“Aurobindo Pharma Limited Q2 FY-18 Earnings Conference Call”

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Moderator: Ladies and gentlemen, good day, and welcome to the Aurobindo Pharma Limited Q2 FY '18 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing * and then 0 on your touchtone telephone. Please note that this conference is being recorded.

I now hand the conference over to Mr. Krishna Kiran – Investor Relations at Aurobindo Pharma. Thank you and over to you, sir.

Krishna Kiran: Thank you, Inba. Good morning and a warm welcome to our second quarter FY '18 earnings call. I am Krishna Kiran from the Aurobindo Pharma Investor Relations. We hope you have received Q2 financials and the press release that we have sent out yesterday. These are also available on our website.

With me, we have our senior management team represented by Mr. P.V. Ram Prasad Reddy – Executive Chairman, Aurobindo Pharma USA; Mr. N. Govindarajan – Managing Director; Mr. Sanjeev Dani – COO & Head (Formulations); Mr. Santhanam Subramanian – CFO. We will begin the call with summary highlights from the management, followed by interactive Q&A session.

Please note that some of the matters we will discuss today are forward-looking, including and without limitation, statements relating to the implementation of strategic actions and other affirmations on our future business, business development and commercial performance. While these forward-looking statements exemplify our judgment and future expectations concerning the development of our business, a number of risks, uncertainties and other important factors may cause actual developments and results to differ materially from our expectations. Aurobindo Pharma undertakes no obligation to publicly revise any forward-looking statements to reflect future events or circumstances.

And with that, I'll hand over the call to Mr. Govindarajan for the highlights. Over to you, sir.

Narayanan Govindarajan: Thank you, Krishna. Good morning, everyone. We are here to discuss the second quarter financial year '17-'18 results declared by the company.

Revenue increased by 17% on a year-on-year basis to 4,436 crores, driven by strong growth across key markets. Gross profit margin increased by 210 basis points on a year-on-year basis to 60.1%. The EBITDA before Forex and other income increased by 20% year-on-year to 1,117 crores. PAT increased by 29% year-on-year to 781 crores.

In terms of the business breakdown, Formulation business contributed 83% of the total gross sales and clocked the sale of 3,663 crores registering a 22% growth year-on-year. API business accounted for the balance of 772 crores for the quarter.

In the Formulations business, the total sales from the US markets stood at 2,099 crores, an increase of 21% year-on-year. On a constant currency basis, US sales witnessed a growth of 26% on a year-on-year basis to US $327 million. The growth was primarily driven by new product launches and improved volumes of existing products. We have received final approval for 2 ANDAs and tentative approvals for 3 ANDAs during the quarter. We have filed 21 ANDAs, including 10 injectables and 1 from AuroLife. We have launched 8 products including 2 injectables in the quarter under review.

Aurobindo USA, the company marketing oral products in the USA, has witnessed a growth of 37% year-on-year driven by new product launches and volume improvements. On sequential basis, the sales increased by 47%. AuroMedics, the injectable business, clocked the growth of 21% year-on-year to US $46 million. We have filed a total of 90 injectable ANDAs as on 30th September 2017, out of which 51 have received approval, including 2 tentative approvals and the balance, 39, are under review.

The company, as on 30 September 2017, has filed 463 ANDAs on a cumulative basis, out of which 294 have final approval and 40 have tentative approvals, including 11 ANDAs, which are tentatively approved under PEPFAR program and the balance, 129 ANDAs, are under review.

The unit-wise filing and approvals are as follows: from Unit III, 126 filed, 102 approved; Unit VII, 160 filed, 103 approved; AuroLife, 27 filed, 16 approved; Unit IV, 89 filed, 42 approved; Unit XII, 20 filed, 19 approved; Unit VI, 11 filed and approved; AuroNext, 4 filed and 1 approved; Unit X, 17 filed; and Eugia 9 products have been filed so far.

Unit III, Unit VII, Unit X and AuroLife manufactures oral, non-betalactam products. Unit IV manufactures general injectables and ophthalmic products. Unit VI and Unit XII manufactures cephalosporin and Semi-Synthetic Penicillin respectively. Eugia manufactures Oncology and hormonal products and AuroNext, which has its facility in Bhiwadi, Rajasthan, manufactures Penem injectable products.

Sales of Europe Formulation including Generis, clocked 1,114 crores in Q2 FY '17-'18, an increase of 37% growth year-on-year. On a constant currency basis, the EU sales including Generis grew by 35% year-on-year, and excluding Generis, grew by 21% year-on-year. The acquired Actavis business continued to improve profitability. As on 30th September 2017, we have transferred manufacturing of 74 products from Europe to India. Growth Markets sales were at 243 crores, growth of 38% on a year-on-year basis. On a constant currency basis, growth markets reported a sale growth of 43% on a year-on-year basis.

ARV Formulations sales were at 208 crores. On a constant currency basis, ARV sales witnessed a decline of 22% year-on-year due to delayed off-take by the customers. During the quarter under review, we have received tentative approval of Dolutegravir, Lamivudine and Tenofovir tablets under the PEPFAR program from USFDA which enables us to launch in PEPFAR markets.

In terms of segmental classification, US Formulations contributed 47% of the overall revenues in Q2 FY '17-'18 versus 46% in Q2 FY '16-'17. Share of EU Formulations increased to 25% in Q2 FY '17-'18 versus 22% in Q2 FY '16-'17. Growth Markets share improvement is to the extent of 6% in this quarter compared to the 5% in the previous year same quarter. ARV segment sales are 5% of the overall revenues in Q2 FY '17-'18 versus 7% in the Q2 FY '16-'17. API business contributed 17% of the total revenues in Q2 FY '17-'18 versus 20% in Q2 FY '16-'17. R&D expenses is at 161 crores during the quarter, which is 3.6% of the revenues. The closing rupee versus US dollar rate was 65.285 in September 2017 versus 64.58 in June 2017. Net CAPEX for the quarter is around US $53 million. The effective tax rate for the quarter is 20% of PBT. The net debt stood at US $616 million as on 30th of September 2017, against US $560 million in June 2017. The rate has increased sequentially due to increase in working capital requirement for the new product launches. The majority of the company's debt is denominated in foreign currency. The cash on bank balance is at US $150 million.

And this is all from our end, and we are happy to take your questions now.

Moderator: Thank you very much. Ladies and gentlemen, we will now begin the question and answer session. Our first question is from the line of Neha Manpuria from JPMorgan. Please go ahead.

Neha Manpuria: Sir, in the US business, 2 parts here. First, our injectable business seems to have ramped up pretty well in the quarter, some color there? How should we look at this going forward? Second, if I were to look at the core oral solid business ex the Renvela sales, how has that performed? How has pricing erosion been especially given you mentioned that you saw increase in volumes of existing products? Thank you.

Narayanan Govindarajan: Injectable business has ramped up well, and we also expect it to grow by the end of the year compared to the previous year by around at least 40% plus. It should be in range of 40% to 50% based on our confidence as of now. And as far as Oral solid is concerned, the erosion has been continuing. In the last quarter, we indicated year-on-year price erosion was 9% to 11%. Now, it is 10% to 12%. On a quarter-to-quarter basis, it was around 5%. Having said that, even though there is pressure on the pricing in terms of the erosion, we still believe that we would be able to grow in terms of the US business because there are lot of opportunities in terms of growing existing volume as well as some new product approvals which are going to come up.

Neha Manpuria: Sir, our approval rates seem to have slowed in the quarter. How should we look at that going forward based on TADs that we have? Should that pickup, which gives you the confidence that the US business will grow even if I exclude Renvela?

Narayanan Govindarajan: This quarter, we got 5 approvals including three tentative approvals.

Neha Manpuria: But a lot of them were tentative, right?

Narayanan Govindarajan: It is unfair to measure an approval rate based on one specific quarter. We believe that actually we should get around 7 to 9 products in the current quarter but then please understand the fact that it all depends on how the reviews are closed and how the approval accrues. Our work is over and we still believe that it should happen. But it can always happen or it can be differed, that is something which we don't control.

Neha Manpuria: Okay. And sir, my last question is, given we had Renvela in the quarter, I would have assumed that gross margins would have been better quarter-on-quarter given injectable did well, we had Renvela. Sir, what is the reason for gross margin pretty much being flat quarter-on-quarter?

Narayanan Govindarajan: We also had certain provisions on couple of injectable products. One of them we had to provide because of certain decisions on IP and discontinuation of that product. All those provisions were done in the quarter.

Neha Manpuria: And how much would that number be?

Narayanan Govindarajan: We don't specifically get into those details.

Neha Manpuria: And that's all in this quarter, the provisions that we have taken?

Narayanan Govindarajan: Yes

Moderator: Thank you. Our next question is from the line of Ashish Rathi from Darsh Capital. Please go ahead.

Ashish Rathi: Sir, just wanted to clarify this point again. You said injectables growth for the full year will be 40% to 50% Y-o-Y?

Narayanan Govindarajan: Yes

Ashish Rathi: So that means around $225-odd million for the year compared to $157 million last year. And which means we should be looking at around $140 million, $150 million for the balance part of the year?

Narayanan Govindarajan: That's our belief

Ashish Rathi: Okay. Because that's a sizable uptick in the run rate right now. From US$ 46 million, we are looking at around US$ 70-75 million for the balance quarters?

Narayanan Govindarajan: We won't divide it in quarter-wise. On full year basis, we are still confident about the growth. Quarter-wise, it can always defer. Instead of this quarter it can happen in the next quarter.

P. V. Ram Prasad Reddy: 40% to 50% increase over last year doesn't mean US$ 240 million. It may be US$ 210 - 220 million.

Narayanan Govindarajan: Yes

Ashish Rathi: US$ 157 million is what you did last year.

P. V. Ram Prasad Reddy we always mentioned 40% to 50% growth.

Narayanan Govindarajan: Over the next 2 quarters, we are still confident of reaching that particular 40% to 50% range.

P. V. Ram Prasad Reddy Overall, we are confident of 40% to 50% growth over last year.

Ashish Rathi: 15% growth for the first half we have seen, we are at US$589 million. Can we expect like a similar 15% growth for the balance and for the full year?

Narayanan Govindarajan: We don't give any projection at all. So we would only say we would be definitely growing as what we have said.

Ashish Rathi: Okay. And sir, secondly, what is driving the growth in Europe? I mean, we have seen a very strong 20% plus on a like-to-like basis as well. What is driving this growth? And also if you could indicate on the margin bit, you have indicated double-digit margin last quarter. Are those inching up higher from there?

Sanjeev Dani: The growth was seen across the major countries. It may not be repeatable but the growth momentum is there, at least in 4-5 top countries in Europe like U.K., Germany, and in France, all the areas and in Spain tenders. All the positive factors took place in one quarter. It may not be to the same extent but definitely growth will be there.

Ashish Rathi: Okay. And sir lastly, Govind sir what is the ARV sales we have seen down 3 quarters now consecutively. What is the outlook here? And any comment on Dolutegravir orders and how the scale up is happening there on Dolutegravir?

Narayanan Govindarajan: Dolutegravir would scale up well. In fact, the real impact of Dolutegravir combination will start seeing from April next year, i.e. Q1 FY2019. Having said that, let me also tell you categorically, that there is tremendous pressure on the existing triple combination because most of the people will get migrated to Dolutegravir combination. There are 2 reasons for decline in sales. One is the pricing pressure. Last couple of quarters was more because a particular pricing pressure has been there and this quarter, more because of certain sales which got deferred and that would reflect in the next quarter is our belief. Overall, the margin is under pressure that is without any doubt as far as ARV is concerned. And we have been consistently maintaining that. We are not under any pressure to somehow only focus on the topline in ARV. If you don't make real margins there, we are not under pressure to just keep doing that, we can always look at other options.

Moderator: Thank you. Our next question is from the line of Kumar Saurabh from Motilal Oswal. Please go ahead.

Kumar Saurabh: Sir, just wanted to understand how should we look at Renvela now as an opportunity? My understanding was that its gaining market share was a time-taking process. And is it fair to assume that now, since it has become a 4 to 5-player market, you will still continue to have a disproportionate market share in this product compared to peers who have launched recently?

Narayanan Govindarajan: It is too premature to say that, as you would appreciate that all these 1 or 2 players have recently come up in the last few weeks. As of now we are having that gap in terms of having a better market share. But it is too premature to say as well. One thing we can only tell you is we are prepared in terms of ensuring that we are better positioned in terms of backward integrating by having our own API and having the position there. So that much I can tell you.

Kumar Saurabh: Okay. And suspension, sir, how should we look at? Until when do you think that we can be the only player in the market?

Narayanan Govindarajan: As of now, there is no one. And in the immediate future, we didn't hear anybody talking about it. But we cannot also say that there won't be anyone for a long time. So as of now, no one and in the near future, we don't see anybody.

Kumar Saurabh: Okay. On the Europe business, just to understand, is it fair that the gross margins, because Europe business has grown at such a fast pace, will that also have an impact on the gross margins? And because of that, the gross margins haven't improved the way it should have?

Sanjeev Dani: The Europe gross margin is a function of 3-4 factors. One is products shift to India. As it picks up momentum, it increases the gross margin. Second is the channel mix. So many times, the pharmacy channel versus the tender channel determine the total % GM. The third one is, the country mix. So we have acquired branded business in Portugal and Orocal brand in France, so that also drives up the margin.

Narayanan Govindarajan: Overall, the answer is yes. Whatever Sanjeev said was specific to Europe. But on an overall basis, your observation is right, that when European business grows and since European margin is not commensurate to the company's margin. So to that extent, yes, there will be some gap. Does it answer your query?

Kumar Saurabh: Yes, and that's very clear. And just one more question. This 20%-plus organic growth, how much of that has come from the tender business and how much of that has come from the regular business?

Sanjeev Dani: No, tender business also is a regular business for us. And many of the tenders continue for 24 months, so it will be very difficult to segregate in that respect.

Kumar Saurabh: Okay, fair enough. And European region, what's our acquisition strategy? We have been hearing that in Russia CIS region, this is one area where still have a gap in the European region. How should we look at the M&A strategy in Europe?

Sanjeev Dani: Yes, Russia is not part of Europe as far as we are concerned.

Narayanan Govindarajan: Yes, We have been consistent. We have said our acquisition will be largely around 2 platforms. One is in terms of market penetration and the other is in terms of any newer technologies and newer platforms. We are still sticking to it. From a market penetration perspective, we always maintain anything which can come across in Eastern Europe would be prioritized. Having said that, we will keep evaluating whichever market we are not present in. If any interesting opportunity comes up, we will keep evaluating. But the most important task perhaps everyone has to understand is that we are not under any pressure to do an acquisition to fill any gap. We have enough opportunities even organically to grow the business.

Kumar Saurabh: Fair enough, and sir lastly on R&D expense. During the quarter also that was not very high. So is this the kind of run rate which we should assume at least for this year or?

Narayanan Govindarajan: No, if you keep the same number and look at the last quarter's topline because the number is the same almost. It would have been around 4.3% or 4.4%, approximately. I would say that we have maintained that it would reach in the short term around 5% and when a couple of Biosimilars Phase III happens together, then it can even reach at that particular point of time to around 8, plus or minus 1% is what we have maintained earlier. We are maintaining that right now.

Moderator: Thank you. The next question is from the line of Anubhav Aggarwal from Crédit Suisse. Please go ahead.

Anubhav Aggarwal: Just wanted to check on Nexium OTC for us. Typically, in an OTC product, national brand retains about 50% of the market. Do you expect the same dynamics to play here? If it's about a US $300 million market, that means that for us as a generic player, let's say together with Perrigo and the other guys, who we would be expecting, would we keep playing this US$150 million market? Or would the dynamics could be different here?

P. V. Ram Prasad Reddy: Regarding this product, 2 generics out there, Aurobindo and Perrigo. Generally, the private label price is around 40% or 35% of the brand price if the product is reasonably good. We cannot expect the private label market size as US$150 million or something. It maybe around US$70 to US$90 million market for both the generic companies.

Anubhav Aggarwal: Understood. Okay. This is you're saying after adjusting for the price difference already?

P. V. Ram Prasad Reddy: Yes. After adjusting the price difference

Anubhav Aggarwal: Sir, when the generics launches, so let's say because of the generic combination price also comes down. So US$90 million start before….

P. V. Ram Prasad Reddy: No, US$70 to US$80 million, approximately at that level because Perrigo definitely is big in the OTC, they will definitely get major share in the private label.

Anubhav Aggarwal: Yes. And just one clarity on this. Is this US$70 million a start because Perrigo has launched. We have not launched as yet. So this US$70 million start before we have launched or because when we launch, we will launch...

P. V. Ram Prasad Reddy: We have launched the product.

Anubhav Aggarwal: Now second question was on this injectable guidance. So far we have seen half of this quarter go by, we have not seen a very major approval for injectables. So guidance of 40%, 50% growth for the full year. Does it imply that the benefit from shortage what we saw in this quarter was not full? And therefore in the third quarter, we're going to benefit largely from the shortage product? Is that driving the...

Narayanan Govindarajan: We are not specifically commenting on product specific or shortage product.

P. V. Ram Prasad Reddy: There are no new shortage products in the third quarter. Whatever is available in second quarter will be available in third quarter.

Anubhav Aggarwal: And sir, how are we guiding for 40% to 50% growth for the year? Because right now, we need to do US$70 million per quarter to reach US$225 million for the year. And this quarter we had only US$46 million.

P. V. Ram Prasad Reddy: This quarter, we are going to reach US$60 million plus.

Narayanan Govindarajan: Anubhav, so we had talked about 40%. Let us calculate on a 40% basis, it will be close to around US$200 million, right?

Anubhav Aggarwal: So we did US$157 million last year so on a 40% basis we will be…

Narayanan Govindarajan: So around US$210-220 million, you see here what Mr. Reddy is talking about approximately US$ 60 million plus per quarter, if you take same rate it would around US$ 130 million in the second half

Anubhav Aggarwal: So if we have done US$ 82 million…

Narayanan Govindarajan: No. I think the percentage of the first 2 quarters was not the same run rate, sir. That is the reason they are asking this question.

P. V. Ram Prasad Reddy: Yes, US$ 45 million, I don't know. But definitely, we have a plan in the next 2 quarters around US$60 million plus level.

Anubhav Aggarwal: Sure, sir. That's helpful. Just for clarity, when do you expect Ertapenem approval for us? Do you expect in the quarter 4 this year or next year?

Narayanan Govindarajan: We cannot specifically give a timeline for a simple reason. We have received some queries and we are working on that. And we'll be responding in the next few weeks. So based on that, we should get approved. The query is related to the bulk, and it's getting addressed. So once that is closed, in our opinion we should expect the approval.

Anubhav Aggarwal: Just one last question for me. On Dolutegravir, Mylan announced in their call that they received a 3-year contract from the Global Fund and similar organizations. What was the status for us? Have you received any?

Narayanan Govindarajan: We also have a 2-year contract from the funding houses. Because the contract was offered for 4 years depending on the price. We were comfortable to take it for currently 2 years and then we can always extend it later.

Anubhav Aggarwal: Yes. So this contract starts on April '18. What's the quantum we're talking about here?

Narayanan Govindarajan: So 2 year's period it can be around US$80-plus million.

Anubhav Aggarwal: Total over 2 years, so annually about 40 roughly?

Narayanan Govindarajan: Yes.

Anubhav Aggarwal: And when does this start, Govind? April '18?

Narayanan Govindarajan: It will start in April. But you cannot just divide that number by quarter or month because it all depends on how the ramping up happens as well.

Anubhav Aggarwal: So the last clarity on this. Is this all we got now? Or is it like part we got from part of the funds and but annually, let's say FY '19, FY '20 this amount could be higher?

Narayanan Govindarajan: Yes. This is one part of the business. We will be doing better than this, as far as the combination.

Moderator: Thank you. Our next question is from the line of Chirag Dagli from HDFC Mutual Fund. Please go ahead.

Chirag Dagli: Sir, how has the U.S. Orals business ex of Sevelamer performed quarter-on-quarter or year-over-year? Any clarity will be helpful.

Narayanan Govindarajan: So on the base business, we have given the clarity about the erosional aspects. So it's a question beyond that...

Chirag Dagli: No, not erosion. Sir, overall for Aurobindo, with new products etc., how has the actual sales done? Not the erosion, but actual sales ex of Sevelamer, how has the business performed? Would it have grown? Would it have not grown?

Narayanan Govindarajan: When we talk about growth, we are not specifically commenting about Oral. We are talking about overall, we would be still growing. The reason being is something we have to balance in terms of considering the erosion plus new product launches and also the volume growth in the existing business as a combination, we have to look at it. Definitely, the oral solid business is under certain pressure. Without any doubt, we have been consistently talking about that both in terms of annualized basis and sequential basis. But we still believe as US overall business, we would still be able to grow.

Chirag Dagli: But Oral Solids in the base portfolio, you are still seeing volume growth, sir?

Narayanan Govindarajan: Yes.

Chirag Dagli: Excluding the new products, on older products also you are seeing volume growth?

Narayanan Govindarajan: Yes. We are seeing volume growth in base business.

Chirag Dagli: Fair point, sir. And sir on the other expenses side, there is a sharp jump quarter-on-quarter. Is there anything meaningful to highlight here?

Santhanam Subramanian: This quarter, the other expenses increased by about Rs. 180 crores. This is mainly on account of the higher carriage outwards for the new product launches and also we had a higher customer settlement charges and other provisions. If you look sequentially, the Unit XVI has been commissioned by June, now this quarter had a 3-month expenditure and also the Generis business costs have been taken for the full quarter. So that is the main reason for the increased expenses this quarter.

Chirag Dagli: So this quarterly run rate is what we should extrapolate, sir?

Santhanam Subramanian: If you adjust for all these things, the quarterly run-rate would be anywhere between Rs. 925 crores to Rs. 975 crores.

Moderator: Thank you. Our next question is from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.

Nimish Mehta: Sir, on the debt increase part, you had mentioned that the long-term debt had increased mainly because of the Generis acquisition. But it is still more than what the full acquisition was valued

at. So what is the color? And second, even on the working capital, I was under the impression that cash flow from Renvela should actually help them reduce so a better color on the debt will be helpful.

Santhanam Subramanian: The net debt has been moved from US$ 560 million to around US$ 616 million. This is mainly on account of increase in the working capital. The increase in working capital on account of the introduction of the new high-value product where substantial value difference between the gross to net, which is very customary in the U.S. Already substantial money is realized in the month of October and this process is expected to take next 3 to 6 months. Also in this quarter, we have certain increased cash outflow on account of the GST implementation, which we expect to be normalize by the end of the year.

Nimish Mehta: So these are the 2 main reasons why working capital has grown. So after that, I guess the Renvela part would mitigate because we would start this. So in this quarter, we have not received any cash flow from Renvela, sir, is it a fair assumption?

Santhanam Subramanian: Yes

Nimish Mehta: Understood. And on the long-term loans?

Santhanam Subramanian: The long-term loan has been raised last quarter for the purpose of Generis acquisition.

Nimish Mehta: Yes. But this quarter are you seeing presentation, it's just still much higher like the other term loans, which is US$ 198 million...

Santhanam Subramanian: No, we would have adjusted between short-term loan to long-term loan because we are predominantly short-term loans. We are also trying to convert some of the short-term loans into long-term loans. But overall, the increase is on account of the working capital only. Nothing to do with long-term loan increase.

Nimish Mehta: How much the total loan increased? Is what we should look in?

Santhanam Subramanian: This quarter, net debt has moved from US$ 560 million to US$ 616 million.

Nimish Mehta: It is from US$ 440 million in March '17 to US$ 616 million.

Santhanam Subramanian: Yes. US$ 440 to US$ 560 million, we explained last quarter itself. It is on account of Generis acquisition. That was around US$135 million.

Narayanan Govindarajan: Subbu, where do you look that debt to go down by end of the year?

Santhanam Subramanian: It will be less than US$ 475 million and we continue to maintain at this stage.

Narayanan Govindarajan: You will get more clarity on debt as we move forward.

Nimish Mehta: Okay. I'm sorry, what is the number you mentioned, it will get to what level?

Santhanam Subramanian: less than US$475 million.

Nimish Mehta: US$475 million. Okay, fine. The other thing I just wanted to know is how has this Protonix IV been doing in the U.S. market? I guess, it is under shortage and but you mentioned that shortage products have not really done I mean any differently than what it used to be. But whatever I understand that this is a product where there is shortage and all this will probably a major player and a supplier. So any outlook, any color on that would be helpful.

P. V. Ram Prasad Reddy: Already Pfizer launched some quantity in the market in October and one more generic has come in October.

Nimish Mehta: Yes. So I mean, what I understand is that Pfizer, though they would have been in the market back but they are not being able to pick up the same market share.

Narayanan Govindarajan: Some quantities have come to the market from the brand. Even though in the regulatory website it has been mentioned that it takes some time but we have seen some quantities. We don't know if it is going to continue or not, we are not sure about it. Our sales would be based on that also. One more player launched recently and there has been dip due to that particular launch as well. So we have to wait and see in terms of how it's going to pan out.

Nimish Mehta: But are we the largest market shareholder as of now, as in, in the last 2, 3 months or whatever? Because Pfizer has practically not...

P.V Ram Prasad Reddy: Yes.

Moderator: Thank you. We'll take our next question from the line of Niraj Gayal from MS Research. Please go ahead.

Niraj Gayal: So I want to ask, how much time does it typically take to go from filing an ANDA application to capturing some significant market share or the market share getting plateaued? Just for my understanding of the timelines from filing to having actual market share?

Narayanan Govindarajan: You cannot generalize it. The approval timelines have improved now, thanks to GDUFA fees. On the market share, it all depends on are you alone in the market or are you sharing with few people. It all depends on that. We have seen surprising things where in terms of erosion on even a Para IV product exceeding 90% during 180 days itself. So you cannot generalize this.

Niraj Gayal: Okay. But from your experience, any color, like 3 years, 5 years or 1 year, any sort of like historical estimate might be useful for me.

Narayanan Govindarajan: No. Niraj, as I've mentioned earlier also, this cannot be generalized. I think what we can do is we can take it off-line in terms of giving you generally how it has panned out in the last years in terms of few products. We can take it offline.

Niraj Gayal: Okay. And one more question. So in the pharma industry, when you file an ANDA application, what fraction of ANDA likely get approved overall? Or is it that some ANDAs just take more time to get approved and you have a lot of back-and-forths between FDA and the company?

Narayanan Govindarajan: See, if you are going to be one of the first launchers then you will always have more queries in terms of getting the approval because the reviewer will be looking that particular generic product for the first time. And then there'll be always more queries and more time it could take in terms of getting approval closer to the launch. Having said that, this again cannot be generalized depending on the complexity of the product.

Moderator: Thank you. Our next question is from the line of Shyam Srinivasan from Goldman Sachs. Please go ahead.

Shyam Srinivasan: Just on the filings that we have done, 21 filings for the quarter, it's a sharp uptick, right, even from our own run rate perspective. So anything that has kind of changed in terms of what's driving this kind of filing frequency? Or it's just been that it's been kind of lumped up this quarter?

Narayanan Govindarajan: You need to include the Eugia filings as well

Shyam Srinivasan: Yes. So Eugia, I thought we had 6 or something, right, this quarter? And they have all been bunched up during the quarter.

Narayanan Govindarajan: That's part of the number as well.

Shyam Srinivasan: Okay. And just stepping back from slightly more philosophical questioning again on the R&D bit, we have had very good filing traction and we have seen where the rest of the industry is. Typically, they've been half of where your filings are. Is there a risk to some of your scientists or any of them being actually poached by other competitors given the kind of frequency? Is that a valid risk at all in the business?

Narayanan Govindarajan: That is a risk which is always there, but all the scientists are not chasing money because they are also looking at expression for themselves in terms of technically what they can add. In fact, most of our senior management in the development front stuck to us because of the excitement they get. Not that they are being paid less, they've been paid equivalent to the market or even slightly better than the market.

Shyam Srinivasan: Okay. So that's an ongoing risk.

Narayanan Govindarajan: It's an ongoing risk and that gets mitigated as it progresses in terms of preparing ourselves. But we have not seen a huge change in that and we don't expect that to change much.

Shyam Srinivasan: Okay. Just last point on this R&D. So you think 5% will slowly start moving towards the rest of the year given this Biosimilar studies that are coming up.

Narayanan Govindarajan: Well, we don't expect that to change much. We only said that the change can happen when some Phase III start. Even if it is Phase I, it will not change much.

Shyam Srinivasan: Okay. My second question is on regulatory updates. If you can just share the status of, I think Unit XI is the only one I recollect. But if we can just see what is the pending action left with the US FDA?

Narayanan Govindarajan: If there is an inspection without any 483, till the time you receive EIR, we cannot say that regulatory action is completed. So Eugia is pending

Shyam Srinivasan: Okay. And I don't recollect, it was like or 1 or 2 observations that Unit VI, right? It's like small...

Narayanan Govindarajan: There are 2 observations.

Shyam Srinivasan: Okay, great. And my last question is on tax rate. We had it slightly lower this quarter. Any specific reason? And what's the guidance for the full year on tax rate?

Santhanam Subramanian : The tax rate for the quarter was low because of the high-value new product launch has been manufactured out of the SEZ Unit plus coupled with the fact that Unit XVI, which is the new injectable unit is also in SEZ. So, this year probably we may see anywhere between 25% to 26% subject to any changes in the tax rate by various governments including US.

Moderator: Thank you. Our next question is from the line of Kartik Mehta from Deutsche Bank. Please go ahead.

Kartik Mehta: How do you view the Sevelamer competition, assuming that not all the competitors have their own API? How much of a factor do you think that will play as we have 4 players and an AG in terms of the way you look at market share? Or do you have adequate inventory even now because you had a very strong launch? And in terms of your sales with inventory in the hands of the distributor, is there any chargeback on those which is pending and which can come in Q3? That's the first question.

Narayanan Govindarajan: I'll be able to give complete clarity on two aspects of it. One is we have inventory in hand both in US and India. Number two is as far as the chargeback for the quarter, we already provided to the extent what we need to provide. And as far as competition is concerned, lot of activity has happened in the last few weeks, and it's too premature to comment in terms of how it is going to

pan out. We still believe we would have an edge because we are backward integrated and we have inventory in hand.

Kartik Mehta: Yes. In terms of pricing, is it fair to assume that 70%-80% erosion has already happened? Or would you expect that...

P. V. Ram Prasad Reddy: Yes. It has already happened.

Kartik Mehta: Yes. And the other one was so in terms of maybe outlook, if you may just be able to help us, not with numbers but with some color. So how does FY19 look now with a base of product like this, U.S. injectables will grow but maybe other than injectables in the U.S., how do you look at it from an overall perspective FY '19 over FY '18?

Narayanan Govindarajan: There are 3 areas we need to look at. As far as Oral is concerned, we need to really look at the new product launches and also keeping the erosion in mind, that is one aspect of it. We have to look at what are the new products which can come up and also look at volume growth in the existing portfolio. While injectable will grow meaningfully, as well as Natrol can also grow. And even OTC can have some significant growth as well.

Kartik Mehta: Yes. So my last one, if I may. In terms of the EU business, is it fair to assume that fair amount of EBITDA can be unlocked there over the next 1 or 2 years depending on how much you move to India? So if we have to just assume that on a standalone EU business, currency remains the same, how much can we increase the EBITDA? Again, I just want a color over the next 2, 3 years based from the run rate that you are moving there.

Sanjeev Dani: When we acquired this business, it was loss-making as you know. Now we have moved to the double-digit in EBITDA%, even though it is early numbers in time. We have already made a lot of progress. And actually, the switch is one of the driving strategies to improve the gross margin. But there are other new products which are being filed ex India, and they will be launched, some of them will be day 1 launches. So we are confident that we'll be able to hold up and move up the value chain. You have seen that in Europe with Euro 800 million to 1 billion in sales, companies are making 20% margin. So we are hopeful of moving up the ladder.

Moderator: Thank you. Our next question is from the line of Prashant Nair from Citigroup. Please go ahead.

Prashant Nair: Just a question on the margin front. So Govind going into next financial year with a slightly elevated base this year due to Renvela and the fact that your R&D spend could go up a bit. Do you have comfort on maintaining your current level of margin or this year's level of margins? Or could we see some improvement? Or do you think we'll see sidestep down before going up again?

Narayanan Govindarajan: Removing the one-off and we believe we can maintain or improve margins, that is what we would say, and not by including the one-off and saying that still we'll go beyond that is not fair.

Prashant Nair: Okay, understood. And on tax rate again, Subbu, so as we move into next year and the year beyond that, I mean, where do we see it settling down as the SEZ contributes more?

Santhanam Subramanian: Yes. If you recollect in the last call or the previous call, we talked about the Naidupet plant getting commissioned in April 2018. That is also a SEZ unit. As we are having our key units in SEZ's and we will have a good tax advantage going forward. Probably around 25% level from next year onwards subject to any changes in the tax rate by various governments including US.

Moderator: Thank you. Our next question is from the line of Surajit Pal from Prabhudas Lilladher. Please go ahead.

Surajit Pal: Govind, could you throw some light on Eugia filings in terms of type of product or the kind of market it is addressing. And the second thing is that in injectable, you have given quite a bullish guidance. And where do we stand in terms of Pantoprazole and Vancomycin products?

Narayanan Govindarajan: The current addressable market of 9 products which we have filed from Eugia is around 1.8 billion. As far as Pantoprazole, already enough discussion has happened like there is one player with brand coming back. So to an extent, there has been a dip. We have to wait and watch on how it is going to pan out. But on overall injectable business front, we have a few more approvals coming up which should improve the business. We are also looking to gain volume in existing products.

Surajit Pal: And I'm talking about Eugia. In terms of category of products, we are looking at. I mean I understood you're 1.8 billion. But the kind of product, if could you throw some light on that, what kind of product...

P.V. Ram Prasad Reddy: In Eugia, we filed only 9 products and we are going to file 4 to 5 ANDAs every quarter. And we are not expecting sale from Eugia in the next 2 to 3 quarters. Our sale will come from middle of the next year. Overall, as we told in the next 2 quarters, we expect 60 million plus per quarter in the injectable business.

Surajit Pal: Sure. As far as U.S. tax rate is concerned, which I think is one of the crucial event to happen very recently. Could you throw some light, what is your effective tax outgo in U.S.? And if it comes down to say to the level of 20%, how much savings can company could get due to that?

Narayanan Govindarajan: We'll take it offline.

P.V. Ram Prasad Reddy: The bill has not passed. Let it pass, then we can have more clarity on this.

Moderator: Thank you. Our next question is from the line of Ranvir Singh from Systematix Shares. Please go ahead.

Ranvir Singh: Most of my questions have been answered, just one. Earlier you indicated that Oncology side we are going to ramp up the products. So can we expect the second half to see more products coming from the Oncology side?

Narayanan Govindarajan: The filing would happen is what we are talking about at this juncture and the revenues would not start until second half of next year.

Ranvir Singh: Okay. And for that combination, ARV drug we got last quarter. So when actually this revenue will start coming?

Narayanan Govindarajan: Meaningful revenue would start from April 2018 is what we had mentioned. We also talked about, there are certain guaranteed contracts in terms of minimum volume for a couple of years which is starting from April '18 till March 2020.

Ranvir Singh: And for Dolutegravir for U.S. market also or do we able to roll out there?

Narayanan Govindarajan: What we are talking about is only for PEPFAR markets.

Ranvir Singh: No. In U.S. after patent expiry, any chances we are going to be able to do...

Narayanan Govindarajan: That's too premature at this juncture to talk about.

Moderator: Thank you. Our next question is from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.

Ranjit Kapadia: Two questions. My first question is on the vaccine. We are working on a pneumonia vaccine for quite some time, so if you can give some update on that. And my second question is related to domestic business. Are we having any strategy for acquiring branded generic business of the existing form?

Narayanan Govindarajan: As far as pneumococcal vaccine is concerned, we are working on the clinical trial and we have also been working with the WHO to get the protocols cleared. That discussion is on, and Phase I should start any time. And for GAVI market itself, it will take considering a 2-year timeline in terms of Phase I and Phase III, and then subsequently you need to sell it in the domestic market for a year. After approval, 1 year in domestic and then only you can go for GAVI. So it will be at least another 3.5-4 years before we can start seeing the GAVI revenue coming for pneumococcal vaccine. On the domestic market, as part of our strategy, that is also one more opportunity for market penetration. We keep evaluating as we had mentioned earlier as well. But we have not been lucky so far. We'll keep looking at it.

Ranjit Kapadia: And one more question. Regarding the OTC business, we have a Nexium OTC. Is there any potential to nutraceutical business to launch some more products in the OTC segment in the U.S.?

Narayanan Govindarajan: Generally pharma OTC is different than the dietary supplement. These two are completely two different silos.

Moderator: Thank you. Our next question is from the line of Rishabh Parekh from Sunidhi Securities. Please go ahead.

Rishabh Parekh: Just want to check status on Fonda and generic Fortamet.

Narayanan Govindarajan: As far as Fonda is concerned, there is nothing pending from our end. Last week we've done some label revision which also in my opinion would have been completed by now. This year we are expecting to launch the product.

Rishabh Parekh: And Fortamet?

Narayanan Govindarajan: Fortamet, the discussions are still on. One is obviously the 30-month stay timeline itself. We have to look at it somewhere in the third quarter of next year. So parallely the discussion is on in terms of finding out if we can get the settlement done before that.

Rishabh Parekh: And are you closer to getting the settlement done than you were last quarter or is it the same status as of now?

Narayanan Govindarajan: We would not like to comment on that as you would appreciate

Moderator: Thank you. Our next question is from the line of Damayanti Kerai from HSBC. Please go ahead.

Damayanti Kerai: Sir, can we have update on Natrol sales? And in terms of operating margins, how we are faring compared to last few quarters?

Narayanan Govindarajan: As far as Natrol sale is concerned, it's around close to $29 million. And the margin would be almost equivalent to company's margin or slightly better.

Damayanti Kerai: Better than company average?

Narayanan Govindarajan: Yes.

Damayanti Kerai: Okay. And so this Vancomycin launch, earlier we have indicated that it should come toward the year-end. So are we still holding onto that?

Narayanan Govindarajan: Still we are holding to the plan of launch before year-end.

Damayanti Kerai: Okay. That's helpful. Sir, just 2 clarifications on your balance sheet. We have seen a significant jump in your goodwill. That's because of Generis acquisition?

Santhanam Subramanian: Absolutely. Yes, you are right.

Damayanti Kerai: Okay. And we are also seeing a significant jump in intangibles under development. So what's happening there intangible assets under development?

Santhanam Subramanian: It has come down from Rs. 220 crores to Rs. 95 crores and not gone up. It has come down mainly because of the capitalization of the brands, which we have acquired in the month of March, the Orocal brand.

Damayanti Kerai: Okay. And sir, lastly, can we have the CAPEX outlook for next year?

Narayanan Govindarajan: For FY18, we should be able to maintain what we have indicated about US$130 million plus vaccines and biosimilar. For FY19, we have not finalized the budget in terms of CAPEX.

Moderator: Thank you. Our next question is from the line of Nishit Shah from Ambika Fincap. Please go ahead.

Nishit Shah: Most of my questions are answered, except in that on Biosimilars, can you give me a flavor if you were to file 1 product, so is the clinical trial started on that product? I'm talking about the microsphere, sorry.

Narayanan Govindarajan: Next financial year, we would be filing.

Nishit Shah: So the clinical trial Govind will start in the next couple of months, right?

Narayanan Govindarajan: It can start in certain timeline. But next year, definitely our filing would happen.

Nishit Shah: And on the Biosimilars, if you were to start the clinical trials Phase I, so that also will start sometime next year or maybe...

Narayanan Govindarajan: The Phase I will start by next financial year, surely.

Moderator: Thank you. Next question is from the line of Chirag Dagli from HDFC Mutual Fund. Please go ahead.

Chirag Dagli: Sir, has the Sevelamer sales that we booked in the Q2, are they at much higher or significantly higher pricing versus where the current pricing is?

Narayanan Govindarajan: It is higher is what I would say

Chirag Dagli: But sir, you are not calling out the number separately. We just want to try and make sense of how the base business is done, ex of Sevelamer, these one-off sales that is where…

Narayanan Govindarajan: On a year-on-year basis, we have got that erosion to the extent of 11% to 12%. We have also said there has been certain volume growth in the base business as well. On a sequential quarter, we said it's around 5% erosion on the base business.

Moderator: Thank you. Our next question is from the line of Charulata Gaidhani from Dalal & Broacha. Please go ahead.

Charulata Gaidhani: I wanted to know with the ramp-up in injectables, how do you look at the profitability in FY '18 and 19? Do you see EBITDA margins around the same level? Or you see some improvement?

Narayanan Govindarajan: We generally don't give individual margins. You also need to understand that the injectable margins are always better than the Oral. But then considering certain pressures on the Oral and some improved margin in injectable is what we will be looking to find out whether we can maintain or improve the margin of US portfolio as well as the company.

Moderator: Thank you very much. Ladies and gentlemen, that was the last question. I now hand the call back to Mr. Krishna Kiran for closing comments. Over to you, sir.

Krishna Kiran: Yes. Thank you all for joining us on the call. If you have any questions unanswered, please feel free to touch with the Investor Relations. The transcript of this call will be uploaded on our website, www.aurobindo.com in due course. Thank you.

Moderator: Thank you, members of the management. Ladies and gentlemen, on behalf of Aurobindo Pharma Limited, that concludes this conference. Thank you for joining us, and you may now disconnect your lines.