"Aurobindo Pharma Ltd. Q2 FY20 Results Conference Call"

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MR. N. GOVINDARAJAN – MANAGING DIRECTOR
MR. SANJEEV DANI – COO & HEAD (FORMULATIONS)
MR. SANTHANAM SUBRAMANIAN – CFO
MR. SWAMI IYER – CFO, AUROBINDO PHARMA USA
MR. KRISHNA KIRAN – INVESTOR RELATIONS

Moderator: Good day, ladies and gentlemen, and welcome to the Q2 FY'20 Earnings Conference Call of Aurobindo Pharma Limited. As a reminder, all participants' 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 '*' 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. Thank you, and over to you, sir.

Krishna Kiran: Thank you, Margareth. Good morning and a warm welcome to our Second Quarter FY '20 Earnings Call. I am Krishna Kiran from the Aurobindo Pharma Investor Relations. We hope you have received the 'Q2 Financials' and the 'Press Release' that were sent out yesterday. These are also available on our website.

With me, we have our senior management team represented by Mr. P.V. Ramprasad Reddy -- Executive Chairman, Aurobindo Pharma USA; Mr. N. Govindarajan -- Managing Director; Mr. Sanjeev Dani -- COO & Head, Formulations; Mr. Santhanam Subramanian -- CFO; and Mr. Swami Iyer -- CFO, Aurobindo Pharma USA.

We will begin the call with "Summary Highlights from the Management" followed by an "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 action and other affirmation 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 the 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 will hand over the call to "Mr. Govindarajan for the Highlights." Over to you, sir.

N. Govindarajan: Thank you, Krishna. Good Morning everyone. We are here to discuss the Results for the Second Quarter of Financial Year 2019-20 declared by the company. Revenue increased by 18% YoY to Rs.5,600 crores, led by healthy growth in our key geographies. The EBITDA before FOREX and other income stood at Rs.1,167 crores, an increase of 14% over corresponding previous period. EBITDA margin was at 20.8% for the quarter under review. Net profit increased by 5% YoY to Rs.640 crores.

In terms of the business breakdown, Formulations business contributed to 85.6% of the total revenue and clocked revenue of Rs.4,794 crores, registering a growth of 22% YoY. API business posted a revenue of Rs.806 crores with increased focus on captive consumption. In the Formulations business, the revenue from the US market increased by 27% YoY to Rs.2,835

crores. On a constant currency basis, US revenue increased by 27% YoY basis to $404 million, led by new product launches and improvement in volumes of existing products. We have received final approval for three ANDAs and launched ten products including three injectables in the quarter under review. We have filed 20 ANDAs including two injectable products during the quarter.

Revenue of Aurobindo Pharma USA, the company marketing oral products in USA, has increased by 14% YoY. Revenue of AuroMedics, the injectable business witnessed a growth of 49% YoY to $75 million. We have filed a total of 118 injectable ANDAs as on 30th September 2019. Out of which 71 have received final approval and the balance 47 are under review. The company as on 30th September 2019, has filed 569 ANDAs on a cumulative basis. Out of which 389 have final approval and 27 having tentative approvals including 9 ANDAs which are tentatively approved under PEPFAR and balance 153 ANDAs are under review.

Europe Formulations revenue came in at Rs.1,401 crores in Q2 FY'19-20, an increase of 21% growth YoY. In Euro terms, the revenue increased by 26% YoY. Growth markets revenue witnessed a growth of 4% YoY basis to Rs.319 crores. On a constant currency basis, growth markets reported a growth of 3% YoY. ARV Formulations revenue declined to Rs.238 crores compared to Rs.244 crores in the corresponding previous period.

In terms of "Segmental Classification", US Formulations contributed to 50.6% of the overall revenue in Q2 FY'19-20 Vs 46.9% in Q2 FY '18-19. Share of EU Formulations increased to 25.0% in Q2 FY'19-20 Vs 24.3% in Q2 FY '18-19. Growth markets share decreased to 5.7% in Q2 FY '19-20 versus 6.5% in Q2 FY'18-19. Share of ARV segment decreased to 4.2% in Q2 FY'19-20 Vs 5.1% in Q2 FY'18-19. API business contributed to 14.4% of the total revenue in Q2 FY '19-20 Vs 17.2% in Q2 FY '18-19. R&D expenditure is at Rs.223 crores during the quarter which is 4.0% of the revenue. Net organic CAPEX for the quarter is around $58 million. The closing rupee versus US dollar rate was at Rs.70.875 in September 2019 and Rs.69.02 in June 2019. The net debt has decreased by $71 million QoQ to $522 million at the end of September 2019 Vs $593 million at the end of June 2019. The majority of the company's debt is denominated in foreign currency. The cash and bank balance is at $305 million. The average finance cost is at 2.75% mainly due to availing multiple currency loans.

This is all from our end and we are happy to take your questions now.

Moderator: Thank you. We will now begin the question-and-answer session. The first question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: Sir, my first question is on the pending FTC approval for the Sandoz deal. Could you give us some color in terms of timelines or why it has delayed?

Swami S. Iyer: With regard to the FTC, you are aware that we cannot provide you precise details of our discussion with FTC, but we would like to say that things have been moving positively and we

believe that we have substantially addressed all the requirements to obtain approval. In terms of timing, the target dates have moved, but our expectation is that FTC consent would be received sometime in the next few weeks.

Neha Manpuria: Sir, you had mentioned even in the last call that you are expecting approval in the next few weeks. What essentially has led to the delay between then and now even if you do not know when that approval would potentially come through?

Swami S. Iyer: The approvals are not in our hands and FTC is external to us. It is a government process; we have to go through the process. But, we can only expect once the documentation is submitted and permission will be given. We really cannot give you the precise details, but we do not believe that it is anything extraneous, it is particularly something to do with the products and the transfer of it.

N. Govindarajan: We would say that FTC has been doing its job, and we have been cooperating as well, but please understand the fact for such a large deal when there are more parties involved like we have to get involved, the seller has to get involved, and also the third-party who has to buy and they have to commit in terms of being in the market. So, it has taken some more time than what we had anticipated. In all fairness what Swami is trying to say is that it should be concluded towards December-end and if not at least by January, that is what our colleagues feel at this juncture. This is, again our best estimation.

Neha Manpuria: My second question is on the US business. We crossed $400 million in this quarter and it seems like the large part has come from the Injectable business which improved sharply QoQ. Could give us some color on the improvement in the Injectable business?

Swami S. Iyer: We should typically not look at this on a quarterly basis, but what we would like to say that on an annual basis we do expect a growth. We had also discussed in the last call that we have done well in Injectables and we continue to do well.

Neha Manpuria: So would this imply that the Injectables revenue could come off in the subsequent quarters and there are some one-offs in this revenue?

Swami S. Iyer: We expect stability and growth. So, we would not say that it would come off.

N. Govindarajan: We are not expecting it to reduce. We do not give any forward-looking statements or projections. We can only tell you that we expect to maintain the growth. We are not expecting any degrowth at this juncture in terms of even QoQ, it is doing well, but the measurement on QoQ is not fair.

P.V. Ramprasad Reddy: At Present it is good, and we can maintain definitely.

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

Damayanti Kerai: Sir, coming back to Injectables sales in the US, you just mentioned that you expect to continue the momentum, but the strong growth during the quarter, is it result of some NBO opportunity which we had previously received for our US business, like how should we look into the very strong US growth for the quarter?

Swami S. Iyer: We had growth in the base products plus we have also added some products from Eugia, and these have contributed to our growth.

Damayanti Kerai: So it is all existing business growth, right, nothing one-off or some exceptional are there?

Swami S. Iyer: There are no exceptional or one-off sales during the quarter.

P.V. Ramprasad Reddy: We have launched some oncology and hormonal injectable from Eugia

Damayanti Kerai: And sir, can you update us on the status of the bag line and the lyo line, I think which we have been speaking for last few quarters for the Injectables?

N. Govindarajan: The bag line has started. We already relaunched one product, second product is also being pushed through and the third product would kick in by next quarter. So, if you remember the bag line had three products before we discontinued. As far as lyo line is concerned, it is continuing, but we just wanted to also clarify, it is continuing with other products rather than Vancomycin because other products seems to be better for us to continue than prioritizing Vancomycin.

Damayanti Kerai: Second question on the FDA pending status at our facilities. So, can you update us in terms of the major pending issues at the plant?

N. Govindarajan: The major pending one is the warning letter for Unit-XI, and also the OAI status for Unit-I and Unit-IX. As far as our commitment in terms of closure of CAPAs, we have committed them that we will be sending our response with the CAPA completion by 15th November. We will be either sending it tomorrow or day after. We have completed whatever we have committed, and there are certain recommendations which would take some more time, but those are not impediment for the inspection. But once we submit, we can expect the inspection by next quarter.

Damayanti Kerai: We expect inspection by next quarter?

N. Govindarajan: Yes, even though if we submit by November, they have to review. December is majorly a holiday season, so we expect them to come between January to March. If not January to March, then may be April.

Damayanti Kerai: We had recent inspection at the Unit-IV plant. So anything to look out there?

N. Govindarajan: Unit-IV inspection is ongoing. It is not fair to comment on that at this juncture.

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

Shyam Srinivasan: Just one on Unit-VII, I know you put a press release out, but Govind and team, if you can update us on what is the status there, we saw a sharp market reaction, I am just trying to understand from your perspective what the issues are and how we can resolve this?

N. Govindarajan: There are seven observations, as you might have observed, and to the best of our knowledge none of them are related to data integrity and we have prepared a thorough response. We have sent the response a couple of weeks back, and now it would be under review.

Shyam Srinivasan: Anything that was the nature of the inspection or have the number of inspectors now significantly increased? And we are hearing this across industry. So I am just trying to get a sense. We counted about 15 warning letters to Indian plants this year. So, is there something that is stepping up in terms of the FDA linked to whatever issues they have seen on the sartans last year and stuff. So, if you can give us qualitative color on the intensity of these inspections?

N. Govindarajan: We would always have more intensity because of the fact that any plant which has more number of filings should always be prepared for more number of inspections and that is our belief. And as you rightly mentioned that the warning letter related to Aurobindo's Unit-XI is related to specific products like sartans. So our understanding is we will have more inspections, it could be more number of inspectors or it could be more frequent because of the fact we have been filing more number of products from each of our facilities.

Shyam Srinivasan: My second question is just on the margin profile. So gross margins now is at about 58%. We have seen API kind of decline. So, is this the new way we should look at it? I know Sandoz will come whenever it comes and that could further skew things towards Formulations. So I am just trying to understand how should we look at the gross margin specifically -- are we looking at this to remain at these levels or still further improve?

S Subramanian: If you recollect previous earnings calls, we said our endeavor is to achieve a gross margin of 57% to 58% and the next phase will be known only after the Sandoz, and we have been making all efforts to achieve that 57% to 58%.

Shyam Srinivasan: My last data point question is on Natrol. If you can just give us what the number is and how the growth has panned out?

Swami S. Iyer: Natrol continues to do well. There have been improvements in operational and sales activities and we are looking forward to a very healthy year based on what we have got in the first two quarters. We will have to look at the annual number; we definitely think it will be better than previous year.

Shyam Srinivasan: You had $38 million last quarter. What is the number for this quarter?

N. Govindarajan: Around $39 million. So one request what Swami had was, do not measure it on Quarter to Quarter basis. Annualized basis it will definitely grow, that is what he is trying to say.

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

Anubhav Aggarwal: If we were to combine our pending ANDAs just from three units, XI, VII and IV, what percentage of our pending ANDAs will come from these three units put together?

P.V. Ramprasad Reddy: Unit IV is injectables facility. There is no issue as of today

Anubhav Aggarwal: You do give numbers for IV and VII, which is there. But I do not know when it combines with XI that is where the confusion comes.

P.V. Ramprasad Reddy: Forty plus are pending from Unit IV and Unit XI is a raw material facility.

N. Govindarajan: You should not combine raw material and finished goods facilities. It will never give a clear picture. So you better restrict to Unit IV and Unit VII.

P.V. Ramprasad Reddy: Unit VII has 30 plus products under review.

Anubhav Aggarwal: I do not want to combine the two, but since you have a warning letter in Unit-XI, and it will have impact on our pending ANDAs, right?

N. Govindarajan: It already had an impact in terms of five products which we had spelled out earlier, and in fact we have said from XI in case if it continues for next year then it would be around 15 products.

P.V. Ramprasad Reddy: Around 15 products, including tentative approvals that would be around 20 products. But majority of the tentatively approved products are expected to get approval in 2023-2024. Up to December'20, the products are affected is less than 15.

N. Govindarajan: And none of these are not significant opportunities

Moderator: Thank you. The next question is from the line of Nitin Agarwal from IDFC. Please go ahead.

Nitin Agarwal: Sir, on the European business, how is the Apotex integration playing out? And with the footprint in Europe being what it is now, fairly broad-based footprint, how should we look at our Europe business when we take a two to three year view of this business?

Sanjeev Dani: Apotex integration is ongoing for last six months since we have taken charge. You can see that growth rate is reflected in the sense that even without Apotex, we are growing at a constant currency of 6%, and with Apotex about 26%. Now, going forward, we are looking to integrate Apotex business into overall Aurobindo Group business, and our first priority is to maintain the

stock supply and the customer satisfaction. As you are aware, in Belgium, we were never present in a significant way and, Poland and Czech Republic are completely new businesses. So, we are launching new products in these markets, at the same time we are streamlining operations into the existing business of countries like Spain and Netherlands. Going forward, for European business, we will continue to leverage on our presence by launching new products and also switching source of some of the products to improve the COGS and improve the market share. Overall 200-plus products are under development. Over next three to four years, they will be launched including the in therapeutic segment like Oncology.

P.V Ramprasad Reddy: Integration will be over in 3-4 months, Sanjeev?

Sanjeev Dani: Poland, Czech Republic and Spain integration actions are completely over. In Belgium, we are in the process of forming a new entity. In Netherland complete integration will be over in next 3-4 months.

Nitin Agarwal: Just to take that forward, how has your experience been the competitive situation in the market or how has been the competitive intensity in the market, and has there been any changes in the underlying pricing dynamics in that market, has it improved, has it worsened over the years over the last few quarters rather, if is it possible to generalize Europe in a very broad sense?

Sanjeev Dani: In Europe, we would say there have been opportunities in some countries and some market segments. Actually because of our diversified presence we are able to benefit out of that. Obviously, on a net-net effect, pricing pressure and rebates have remained more or less similar.

Nitin Agarwal: On that point, how has the pricing situation been in the US? There has been incremental commentary from different players that the overall situation is improving and it should get significantly better than what it is right now, what is your take on it, sir?

Swami S. Iyer: Pricing is not much improved or not much gone down, it is more or less stable nowadays

Nitin Agarwal: Lastly, on debt, Subbu, how should we look at the debt position for the business over the next six months?

S Subramanian: We said during the year, we will reduce debt between $150 million to $200 million and we have already achieved that. We will continue to maintain the guidance because we will take a view about it only at the end of current fiscal year. On the long-term front, based on the experience which we had in the last 2-3 quarters and we are targeting to achieve zero debt in the next three years on the existing business.

N. Govindarajan: That is without considering Sandoz. Subbu, is that fair to say?

S Subramanian: Yes, on the existing business, without considering Sandoz.

Nitin Agarwal: Sir, we are looking at probably managing even the working capital requirements of the business with accruals going in the next three years?

S Subramanian: Yes

N. Govindarajan: That is true. Subbu was mentioning that, he has considered working capital requirement as well. But again a disclaimer is that without considering whatever increase in inventory need etc., on the Sandoz.

Moderator: Thank you. The next question is from the line of Vishal Manchanda from Nirmal Bang. Please go ahead.

Vishal Manchanda: I have a question related to Sandoz. So, with the closure expected shortly, could you provide a number as to what sales will we be acquiring adjusted for the divested products?

Swami S. Iyer: We have always given the sales without the divested product. We would not like to discuss that before the FTC approval is given, it would not be appropriate. We had earlier given a guidance of $900 million before the FTC divestment and we stand by that.

Vishal Manchanda: If there has been significant erosion on the business, excluding divested products that...?

P.V. Ramprasad Reddy: We have indicated sales of $900 million. We believe more or less similar, plus or minus around 10% maybe.

Vishal Manchanda: One more on the US market. Is there a large part of your portfolio under shortages in the US? So, any sense on what percentage of sales would be experiencing shortages from your portfolio?

Swami S. Iyer: It will not be appropriate to say major or minor. We always get the shortages, it is for some period of time, but we do get shortages and we take advantage because we have a fairly good supply chain. We take care of the shortage to the extent what we can.

Vishal Manchanda: On the Ranitidine part, is this API owned by you or you are getting it from a third-party?

N. Govindarajan: It is from a third-party

Vishal Manchanda: Final one on Spectrum. Has the product Khapzory benefited from Levetiracetam injectables shortage in the US?

P.V. Ramprasad Reddy: We will take this offline as concerned person is not available.

Moderator: Thank you. The next question is from the line of Kaushik Poddar from KB Capital Markets. Please go ahead.

Kaushik Poddar: Can you speak a little bit on your foray into biosimilars, I mean that you are planning to get into in a bigger way?

N. Govindarajan: We have started Phase-I for lead molecule in New Zealand. In fact, if everything goes well, we may start Phase-III trials in the next year. We would be doing clinical trials towards market authorization application (MAA) for two more products in the next year. Both these trials, would get concluded in the next year itself and we would be even filing in the next year. After filing, it could be around 210 + 30/40 days, we expect to get an approval. Subsequent year again few more products should come up for clinical trials. So it is progressing well as planned.

Kaushik Poddar: Your FDA observations regarding those three units. I mean, do you think the closure should happen by March?

N. Govindarajan: As indicated inspection should happen before March or by March-April timeline is what our best estimate. We are preparing ourselves to ensure that the inspection goes well. So, based on the inspection outcome, it should get cleared.

Kaushik Poddar: All the three units, right?

N. Govindarajan: Yes, all the three units because all the three were related to the sartan as these are 'For Cause' audits. Currently, Unit XI is under warning letter and other two are under OAI status.

Moderator: Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: First question on the Sartans. I see your market share both for Valsartan and Losartan are actually healthy and it is increasing. So what is the position in terms of US FDA? They have been recalling few of these products. What is our stance? Are we continuing to sell and some bit on the pricing please?

N. Govindarajan: I do not think that we are increasing our market share in Valsartan at this juncture because right now our API is yet to be cleared. We have filed a CBE-30 and we are waiting for an approval. We expect approval by this month or next month, once approval comes, we would go back to the market.

Swami S. Iyer: As far as Losartan is concerned, we continue to sell the product and we are maintaining our market share. It has been doing well for us; at least, we do not foresee any problem with regard to Losartan.

Prakash Agarwal: But is the pricing healthy, would have improved over a period of time given the shortages?

Swami S. Iyer: We are quite happy with the pricing

P.V. Ramprasad Reddy: Pricing is more or less same in the one or two quarters

Prakash Agarwal: Valsartan, what I heard right is currently...?

P.V. Ramprasad Reddy: Other than Losartan, we discontinued majority of the (around 95%) of the sartans. As Govind indicated once we get CBE-30 approvals, and then we may relaunch.

Prakash Agarwal: This is just for Valsartan?

P.V. Ramprasad Reddy: No, majority types of Sartans.

Prakash Agarwal: Other than Losartan?

P.V. Ramprasad Reddy: Yes.

Prakash Agarwal: And secondly on China, so you made an entry in the Inhaler space. We see a huge pipeline that you are building for the US; we already have large injectable approved products. So, if you could highlight, what is the kind of portfolio we would be looking at in China over a period of three to five years?

P.V. Ramprasad Reddy: We are setting up an oral and an injectable plant. Also, we have ~ 30% stake in joint venture for inhaler solutions.

Prakash Agarwal: Oral, Injectables and Inhalers?

P.V. Ramprasad Reddy: Yes

Prakash Agarwal: Looking at the R&D, percentage of sales around 4%. And as earlier mentioned we would be heading for depot work also. So what is the outlook for second half and next year please?

N. Govindarajan: So we are not giving any forward-looking statement as projections. But one thing we can assure you that we are pretty comfortable about the growth. Regarding depot injection, you are right, by the next year end, we will be filing even the depot injection. That would take some time for approval. We have a healthy pipeline in depot injections. We had only talked about the first product filing, but every year, we expect one or two dosages to be filed and that would continue for a foreseeable future. Definitely, there is a very-very healthy future as far as the injectables are concerned. We will grow.

Prakash Agarwal: No-no, growth is given, I am asking about the R&D cost percentage to sales for...?

N. Govindarajan: R&D cost, once the biosimilars, let us say two Phase-III happens together, from the 4-4.5%, it can go to 6-6.5%.

Prakash Agarwal: This is or next year?

N. Govindarajan: This is for next year, but the reason why we are also talking about a reduced number compared to the earlier 8% to 9% is because the top line would also get added because of the Sandoz acquisition numbers as well.

Prakash Agarwal: This year you will remain at 4%, 4.5%?

N. Govindarajan: 4-4.5% is a fair number for this year

Prakash Agarwal: Lastly, you mentioned you just started the launches. So these are oncology launches and I understand these are fairly generic side. Would that be a fair statement or we have a couple of products we are seeing larger traction to move the needle in terms of the QoQ improvement that we have seen?

P.V. Ramprasad Reddy: Oncology and hormonal products.

N. Govindarajan: So one or two products are okay sort of, it is not a major puller. But we would say quarter-by-quarter this particular pipeline would increase. By next year, we should see far better numbers than what we would be achieving this year as far as Eugia is concerned. You would agree with that, sir?

P.V. Ramprasad Reddy: Yes.

Moderator: Thank you. The next question is from the line of Nitin Agarwal from IDFC. Please go ahead.

Nitin Agarwal: Sir, you have talked a whole lot about our injectables business in the US. Where do we stand with respect to replicating? I presume that there would be an opportunity for this portfolio even in the non-US markets. So, how do we sort of look at that part sir?

P.V. Ramprasad Reddy: As on today, we are not much in the Europe and emerging markets. That is what we are going for China.

N. Govindarajan: The facility in the China has the capability to export to Europe and other markets. It will get inspected by those regulators. Currently Unit-IV is catering to the US market. Once china facility kicks in, the capacity will be available for selling in other markets.

Nitin Agarwal: And Govind, as qualitatively how big this Unit, the China one, when would that come through?

P.V. Ramprasad Reddy: Not so big. It will come through only by end of next year.

Nitin Agarwal: Lastly, on the emerging market, it is a reasonably size business now. How are we looking at this piece of the business in terms of growth prospects for this piece?

Sanjeev Dani: We are looking at about 15% growth on annualized basis and in terms of constant currency i.e. US dollar basis.

Moderator: Thank you. The next question is from the line of Tushar Manudhane from Motilal Oswal Financial Services. Please go ahead.

Tushar Manudhane: Sir, just on the other expenses excluding R&D has grown at a higher rate compared to the revenue. So any read through in that?

S Subramanian: The other expenses are a combination of fixed overhead as well as the variable overhead. Because the sales have been growing, etc.,. the variable part of the selling expenses, carriage outwards have gone up. But as a percentage if you really see, we are not so wide off.

Tushar Manudhane: So on absolute basis, this should be the kind of a run rate at least to go in?

S Subramanian: Yes

Tushar Manudhane: And this does not include any meaningful remediation related expenses?

S Subramanian: There are not much of remediation expenses to be shared. What we incur in the normal course, we continue to incur. To the best of that, there are no significant one-off expenses.

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

Nimish Mehta: I am referring to the Valsartan and Ranitidine issues. What I understand is that the real culprit is actually the NDMA impurity that is being used in this trial. So can you give us a sense of how many products contain these kinds of NDMA impurities and how many of them are remanufacturing for the US or for the regulated markets?

N. Govindarajan: We would like to clarify; all these impurities are brought under a large family of impurities called nitrosamine impurities. If you take an example of Valsartan, originally the focus started with NDEA, then it moved to NDMA and then it moved to three more. Depending on each process, the number of nitrosamine impurities can vary. It is not restricted to one or two. There are certain processes it can have five to seven nitrosamine impurities as well. As far as Ranitidine is concerned, you are right; it is only NDMA at this juncture. We have evaluated all our molecules in terms of all nitrosamine impurities. There are possibilities of nitrosamine impurities formulation in certain products based on some raw material and also the process in terms of it can add up to a nitrosamine impurity. We have already put in the checks and balances to the extent. We are talking about at the API level because most of this particular nitrosamine will always start from API only. It would get carried forward to the finished dosage. It is a rare occurrence and to the best of my knowledge it may not even happen in the finished dosage. So, we have evaluated all our products and to the extent of whatever 15-molecules of possibility are

there, we have already put the checks and balance, and we have tested all those molecules also to check the absence of those particular impurities.

Nimish Mehta: Once you have tested… I know it is not so exactly figured out, but how many of the products would be exposed to the nitrosamine impurities?

N. Govindarajan: Would like to reiterate and clarify that we have already tested and there are two sets of actions here -- One is evaluating the possibility where it can from. Based on the evaluation, our development group has come back with a possibility in around 15-products or so for which the additional checks and balances has been put in the process itself, not to allow this formation itself, and over and above that, all the products what we produce has been tested for nitrosamine. We have checked and we did not find any nitrosamine in all the products that we have checked, which was part of our CAPA action is as well.

Moderator: Thank you. The next question is from the line of C. Srihari from PCS Securities. Please go ahead.

C Srihari: Two questions in particular. Firstly, your branded Oncology business is now tracking at around $100 million p.a. So, if you could please give some kind of long-term perspective for this piece?

Swami S. Iyer: We estimated about $100 million and we are on track or we are doing slightly better. What we expect is as we go forward; we would probably add one or two products sometime in the medium to long term. But at this point of time, it is pretty stable as per our expectations.

C Srihari: Any possibility of giving let us say two to three years kind of a guidance, how big you expect this piece to be?

Swami S. Iyer: At this point, we would not like to say much about it because we are still in the stage of exploration on the various options that we have. All that we can say is we would definitely add couple of products. In fact, one of them would come with the Sandoz acquisition and then we would have one other product added sometime soon. So, apart from that, we are looking at all the options and we would like to inform at appropriate time.

C Srihari: The second one pertaining to product shortages. One of your competitors was very gung-ho about some major opportunities opening out. So, do you have anything like that either in the dosages or the API side?

N. Govindarajan: As far as shortage opportunities are concerned, whenever it happens, we would be able to grab it as long as it is in our portfolio is what we would say. Like, we are not commenting on specifics on what is currently there in the market.

C Srihari: Anything from let us say the products which have either discontinued or whatever which can get relaunched?

N. Govindarajan: We have not seen such opportunity at this juncture. If the opportunity happens, we will be able to take advantage of that.

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

Chirag Dagli: If I remember correctly 2Q FY'19, we had seen some benefit of pricing on sartans. And in the call you mentioned that now there are hardly any sartan sales except for Losartan. Is that understanding right that in the base quarter, there was significant price hike for sartans and now there is hardly any sale except for Losartan?

N. Govindarajan: That is true.

Chirag Dagli: The growth that we are seeing is despite that?

Swami S. Iyer: Correct.

Chirag Dagli: Can you split the total number between what is the amortization and depreciation? This run rate is what we should extrapolate for FY'21 or do you think FY'21 will increase meaningfully?

S Subramanian: I do not see because this increase is predominantly on account of the amortization of the intangibles which we have bought it for the Spectrum, and also there is a change in the lease accounting policy. I do not see anything significant new will come for the next year. Regarding, the ratio between the depreciation and amortization will be 75:25.

Swami S. Iyer: I would like to add from the US side. After the Sandoz, there could be some change. Obviously what Subbu is saying is without Sandoz and Sandoz is a large chunk of business. So, he is talking about the base business.

S Subramanian: Absolutely.

Chirag Dagli: Just on Sandoz, there is no change in guidance of what we acquired $900 million sales. And is there any change to the profitability numbers?

N. Govindarajan: So we are just maintaining whatever we have given as initial statement. We can answer any queries properly only after we get into it.

Moderator: Thank you. The next question is from the line of Dipan Mehta from Elixir Equities. Please go ahead.

Dipan Mehta: Sir, my question relates to US FDA inspection. What I wanted to understand from the management is that once the plant has been inspected by the US FDA and cleared say two years ago, or three years ago, then why within a relatively short period of time the same plant when it

is inspected again by US FDA has so many violations or non-compliances? Is it that the US FDA keeps changing its goalpost or is it that the company then tends to relax its own internal compliances because of which we get all these kind of noncompliance issues?

N. Govindarajan: First of all, I disagree in terms of the frequency of inspections are only related to some issue. Most of the inspections has gone without any major observations, but the frequency of inspections is in fact more. The reason the inspection frequency is more particularly in our case is because of the continuous filing. FDA has an obligation in terms of doing pre-approval inspection, which they will do it for a bunch of products; they will come and inspect it. So we would not say the whole process changed or anything is not a fair statement to make.

Dipan Mehta: Sir, my question is that handling US FDA inspection is a core function. And if you say the frequency of the inspection is almost 12-months or a little bit more than that. And if USFDA has already cleared one or most within a single plant, why again and again it should keep getting into an issue with USFDA because they have to point out violations. I do not understand it. Common sense is that if you got one manufacturing plant right, in terms of quality compliance, then it is a process, it is not an event. So you got the process right. Once you got the process right, then why should the US FDA point out so many flaws in your compliance methodology?

N. Govindarajan: I would like to clarify, when you are talking about the process, the process is related to certain manufacturing aspects or certain quality aspects which are standardized and most of the companies would have standardized it as well. And I am sure you would have gone through the observations of not only us, most of the companies are not related to the general GMP practice, it is more related to certain investigation or certain methods or certain other aspects of it. Every product will have its own set of process and every product will have its own set of aspects which are different. So to that extent, if out of specification happens or if there is a market compliant or if it is in terms of related to method or in terms of cleaning validation, it varies from each product-to-product. So I would not like to generalize a statement stating that, if you have learned from one product that means everything should be through is not how it can be viewed again.

Moderator: Thank you. The next question is from the line of Manthan Desai, retail investor. Please go ahead.

Manthan Desai: I would like to understand the cash flow generated from operating activities. So if I see the six months cash flow compared to the last previous financial year cash flow, the more cash flow has been generated. So, is there one-off kind of thing or something like that?

S Subramanian: We generated around $260 million net cash profit during this year. As you have seen that we have also spent around $106 million of CAPEX. So the net cash outflow of total including the working capital release of around $58 million, thereby generating a total cash surplus of around $201 million which is what the reduction in the debt.

Manthan Desai: Can I know what are the other financial assets in this cash flow because that is the major portion which has helped to generate the cash?

S. Subramanian: So what has happened is, \we reduced the coverage of the receivable purchase program because we were able to collect it better. Earlier, we have a certain percentage, now they have reduced the percentage significantly, because of that you can see that receivables had gone up, Otherwise, as per the accounting standards, this has been classified under the other financial assets, now that the coverage has been reduced, and we are showing it as part of the trade receivables. You can see that there is an increase of around Rs.700 - 800 crores in trade receivables.

Moderator: Thank you. The next question is from the line of Aditya Narayan, an individual investor. Please go ahead.

Aditya Narayan: Sir, my question is just in further of what Dipan was speaking about and it is not specific to the observations that we have had in the past but in general. Would it help if you had a team of consultants or a team of auditors who would look at all of your products and processes across geographies, would it help in reducing further observations or reducing the drug recall list in general?

N. Govindarajan: First of all, we have a strong internal audit team and we also engage consultants wherever we think it would really help us in terms of enhancing our knowledge and also improving our culture. But please understand the fact that if you are talking about recalls, each of them had a different reason or if you are talking about observations, it is not a same set of observations. So to that extent, we take help wherever need be, and it has also helped us in terms of improving our system, the standards and the culture as well. But we still need to further improve is what we would say.

Moderator: Thank you. Ladies and gentlemen, due to time constraints, that was the last question. I now hand the conference over to Mr. Krishna Kiran -- Investor Relations for closing comments.

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

Moderator: Thank you. On behalf of Aurobindo Pharma Limited that concludes this conference. Thank you for joining us and you may now disconnect your lines.