“Cadila Healthcare Limited Q2 FY22 Post Results Conference Call”

October 29, 2021

MANAGEMENT: **DR. SHARVIL PATEL – MANAGING DIRECTOR, CADILA HEALTHCARE LTD**
MR. GANESH NAYAK – EXECUTIVE DIRECTOR, CADILA HEALTHCARE LTD
MR. NITIN PAREKH – CHIEF FINANCIAL OFFICER, CADILA HEALTHCARE LTD
MR. VISHAL GOR – SENIOR VICE PRESIDENT (CORPORATE FINANCE), CADILA HEALTHCARE LTD

Moderator: Ladies and gentlemen, good day and welcome to the Cadila Healthcare Limited Q2 FY22 post results conference call. As a reminder, all participants' lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference, 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. Ganesh Nayak – Executive Director, Cadila Healthcare. Thank you and over to you sir.

Ganesh Nayak: Good evening, ladies and gentlemen, welcome to our post results teleconference for the quarter ended September 30, 2021. I do wish that you and your family members are keeping safe and well. For today's call, we have with us Dr. Sharvil Patel – Managing Director, Mr. Nitin Parekh – Chief Financial Officer and Mr. Vishal Gor – Senior Vice President (Corporate Finance).

I am sure you would have gone through the quarterly results investor presentation which we have posted on our website and filed with the stock exchanges. The quarter gone by was a promising one for our India geography as it continued to build on the momentum and recorded a double-digit growth during the quarter. In fact, both human formulations business and consumer wellness business in the India geography grew in double digits during the quarter. On the human formulation front, amidst the receding impact of the pandemic, the growth was driven by key existing brands and new products which were launched during the last few quarters. On the back of improving consumption, the consumer wellness business grew during the quarter and continued to unlock the operational efficiency with strong on-ground execution despite challenging economic conditions. Overall, the India geography which contributed 43% to the consolidated revenues during the quarter posted a growth of 12% on a year-on-year basis and registered sales of Rs. 15.9 billion.

With that let me take you through the financial numbers for the quarter gone by. During the quarter, we posted a consolidated revenue of Rs. 37.8 billion up 3% year-on-year. Consolidated EBITDA improved during the quarter and stood at Rs. 8.6 billion up 6% year-on-year. Reported EBITDA margins for the quarter stood at 22.7% which is an improvement of 50 basis points on a year-on-year basis. We made a one-time inventory provision for COVID related products during the quarter. Excluding the impact of this provision, EBITDA margins for the quarter were at 23.8%. EBITDA margins improved despite a year-on-year decline in the US revenues as business in India and the emerging markets performing well and in turn drove the overall margin improvement. Adjusted for certain exceptional items and one-off gain on the account of sale of our animal health business, the consolidated PAT for the quarter stood at Rs. 6 billion up 6% on a year-on-year basis. Our net debt as on the 30th of September 2021 came down to Rs. 4 billion from Rs. 35 billion as on the 31st of March 2021 and as a result, our net debt to EBITDA ratio also came down to 0.12 times as on the 30th of September 2021 from 1.1 time as on 31st of March 2021.

Now let me take you through the operating highlights for the second quarter of FY22 for each of our business lines. Starting with our human health business in the India geography, overall, our human health formulations business recorded sales of Rs. 12.1 billion during Q2 FY22 up 12% on a year-on-year basis. Excluding the institutional sales of COVID products, the growth actually was 17% which was driven by strong volume growth and new product launches. We gained market share in our core therapies of antidiabetic and cardiovascular therapeutic areas during the quarter on a y-o-y basis.

In the digital space, we have made significant investments towards the adoption and implementation of digital tools and practices to reach out and connect with our doctor community and patients and we have better equipped our field people in their daily working.

Going forward with the recovery in the pharma market and normalization of the health care delivery infrastructure, growth will be driven by focus on key brands identified to fuel future growth. As I mentioned earlier, our consumer wellness business, despite challenging economic environment, also registered a double-digit growth during the quarter. Overall, the business posted revenues of Rs. 3.8 billion with a growth of 13% during the quarter. On the brands front, Complan, Everyuth and Nutralite registered a double-digit growth during the quarter. Nycil and Glucon-D also performed well and continued to lead in their respective categories despite low season and high channel inventory.

Now, let me take you through the performance of our US formulation business. The US geography comprising of generics and the speciality portfolio posted sales of Rs 15 billion during the quarter up 3% quarter-on-quarter. The business saw a growth in revenues over the preceding quarter despite heightened competition and a tough pricing scenario. Overall, volumes grew during the quarter despite reduction in the volumes of our mesalamine products as there was a gain in the volume of other existing products and new launches. We launched three new products during the quarter including a complex injectable namely, Enoxaparin Sodium Injection, which is an in-licensed product. This is the first generic launch of this product by an Indian player which reinforces that our efforts of in-licensing of complex products have started yielding results. Enoxaparin Sodium Injection is the second in-licensed complex injectable product after Fondaparinux. Though supply issues in the US have dwindled leaving limited one-time opportunities, we will continue to prioritize products and maintain safety stock of key products to be able to take advantage of opportunities arising in the market. On the emerging market front our business has witnessed a strong growth of 48% on a year-on-year basis and posted sales of Rs. 3.5 billion. On a sequential basis, the business grew by 26% during the quarter.

As mentioned during the last quarter's earnings call, we have undertaken many initiatives aimed at enhancing operational efficiencies to drive improvement in operating margins. One such initiative is the zero-based budgeting approach for human health formulations business in India. As a part of this initiative, we have identified multiple levers across the entire value chain of the

business which are in the process of getting implemented. We expect the benefits to accrue from the next calendar year. Another such initiative is being implemented in the manufacturing operations which aims at using advanced digital and analytics tools to enhance compliance and efficiency through simplification. Potential areas for improvement are being identified across work streams, SOPs are being simplified and various digital tools are being designed for digital performance management. The implementation of this initiative will be spread over the course of the next year. Both these initiatives put together are expected to improve our overall operating margins by 80 to 100 basis points.

This concludes the business review. I will now request Dr. Sharvil Patel to take you through the progress and initiatives in our innovation program. Thank you.

Sharvil Patel: Thank you, Dr. Nayak and good evening, ladies and gentlemen. As you all know, we have received the emergency use approval from the Drug Control General of India (DCGI) for COVID-19 vaccine candidate ZyCoV-D during the quarter. It is the first ever plasmid DNA vaccine for human use approved anywhere in the world. The plug-and-play technology being offered by DNA based platforms will help in rapidly adapting the vaccine in case of any future mutations to the virus. In fact, we have already developed the DNA vaccine candidates for the Alpha, Beta, Kappa Delta, Delta Plus and Lambda variant and established process for the same as well in a very short period of time, which will provide a flexibility in programmatic implementation to switch to newer vaccine candidates based on new variants and thereby will provide faster control over the pandemic. This will be difficult in case of vector-based vaccines due to anti-vector immunity and also in case of inactivated viral vaccines. As the subject for the phase III clinical trials also included adolescents in the age group of 12 to 18 years, ZyCoV-D is also the first approved vaccine for adolescents in this age group in India. The results of the phase one clinical trial for ZyCoV-D have been published in the E-Clinical medical journals of Lancet and we have already submitted for phase three clinical trial data for the ZyCoV-D for publication.

Recently in the month of September, we have entered into an agreement with Shilpa Medical Limited for production and supply of drug substance of ZyCoV-D vaccine from its manufacturing facility. Production volumes of the vaccine from this facility will be mutually agreed upon by both parties. This will help us augment the capacity for the vaccine. In order to offer therapeutic solutions for COVID-19, we have developed a novel biotherapeutic cocktail of monoclonal antibodies targeted at treating COVID-19 patients having mild symptoms. Phase I/II clinical trials of this molecule were initiated during the quarter.

On the NCE front, we have initiated enrollment of patients for the EVIDENCES-X, a global pivotal phase two B clinical trial of Saroglitazar Magnesium to evaluate the efficacy and safety of the molecule in subjects with non-alcoholic steatohepatitis and fibrosis indications. Recently, in the month of October, the first patient was randomized into the phase two B prospective multicenter randomized double blinded placebo controlled clinical trial. 40 sites have been

identified in the US and 10 sites have been identified in Argentina for this study. The positive results from the phase two A global clinical trial evaluating Saroglitazar Magnesium in patients with NASH were published in October 2021 issue of a peer reviewed medical journal "Hepatology" with a very high impact factor. The study of Saroglitazar for post-transplant metabolic syndrome, which is PTMS in the US reached the targeted number of 15 patients out of which 10 patients have completed the study. The interim results of the study have demonstrated significant reduction in lipid levels and no effect on immunosuppressive drugs and the S-creatine in these patients. This paves way forward for Saroglitazar for additional indications as we build the molecule.

For our anti-malarial compound ZYI19489, LANCET has accepted our Single Ascending Dose (SAD) study which was conducted in Australia. In India, the DCGI has approved the Single Ascending Dose (SAD) study and the Multiple Ascending Dose (MAD) study of the molecule. The first cohort of the single ascending dose study has already been completed. With regards to our efforts on the biosimilars, we have submitted an application to DCGI to initiate phase three clinical trial for one more monoclonal antibody treatment during the quarter. On the global development front, we initiated development of two biosimilars during the quarter.

Talking about our 505(b)(2) and specialty initiatives, recently in the month of October, our wholly owned subsidiary company Sentynl Therapeutics and its licensing partner Cyprium Therapeutic, announced positive results from an efficacy and safety analysis of data integrated from two complete pivotal studies in patients with Menkes disease treated with Copper Histidinate product CUTX-101. In both pre-specified primary and secondary efficacy analysis, the treatment with CUTX-101 demonstrated a significantly greater median overall survival compared to untreated historical controlled patients. The rolling submission of an NDA for CUTX-101 is expected to begin from the current quarter.

Coming to the pipeline of 505(b)(2) products. We received a tentative approval from the USFDA for a new drug application for Sitagliptin base tablets. Tentative approval was granted upon completion of the first cycle review by the USFDA. We have also submitted an IND application for a pain management product during the quarter and the NDA for this product is expected to be filed by the end of the current financial year.

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

Moderator: Thank you. Ladies and gentlemen, we will now begin the question-and-answer session. The first question is from the line of Harith Ahamed from Spark Capital. Please go ahead.

Harith Ahamed: The first one is on the profit of over 100 crores that we have booked for the quarter related to sale of brands by one of our subsidiaries Zydus Healthcare. So, how much is the sales from these divested brands? And will you be able to provide some more color on the rationale for this divestment?

Sharvil Patel: The rationale for the divestment is these were OTH brands and they were not prescription-oriented brands in our current portfolio and in terms of our priority of coverage of the molecules this was not in the top five, so we looked at divesting it at an appropriate time and we found a suitable partner who wanted to take this product ahead for further developments.

Harith Ahamed: S, these were contributing how much to our domestic formulations business?

Sharvil Patel: 30 to 35 crores.

Harith Ahamed: On CUTX-101, we have announced results from the pivotal trials and based on the positive data when can we expect our rolling submission to commence? If you can provide some color on the opportunity size here in Menkes disease for this product?

Sharvil Patel: The rolling submission will begin in this quarter, as we said. And this has been designated as an orphan drug and has got a priority review. So, we believe that there is a possibility that by end of calendar year CY22 we can see the approval or otherwise latest by first quarter of calendar year 2023. And this is a unique product where we are talking about increasing the life expectancy for children who suffer from this disease. The opportunity is very good from our business case point of view where we can see a strong EBITDA movement starting almost from the first year and breakeven also in the first year of launch.

Harith Ahamed: Last one from my side. On Saroglitazar phase two B trials which we have recently commenced for NASH indication, just trying to understand the timelines around this. And given that this appears to be a fairly large trial, will we be able to go into a submission to the FDA with the phase two B data or will it require a larger phase three trials before we get into a filing stage?

Sharvil Patel: There are two trials where it is Saroglitazar which are in advanced stages. One is for PBC indication which we are starting and that we believe we can see a filing by 2023, calendar year middle or end of 2023. And for the NASH indication, it is a longer trial. It's an adaptive phase two B three trial, and that we are looking at a 26-27 kind of filing.

Moderator: We will take our next question from the line of from Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: On the vaccine side wanted some clarity. the delay in the vaccination or supply of the COVID vaccine, how should we see this, whether it is the price negotiation only which is getting delayed, or it is debate over below 18 children or not?

Sharvil Patel: Related to the ZyCoV-D vaccine, as I said, we have commenced our scaled-up manufacturing from our new facility from the month of October, we already have an approval by the DCGI as an emergency use for the ages of 12 and above. But for the government immunization program it has to go through the committee for immunization approval. So that is in progress. Also, the pricing has been a discussion point, which is come closer to an alignment, and we hope that in

the next few weeks we can see that clarity coming, which we will immediately update everyone as soon as it comes. But we are hopeful and positive that we should see some clarity in the next 1-2 weeks.

Surya Patra: Okay. But it is not the debate over whether to start the vaccination of the children, that is not the case, right?

Sharvil Patel: No, it's not. For an immunization program in the government, they need to go through the approval beyond the regulators also and they need to decide on which cohort of adolescent population will be given the vaccine and they need to prioritize this, as you know the quantities for adolescents also need to be worked out. Like for example adults, so first they will look at the vulnerable population and then open it up for the larger population. So, all those deliberations are ongoing.

Surya Patra: Two related questions on this. You just mentioned that your tie-up with Shilpa Medicare is for the drug substances only, is that right? And what is the thought process here? Do we have a kind of a greater capacity so far fill finish is there, that is why we are kind of monetizing better?

Sharvil Patel: We have enough fill finish capacity.

Surya Patra: In terms of the export potential there I think soon the export of vaccines to outside India will be allowed. So, is there any progress for your product that you have seen in terms of getting the product approved by other countries or is there some kind of an alliance with the other international agencies like that? Some clarity on that would be helpful.

Sharvil Patel: With regards to ZyCoV-D vaccine we already have expression of interest from many countries. We have also had discussions there. Obviously, the first phase for us till we scale up to very large quantities is to supply to the Indian immunization program and once that is sufficiently catered to, then we will also get export permission for the vaccine. So, I think in the near term it is more driven towards making sure we can supply the quantities for the India and then later on also look at export. We are also looking at partnering with one CMO outside of India who also has drug substance manufacturing capabilities. And that will further boost our manufacturing and supply for international markets.

Surya Patra: Next question is on the other expenses side and something on the margin side. So, we have seen the other expenses, there is a sequential improvement that we have witnessed. You have also talked about the expenditure on the digital adoption and potential savings because of that initiative. Also, there was a point that in the previous year there was saving because of the saving on in terms of this distribution and promotional side. Considering all these three things still we have seen a kind of an improvement. Saving of last year would have come if we are saying that there is a normalized in the trade. And you have done incremental spend on the digital side. And that would also to some extent helped you with savings. So, how should we see all this? And

you mentioned in the opening remarks there is an 80 to 100 basis points kind of an improvement in the margin. So, what margin and for which period that you are trying to this?

Sharvil Patel: With regards to expenses, one, when you look at quarter-on-quarter, we need to factor in the difference in expenses with respect to the wellness business. As you know that quarter four and quarter one are the large expenditure months with a larger revenue also. And quarter two and quarter three have lower expenditure. So, one of the reduction is on account of a reduction in wellness on the marketing side. The other is, what you say is right, we have reduction in R&D expenses which is also a little bit of a timing issue. But we have been able to sufficiently manage our R&D expenses over many years. So, we continue to believe that we will efficiently do that spend. And with regards to other things, while we had a higher increase in the digital and other side, we also had savings which we talked about, we are running at least three to four initiatives and we have talked about saving, improving margins by a 100 basis points because of the savings that we are accruing, you know base budgeting on the other manufacturing and other areas. So, that is all helping us. But on a normalized basis going forward we can see around 950 crores kind of number for other expenses.

Surya Patra: Just one question if you allow. It is on your injectable initiatives. See, obviously the Doxil and Enoxaparin have been the recent key launches in the US. And you have also indicated that injectable portfolio is like to do great going ahead. So, on that front what is the progress and what is the run rate now we have received and where we are looking this is related to contribute?

Sharvil Patel: I think we are just building upon; we had a very-very small base on the injectable side with the launch of Liposomal Doxorubicin, Enoxaparin, Doxorubicin and others, we have seen a good traction of niche launches, and we are seeing a good buildup on this. But as I said, if you take a three-to-four-year view, we are looking at building at least US$ 250 million plus franchise on the injectables front with filing of many complex injectables, and also partnering for many of the complex injectables. So that's our current plan. Obviously, the current scale-up is very large because the base was very small in terms of growth. But you will see substantial contribution coming in from calendar year 2023.

Moderator: We will take the next question from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.

Anubhav Agarwal: Actually, just taking this previous question again, even excluding R&D even excluding wellness, our other expenses were still down 63 crores in this quarter. I am talking versus the June quarter, quarter-on-quarter. So, can you throw some light that all the initiatives that you are talking about will accrue from the quarter three onwards. What led to such a sharp decline in other expenses in this quarter?

Sharvil Patel: Versus the last quarter, we have lower marketing and manufacturing expenses and as I said lower R&D expenses and lower quarter-on-quarter wellness expenses. So, those are the three

contributing factors. On a consistent level, next quarter onwards, we see around a 950 crore other expenses.

Anubhav Agarwal: Can you call out roughly how much is the COVID sales in the quarter, on your topline about 3800 crores, will it be like 250 crores 300 crores, 200 crores, can you just give some range on the COVID sales?

Sharvil Patel: COVID sales? COVID sales there has not been any major growth because the last year also was a very high base so actually, we have a de-growth this quarter.

Anubhav Agarwal: But you have a very strong emerging markets as well. So, I don't know whether that's more driven by sale of COVID products or what has led to such a sharp growth in the emerging markets?

Ganesh Nayak: From the emerging markets we have not sold COVID. In fact, I made a mention in my opening talk that domestic business which has grown at 12% if you take out this COVID factor this was actually 17%.

Sharvil Patel: And on the emerging market front, we have only export towards institutional sales that we have done for COVID products. That growth, removing that I don't have for emerging markets, but I will ask Vishal to give it to you.

Anubhav Agarwal: Couple of question on the US market. One is on Mesalamine. Your current volumes versus last year when the product was normal, what percentage of volumes are down? Are we down 20%-30% on this in terms of what volumes we were doing at that time? Can you give some indication?

Sharvil Patel: Yes, we are down on both Mesalamine, on Lialda as well as Apriso and on Lialda is because of obviously more competition, but still, we continue to hold significant share. And on Asacol also because of the volume of the prescriptions coming down. And also last year there was a shortage so that has obviously got cleared also. So, on account of both of that we have seen a de-growth in volume and value. And if you look at our number, it has been compensated more by the existing and new products.

Anubhav Agarwal: Can you just help on Asacol? What kind of volume decline are we talking about? Are we talking about 20%-30% higher or lower than that?

Sharvil Patel: Maybe 10. I don't have the exact number but on the volume side I think it would be around 10%,

Anubhav Agarwal: Lastly, on the outlook for the US business. This quarter we had done about $ 202 million. In your previous comments you mentioned that the second half, can we do a run rate of about $ 230 million each?

Sharvil Patel: No, currently looking at the pricing pressures and obviously assuming there will be some competition on Asacol which we are not very clear yet, we are looking at least the next quarter we believe we can have the same base as this quarter. And quarter four is a little difficult to predict, but our view would be to make all efforts to make sure that we maintain our base. But we could see reduction in quarter four depending on how intense the competition is on Asacol.

Moderator: We will take our next question from the line of Kunal Dhamesha from Emkay. Please go ahead.

Kunal Dhamesha: First question, we are targeting a lot of growth from injectables, and we will be using in-house R&D and partnering as a tool. So, on both of these parts once we start putting money in terms of R&D, is it going to increase because we will also have a lot of costs coming in from Saroglitazar trial in US. Secondly, if you are going for a partner in route, does the margins in that route make sense? Would it be accurate into current EBITDA margins?

Sharvil Patel: When you are talking partnering, are you talking about the injectables franchise?

Kunal Dhamesha: Injectables. So, the likes of Sepharin.

Sharvil Patel: In relation to the Saroglitazar and the R&D investments, so in this last couple of years also we have had continuing studies on Saro on vaccine and on other fronts also. So, currently with our revenue growth expectations we believe we can be around 8% of spend on R&D as a percentage of sale. But on a year-on-year maybe there will be one year 9 and lower, but around 8% is a figure that we can look at in terms of our R&D expenses, assuming all of the costs that we are looking at. Because the trials are done over a period of three to four years. So, it's not everything that is spent over one year. And we do manage all of the Saroglitazar trials internally in majority of the manner, which is allowing us to recruit better and manage our costs also. So, that is to do with that. With respect to the injectable business, yes, if you look at it from doing it on your own versus in-licensing, the margins are shared. But if you look at in terms of return on the investment, it is significantly better than doing it on your own because the fixed investments are significantly lower. When we are looking at doing licensing for complex injectables all of them require dedicated facilities either from the API side or on the formulation side. So, when are able to in-license we are removing many of these fixed costs? So, on that point of view the profitability would be far better in terms of the investments that we will make. And it will also de-risk us because we believe this is a better model in terms of de-risking from the regulatory side also. So, I think it's a mixed part, but on the overall side, the profitability with these products would be very good because they are all complex and they would drive better profitability than the current profitability even if it is shared.

Kunal Dhamesha: Secondly, again coming back to vaccine, how has your view on the potential of the vaccine changed over the last let’s say 3-4 months given the vaccination levels where we are currently?

Sharvil Patel: If you look at current position of the vaccine, we are currently the only vaccine that is approved for adolescents between the 12 to 18 years age group, and we believe the population there is about almost 40 crores when you look at children. And even assuming two doses or three doses, you are talking about 80 crores to 120 crores dozes required. So, from our point of view from the capacity that we have built for, and the advantages that we offer for the vaccine, we believe that it will still be a very good opportunity for us, because there will be limited competition and there are significant benefits to this vaccine and that will help us build for this. We believe that the government will actively be involved in acquiring the vaccine for the immunization program. And we also see, at least currently a very good private market that we can participate in. And we would definitely get 25% of our volumes to be supplied to the private market which will be also good in terms of building up the traction for the vaccine. And I also suggested that internationally we are looking at partnering with one more player for making the vaccine available for the international markets.

Kunal Dhamesha: So, you don't see a lot of competition in fact with Biotech approval, the potential remaining the same for the adolescent market? And additionally, the follow-up would be, are we also conducting the trial on mix and match study?

Sharvil Patel: We are doing the trial now for the ages of five and above. So that will be the additional age group that will get included once we complete that trial. With respect to competition, you can look at the overall supply of some of the other vaccines and it's not been anything very significant. So, I think from the overall opportunity size, which I told you is about 80 crores to 120 crores doses, there is plenty of opportunity for a player like us which is talking about currently 1 to 2 crores doses on a monthly basis on a steady state. For us, I think it doesn't seem to be a concern and I think we should be doing well in India and further capacities we should be able to use for export.

Kunal Dhamesha: Are you conducting any mix-and-match trials for your vaccine?

Sharvil Patel: Yeah, the discussions are underway, and we are still under discussion for the mix and match trials.

Moderator: Our next question is from the line of Keshav Mishra, an individual investor. Please go ahead.

Keshav Mishra: My question is on Saroglitazar. In domestic market in India, we already have the approvals. How has been the growth like over the last two years?

Sharvil Patel: With the additional indications we believe the main scale up of the Saroglitazar you would get to see in these two years. But the growth in the last three years has been obviously significantly better than our overall business and it has become one of the top 20-25 products of the company.

Keshav Mishra: Related to the trials that we are having specially for PBC in US, what is your view about the competition doing in terms of trials for similar indication and at what stage they will be. Can you just give a flavor on that?

Sharvil Patel: With our current understanding on the PBC indication, we believe we can be amongst the first wave of launches, assuming there are a few more companies, but we definitely believe we will be in the first wave. Either of course, so we are the first wave but very strongly we can be there. With respect to NASH, it's an ongoing effort, a lot of trials have failed, a lot of molecules have failed with studies done on NASH. So, assuming that we are coming to market in 2027, we believe we can be in the first wave or close to the first wave of launches.

Moderator: Our next question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: Dr. Sharvil, if you can really help us understand the contribution from Asacol and Lialda at this point in your US revenues, because we are going to see competition. So, if you can guide us, it will be really helpful.

Sharvil Patel: As I said, we don't give individual product related value. I did mention that on Lialda and Asacol, we have seen de-growth in this quarter in the US and assuming that we will see some competition, in next quarter we still believe we can maintain our base of quarter two. And quarter four we can see some erosion depending on how intense the competition is. But I think as I told you, the Lialda we have now enough competition on that.Asacol HD is something that we still have exclusivity on. But after exclusivity we still believe we will see very good margin profile on this business. But to give individual absolute value would not be possible.

Saion Mukherjee: But IMS actually shows very high number for both the products, more than 200 million if I am not wrong. So, if you can give some sense, like top five products or something like that, how much contribution is there, so that it's easier for us to model up.

Sharvil Patel: Saion, you are asking me one way or the other, but IMS is obviously you know is always a little inflated. So, IMS will not be the full reflection of sales of it. So, that is not the way to look it. But as I said, our current guidance is that assuming competition, at least in this quarter we still believe we can maintain our base. Lialda already there is erosion, but on Asacol once the erosion is seen, we believe that going forward and from calendar year 2023 onwards we can more than compensate for the gap that will be created in the coming year.

Saion Mukherjee: The second one is on your specialty. You mentioned about CUTX which possibly will be launched in the 2023 calendar year. So, what is the kind of investment in terms of commercial front that you need to make? And you also mentioned it's kind of going to breakeven on year one. And also, if I take a slightly longer-term view given the PBC trial on Saroglitazar so what's your overall plan in terms of commercial expansion for the specialty business in the US?

Sharvil Patel: On the CUTX-101 next coming calendar year 2022 we are starting to recruit people in the field. This is an orphan indication. So, we are talking about not a very large team, but a team considering between 10 to 15 front-end team that we are trying to recruit for, to be prepared for launch either by end of next calendar year or early part of 2023. As I said, the current business model that we have built is we can see breakeven in the first year, full year of commercialization. And then it will obviously significantly add to the profitability of the company as we move forward. We have obviously IP and patent for it. So, it's a very attractive model. From the investments that we made so far, we can see this being a very lucrative investment with at least less than a three-year payback, from what we have done in terms of once we launch it commercially. Also, from the Saroglitazar point of view, we had looked at the market on PBC. We have fast track and priority delivery designation on this. And if we are achieving closer to first wave launch and with the current assumption, it is definitely a very-very large opportunity anywhere between $ 350 to 600 plus million opportunity on a peak sale revenue on a conservative side. Obviously, there are things that we need to look at in terms of upside and downside. But if you look at all the additional work, we are doing related to transplant, related to the other indication, I believe this molecule is fit to have at least two to three indications on the label, which will make it very sizeable. NASH is obviously a significantly large opportunity, and we are looking at reduction in fibrosis score, beyond just improvement in NASH. NASH scores so that is going to be a significant achievement if we are able to show that which we believe the molecule has the potential to do. So, if all of those things go well, if we get the right indications and all of that, this is potentially obviously a very large speciality business that we are creating on the back of Saroglitazar followed by some of the other orphan drugs that we would want to add. The commercialization space for Saro is still maybe late 2023 or not for the at least calendar year 2022.

Saion Mukherjee: How large would be that team for Saro at least in the initial stage?

Sharvil Patel: It can be anywhere between 60 to 90 size full team in terms of what we need to do.

Saion Mukherjee: If I can ask one last question before I join back. On these injectable partnered products, I think you mentioned there were two products where you may have sole exclusivity. Can you give some indication about the timeline and the market size for these molecules?

Sharvil Patel: I think the opportunity is very large. We can set up some other time to give you that detail, because I don't carry it. But I think what we will make an effort on is to make a detailed presentation on the injectable side in terms of where we are looking, at least what we have currently been able to do, we can talk about it and something that is under discussion, we can't talk yet. But as soon as we are able to file some of these products, we can obviously discuss it further, but I will definitely give an overall scope on the complex injectable as to what type of products we are filing for.

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

Charulata Gaidhani: My question pertains to US. So, FY23 what type of a growth would you anticipate in terms of internal estimates?

Sharvil Patel: FY23 our current best guess estimate is about around a 5% kind of growth for the year. But that is a best estimate right now. It's a moving figure. That's what we are building for right now.

Charulata Gaidhani: In that how many launches, would you expect other than the orphan drug?

Sharvil Patel: When I talk, I am talking about the generics business not the branded business. So again, our pipeline talks about we have a potential to launch 50 new products in FY23. And if all regulatory things go well, if pre-approval inspections go well, if our clearances are done, which we are hoping will happen, then additionally we can achieve closer to that 50 number.

Charulata Gaidhani: Because currently you have quite a few quality approvals. Many of them are tentative also.

Sharvil Patel: So, our current expectation is that if Moraiya clears, we are looking at 50 plus new launches.

Charulata Gaidhani: And do you have any expectations for the inspections?

Sharvil Patel: As I had communicated, we have completed our corrective actions and we are now scheduled for an audit at least from our completion point of view. Looking at the current scenario where audits have started in India, we believe that we will potentially have on audit we hope in the next one to two quarters. So that's our current best estimate.

Charulata Gaidhani: And why have the interest costs gone up in the quarter?

Ganesh Nayak: During this quarter we have increased the proportion of Rupee borrowing. So, on the apparent basis you find that the costs are going up because the coupon rate on rupee loan would be certainly higher than the foreign currency loans. But at the same time, we have entered into certain forward contracts. So, on net-net basis we are the gainer.

Charulata Gaidhani: And what is your average cost of debt?

Ganesh Nayak: It is about 2%.

Charulata Gaidhani: And how much CAPEX do you expect to incur in FY22 and FY23?

Ganesh Nayak: It would be about 800 to 900 crores in the current year. FY23 it can be lower.

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

Prakash Agarwal: A question on the US business. So, very few companies have been able to grow Q-on-Q so while I hear you were talking about pressure on volumes on your large products. You also spoke about

some new products being launched. Can you give some color, is it the new launches primary which led to the incremental growth or there has been some volume increase in your base portfolio also?

Sharvil Patel: Some it's related to new products. Volume is a mixed bag. Because of significant pricing challenges we are seeing we have to wait and see how it builds up. But currently it's mostly driven by some of the new products that have been launched.

Prakash Agarwal: And how are you seeing the flu season. I mean, is it already started to bake in your numbers, how are you seeing the flu season?

Sharvil Patel: We really don't have any numbers on the flu.

Prakash Agarwal: So, these are entirely new set of product launches that you have done?

Sharvil Patel: Yeah. And the earlier launches which have also scaled up. We had 21 launches. We have some 22 launches, so those scale-ups have also happened.'

Prakash Agarwal: And the outlook you are giving is kind of flattish for the second half of the year?

Sharvil Patel: For the next quarter it's flattish. For quarter four we may see a dip, but it's again we are only assuming depending on the competition on Asacol. The current best estimate if competition is very steep, we can see some de-growth in the quarter four, so that's our current best estimate.

Prakash Agarwal: And for 2023 you are talking about, in the last calls you have talked about some complex injectables and some complex generic products, but that too more so from second half of fiscal 23 is what I understood.

Sharvil Patel: Yeah. So, I think if you look at our business, second half will be very critical on three factors. One is the complex launches that will come up. The second is the clearance that we expect for our Moraiya, and which will allow us then to commercialize our transdermal portfolio also, and some other important products also. So, if both of those triggers go well, we would see a much better second half of FY23. And as I said, if we are successful in all of these things, we can aspire to launch 50 plus new products.

Prakash Agarwal: Secondly, on gross margins you have called out 110 basis points for COVID related inventory provision, but there is more to it, right? Have you seen raw material price or what is the other 100-200 basis points kind of movement?

Sharvil Patel: So, going forward the raw material prices are definitely going to be a challenge for the industry, both related to China and the disruptions that have happened in China and obviously other costs that have been going up for commodities and other things. So, the good thing for the organization is that we generally see this much early on. So, we did plan an initiative to cover up inventory

for three to four months and take that cash kind of investment in it. So, that will allow us to tie towards certain aspects of it. But with the current understanding what we see, we believe that there will be increases in material costs as we move forward which can only be offset by better efficiencies and better cost reduction initiatives which the company is geared to do. But there is going to be a challenge in terms of cost pressures actually for all markets. The first pressures come to India and then it trickles down to the US business later on.

Prakash Agarwal: But the inventory provision for COVID related products is largely done?

Sharvil Patel: We have provided for majority from our best visibility point of view.

Prakash Agarwal: Lastly, on other expenses you have talked about three reasons but in general what we hear from the street is the freight costs, etc., the activities on the field in branded generic business all are back. So, what is really that you have done for the cost savings? One, you said wellness business, the second is some of the costs initiative you talked about.

Sharvil Patel: If you look at that cost initiatives that we are running, if I talk about a zero-based budgeting, we are talking about significant 100 crores plus of kind of savings that we are trying to target there. If you look at our SLIM and PRISM, we are looking at upwards of 100-150 crores of saving. When we do our other programs like efficiency improvement which is again another 55-60 crores for two plants. So, a significant amount of cost programs, our efficiency programs more importantly have been running the organization. And also, while things were back to normal our marketing spends have been lower both for the wellness market because of sequentially it being lower and also for the India business. So, I think all of that has led to a better other cost expense, so lower other cost and lower R&D expense this quarter.

Prakash Agarwal: But apart from R&D which you said will come back, are the other cost savings all sustainable?

Sharvil Patel: Our best estimate right now is looking at all of those things, we are looking at around a 950 crore plus number for the next quarter.

Prakash Agarwal: Which is coming back quite a bit.

Sharvil Patel: Not quite a bit, but by 7%-8% more than the current.

Moderator: Our next question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: Thanks for the follow up. Just on Saroglitazar in India how has been the response to the fatty liver approval that you got? And what's your expectation here in terms of the brand size that you see over the next few years?

Sharvil Patel: So, we have two important products. One is Saroglitazar where we believe it is definitely going to be at least a 200 crores plus product and it will be amongst the top 10 products for the

organization in the next two to three years. We have a follow-on molecule which is Desidustat which is for the treatment for CKD patients on dialysis and not on dialysis where the trial is just concluding, and we hope we can also commercialize this in the coming year which also has a potential to be a 150-200 crore molecule. So, both of these IP driven molecules will be among the top 10 molecules for the organization.

Saion Mukherjee: When you expect Desidustat launch in India?

Sharvil Patel: If everything goes well, we can look at a quarter one next financial year.

Saion Mukherjee: In terms of IP protection for both Saro and Desidustat how long is that? Is there a risk of competition?

Sharvil Patel: No, we do have a significantly long runway for IP until 2036 for Saro and also for Desi we have a good amount of in that.

Moderator: Our next question is from the line of Ranbir Singh from Sunidhi Securities. Please go ahead.

Ranbir Singh: For FY22 how much products we have planned to launch, how much we have already launched in US in first half and what remains to be launched in second half?

Sharvil Patel: As I said, this year we will look at launching close to 20 products in this financial year. And next year assuming certain aspects we can target about 50 plus launches provided we are above to resolve our current warning letter.

Ranbir Singh: In this context earlier, we guided some 30-35 product launches in FT22. That's why I just wanted to understand that whether we have curtailed our launch of for any reason, if you could give more detail on it?

Sharvil Patel: There are two aspects to that. Your point is right. One is, we because of the market conditions a few molecules we have chosen not to launch because the pricing is not very progressive. The second part is that we have, as you know, PAIs need to be completed and for some of the molecules we required a preapproval inspection. So, that has led to some of the delay. So, between these two things are the delay and some are getting pushed out to quarter one because of the approvals came late so the launches also get staggered late because of the response letter and the goal date.

Ranbir Singh: So, even for 2023 also the number of launches seems very low despite we are assuming that Moraiya facility would get cleared.

Sharvil Patel: 23, I am talking about 50 launches.

Ranbir Singh: Second question was related to the ZyCoV-D vaccine. In this just wanted to understand because the opportunity size has already shrunk. Whether we will get a fair return on the investment given the situation or the return would be in line with the company's average return.

Sharvil Patel: On ZyCoV-D our view, first and foremost, I think what we wish to do was to make sure that we can work on the research efforts that we can make ourselves self-reliant to be able to invest be an R&D and invent or bring a new platform technology to the country. And I think I am very happy to say that on that front definitely we have succeeded, and we are the world's first DNA plasmid vaccine. And it's not only a great thing for us, but a great thing for India because this has been recognized globally everywhere in the world for this aspect. Now, is second to the commercial potential, as I had explained and I'll explain one more time, our current capacities are around 1 crore doses monthly which we are trying to produce. Going forward we look to enhance that capacity. If you look at the target segment of only children, we are talking about requirements of 100 to 120 core doses and we are talking about producing 1 crore doses a month. So, from our opportunity side, we have enough opportunity to cater to. Actually, the expectation would be higher that we could produce more, but obviously we are just building on this new technology and trying to scale it up. But from our commercial potential, we are still on track to be able to fulfill the overall demand in terms of our expectation which is to produce 1 crore doses and sell 1 crore doses.

Ranbir Singh: So, of that 1 crore doses, 25% we will have opportunity to launch in a private market.

Sharvil Patel: Yes.

Ranbir Singh: So, my question was in that context only. Because in private market still we have competition, then we will have some agreed price for government supply and then another opportunity is for export. So, given a different price scenario, that I wanted to understand that the kind of investment we have done for that 1 crore vaccine in terms of building capacity or R&D so whether we will get a fair return on that investment given the current scenario?

Sharvil Patel: Yes. We will get much better than our other businesses.

Moderator: Our next question is from the line of Keshav Mishra, an individual investor. Please go ahead.

Keshav Mishra: One question on the vaccine portfolio that Cadila already has. Since we have now developed ZyCoV-D can you just give a flavor of what strategy and what kind of growth we can see from the entire vaccine portfolio that we have developed apart from ZyCoV-D.

Sharvil Patel: So, I think ZyCoV-D is obviously something that we have done this year, but if you look at our current vaccine portfolio, we have very important vaccines. As I had said, we have 3 vaccines which are going to be part of the India public market as well as the WHO supplies. One is the typhoid conjugate vaccine. The other is an MR vaccine and obviously our rabies vaccine which

is WHO pre-qualified. So those are important vaccines for us. And they have different launch plans in the next coming years, and they will become sizable part of it and that's where the investment is also being made. Then we have niche vaccines like the Varicella vaccine where we are the only company to do so in India and that is going to be a very attractive, not a very large business, but a very profitable and very attractive business for us when it comes to Varicella. And there are whole of this private market vaccines like the flu we already have, what call as the flu vaccine. We are working on the HPV vaccines and the whole hepatitis A, B and E range of vaccines. And all of these are going to be significant for us. So, our aspiration is to build at least a $250 million franchise out of the vaccines by 2025-2026 including being part of the WHO qualified programs. And we are well on track to do that in terms of building our portfolio for them from the current point of view. We also are working on malaria, chikungunya, and other Pentavalent and Hexavalent vaccines which are under various stages of development. We also have a monoclonal therapy which is a Twinrab which also has a potential to become a very important product with the treatment for dog bites with the vaccination related to using rabies vaccine as well as treatment option using Twinrab.

Keshav Mishra: And when you say you want to build a $250 million franchise and FY25, what is this current base looking like? What is the current size that we are already doing?

Sharvil Patel: We are about $10-12 million base right now.

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

Prakash Agarwal: Thanks for the opportunity again. Just missed your comment on the opportunity for exports on the vaccine front. Currently you are awaiting government approval, or no, approval is there but for the launch, the pricing, etc. But what is the opportunity at the ROW markets?

Sharvil Patel: I think from what we produce currently in India and the requirement that is there in India, I think largely the Indian manufacturing will be, on the immediate basis, only supplied for the India market. We are also looking to partner with international contract manufacturing company which has large capacities on COVID on DNA. And if all of that goes through well, then that capacity we can use for selling in the international market.

Prakash Agarwal: And when you say international, this is ROW markets.

Sharvil Patel: Yes.

Prakash Agarwal: Ex-US, Ex-Europe.

Sharvil Patel: Ex-US, Ex-Europe. Already we have a lot of expression of interest, and we have agreements in place to do that. Once we are able to produce sufficiently then we will be able to do some of these contracts.

Prakash Agarwal: How this works in terms of approvals given that you already have approval in India now, so are these approvals can be replicated or you need a WHO or some other regulatory approval?

Sharvil Patel: We will go through a three-phase approach. One is with the India approval we will be able to directly give the vaccines in many countries without registration or a quick supply, which is under emergency use. Second, we will be filing doses in some of the markets for a registration of the vaccine. Third is, go for a WHO qualification for the vaccine, and which will obviously be the third phase of what we need to do.

Moderator: As there are no further questions, I would now like to hand the floor back to Mr. Ganesh Nayak for closing comments. Over to you, sir.

Ganesh Nayak: Thank you very much. Wish all of you a very happy Diwali, a very happy Christmas, a very happy new year and look forward to interacting with you again on the third quarter results in the month of February. Have a good evening.

Moderator: Thank you. On behalf of Cadila Healthcare Limited that concludes this conference. Thank you for joining us. You may now disconnect your lines.