to the customers, and giving better services in the market. So exciting next step for Teva in the future.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Next question?

Operator

The next question comes from the line of Gregg Gilbert.

Gregg GIlbert - *Deutsche Bank - Analyst*

Yes, thanks. Good morning, good afternoon. First for Erez and Eyal, how much dry powder do you have right now to make acquisitions, and is it fair to say your strategy on acquisitions is much more focused on specialty brands versus generics at this point? And then secondly, for Siggi, not to steal thunder from your upcoming Analyst Day, but how can you best support your confidence in that strong mid single-digit growth outlook for generics over the next several years, in light of just that mid single-digit erosion? Can you give us a little bit more color for that? Thanks, guys.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So we expect to generate, and I said it and I'm reiterating it now, more than $25 [billion] of free cash flow from the close until the end of 2019, $5 billion basically are there for dividend distribution until the end of 2019, and the rest is going to be divided between paying down debt, and entertaining attractive specialty deals. We might also look at attractive platforms in key growth markets. That is the focus, and that's how we have been shifting the focus from BD perspective to basically to two years, and I'm reiterating it to attractive specialty assets.

Gregg GIlbert - *Deutsche Bank - Analyst*

Okay.

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

And Gregg, on my confidence on the mid single-digit growth. Obviously, we have only had the keys for about two days, so it doesn't give me a lot of time to validate what we have talked to before. But everything we have seen in the last 48 hours, has built even more confidence in the data. So what we are doing now, is that we are validating the pipeline. We are validating the IP situation.

We are validating the regulatory affairs to understand them, build it up per year. And then, in September hopefully in first half of September, we want to come out with -- to investors and show you the pipeline, and how the possibility it could align throughout the years. With everything we see after 48 hours, it has only built the confidence. But I think you need to wait up until September, so we can show you the real picture, and maybe give you some hint of the molecules, when they could come.

Obviously, there are some dates, certain settlements that we want to highlight to investors. But overall, it's the same formula as we talked about before, rebuild about 5% erosion from volume and price, and then a 10% increase from new product launches, which would give us a 5% or mid single-digit overall growth of the business, which I think is reasonable. And we are still sticking by what we talked about before, approximately 1,500 product launches in 2017.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

And Gregg, as far as 2016 is concerned, we have the capacity of $3 billion to $4 billion for potential BD deals until the end of 2016.

Gregg GIlbert - *Deutsche Bank - Analyst*

Thanks for that color.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Next question?

Operator

The next question comes from the line of Jason Gerberry.

Jason Gerberry - *Leerink Partners - Analyst*

Hi, thanks for taking my question. Just to dovetail I guess off Gregg's question. Siggi, you guys, it looks like you guys were able to keep both Advair programs, yours and Teva's. So kind of curious where you guys stand in the race for a generic Advair? I'm just curious, if you have an updated view, now that you've got both assets?

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

Yes. So Jason on the Advair program, obviously again only 48 hours, but both programs, we are going to take two shots at goal. And I think that it highlights that, because we keep both clearly, neither program has completed the Phase III study. So our goal is still to file this by the end of next year, beginning of 2018.

We have to see, obviously, there's many risks in the way, but I think that it gives us an opportunity in taking at least two shots at goal. Our intention is to continue with both programs, so we have a better chance of introducing a generic interchangeable AB-rated Advair to the market, in not so distant future. But we are not at a point in time now where we can give you more exact time lines.

Jason Gerberry - *Leerink Partners - Analyst*

Okay. And if I could squeeze a follow-up in just on -- actually on Vamil's question around the Medicaid mix. Is that just a 2Q phenomenon, or are you kind of transitioning away from the Medicaid business, and should we expect better gross to nets as a by-product of that on a go forward basis? Thanks.

Mike McClellan - *Teva Pharmaceutical Industries Ltd - SVP & CFO, Global Specialty Medicines*

Yes, what we've seen in the quarter is that, the Medicaid scripts tend to come in on a 9 to12 month lag. So as we had the launch of Glatopa, as a competitor, we've made estimates over the quarter. And what we've seen as a slightly favorable mix come in. Some of that is affecting the go forward business, but a chunk of it is a revision of past estimates, which the underlying business as we said before is relatively stable. So the upside you see versus last quarter -- last year is basically the revision estimates.

Jason Gerberry - *Leerink Partners - Analyst*

Okay thanks.

Operator

The next question comes from the line of Umer Raffat.

Umer Raffat - *Evercore ISI - Analyst*

Hi thanks for taking my questions. Perhaps a few if I may. Erez, how are you thinking about the timing of capital deployment in specialty? And I know you mentioned four core therapeutic areas, so I know it's neurology, pain and respiratory. Is your fourth one, oncology, and are you open to BD on oncology?

Siggi, so on generics, it seems like volumes are down 10% sequentially versus first quarter, and the reported sales are also down similar numbers. So what I'm trying to understand is, are you sticking to like a 4% price erosion, and is anything, is there any part of the portfolio that's eroding price beyond that where you're surrendering volumes. Just wanted to understand what we're seeing in IMS?

And then finally, Eyal, I had a question on non-GAAP. So the 20% royalty on Bendeka is not reflected in the non-GAAP P&L. So I just wanted to understand, how can investors better understand non-GAAP results, especially if Bendeka continues to be an important part for many years to come?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So Umer, thank you for the questions. The four therapeutic areas encompass neurodegenerative diseases/ movement disorders, headache/ migraine, pain, and respiratory. We might pursue BD deals in -- already in 2016 and 2017.

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

So Umer, quickly on the volume. So first of all, there's probably three or four things to this question. Overall, the IMS volume is not as accurate as we would like it to be. It's still a decline, but it's not really at the 9% we are talking about. So there are a few things that play into it.

First of all, the three products that we talked about, obviously play into it. The second thing that plays into it is the Godollo issues which we mentioned before, the quality issue we have in our injectable site. But we also have versus previous years, there's an impact from a third-party manufacturer in India, Emcure which has a significant volume impact, but very little impact on our profitability or the top line.

So overall, the business itself is fairly stable. As I mentioned in the beginning, we are seeing exactly the 4% price erosion. There is such not much movement in the other volumes. If you take away these two exceptions, the rest of the volume seems to be intact. And then some of the product there has been a small volume increase. So overall, a stable business, 4% price erosion in the US, and I think a great base to build on now, when we combine the two businesses for the future.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

And Umer, on the Bendeka royalty. The Bendeka royalties are a charge into the GAAP and into non-GAAP. What you have seen on a regular basis, what you have seen is as a result of the win that we had, we had to increase the future value of the Eagle transaction, and that is the -- a bit over $100 million entry that we have in the GAAP result, that was eliminated to non-GAAP. But on a regular basis, the royalties are part of the cost.

Umer Raffat - *Evercore ISI - Analyst*

Thank you very much (multiple speakers)

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

Just to give you a little bit more flavor, in the four therapeutic areas. Of course, migraine and pain is our leading areas, with total number of programs around 35, 12 in migraine and pain, 10 in movement disorders, neurodegeneration, around 9 in respi. And then, we had some others, for example, neuropsychiatry as well, and biosimilar development. So it's quite focused, and very specifically focused in the areas that we've spoken about in the past.

Umer Raffat - *Evercore ISI - Analyst*

Thank you.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Rose?

Operator

Your next question comes from the line of David Risinger.

David Risinger - *Morgan Stanley - Analyst*

I have two questions. The first is for Siggi, the second is for Michael. So with respect to the Anda business that you're acquiring, could you just provide a little bit more perspective on whether you expect Anda to lose supplier customers, because suppliers are less inclined to work with Teva as a much bigger leader in the US generics market? And then second, with respect to SD-809, Michael, are you planning to launch the drug next spring, meaning how high is your conviction that you'll be getting the drug approved next spring, or is there enough uncertainty that you can't have extremely high confidence at this point? Thank you.

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

Thanks, David. So on the Anda thing. So first of all keep in mind, that Anda will be -- when we close the transaction, a standalone function within Teva. There will be a Chinese wall, it's not part of the ongoing business, and we will report it separately.

Second thing to think about is Anda is a great service function to the other pharma companies, so they really want to work with Anda. Anda has a great business working with the independent pharmacies. And also their role of being, as I mentioned before the primary/secondary, I think even though we are competitors in the market, I think the companies see that as a great opportunity to be in the position to work with Anda. And Anda has a reputation in the market to be one of the best supplier, best service, great phone centers. And maybe the third point to mention, yes, there has been a regular competition between Actavis and Teva, but Teva always has used Anda in the past.

Anda has been very professional. And it's also for that reason why we are so comfortable with Anda, because we knew that the confidentiality of any Teva information never went over to Actavis, or the other way around. So I think this is an opportunity for the customers, for our competitors. In terms of the customers, how they react, I think Anda as I mentioned before is a relatively small, it's more of a service, it's a service more to the independent. It can help the big three customers, if anything, so I don't see them as a big threat to the big three customers.

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

And David, with regard to SD-809, we're confident that we will be able to launch this by the end of the first quarter in 2017. Important, the issues we believe have been resolved. Important, also to remember that this would be only the second drug ever approved for Huntington's disease in the United States, the last being tetrabenazine itself in 2008.

This is a fine proved product, with improvement in movement disorder, chorea, improvement in appetite, no swallowing difficulties, walking, and a whole host of others that improve the quality of life of patients, without some of the obvious and terrible side effects associated with tetrabenazine, particularly including a tendency to depression and suicide, which is frequent in these patients. This will represent a major advance for patients, and we do know recent publications that the number of patients with Huntington's disease has probably been underestimated. It may be a significant increase on what is seen previously. So we're confident about the response that we have. And we also recognize importantly, the unmet need in terms of patients, and the broad spectrum of possibility in terms of improvement in the quality of life of these patients. So we're looking forward to the launch of the second product for Huntington's disease in the United States early next year.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. And one quick follow-up on that. Why did the FDA assign a six-month review clock rather than a two month review clock, given the desperate need of many patients in the United States?

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

That's an excellent question. It's technical, so if you look at the Type 1 or Type 2 submission, Type 1 says, that it's a review of data and no new data. Type 2 refers to new data. So the FDA has the opportunity, if it's very technical, they could go as much as six months. Of course, we're hoping for

less. But we don't know how they'll interpret this as totally new data, extrapolation of old data so. And the FDA has not yet determined this, because we haven't really, they haven't yet seen the data. So we're giving the outside view of this. But of course, we would hope this might be earlier in view of the unmet need.

David Risinger - *Morgan Stanley - Analyst*

Thank you.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Next question?

Operator

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

Randall Stanicky - *RBC Capital Markets - Analyst*

Great, thanks. I just have two. The first is for Siggi, and then for David. Siggi, has some of your Indian peers collected approvals that they are not launching, or at least have not yet launched? And we see some of our domestic competitors here, having some pretty significant competitive challenges, how much risk is that of irrational behavior, or an opportunity for you is that? How do you view that?

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

Yes. So Randall, with the 208 generic companies in the US market, the competition is fierce. There's no question about it. There has been more approvals, you have seen -- there is a pick up of approval, but overall, there hasn't been so many launches. Because also, I think companies know and we know it ourselves, if you are the eighth or the ninth approval, it is a very difficult market to up value to the customers to bring a product to the market.

So many of the approvals, because you see a lot -- many product approvals, but they are not the exclusive approvals so much. So I think the companies are different. I think most companies have started to understand how the market functions. But it is a fierce competition in the market. There's no question in my mind, that with 208 companies with an --on average now from the FDA, approximately 55 to 60 approvals every month, we need to be on top of our game.

The other side of the coin is, of course, that we have 336 ANDAs pending at the FDA in the new combined Teva. So when the FDA picks up the pace in approving our competitor's products, we have approximately 10% of all ANDAs is in the name of Teva now at the FDA. So I think we will also see the benefit from the FDA picking up the pace. And that will give me, that gives me the comfort of the mid single-digit growth. But you're absolutely right. This is a crowded market. There's a lot of competition and there's new approvals coming.

Randall Stanicky - *RBC Capital Markets - Analyst*

Great. And just if I can switch -- just to Dave for a second on Copaxone. The next major data point we're going to have here, are going to be the three IPR decisions later this month. And if they go against Teva, I guess, a couple questions. Do we know how Judge Sleet is going to treat those, if he will include those in the litigation or not? Obviously, the fourth patent would be included. And then, does that have any impact relative to the PTAB finding, if relative to what Judge Sleet views on those patents. Can you get an injunction off of anything he may find?

David Stark - *Teva Pharmaceutical Industries Ltd - SVP, General Counsel, Global Markets & GSM*

Yes, hi, Randall. This is David. Thanks for the question. So the judges have discretion, in terms of how they manage their docket. But that said, we have a pretty high degree of confidence that, in that fact pattern that you described, that Judge Sleet would go ahead, just as you mentioned, and particularly on the fourth patent which is not going to be part of the IPR decisions. So our view is that there's a very high degree of likelihood that the trial will go ahead. And thanks for the question around the injunction, because those patents are in the Orange Book, and unless and until those patents would be cancelled, there would be an automatic injunction if we were to prevail in front of Judge Sleet.

Randall Stanicky - *RBC Capital Markets - Analyst*

And can he re-litigate the patents, even if the PTAB invalidates them?

David Stark - *Teva Pharmaceutical Industries Ltd - SVP, General Counsel, Global Markets & GSM*

So again, if the PTAB rules against us in the IPR, that would be appealed to the Federal Circuit, just as Just Sleet's decision would be appealed to the Federal Circuit. And until the PTAB procedure completely runs its course, we would still have an injunction, an automatic one in front of Judge Sleet if we were to prevail. I hope that gets to your question.

Randall Stanicky - *RBC Capital Markets - Analyst*

No, it's helpful, thank you.

Operator

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

Ken Cacciatore - *Cowen and Company - Analyst*

Hi thanks, just a couple. First Siggi, I know it's been brief, but you should have some insights at least into the Allergan's generic business operating margin maybe? And just general health, even though it's been a short window of time, if you could just maybe compare and contrast to your current operations standalone? And then also just a general question whoever wants to field it. On Mylan's Advair, you all are clearly an interested party here, you're a major shareholder. So can you give us any insights into your belief as that around a shareholder? Clearly, you own a lot, and would, could be a good liquidity event, so wanted your perspective if you thought it could be AB-rated and approved?

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

A good question, Ken. So first of all on the operating margin, we obviously, we cannot comment on their quarter two business. I think Allergan has their results next week. But overall, we are very pleased with what we see. We have a stable business, it's growing, I think a very interesting pipeline. And we also highlighted, when we gave our guidance to the Street that really, on both sides in Teva and in Actavis, both R&D groups did amazing jobs over the last 12 months to continue to build the pipeline.

In terms of the operating margin, we have to see, we have to do the calculation. As I mentioned before, we are at close to 27% in the generic business in Teva for this quarter. My guess would be they are at about just over 30% in their operating profit. You have then to keep in mind that we are swallowing all the negative synergies now, because all the divestitures will come in now, and all of the costs will still be on the books.

So there will be a small hit on the operating profit for the first few quarters, until we start to realize the synergies. So there will be a negative bump in the beginning, which will then over the three years, until the end of 2019, I would foresee the generic business to be in the mid-30s in terms of operating profit. But you need to I think model it pretty accurately because of the negative bump you will see in the beginning, due to the divestitures hitting us on day one.

In terms of Mylan Advair, I think it's not for us to comment. I have to say, I think it's a great achievement that they submitted an ANDA that is under review. We can't comment, we haven't seen the dossiers. But they have a targeted action day, not so -- quite close in time. But we can't comment on their approvability, but clearly, an achievement to finish and submit a dossier in this time frame they talked about.

Ken Cacciatore - *Cowen and Company - Analyst*

Thank you.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

Maybe just to clarify on what Siggi just said, 2017 already net synergies, after the negative synergies is positive, $0.4 billion of positive net synergies. That's something that we shared with the Street two weeks ago. So just to give meaning to the statement made by Siggi, we are positive already $400 million positive after negative synergies in 2017.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Rose, next question?

Operator

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

David Maris - *Wells Fargo Securities - Analyst*

Good morning. Just first, one clarification. What were the Takeda revenues in the quarter, and is that a fair run rate and is it growing? And then, Erez, in a recent interview, and previously you've spoken about the merging of information, technology, and therapeutics as an important part of healthcare, and that Teva's going to participate in that. Can you maybe describe what your efforts are there right now?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

Sure. I think the best way to describe things at this stage is as follows. First, we focus on unlocking value from generics, unlocking value from specialty. There is a huge opportunity for us to generate value to our shareholders from generics, and from specialty on a standalone basis.

Over time, we strongly believe that the focus in the industry will over time shift from products only to the broader unmet needs of patients, increasing adherence compliance, addressing prevention, prediction. And basically, that's an opportunity for us, we believe that we are positioned as a Company to address broader unmet needs of patients in a way which is not confined to medicines only.

On a step by step basis, continue to unlock value from generics and from specialty, will catch the synergies, and we will create more [proximity] with patients. And in moves that we have been already carrying out, we'll be in a position to share that with the Street, I believe early next year or in the course of 2017, with more detail.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

And David, on the question on the Takeda revenue contribution. We are not providing country by country, and also the confidentiality agreement with Takeda prevents us from being specific. But there is a view, if you go into the details in our P&L, you can see some estimate of profit contribution with the minority interest line, because we get 51% of the profit.

David Maris - *Wells Fargo Securities - Analyst*

Great, thank you very much.

Operator

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

Chris Schott - *JPMorgan - Analyst*

Great. Thanks very much, just two here. Maybe first, can you talk about price opportunities on the combined generic portfolio, now that the deal is closed? As you kind of review the pro forma business, do you see the opportunity to raise price on select products here? Second question was on the environment for business development right now? I think you talked earlier about maybe $3 billion to $4 billion of capacity in the near-term and a lot more over time. But how attractive of a market are you seeing out there? Have you seen any change in expectations either from sellers or in the competitive environment for assets, that make this either a more or less attractive time to be pursuing some of the specialty products? Thanks very much.

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

Yes, thanks, Chris. On the pricing, as you know, and we know that, the size really doesn't affect the pricing. And I have a strong feeling when you have over 200 competitors, size has nothing to do about pricing. I think the pricing comes with shortages in the market. If you have an exclusive product, if there's some kind of dysfunction in the market, there might be a small pricing opportunity that usually comes in and comes out. But overall, the size, and being a combined company doesn't play into that. I feel quite strongly about that.

The environment has to do with shortages, new products. And of course we have a lot of exclusive products. As we mentioned, about 115 first-to-files that are pending, and I think those are the biggest pricing opportunities we have in the future. I think also what we are going to do, Chris. And this is part of it, is we are working hand in hand with our TGO, our operation colleagues, to have our products available. Because when there's a shortage in the market, the opportunity is to service our customers even better than we do today. And this is now an initiative, so that we are working on very hard in the new Teva, in the new combined Teva, is how can we have more products available? Because when there are shortages in the market, the opportunity comes that we have the products available on a short notice to service our customers. So I think that will be the focus, much more than day one, we can increase the prices. I don't see that in the cards.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

And on the second one we see attractive opportunities to grow our business through BD with complementing core TAs. We don't see basically shifting the expectations of potential sellers. What plays in our favor is basically, I would say the perception, and the way we have been growing and developing our specialty franchise. And there is more willingness of potential sellers or potential partners to collaborate with us, so to discuss with us potential deals. And the more we are able to increase the critical mass, and to cement the competitiveness, executing on our strategies that was [crafted for each one] of the TAs, there are more attractive opportunities for us, and more willingness to entertain deals with us. And that's maybe the most important factor, the influence is likely of potential successful deals that we might entertain.

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

And if I could just add to that, as we look at more focus in some of our colleagues and other pharma companies with AZ and Takeda and others refocusing their pipelines, and the recognition of Teva becoming a significant player in migraine, pain, movement disorders, neurodegeneration and respi, we're seeing a significant number of opportunities, very exciting come our way.

Also looking at innovative types of partnerships, sharing the risk, sharing the benefits, novel complementarities. And also the partners that we are looking at, are not just around product, but also around technologies that can enhance in compliance and adherence, and add to the quality of life of the patients we serve. So we are extremely busy looking at numerous products. And I think Teva is becoming recognized as a place to think about for the appropriate development, because of the capabilities in the TAs that we focus in.

Chris Schott - *JPMorgan - Analyst*

Thank you.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Rose?

Operator

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

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Jami?

Operator

Jami, please ask your question. Hello, Jami please ask your questions?

Jami Rubin - *Goldman Sachs - Analyst*

Hello?

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Jami, you're on. Rose, we'll come back. Next question.

Operator

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

Ronny Gal - *Sanford C. Bernstein & Co. - Analyst*

Good morning, and thank you for taking my questions. I have three. First, you guys, as I think Umer mentioned, you've got a bit of a lower run rate on some commodity products, and you now have Anda as a differentiated distribution business. If we think about Teva's mix going forward, should we think about you kind of following the good old path, [Watson track], and having a lot more differentiated product, the commodity products, or are you kind of plotting a comeback on commodity product, as you bring more interesting products as well?

Second question, looking at OUS generic, [Siggi], this feels like a good quarter to ask about the mix of gross profit between the US and OUS? You seem to have similar revenue numbers between the two. Can you just comment on the profitability, kind of like in rough sense between the US and OUS, when it comes to generic profits? Obviously, it will change a lot with Actavis, but would be good to see. And third, for I guess, a bit on the IP.

I noticed the last patent you listed, the 874 patent, which is I guess the last one to be resolved in terms of IP, that one looks very similar to the three patents which are under IPR, it terms of being dependent on the 3 times per week indication. Is this fair, that is, is this patent completely separate in terms of the decision, than the first three? Or frankly should we think about if the argument around 3 times per week gets overturned by the court or the IPR, we should think about 874 following track?

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

So Ronny, maybe I'll start around the portfolio of the generics. I think clearly, with combination of Actavis Generics and Teva, we will have more differentiated portfolio. And with all the exclusive first-to-files that we are introducing over the next few years, there will be a movement there. But we will never be solely on that, because commodity generics will still play a big part.

Remember that because of TAPI, our own API, we can compete in the commodity much longer. Over 40% of our products have our own API in it, which is such a benefit to the long-livity of our portfolio, and we can still compete. But we also know that when there's many competitors in the market, and if we can't make a profitable business, we have no hesitation and focus on different. But we really think we can offer the whole range. As we have mentioned before, we're all the way from a very complex biologics specialty products to a commodity and everything between. But we really want to drive the overall portfolio, with a special emphasis on the more complex generics which we are extremely good at.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

On the profitability of our generic pieces, obviously, we are not breaking this down, but what you've seen is that the level of profitability was similar to Q1, 26.8%. The difference from last year, mostly due to the three major products that saw a much more intensive competition in the US market. We're happy with the improvement in Europe, our European business showing very nice improvement in profitability, some uptick in the rest of the world. Other than that, the mix is not substantially changed.

Ronny Gal - *Sanford C. Bernstein & Co. - Analyst*

But I guess, the question there is, if I have to think about revenue split between the three geographies, is it fair to say that operating profit split is roughly the same? Is the US more profitable, less profitable, just a ballpark of how the profits divide?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So rest of the world catching up, Ronny. There is one. Second, we see for us, huge opportunities at the end of the day. Most of the time, we focus on the US, but as a global generic business, we see huge opportunities ex-US. We have been expanding our opportunity in key growth markets and we'll continue to do that. We continue to grow the business, also outside of the US, and with increasing profitability out of the US will unlock more and more value.

David Stark - *Teva Pharmaceutical Industries Ltd - SVP, General Counsel, Global Markets & GSM*

Hey, Ronny, this is David. Thanks for the question. You're right that, that fifth patent is similar to some of the other patents that we have, but there are differences.

This isn't the right forum to get into the details of what those differences are, which would touch on our litigation strategy. But I would also keep in mind, that what we might do going forward with the fifth patent, in particular, it's possible that could end up in front of a different panel at the PTAB, or even a different judge. And that could also lead to a different decision. So there are many variables in the mix.

Ronny Gal - *Sanford C. Bernstein & Co. - Analyst*

Ah, got it. Thank you guys.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Rose?

Operator

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

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. Can you guys hear me now?

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Yes.

Jami Rubin - *Goldman Sachs - Analyst*

Can you hear me? Okay, great. Thank you, apologies for that. Eyal, maybe can you explain what is going on in Venezuela? I saw that rest of world sales were up quite a bit, ahead of our expectations, and some of that was driven by sales in Venezuela. And in addition, other sales or OTC sales have benefited from the inflationary environment in Venezuela

I'm just wondering if you can, A, quantify what your revenues are, and just explain what's going on? Because it seems that every other company that we cover, certainly, large cap pharma, and other generics, have been writing down on that business, or getting out of it altogether, and while you're going in the other direction? So if you can talk about that? And secondly, can you, Eyal, tell us what you're assuming for the ProAir franchise going forward? I believe Perrigo will be launching a generic end of year, early next, and how we should think about revenues? Thanks.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

Okay. So on Venezuela. So Venezuela is [not] taking a big piece of our business, actually quarter after quarter, it's a bit down on sales and profit. Total sales, We will publish our full 6-K for the report later on today, our total sales were just above $200 million, split 50/50 between the generic

sales and the OTC sales. Our profit contribution is not very high again, a bit down compared to what Q1 this year, a bit up compared to last year. So it doesn't really move the needle substantially right now.

Jami Rubin - *Goldman Sachs - Analyst*

Eyal, what's the outlook for that business? And how should we think about your treatment versus other companies?

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

Well, one thing that differentiates us from most foreign companies that this pharma companies operating in Venezuela is that all our sales are produced locally. We don't import finished products, we have a plant that produces, this is a necessity in the country right now, and we are producing really essential drugs. The economy of Venezuela, this is neither the time and place to analyze, but we know that the economy there is not in good shape, to say the least, and we see what the future will bring. Lots of uncertainties, I wouldn't speculate on this either way.

Sven Dethlefs - *Teva Pharmaceutical Industries Ltd - Head of Global Respiratory Medicines*

This is Sven, for the ProAir question. So ProAir has seen a slight growth in this quarter over last year, primarily driven by gross to net conversion. We have introduced the RespiClick, the new breath-actuated device into the ProAir franchise. We see a steady, but slow uptake.

We are round about a 3% market share in total prescription volume in the US so far with ProAir Respiclick. And we expect this trend to continue over the next month. Concerning the overall development of the franchise, I think we have to look at whether Perrigo gets, and when it gets the approval for the generic competitor to the ProAir HFA device that we have. Internally, we plan that we have a full generic entry, or let's say generic competition more towards the mid 2018 than in the near future.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you.

Kevin Mannix - *Teva Pharmaceutical Industries Ltd - SVP & Head of Investor Relations*

Thank you, next question?

Operator

Thank you. Your next question comes from the line of Irina Koffler.

Irina Koffler - *Mizuho Securities USA - Analyst*

Hi thank you for taking the question. There was nice growth on Treanda and Bendeka, and I was just wondering if there was any stocking this quarter? And also is Teva undertaking any additional activities to try to preserve Bendeka beyond 2019? Thank you.

Eyal Desheh - *Teva Pharmaceutical Industries Ltd - CFO*

Yes, so on the businesses, yes, there was some stocking this quarter, once our customer realized that we won the a trial, and remain exclusive. So the regular run rate is a bit lower than what you see from Treanda. And Bendeka, we're happy to see a very nice conversion to Bendeka, over 80% right now. Beyond 2019, our settlements are September 2019.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So it is not realistic to expect that we maintain the business beyond the end of 2019.

Irina Koffler - *Mizuho Securities USA - Analyst*

Thank you.

Operator

Thank you. Your next question comes from the line of Rohit Vanjani.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Thanks for taking the question. I had a couple questions on the Copaxone litigation, and then one follow-up on the Anda acquisition. So when Mylan and Amneal initiated the IPR and PGR processes, was the fifth patent issued, the 874? And if not, would they still have to definitely invalidate that patent?

David Stark - *Teva Pharmaceutical Industries Ltd - SVP, General Counsel, Global Markets & GSM*

So this is David speaking. The answer to the question is no. When they initiated the proceedings on those four patents, had not yet obtained the fifth patent, so the fifth patent recently listed in the Orange Book. And we haven't taken any action yet with respect to that.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

And then, I know you said that if the PTAB invalidates on the three patents, it would be appealed to the Federal Circuit. But if Judge Sleet goes through the case, he can come to a different conclusion on those three patents correct, because he has a higher bar to clear? And he's the only one that can lift the 30 month stay, so in a sense he can (multiple speakers) sorry go ahead.

David Stark - *Teva Pharmaceutical Industries Ltd - SVP, General Counsel, Global Markets & GSM*

No, sorry. I didn't mean to cut you off there. Absolutely correct.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Okay. So in a sense he can relitigate those three patents?

David Stark - *Teva Pharmaceutical Industries Ltd - SVP, General Counsel, Global Markets & GSM*

Yes.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Okay. And then on the Anda acquisition, do you know if, Siggi, they had a retailer alliance? And then, I know you said that it's no where near the big three, but can you grow it, and can you use it to offset some of the generics deflation?

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

So I think what -- how they do is, is they work with the independents more than anything else. And then, they are basically a support of the secondary to the primary accounts with the bigger. I don't know, obviously, we haven't closed the transaction, so we don't know the details about their contracts and things like that. But overall, obviously, throughout the years, knowing the business for the last six or seven years, it's a very steady business. It will not be a threat. You think about it, the third-party revenue is just in excess of $1 billion, so it's not a real threat to the big three.

I think what this gives us, is the flexibility, better service to all our customers, the big three, but also the independent. And a new way to get into the market is an opportunity when we have an exclusive launch, to get it to all of the pharmacies within 24 hours of launch. And all these added benefits, I think it's incrementally better for the business.

But it's also the next step in serving our customers better. But will it be a real threat to the big three, or can we grow it to tens of billions? That's not in the card. It's really the step of maintaining and serving our customers better than we do today.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

But as far as you know, they don't have a formalized alliance as AmerisourceBergen and Walgreens or McKesson and Rite Aide, or something like that?

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

I don't know the answer to that question yet.

Rohit Vanjani - *Oppenheimer & Co. - Analyst*

Okay, thanks.

Operator

Your next question comes from the line of Sumant Kulkarni.

Sumant Kulkarni - *BofA Merrill Lynch - Analyst*

Thanks for taking my questions, I have three quick ones. First, Teva by itself was quite large in terms of facilities. Now that you've had the keys for a couple days, could you give us an update on the rationalization of facilities? And is it fair to assume the $[1.4 billion] in synergy does not assume anything major there? Second, in the new Teva generics side, is there still anything you're relatively less strong in terms of capabilities, that buying might be more efficient than building? And third, could you rank order your prioritization of biosimilars within the $3 billion to $4 billion of business development dollars that you set aside?

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

Yes, so let me start. So the overall as we mentioned the $1.4 billion of cost and tax synergies, we didn't identify any new facility. What we mentioned was, a decision that had been taken in Teva, independently of the transaction, and have been taken in Actavis independently of the transaction, we're going ahead with those movements. But overall, any synergy movement, closing of the facility, no decisions have been made. And they are not included in the $1.4 billion.

Because also you need to keep in mind, from the time we announce a closure, or decide to close a facility, until we see a benefit, is more than three years. So overall, it's not built into that plan. Obviously, we will look at it. We have a lot of facilities, over 80 manufacturing plants around the world. So there might be something we look at, but there's no decisions being made, since we signed on any future further facility closures.

With regards to the new generic business, where it might make sense to buy instead of build, you in a way answered that in your third question. I think biosimilars, is probably the point where it might make sense to buy something, instead of building it from ground up. We are obviously looking into that.

In terms of other dosage forms, I think we really are covering the whole range, from anything from a very complex injectable where Teva has been the leader, in terms of slow release injectables, in terms of proteins, in terms of delivery system, all the way to patches, semi solids, liquids that Actavis has been the leader in, and really everything in between there. But clearly, where we are lagging behind is, is on the biosimilars where our pipeline is quite thin for the short-term. But clearly for the long-term, when we talk about Wave 3 after 2021 we have a very exciting pipeline that we are working on. And on the BD front for biosimilars?

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So we don't rule out the possibility of a potential acquisition of biosimilar assets or activities. We are assessing the landscape. And with the right one, we might entertain a deal.

Sumant Kulkarni - *BofA Merrill Lynch - Analyst*

Thank you.

Operator

Thank you. I would now like to hand the conference back over to Erez Vigodman, President and CEO for final remarks.

Erez Vigodman - *Teva Pharmaceutical Industries Ltd - CEO*

So thank you for joining us today, and have a great day.

Operator

Thank you, ladies and gentlemen for participating today. For those of you wishing to review this conference, the replay facility can be accessed by dialing within the UK, on 0845-245-5205, or alternatively on the country code of plus 44-1452- 550000, and the reservation number is 52122137.
