“Cadila Healthcare Limited Q4 FY-19 Post Results Conference Call”

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Moderator: Ladies and gentlemen, good day, and welcome to Q4 FY-19 Post Results Conference Call for Cadila Healthcare Limited. 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 * then 0 on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Ganesh Nayak – COO and Executive Director of Cadila Healthcare Limited. Thank you, and over to you, Mr. Nayak.

Ganesh Nayak: Good evening, and welcome to our post result teleconference for FY-19. We have with us Dr. Sharvil Patel – Managing Director; Mr. Nitin Parekh – Chief Financial Officer and Mr. Vishal Gor – Senior Vice President, Corporate Finance.

We started the financial year 2018-19 with the high base of 2017-18, which was created on account of a launch of a few high-value products in the U.S. market. Despite this, we were able to grow our top line, operating profit and net profit during the year, albeit at a slower pace. In terms of new product approvals from the US FDA, the year 18-19 was similar to the previous year as we received 74 new product approvals, includes our 14 tentative approvals after receiving 77 new product approvals in 17-18

Our new product approvals include the final approval for rivastigmine transdermal system, which is our first transdermal approval. We launched 43 new products in the U.S. during the year, which is the highest so far.

On the regulatory front, our oral solid dosage formulation manufacturing facility located in Ahmedabad SEZ, the injectable formulations manufacturing facility of Alidac Pharmaceuticals located, again, in Ahmedabad SEZ and the biologics manufacturing facility located at the Zydus Biotech park in Ahmedabad successfully completed the US FDA inspections during the year. We received the first approval from our Liva injectable facility with the receipt of the final approval of the supplemental ANDA by the US FDA during the year.

Our India formulations business, the second largest contributor to the top line, registered muted performance in the second half of the financial year as we undertook an initiative to rationalize our portfolio to have better focus, improved margin and supply chain efficiencies to control inventory, which resulted into some supply disruption and impacted the performance of the business.

In the consumer wellness space we expanded our portfolio by acquiring Heinz India Private Limited, which has 3 iconic brands, namely Glucon D, Nycil and Complan. All the 3 brands have a legacy of over 50 years, and Glucon D and Nycil are the market leaders in their respective categories.

The transaction is expected to strengthen our core business of food and nutrition, bolster the supply chain and provide ready infrastructure comprising of a strong distribution network of over 800 distributors and more than 20,000 wholesalers, covering 29 states.

With that, first of all, let me take you through the broad financial numbers:

During the fourth quarter of the financial year 2018-2019, on a consolidated basis, our total income from operations was up 15% year-on-year to Rs. 37.3 billion. On a Q-on-Q basis, the growth was 4%. Financial numbers for the quarter 4 include numbers of the Heinz business for 2 months. Excluding the Heinz business, the total income from operations grew by 7% year-on-year during the quarter. The EBITDA was down 6% year-on-year to Rs. 8 billion. On a quarter-on-quarter basis, the degrowth in EBITDA was 5%. The EBITDA margin for the quarter was 21.4% versus 23.5% reported in the last quarter. Profit before tax was down 18% year-on-year to Rs. 6.1 billion and on a quarter-on-quarter basis, the degrowth in PBT was 10%. Our net profit was down 22% year-on-year to Rs. 4.6 billion. On a quarter-on-quarter basis, the degrowth in net profit was 10%. The net profit margin for the quarter was 12.2% versus 14.3% reported in the last quarter.

Coming to the financial year 2018-2019, on a consolidated basis, our total income from operations was up 10% year-on-year to Rs. 131.7 billion. Excluding the Heinz business, the total income from operations grew by 8% year-on-year during the year.

Earnings before interest, depreciation and tax was up 4% year-on-year to Rs. 29.7 billion. The EBITDA margin for the year was 22.6% as against 23.8% registered last year. Profit before tax was up 2% year-on-year to Rs. 23.8 billion.

The net profit was up 4% year-on-year to Rs. 18.5 billion, and the net profit margin for the year was 14% as against 14.9% registered last year. Our consolidated debt at a gross level stood at Rs. 79 billion and debt net of cash stood at Rs. 70.2 billion. Our net debt equity ratio was 0.68 as at 31st of March, 2019.

So, let me share some of the highlights of the operations for the year:

In the U.S. generics markets, we launched the highest number of new products during the year with 43 new launches in FY-19. Key new products launched during the year are our own version of mesalamine 800 milligrams DR tablets, which is the generic version of Asacol HD; the authorized generic version of testosterone gel, a generic version of AndroGel; metoprolol succinate ER tablets, generic version of Toprol XL; lansoprazole DR OD tablets, generic version of Prevacid; and atorvastatin calcium tablets, which is the generic version of Lipitor.

New launches include Clobetasol Propionate ointment and Clobetasol Propionate spray, the first topical products launched from our own pipeline. We filed 29 additional ANDAs with the

US FDA, taking our accumulative filings to 360. We received approval for 74 ANDA inclusive of 14 tentative approvals during the year, taking the cumulative number of approvals to 254. These include the final approval for rivastigmine transdermal system, our first transdermal product approval.

Overall, our U.S. business posted sales of Rs. 62.8 billion, up 8% during the year.

On the India formulation front, apart from our initiative on the portfolio rationalization, we also undertook 2 more initiatives from October 2018 for an increase in field productivity, better management of the brands and success of new products.

We launched 53 new products, including line extensions in India during the year, of which 8 were First-in-India launches. Overall, our India formulations business posted sales of Rs. 35.3 billion, up 6%.

In the consumer wellness space, we continued to invest resources on various media and nonmedia initiatives to grow the existing portfolio of Sugar Free, EverYuth and Nutralite brands. Overall, our consumer wellness business posted sales of Rs. 8.1 billion, up 64% and a net profit of Rs. 1.7 billion, up 26%. Top line growth, excluding the impact of the Heinz acquisition, was 10% during the year.

On the animal healthcare front, we launched 8 new products in India and received 25 new marketing authorizations for our export business during the year. Overall, our Animal Health business posted sales of Rs. 5.1 billion, up 15%.

Coming to the emerging markets:

The Asia Pacific region, Latin America and South Africa registered robust growth during the year, while challenges in the macroeconomic and political environment persisted in the African region. In Brazil, we filed 3 new product dossiers and received approval for 4 new products while in Mexico, we filed 2 new product dossiers and received approval for 4 new products from the regulatory authorities of the respective countries during the year. We launched 11 new products in different countries of Asia Pacific region, 6 new products in different countries of Africa, 1 new product in Brazil and 4 new products in Mexico during the year. Overall, our emerging markets business posted sales of Rs. 8.3 billion, up 9%.

Coming to our JVs and alliances:

Injectable formulations manufacturing facility of Zydus Hospira, located in the Ahmedabad SEZ successfully completed the audits by the US FDA, MHRA and ANVISA during the year.

On the biosimilars front:

We initiated Phase-III clinical trials in India for 2 more products during the year. We submitted 16 new dossiers to the regulatory authorities of different countries of the emerging markets and received 11 product registrations during the year.

On the Novel Biologics front, we completed Phase-III clinical trials in India for Rabimabs during the year and submitted the marketing authorization application to the DCGI.

On the vaccines front:

We received the marketing authorization from the DCGI for 2 more vaccines during the year. We completed Phase-II and III clinical trials for one vaccine and initiated Phase-II and III clinical trials for one more vaccine during the year. We received our WHO prequalification for the purified chick embryo cell culture rabies vaccines during the year.

On the NCE front:

We completed Phase-II clinical trials of Desidustat in the non-dialysis dependent chronic kidney disease patients with Anemia. and announced Phase-III trials of Desidustat in the CKD-ND indication.

We entered into a collaborative research agreement with the Council of Scientific and Industrial Research, Institute of Microbial Technology to identify new drug candidates for the treatment of drug-resistant infections.

Earlier this month, the US FDA inspected our Moraiya formulations facility and issued 14 observations upon completion of the inspection. We have submitted our response along with the action plan for remediation. We are fully committed to resolve these observations at the earliest.

Thank you, and we will now start the Q&A session. Over to the coordinator for the Q&A.

Moderator: Thank you. We will now begin the question and answer session. The first question is from the line of Neha Manpuria from JPMorgan.

Neha Manpuria: My first question is on Moraiya. As you were addressing the observations outlined in the Form 483, would there be any supply disruption that we're expecting during remediation given the observations listed?

Sharvil Patel: No. Not for the midterm.

Neha Manpuria: So, you're not seeing any supply disruptions to implement, to address the concerns that the FDA has outlined?

Sharvil Patel: Well, we have already voluntarily recalled 3 products, which were high potent and which we will resume production once we are able to clear those. So, other than that, we don't expect any significant, any other major disruption.

Neha Manpuria: Okay. And this recall has taken place in the first quarter?

Sharvil Patel: No, it happened in this quarter.

Sharvil Patel: The first quarter.

Neha Manpuria: After the inspection.

Sharvil Patel: Yes.

Neha Manpuria: And my second question is as we look at the other facilities in our network, are there any facilities where we have pending Form 483 from the FDA?

Sharvil Patel: No.

Neha Manpuria: There are no facilities coming up for inspection?

Sharvil Patel: I don't know, but the major facilities like SEZ, Liva are recently audited.

Neha Manpuria: Okay, including all our international facilities, right?

Sharvil Patel: Nesher also was recently audited.

Neha Manpuria: And okay, fair enough. And my last question is on India. You have mentioned the entire process of rationalizing the portfolio, MR productivity would pick a couple of quarters. So, how far along are we in the process? And therefore, how should we look at growth for India in FY-20?

Sharvil Patel: So, I already said the majority of the impact has happened in the last 2 quarters. April onwards, I think we would see some recovery and our branded formulations business will come to 8% to 9% growth for the quarter. And going forward, we would see it coming into the low teens.

Neha Manpuria: And this would be a better profitability?

Sharvil Patel: Yes.

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

Prakash Agarwal: Sir, on the Heinz business, we have seen a good 10% growth Y-o-Y, so is it a function of stocking, or there has been a sales push? Or that's the number we should work forward?

Sharvil Patel: You are talking about ex-Heinz?

Prakash Agarwal: No, no, of the acquired portfolio of Heinz.

Sharvil Patel: So, of the acquired business of Heinz, since we acquired it at by the end of January till now, I think the season was delayed, actually. So, actually, the Feb, March numbers were subdued, April, May, June would be far better numbers because of the onset of summer which was delayed.

Prakash Agarwal: And what is the annualized number we should look at?

Sharvil Patel: That guidance we are not giving, but in terms of annualized number, we hope to grow by 8% to 10% on the business.

Prakash Agarwal: Yes, I just wanted the base of it on which we are expecting 8% to 10% growth?

Sharvil Patel: 1150.

Sharvil Patel: That was the base of acquiring that.

Prakash Agarwal: Understood. And secondly, again on the Heinz only, so on the balance sheet side, most of it, Rs. 40 billion has been part of goodwill and about 5 as intangibles. So, we are not taking any right off? Or we will just carry the goodwill going forward?

Nitin Parekh: So, if we look at the balance sheet, we have created about Rs. 3800 crore for goodwill and about 500 crore plus was for intangibles on brands. And we are going to test them for impairment. So, they are not going to be amortized in the books.

Prakash Agarwal: Okay. And lastly on the U.S. outlook, if you could share broad level kind of launches and approvals you are expecting?

Sharvil Patel: For the U.S. market?

Prakash Agarwal: Yes, sir.

Sharvil Patel: For the coming financial year FY-20, we are expecting around 35 approvals and between 35 to 40 launches.

Prakash Agarwal: Okay. And this is irrespective of Moraiya?

Sharvil Patel: This is without Moraiya.

Prakash Agarwal: This is without Moraiya? And if suppose Moraiya comes back then?

Sharvil Patel: Then we would see another 8 to 10 more launches.

Moderator: Thank you. The next question is from the line of Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: Sir, can you just say what is the revenue base of Sentynl Therapeutics for the full year, after the competition, what they would have seen?

Sharvil Patel: We're not giving individual numbers on Sentynl.

Surya Patra: Directionally said, what could be the dent on this?

Sharvil Patel: Sentynl, the business has gone down by almost 35%, because of the generic entry and that is stable now, and we might hope to gain a little bit more by tapping some of the distribution channel. But I think the business has taken us a dip because of the generic. But now, the market share is stable as of now. We have launched a new line extension. So, if the line extension does well, then we can see some market share gain back again.

Surya Patra: Okay. And with regards to Heinz again, any synergic benefit that we are likely to see here for our existing set of portfolio in the consumer business? Or what initiatives that we have already integrated, but if you can think what is our key goal plan for this integration and for the overall business if you can?

Sharvil Patel: So, there are a couple of synergies that we are looking at. On the distribution front, there is an immediate synergy by which individually both businesses are direct distribution of 2.2 lakh to 2.5 lakh coverage, which will with the combination increase we target to hit between 3.5 lakh to 4 lakh direct coverage. So, we can see at least almost a doubling of 40% to 50% between increase in distribution coverage, which will benefit both brands, in both portfolios of the business. The other is we do see some cost saving measures possible where we can see between Rs. 30 crore to Rs. 40 crores of savings in the next 12 months, which will again add to the profitability of the business. And more importantly now we should be able to see improvement on trade spends and sort of rationalization on trade spends and also on the distributed margins front. So, on the midterm side, we will see those kinds of synergies also coming through. And then lastly, also we are the largest city of marketing expense that we have, so we should be able to do the right thing for the required brands.

Surya Patra: Okay. Are you thinking also, sir, of expanding the portfolio, let's say, nutraceutical using the brand of Complan or something like that? Or anything of that sort is there in your mind or...

Sharvil Patel: We are going to do line extension. We are not going to launch any new brand, but we will definitely be doing line extensions for all of the iconic brands that we have.

Surya Patra: Of course, it is a similar brand but it is a different product, right?

Sharvil Patel: No, for example, in Complan, we will do better segmentation of different age groups from toddlers to teenagers and do those kind of line extensions. As we will also look at bringing in some more value-added products in that area. Similarly, in Glucon D and Nycil, we will look at line extension. But they will be in the similar categories, not in other different categories.

Surya Patra: Okay. And just last one, question on the domestic formulation business, again. See interestingly, you have said that you have launched around 53-odd products during last 1-year period, which is a significantly better than the general trend what it is visible for other peers. So, yes, I think the new launches when dried out significantly for many of the competitors and against that you have introduced so many. And simultaneously, you have also rationalized the field force and all that. So, here what is the kind of our process there? And are you trying to introduce relatively better valued product and discarding significant commodity-based product? And also setting some goals for productivity purpose or not something like what changes that you are witnessing here, sir? And what can ultimately achieve better profitable growth for your domestic formulations business?

Sharvil Patel: Over the last few years, business has definitely improved on profitability. The key area of focus for Zydus is going to be productivity, as we've said. So, with the mindset of productivity, we are looking to improve profitability and sales. The other aspects of new product launches, we have new super specialty business, which is constituted of biologic vaccines and those therapeutic areas of renal sciences and hepatology. So, that is where a lot of new introductions have happened. And also similarly some line extensions were important brands in the core pharmaceuticals, in the India formulations business as well.

Surya Patra: Okay. Just can you continue with this kind of new launches in the domestic research, is it possible?

Sharvil Patel: We can because we do have the R&D engine to do that. But we would be having, we would definitely be not launching 50 to 55, but at least between 30 to 40 new launches.

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

Anubhav Aggarwal: One question on the U.S. sales outlook, actually. You mentioned about 35 new launches, Sharvil sir, do you think you can maintain this year $900 million base or grow on top of this next year?

Sharvil Patel: For this year we would definitely be able to maintain the base of the current year for the generics business in the U.S.

Anubhav Aggarwal: Yes, so $900 million kind of net we can expect in FY-20 as well?

Sharvil Patel: So, $900 million includes the branded business.

Anubhav Aggarwal: Brand you include what? You include the Sentyn product?

Sharvil Patel: Yes. It includes the Sentynl business as well. For the generic business, we will grow in low single digits this year.

Anubhav Aggarwal: Low single digits. Okay. And just a clarity, when you mentioned Sentynl sales are down 35%, are you talking about the current run rate of down, so that when you started the year quarterly, sales are down from Q1 to Q4 exit are down 35% or the full year sales are down 35%?

Sharvil Patel: Q1 to Q4.

Anubhav Aggarwal: So, it's exit because the reason I was asking was because IMS shows that the new generic company has taken 50% share at the IMS level, that's why I was thinking that when we say 35%, maybe the IMS numbers or the market shares are not right?

Vishal Gor: So, one correction, Anubhav, it's 25% Q-o-Q, not 35%.

Anubhav Aggarwal: 25% Q-o-Q? But Vishal, the competition came in third quarter for us. So, let's say when you compare 2Q to 4Q, that would be the best comparison?

Vishal Gor: That is the number which I don’t share, I don't have that number right now.

Anubhav Aggarwal: And when we see 25% to, let's say, 25% in fact, so the prices for us has not changed all. So, it is all impact on the volume side?

Sharvil Patel: Well, it's a mix of both price and volume, but the larger part is volume.

Anubhav Aggarwal: Okay. So, then certainly the IMS numbers are not correct, which shows 50% share impact is much less.

Sharvil Patel: Yes.

Anubhav Aggarwal: And the impact on the other side, the mesalamine 1200 one, is that large part of the price and the volume impact from Mylan launch has come in this quarter already?

Sharvil Patel: Yes, mesalamine 1.2 is now not a sort of significant contributor to the overall business, for the quarter 4.

Anubhav Aggarwal: Again, so you would say that now your share has stabilized with the new generic coming.

Sharvil Patel: Yes, it is stable and it's only, it's not even, it's a small percentage of the overall revenue.

Anubhav Aggarwal: Okay. And just one question on the other expenses. Now other expenses in this quarter expanded descent actually, part of it could be understood by the Zydus Wellness for the Heinz acquisition. But for the core business also, the other expenses were up, what would drive that, is that a year-ended phenomena or there was some one-off expense in this quarter?

Vishal Gor: So, Anubhav, obviously one reason is inclusion of Heinz. And as Dr. Sharvil Patel mentioned, quarter 4 is the main season for Heinz business. So, obviously, the expenditure on the marketing and promotion was also high. Apart from that ex-Heinz business, the other expenses have gone up Q-on-Q by about Rs. 30 crore to Rs. 35 crore. That is largely because of certain one-off expenditures, mainly political donation of about Rs. 15 crore to Rs. 17 crore and a onetime entry tax related to fees which we have paid in the state of West Bengal. Excluding them, the other expenses were largely in line with the last quarter.

Anubhav Aggarwal: When you say entry tax in the state of West Bengal, what does it mean for the India formulation business?

Nitin Parekh: That was an old matter which was pending, and that was the case for so many companies. So, West Bengal state actually came out with some scheme to go for a settlement. You don't have to pay any interest or penalty. So, we opted for that route and paid the old pending dues of about Rs. 12 crore, Rs. 13 crore.

Sharvil Patel: I think all companies have done that.

Nitin Parekh: Yes, many companies have done that.

Anubhav Aggarwal: So, these 2 accounts were Rs. 30 crores of that line of expenses.

Nitin Parekh: Yes.

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

Tushar Manudhane: Sir, just a clarity on Moraiya. You referred that supply disruption would not be there for the near-term. So, is that to do with because of the inventory in the system?

Sharvil Patel: So, yes, we do have inventory. And so that inventory does take care of some of the existing business and we have resumed the manufacturing for some of the affected areas. So, we do not see any significant issue of supply for the next, I mean, for the whole year.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: Sharvil, when you were talking about the U.S. business outlook, is it possible for you to help us with some of the pluses and minuses when you expect the generic business to be up in single-digit you mentioned?

Sharvil Patel: So, new products and lower price erosion in existing products, which we've only seen a price erosion of about 2% to 2.5%. So, assuming that the price erosion is stable on that side and it is the launches between 30 to 35 new products that we are launching and the last year's base of new products that we have launched. Earlier, we were thinking of a larger growth, but because of the Moraiya issue, we are assuming a single-digit growth for the generic business.

Sameer Baisiwala: Okay. And when we annualize the impact of Lialda because, in this case it was only for one quarter.

Sharvil Patel: Lialda and combined is only about 6%, 7% of our overall revenue.

Sameer Baisiwala: For Q4?

Sharvil Patel: Annual revenue, annual.

Sameer Baisiwala: So, Sharvil, when you think about new launches in fiscal '20, are there any niche, high-quality, larger products over there?

Sharvil Patel: So, yes. Of the 35 to 40 launches that we might be able to do, at least there are 4 to 6 products which are decent sized and then another 6-odd product which are midsized. So, we do still have a portfolio of about 10, 12 products which have decent value in terms of opportunity.

Sameer Baisiwala: Okay. Sharvil, and just one on overall business, what's the outlook for margins for fiscal '20 versus fiscal '19?

Sharvil Patel: Our Q4 margins still hold true for current year. It's about 21.4%.

Sameer Baisiwala: Okay. Which is a bit lower than your full year, which is 22.6%.

Sharvil Patel: Yes, correct.

Sameer Baisiwala: Okay. And one final question, if I may. How is net debt going to move going forward a year or 2 years out?

Nitin Parekh: So, net debt-to-EBITDA this year was about 2.36. Earlier, we were expecting it to go down to about 2.1-2.2. Even after Moraiya thing we expect that it should go down from the current level, though it may not reach up to 2 or 2.1.

Moderator: Thank you. The next question is from the line of Saion Mukherjee from Nomura Securities. Please go ahead.

Saion Mukherjee: Sir, on the brands which are discontinued in India, can you quantify the revenues, let's say, in terms of in fiscal '18? I want to know how large is that potentially?

Sharvil Patel: So, they were all the tail end brands that were discontinued. So, we discontinued almost, I think, 158 SKUs. I don't have the exact value of the discontinued because there were two issues, one is discontinuing of sale and then return of goods. So, I think Vishal can then collect that and get it to you.

Saion Mukherjee: Okay. And also in the U.S., the 3 products, which I understand you have discontinued for the Moraiya facility, how large is the impact and how big are those 3 products?

Sharvil Patel: So, we have not discontinued these products. We have recalled these products. And once we resume manufacturing, we will bring them back to the market, but they were not very significant in the overall revenue of products.

Saion Mukherjee: Sir, you mentioned about 6% to 7% of overall revenues is Lialda, right, for U.S.?

Sharvil Patel: Yes.

Saion Mukherjee: For FY '19. Sir, is it possible to share Asacol HD also there?

Sharvil Patel: No.

Saion Mukherjee: Because that would be the largest…?

Sharvil Patel: Yes. Asacol is an important product for us. We believe there is no competition for the foreseeable future. I don't think we'll be able to give out individual value for that product.

Moderator: Thank you. The next question is from the line of Kunal Mehta from Vallum Capital. Please go ahead.

Kunal Mehta: Yes. So, we have guided for around maintaining the U.S. revenues at the same level of around $900 million. So, can you just give us an understanding of what could be the average in terms of the new launches, what would be average size we could take for those launches? Because you would have seen some good erosion in the Sentynl product portfolio and some of the other products which we have where we are gaining meaningful revenues.

Sharvil Patel: Yes. As I said, for the new product launches, first, the overall generic business of U.S. is not $900 million. It includes Sentynl. We said that we would see some growth in the generic business, but in Sentynl there would be a de-growth. For the new product launches, of the 35 to 40 new products that we will launch in FY-20, about 10 to 12 of those products are high-value products for us, which will drive significant value. And then depending on the opportunity size, the other products will become relevant. So, it's very difficult to predict the sale of each product and give you an average value, but of the portfolio, about 12 to 13 are high-value products.

Kunal Mehta: Sure. The second question I had was that in terms of the outlook for FY-20, how would you look at it? Because assuming that, just because looking at the 483, assuming the rest of the inquiries are related to contamination, this has some potential to escalate to a OAI too considering what is happening with the other players. So, assuming worst case, if we do reach that status, just playing devil's advocate, how would we look at FY-20 considering that I could continue my ability to get new approvals from the Moraiya site?

Sharvil Patel: Currently, what I mentioned to you about the approvals was without Moraiya approvals, if Moraiya approvals continue as, once we have responded to the FDA and it finds that response suitable, and if so then the Moraiya approvals will be on top of these approvals.

Kunal Mehta: Sure. And the final question I had was any updates would you like to give on the number of launches in the transdermal pipeline?

Sharvil Patel: We have launched one, which is rivastigmine. And the future launches will be in the coming FY-21.

Kunal Mehta: Okay. So, this year we do not see any major launches on transdermal side?

Sharvil Patel: Yes.

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

Nitin Agarwal: Sir, on Q4, on exit quarter basis, would AndroGel be a reasonable product in this quarter, a reasonably sized contributor?

Sharvil Patel: In which quarter?

Nitin Agarwal: In the Q4, just the ended quarter, Q4 quarter.

Sharvil Patel: Yes.

Nitin Agarwal: And that, I guess, should reduce dramatically now going forward as multiple players have come through post exclusivity expiry?

Sharvil Patel: Yes.

Nitin Agarwal: Okay. And secondly on just to sort of confirm that, we will not be taking any impairment of either the intangibles or the goodwill that is there because of the Heinz acquisition?

Nitin Parekh: No. So, we will not be amortizing them in the consolidated financial. They will be tested for impairment every year.

Nitin Agarwal: Both intangibles and goodwill?

Nitin Parekh: Yes.

Nitin Agarwal: Barring any impairment, there will not be any meaningful charge of amortization that will arise because of the transaction on the consolidated books?

Nitin Parekh: Yes, that's correct.

Nitin Agarwal: And just secondly, what would be our average cost of debt now on that gross debt that we carry?

Nitin Parekh: About 3.7%, yes.

Nitin Agarwal: Okay. And then lastly, on the emerging market piece, how should we look at this piece? We have talked a lot about in the past in terms of the biologics and the vaccine business driving growth in that portfolio. When do you see a real meaningful pickup in growth in this segment of the business?

Ganesh Nayak: Yes. Answering the question which you have raised just now from the emerging markets, see, keeping the biologics aside for a moment, on the existing one, we had some challenges in the African market, mainly in Sudan. But I think in terms of a base, we have gotten over it. So, we, in this year, FY-20, should be expecting growth in the mid teens. And on the biologics, we have got our registrations in 5 or 6 countries, which should start monetizing by the end of this calendar year. So, most of it, we will start seeing in FY-21.

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

Prakash Agarwal: Just one clarification on the gross margin side. Is there any impact of recalls and especially for the sartans and also the client claims?

Sharvil Patel: We don't have any recall of sartans. So, there and there are no gross margin impact because of that of that, or any other reason.

Prakash Agarwal: Okay. There is no one-off in the gross margin, right?

Sharvil Patel: No.

Prakash Agarwal: Okay. And secondly, just to understand the ramp-up in the transdermals, so we got approval in March. How is the journey been and how do we expect in '20?

Sharvil Patel: So, we have gained certain market share and now with the more supply, we are trying to double our market share into the market. So, we would be at a healthy market share. Generally, a good market share is between 15% to 20%, and we will hope that we will be able to achieve that kind of share.

Prakash Agarwal: So, would it be fair to assume that this would be one of the key products which would help in offsetting the declines seen, that would be seen in Lialda and AndroGel also?

Sharvil Patel: So, Lialda, already the decline is already built in. So, I don't think there will be any further decline. And this is one other product which is not the most important product. It is not in the coming launches.

Prakash Agarwal: Understood. And since you said Lialda already declined, my understanding was there are a couple of more players who have been approved and not in the market. Do you not envisage more competition and more erosion of market share and pricing?

Sharvil Patel: As I said Lialda is not significant now in terms of the overall value to the overall size of the generics business. So, I think even with additional competition, we don't see any further significant downside which we cannot mitigate for Lialda. They are already built in our projection for the competition.

Prakash Agarwal: Okay. And on the R&D side, if you could just break up your current spend that you plan for 2020, in terms of generics and the biosimilar programs and vaccines, what is your ballpark spend?

Sharvil Patel: So, the largest is in the generics U.S. R&D piece. The exact break up, I think, I will request Vishal if he can provide it to you, but a large part of the spend is driven towards generics.

Vishal Gor: Certainly. In 18-19, out of 7.2%, about 6% was for generic product development.

Prakash Agarwal: Okay. And that share could continue for 2020 also?

Vishal Gor: More or less, when we talk of 7% to 8% total R&D spend, it would be in that range only. It won't be a material change in the composition.

Moderator: Thank you. The next question is from the line of Rahul Sharma from Karvy Stock Broking. Please go ahead

Rahul Sharma: Just one. If you take us, what were the key reasons for Q-on-Q decline in U.S. business despite rivastigmine and Tamiflu having good season?

Sharvil Patel: The largest is Lialda and levorphanol, levorphanol is a branded business and Lialda is a generic, which we have better margins earlier.

Rahul Sharma: Do you think that this could be the base, okay, probably you will have to factor in AndroGel and then probably in this quarter?

Sharvil Patel: Yes.

Moderator: Thank you. The next question is from the line of Harith Mohammed from Spark Capital. Please go ahead.

Harith Mohammed: On your vaccines business, can you talk about how much capital you have deployed in this business till date, both for creating capacities and on the R&D side? And your revenue target of 200 million to 250 million for this business in 4 to 5 years, how much of this will be from UNICEF tenders versus branded business in domestic and emerging markets?

Sharvil Patel: So, the capital so far that we have spent on plant and machinery and all of that is about Rs. 150 crores for the vaccine. In terms of R&D revenue, Rs. 20 more crores if you want to add to that, about Rs. 170 crores. But we don't capitalize R&D, so that's why it doesn't makes sense to show you and it's not part of the capital expenditure. And in terms of the projection going forward, we would participate. The rabies will be an important product for the initial few years because we are WHO pre-qualified for rabies and there's a huge shortage in the market and we are ramping up our capacity. So, that should become a significant product for the next 2 years. Also, some of our launches, which are, again, very limited competition like the typhoid conjugate vaccine, the influenza vaccine and coming forward and coming with which is the varicella vaccine is going to be important from the private market point of view. So, we will

build this business in India on the private market side. We have already a commercial team which has already started selling this. So, once we ramp up our capacity this year, you will see a significant trajectory towards that. So, I would say large part of our business currently is planned on partnerships and on private market vaccine and also participating in the Indian government tenders. And then there be whole part of participating in the WHO prequalification will happen once we are prequalified in the next 12 to 18 months. And then, I would assume a good part of revenue will then get started getting registered from the UNICEF tenders, but that is still about 2 to 3 years away.

Harith Mohammed: So, would that be a major contributor to the 200 million-250 million target that you have?

Sharvil Patel: It would be an important contributor, but not very significant because we have not built a very large projection on that yet because we are still prequalified.

Harith Mohammed: All right. On the saroglitazar trials for NASH, can you confirm the time lines for completion of Phase-III in India and the Phase-II in the U.S.? And then post-Phase-II in the U.S., will you be looking for partners to take this molecule forward into Phase-III?

Sharvil Patel: For Saroglitazar, one of the Phase-IIIs is completed in India. The majority of the Phase-II and Phase-III readouts for U.S. and India will come out in quarter 3 of this financial year. And that will be a significant milestone for the company because our trials are in important indications of NASH and PBC in U.S. and type 2 diabetes in India and also trials in Mexico. So, we would have 3 country trials getting released by quarter 3 of this financial year, which would be an important milestone for the Saroglitazar program.

Harith Mohammed: You also had a NASH trial in India, right? Phase-III trial?

Sharvil Patel: Yes. So, a NASH trial in India, NASH trial in the U.S., PBC trial in the U.S. and Mexico, NASH also in Mexico and the diabetes type 2 trials we just finished also in India. So, we will have at least 3 to 4 important clinical trial outcomes.

Harith Mohammed: And then lastly, what's the kind of spending for a Phase-III for this kind of a molecule in the U.S.? And would you be looking for a partner?

Sharvil Patel: It's very early to say that. We have to wait for our Phase-II data and then make the right recommendations later. So, until we release our Phase-II data, I think it will be too early for me to plan and explain the Phase-III because, as we all said, we are in consultation with the US FDA. Our Phase-II data, I will also say, is very meaningful because it's a large patient population. Recently, there are some trials that showed 10 patient data and all our trial sizes are at least significantly higher, 200 to 300 patients, in diabetes, 1,000 plus patients. So, I mean, that is pretty large for Phase-II. So, Phase-III is very early to predict because we don't have that data. We'll first go to the FDA to discuss this.

Moderator: Thank you. The next question is from the line of Neha Manpuria from JPMorgan. Please go ahead.

Neha Manpuria: Sir, on the India business, given we are talking about portfolio rationalization and cutting tail end brands, why do we continue to have such high number of launches given you want to focus on making your new launches more successful, creating mega brands? I'm just not able to put both of them in context.

Sharvil Patel: See, we have, depending on the specialty, supposedly we have 33 business units. Even if I just do one line extension of one brand, I would be launching at least 30 to 35. So, I don't think there is a very large number of launches and according to each product line extension or a new molecule like in cardiovascular and diabetes, in areas of nephrology, also we have been able to license in some products. So, as the whole biologics portfolio and vaccines where we will launch at least 2 biologics and at least 3 vaccines. So, I don't think these are significantly a large amount of launches. Of the size and scale of our business, we could have much significantly more launches. But we have definitely rationalized the last, I would say, 7, 8 years of launches, which some of them have not worked.

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

Anubhav Aggarwal: On Moraiya facility, just one data point. How many of our pending ANDAs are from Moraiya?

Sharvil Patel: 31.

Anubhav Aggarwal: 31. And on levorphanol, the question was that how many reps are promoting this product right now?

Sharvil Patel: 30.

Anubhav Aggarwal: 30. And in case if, let's say if a bad scenario comes that we are not able to really ramp up the 3 mg product, then what point you think that this product does not require promotions anymore?

Sharvil Patel: We will take that call, that is the right question. If we do not see significant traction on prescription, then we will take that call, if we don't have any other new product to launch. But we are also at the same place working on being able to commercialize more product. So, if that happens, we will continue. Otherwise, we will downsize if the sales goes below certain threshold.

Anubhav Aggarwal: I mean, we don't have any 505(b)(2) products similar in the portfolio. So, you may be looking to acquire one more similar kind of product.

Sharvil Patel: Licensing. We are looking to licensing and we have active discussion for licensing also. And we do have our own portfolio, but it is a little at least a year or throughout.

Moderator: Thank you. The next question is from the line of Kunal Mehta from Vallum Capital. Please go ahead.

Kunal Mehta: Sir, what would be the capital intensity for the next 2 years, I mean, in terms of the CAPEX?

Nitin Parekh: Rs. 800 crores.

Kunal Mehta: Okay. For each of the next 2 years?

Nitin Parekh: Annually.

Moderator: As there are no further questions, I would now like to hand the conference over to Mr. Ganesh Nayak for closing comments.

Ganesh Nayak: Thank you very much. I look forward to interacting with you again in the month of August for the next quarter results. Thank you and good night.

Moderator: Thank you. On behalf of Cadila Healthcare Limited, we conclude this conference. Thank you for joining us. And you may now disconnect your lines.