“Cadila Healthcare Limited Q4 FY21 Results Conference Call”

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Moderator: Ladies and gentlemen, good day and welcome to Cadila Healthcare Limited Q4 FY21 Results Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during this conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. As the participant is connected on both the webcast and the audio bridge, you are requested to mute the audio from the webcast to avoid echo. I would now like to hand the conference over to Mr. Ganesh Nayak, COO & Executive Director from Cadila Healthcare. Thank you and over to you, Mr. Nayak.

Ganesh Nayak: Thank you. Good afternoon, ladies and gentlemen. Welcome to our post-results teleconference for the quarter and the year ended March 31, 2021. I do wish that you and your families are safe and well. For today's call we have with us Dr. Sharvil Patel - Managing Director; Mr. Nitin Parekh - Chief Financial Officer; Mr. Harish Sadana - Chief Strategy Officer and Mr. Vishal Gor – Senior Vice President (Corporate Finance).

We continue to be at the forefront in the fight against the pandemic. While the uncertainty and challenges related to the pandemic are evolving, we stayed committed to service the demand across the markets on the back of resilient manufacturing, supply chain and distribution. In a bid to ensure access to the affordable treatment options to the people across the globe in a fight against the pandemic, we as a healthcare organization have taken initiatives across the spectrum from prevention to treatment of COVID-19 using a diverse set of capabilities in small molecule therapeutics, biologicals and vaccines, even using our range of wellness products for sanitization and overall immunity enhancement. As a part of this endeavor, we launched several products like Remdesivir injections, hydroxychloroquine, dexamethasone injections etc. at the most affordable prices. We are also exploring the innovative ways to fight COVID, about which Dr. Sharvil Patel will speak at length in innovation section.

With that let me take you through the financial numbers for the years gone by. During the year, we posted consolidated revenues of Rs. 151 billion up by 6%. Consolidated EBITDA for the year was Rs. 33.4 billion up 20% on a year-on-year basis. This year's EBITDA is the highest every EBITDA achieved by us. Improvements in the EBITDA was achieved by improvement in gross margins as well as by cost savings. The improvement in gross margins was achieved due to a better product mix, supported by an innovative products portfolio. Cost rationalization initiatives helped in either lower growth in expenses or absolute reduction in expenses as compared to the previous year. We expanded our EBITDA margins by 260 basis points to 22.1% against 19.5% registered last year which is FY20. Consolidated PAT for the year was Rs. 21.3 billion, up 81%. Excluding certain exceptional and non-recurring items, our PAT grew by 44% during the year. In the last few years, we have made a concerted effort to build our India geography in line with US geography. From nearly 50% of revenues coming from the US and about 37% coming from India in FY18, we closed FY21 with both the geographies contributing almost equal amount. Further, our efforts to strengthen the balance sheet have resulted into a net

debt reduction of Rs. 35 billion and our net debt stands at Rs. 35 billion as of the 31st of March 2021, against Rs. 70 billion as of 31st March 2019. Net debt of Rs. 35 billion and net debt to EBITDA of 1.06x as on the 31st of March 21 are the lowest in the last 5 years. The reduction of debt was partly supported by the equity capital raised by way of preferential issue of Rs. 350 crores to the promoter family and QIP issue of 650 crores, which received overwhelming response. Meanwhile, the acquisition of Heinz by Zydus Wellness has been integrated well and is on the growth path which is also well recognized by the investor community.

Coming to the quarter financial numbers, during the fourth quarter of FY21. we posted consolidated revenues of Rs. 38.5 billion up 3% year-on-year. Consolidated EBITDA for the quarter stood at Rs. 8.6 billion up 8% year-on-year. Overall, we have expanded our EBITDA margins by 110 basis points to 22.2% against the 21.1% registered in Q4 FY20. Consolidated PAT for the quarter was Rs. 6.8 billion, up 73% year-on-year. Excluding certain exceptional and non-recurring items, our PAT grew by 21% during the quarter.

Despite all the challenges paused by the pandemic, our India geography comprising of human health, consumer wellness and the animal health witnessed a very strong growth of 18% on a year-on-year basis registering sales of Rs. 17.7 billion during the quarter. For FY21, our India geography business registered a robust growth of 9% and posted sales of Rs. 64.8 billion.

The US geography comprising of generics and specialty portfolio, registered sales of Rs. 15.1 billion during the quarter down 6% quarter-on-quarter. Lower offtake coupled with pricing pressures in some of our products constrained the revenues for this quarter. In addition, Asacol HD is also signaling offtake pressures. We expect this trend to continue for the current quarter two. On a full year basis, the business posted sales of Rs. 64.45 billion, up 3%. Our emerging markets business witnessed a healthy growth of 46% during the quarter and posted a sales of Rs. 2.5 billion. On a full year basis, the business posted a sales of Rs. 10.17 billion up 16%.

Now, let me take you through the operating highlights for the fourth quarter of FY21 for each of our business lines. Starting with our human health business in the India geography, the pharmaceutical market in India showed signs of sustained recovery as it grew in a mid-single digit for the second quarter in a row with a 5.3% growth during the Jan-March 21 quarter. Performance of our business also showed signs of recovery over the last two quarters on the back of steady improvements in demand. In fact, we were the 3rd fastest growing company among the top 10 Indian pharma companies during the quarter gone by. Our specialty cluster grew faster vis-à-vis the mass cluster and in turn led to a better performance vis-à-vis the market. Overall, the human health formulation business posted sales of Rs. 10.23 billion during the fourth quarter of FY21, up 15% on a year-on-year basis largely driven by volume growth. Branded generics business grew by 16% on a year-on-year basis during the quarter. On a full year basis, the business showed a sign of revival and posted sales of Rs. 40.4 billion with a growth of 9%. We have observed a significant shift in the way the interaction amongst doctors, patients and the pharmaceutical companies is happening with the use of digital mode during the

second wave of COVID 19 and we believe that the demand to consult patients through digital mode will continue to be on the rise.

On the back of continuous revival in the economy coupled with the lower base impact, our consumer wellness business witnessed a strong surge in revenues with all the brands growing in double digits during the quarter. Overall, our business grew by 22% on a year-year basis to Rs. 6 billion led by volume expansion. Sales growth for the year was 6%.

Our animal health business posted a sales of Rs. 1.5 billion during the fourth quarter, up 25% and Rs. 6 billion during the year up 25% and Rs. 6 billion during the year, up 16%. Recently, Zydus Animal Health and Investment Limited, a wholly owned subsidiary of Cadila Healthcare Limited has entered into an agreement to sell and transfer its animal healthcare established markets undertaking to Multiples Alternate Asset Management led consortium.

Now let me take you through the performance of our US formulations business. Despite increased competition and pricing pressures, our US generics business continues to grow the overall volume and maintained a top 3 ranking in about 60% of the product families that we are in. During the quarter, we launched 13 new products in the US taking the cumulative number of new product launches for the year to 30. We received approvals for four new products during the quarter taking the cumulative number of approvals for the year to 35. New products approvals for the year includes 7 first cycle approvals, 2 first generic approvals and 2 first wave generic approvals. We filed 22 ANDAs with the US FDA during the year. With that our cumulative number of ANDA filings and approvals now stand at 412 and 317 respectively. We are building a portfolio of complex injectables in the US. We have launched a few complex injectables such as fondaparinux and Doxorubicin Liposomal injection in the last couple of years and we expect to launch one more complex injectable soon.

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

Dr. Sharvil Patel: Thank you, Mr. Nayak and good evening ladies and gentlemen. As you are aware in the fight against the COVID-19 disease we have been exploring various innovative ways apart from our initiatives in therapeutics as well as the wellness space**.** This includes development of two vaccines to combat the spread of the virus, exploring the biological root including repurposing of existing drugs to offer alternate treatment options to the patients and evaluating a few small molecules to treat COVID related complication.

Let me first give you an update on our COVID portfolio. As you already know our DNA vaccine candidate ZyCov-D targeted at combating COVID-19 is currently undergoing Phase-III clinical trials in India and post SEC and DCGI approvals of phase-1/ Phase-II adaptive clinical trial results. The trials are being conducted in over 28,000 subjects across 60 sites to evaluate the efficacy of the vaccine. The population selected for the trial includes people in the age group of

over 60 years, those between the age group of 18 to 60 years with and without comorbidities and those in the age group of 12 to 18 years. We have submitted the data to publish the results of our Phase-I clinical trials and the results will be published soon in a peer review journal. We have also put up a plant for the production of large-scale manufacturing of ZyCoV-D vaccine and the plant is expected ready for commercialization by end of June 2021. For, our second vaccine candidate ZyCoV-MV targeted at COVID-19, we have received an approval from the RCGM to carry out the preclinical and/or safety toxicity studies during the quarter.

Coming to Biologics. We have successfully completed our Phase-III clinical trial for Pegylated Interferon alpha-2b (brand name Virafin) in the treatment of moderate COVID infections in adults. Recently in the month of April, the DCGI did grant us the emergency use approval for Pegylated Interferon alpha-2b in the treatment of moderate COVID infection in adults. In order to facilitate the treatment of COVID-19 globally, we will be seeking permission from other regulatory authorities in different countries to file for registration of the product in those markets. The molecule is a very potent anti-viral agent and post its launch the initial results are extremely encouraging as we have seen an increased demand from many of the hospitals and government institutes. The product is a part of Karnataka State treatment protocol and four other states are considering it to include the same in their treatment protocol. During the quarter, we completed a pre-clinical toxicity studies for our novel biotherapeutic cocktail of monoclonal antibody directed against the spike protein of the virus SARS-CoV-2. The novel biotherapeutic cocktail of monoclonal antibodies can emerge as one of the main treatments for mild COVID-19 cases as it has been designed to have a long half life providing protection for a long period of time, has reduced immune-effector functions to minimize potential tissue damaging side effects of the virus neutralizing monoclonal antibodies and are better equipped to deal with variants than single monoclonal antibodies base products cannot. We are currently seeking permission from the drug regulator to initiate a clinical trial for this cocktail of monoclonal antibodies. On the NCE front, our Desidustat successfully completed phase-2b trials in Mexico for the treatment of hypoxia in hospitalized COVID-19 patients as the data shows potential of Desidustat in helping prevent the ARDS disease.

With this let me take you an update about the progress made by us on the other critical R&D projects that are also targeted. On NCE front, this year has turned out to be a very encouraging one as our lead molecule Saroglitazar Magnesium received an approval from the DCGI for the treatment of nonalcoholic fatty liver disease which is called NAFLD and thus became the first medicine for the treatment of NAFLD. In fact, the drug has been approved by DCGI in India for 5 indications viz. diabetic dyslipidemia, hypertriglyceridemia, NASH, NAFLD and type-2 diabetes. On the global development front, this molecule is at different stages of clinical development for multiple indications in the US.

Coming to the progress made for Saroglitazar during the quarter. Recently we have received an approval from the US FDA to initiate the phase-2b trial of Saroglitazar for NASH and F2/F3 Fibrosis. These trials shall be initiated next month. We have also submitted the protocol to the

USFDA to get an approval for initiating phase-2b/3 clinical trial of Saroglitazar Magnesium for primary biliary cholangitis indication. We expect to start this trial from the month of August after the securing the necessary approvals. The trial will be conducted in 192 patients across 100 sites globally. For NAFLD and PCOS indications, patient enrollment is ongoing at present in the US for the Phase-II clinical trials which is expected to be over by Q3 of FY22. We are also developing a novel oral small molecule candidate known as ZYIL1 targeted at selectively suppressing the inflammation caused by the NLRP3 Inflammasome. The Phase-I clinical trials are currently ongoing in India for ZYIL1 and this molecule could have a potential to treat the inflammatory diseases like IBD as well as rare autoinflammatory diseases like CAPS.

Coming to the Biotech research side, we completed Phase III clinical trials of Rituximab for the India market during the quarter. On the international front, dossiers of four biosimilar products are under different stages of review cycle by the regulatory authorities of Mexico and Columbia. We are also very happy to say that we launched our first biosimilar of Pegfilgrastim in Russia during the quarter which is a significant market for biosimilars among the emerging market countries. This was also the first biosimilar launch of Pegfilgrastim by any player in Russia. We have launched this product by filling activities being carried out by local partner which will enable us to participate in the procurement activities by the government of Russia. Further the approval in Russia opens up the door for us in the CIS region, enabling us to get approval on fast-track basis for other CIS countries. We also filed dossier of one more product with the Russian regulatory authority during the quarter. Also, now as part of the global biosimilar program we have selected two candidates for global market development. These products are selected with an aim to have a robust presence in the oncology biosimilar space of the regulated markets of Europe and US as the approval in this markets will make us eligible for approval in many other countries as well. We are evaluating various possible partnership with the focus on co-development partnership model.

Coning to 505(b)(2) and specialty initiatives, in the specialty, our focus areas include pain, CNS, orphan and rare disease drugs etc. We have developed a portfolio of 9 products including 2 in the orphan disease space with the focus on CNS and pain and other opportunistic areas. During the year, we have filed one ANDA, one PNDA and 5 PINDs with the US FDA. We also received an acceptance from the US FDA for one NDAs filed in the area of metabolic disorder with the PDUFA goal date in September 2021. We are planning to file one more NDA in the pain management area in FY22. As you are aware that orphan and rare disease space is an area of strategic interest for us in our specialty portfolio build-up and as part of that strategy we have acquired rights to CUTX-101 from Cyprium Therapeutics. This drug has been granted orphan drug and fast track designation by the US FDA for Menkes disease which is a rare and fatal pediatric disease caused by mutations in the copper transporter genes due to which a new borne is unable to absorb copper. If untreated, it may cause premature death within the first 3 years. The product is under rolling submission and all modules are expected to be filed by December 2021. Being a fast-track designated product, we may receive approval in the first quarter of 2022 in the best-case scenario. We continue to explore the potential strategic collaborations and

licensing opportunities to grow our specialty and complex generics business. Till date we have successfully in-licensed 20 products to build the portfolio of complex generics. Seven such deals were concluded in FY21 and out of this 2 were concluded in the last quarter of FY21. Out of all the in-licensed products, for two products, we are likely to hold an exclusive first-to-file status and are likely to have a 180 day exclusivity upon launch.

Thank you. And now we will handover for the Q&A session.

Moderator: Thank you very much. We will now begin with the question-and-answer session. The first question is from the line of Damyanti Kerai from HSBC. Please go ahead.

Damyanti Kerai: My first question is on India business. So last two quarters we have seen very good momentum. So first, can you tell us like what is the contribution from COVID related products? And my second question related to India is like how much is specialty and mass and how do you see India growth trajectory in coming quarters?

Dr. Sharvil Patel: For the quarter gone by, there is no major or significant contribution from any COVID related products for the quarter four. So, the growth or the value that you are seeing is only driven by our established products beyond the COVID portfolio. If you look at the split of our business, we have about 60:40 split between mass and specialty for the last quarter. And both the businesses have grown better than the market. But the specialty business has significantly done better than the market. And moving forward we definitely see this trajectory still continuing in the coming quarters also and with the important launches that we have had earlier and some of the new brands, they are also tracking very well in the diabetic space and in the cardio space. So that business continues to deliver and with the improvements that are happening on the acute side also we can see good momentum during the quarter as well.

Damyanti Kerai: So broadly the base portfolio is driving the growth with little contribution from the COVID product so far, right?

Dr. Sharvil Patel: Yes, quarter four COVID had almost insignificant contribution.

Damyanti Kerai: My second question is on your long-term business view. So, in one of the last interactions, you mentioned that you are reviewing your strategy for next 10 years. So, if we look at the business split right now, US and India contribute around 80% and other businesses are slightly subscale. So in next 5 years to 7 years how do you see your mix changing like India US and other segment?

Dr. Sharvil Patel: So as part of our next 5-to-10-year strategy, we believe that the two markets will remain the strongest markets for us which is US and India. India will be strongly driven on two principles; one is on access and affordability. So, with the launch of biosimilars and vaccines beyond what we do on small molecules front, I had earlier stated once that we have 30 products that we want to launch in India in this biomolecular front also which have potentially strong opportunity. So,

some critical new products. The biosimilars and vaccines business which is doing extremely well and our proprietary IP driven products like Saroglitazar, Desidustat and a few more products in the future to come, will aid strong growth in India and which can also be taken for many of the developing countries. With respect to US, it will be on two strategies, building continuing to manage the base of the oral solid products which is very large, launching the whole new range of complex injectables and the whole injectable franchise which is currently very small and we believe it can be a sizeable 300 million franchise for us n the near term and then obviously our role to play on the specialty front which we want to do in the orphan drug and in the niche indications like CNS, pain, which we were looking at and GI, which will add to the value creation in the specialty space in the US and obviously the large opportunity is going to be for Saroglitazar in the areas of PBC which we still believe we can have an NDA submission by end of 23 or early 24 and in the next 1 year to 2 years for NASH as well. So that is the trajectory for the growth for that. So base business growth, coupled with vaccines and biosimilars for developing country and also now we do nominate at least two biosimilars for the developed markets which is beyond 2025.

Damyanti Kerai: And my last question, if I can squeeze in. Any update on transdermal products for the US markets?

Dr. Sharvil Patel: We need a resolution for our Moraiya facility for us to commercialize these products in the US. Currently, our best timeline looks like end of this year, if we can go through this audit process and other than that we have currently one or two products that we have launched, but the large part of the hormonal products which are yet to be launched are filed out of Moraiya. So, post the clearance of Moraiya facility we are seeing at least 4 critical launches, which are very important for us.

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

Surya Patra: My question, sir, having developed one of the strongest COVID portfolio in the country, so can you please provide some more scope and visibility for your key product opportunities on that side in terms of let us say vaccines, what is the volume that you are targeting there? Because there are multiple media updates that we have received about the likely long timeline, likely the volume that you would be doing and even if you can indicate something about pricing strategy that you are thinking about given the large branded market opportunity that has opened up after the government policy about Virafin as well as antibody cocktail which is could be a kind of ultimate answer to the COVID treatment. So, if you can provide some scope and visibility on that front, sir?

Dr. Sharvil Patel: Thank you for the question. I do agree, I think the kind of effort on the R&D front has been really good by the team of scientist and clinicians that are at Zydus. On the three opportunities that you spoke of, on the ZyCoV, the DNA platform vaccine, as I said we are in the final stages

of waiting for our events data to study the efficacy of the product. We have already good data on the immunogenicity and safety and we are just awaiting to achieve an event number which we have to for efficacy and as soon as we do that, we will file for an emergency use authorization which we believe can happen in the next two weeks. It is all dependent on the events number that we get. We have committed to initially start producing one crore doses per month, for the vaccine and with partnership with the manufacturers as well as also looking to see if we can debottleneck and improve our yields going forward, we can come between 2.5 to 3 crores doses over a period of next 4 to 6 months. So that is our current plan for the vaccine. This vaccine also uses a device and we have also secured the whole supply chain for the device as well. Because it is the only intradermal device and the only application in the world which is a needle free application of vaccine. So, this talks about again the strong capability of the company that not only could we develop the vaccine but we have the whole device which is also made in India, now assembled in India and going to be distributed. So that is to do with the first vaccine. The second vaccine still in early days of trial. With respect to Virafin, we are seeing very good results so far in a controlled release of the molecule at the institutions and major hospitals. We have extremely positive feedback on the results that we are seeing, which we have demonstrated in our Phase-III also. So, this drug has potentially a good opportunity to become a very critical product for the treatment of COVID for people who are diagnosed and definitely stops the severity of the disease. And we are very confident that this drug for the near term will be a very important drug for the treatment of COVID. Among all the antivirus it is showing one of the strongest antivirus properties and as we always say that pegylated interferon or the interferons are naturally occurring protein in the body. So, we are actually not adding anything, any new drug or any new substance which can harm the body. So, it is doing very well for us on that front. On the monoclonal therapy again this talks about our research capabilities that we have now demonstrated in animal studies and others that the monoclonal cocktail of antibodies not only protects creation of antibodies and protects against COVID as the therapeutic and prophylaxis but also reduces immunosuppression or immunoexpression which also helps in lung damage, reduction of lung damage and other areas which are comorbid conditions of COVID and we are hoping that in our Phase-I, Phase-III trial we get to demonstrate this. The drug has been designed which will have a longer half life than any other monoclonal therapy available in today's market. So, we also believe that the efficacy off this monoclonal therapy could be longer than any of the current therapies available. And all of these 3 will remain an important area from the therapeutic point of view for the treatment of COVID and we are working on it. We also have some oral drugs that are under development. And our commitment has been that we will continue to develop drugs for COVID.

Surya Patra: Sir, just if you can add on to the, let us say, for Virafin, so how is that different from the prescription point of view compared to that of the Pegihep of your own product and other interferon alpha that is there in the market? That is one. And also on this COVID portfolio, having kind of a dedicated effort to build a kind of one of the strongest portfolio, how sustainable are opportunity that you looked at?

Dr. Sharvil Patel: So, on pegylated interferon, it is a biological product. So, every biological is not the same. Every biological is considered as a new drug. So I think it is biosimilar, biologic is different than the other and they all have to prove their clinical efficacy and we have proven the clinical efficacy. It is very critical how you pegylate the molecule and how you produce the interferon which is a very complicated process. So, I don't think we can compare two interferons in the market. And second part to your question is, I think COVID treatment protocol will remain critically essential and we have committed to being able to provide that.

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

Neha Manpuria: On the US, we did see erosion quarter-on-quarter in the March quarter. In the opening comment there was something about Asacol HD seeing lower offtake or signaling some offtake pressure. So, if you could give some color on the US business and how we see that panning out, the base business?

Dr. Sharvil Patel: I think on the Asacol front the market shares have remained stable. So, there is no issue with that. The offtake are on two things. One is because of COVID issues in the US also, maybe there was, I mean the prescription had slowed down for all drugs and potentially for Asacol also. So that is one impact of it and the other is the stock adjustments that happen quarter-on-quarter which would lead to some of that correction. So, we believe that from quarter 2 onwards we would see a normalized activity on that. And so that is to do with Asacol and with respect to others, we obviously didn't see any of the season related flu which was obviously major impact at the start of the quarter and we are now seeing some price erosion with price challenges which will be offset over a period of time by more volumes and new products.

Neha Manpuria: And sir, in the US, we launched about 30 products this year. And this is the momentum that you can continue for the next two years?

Dr. Sharvil Patel: Yes, so our aspiration is that we will do 40 to 45 launches but comfortably at least 30 plus launches every year.

Neha Manpuria: And for the R&D, since we are starting Phase-II trials for Saroglitazar, now that we have got FDA approval, how should we look at R&D going forward?

Dr. Sharvil Patel: So, I think for the near term, in the next 1 year to 2 years we are, I think we are still okay at around 8% of revenue as R&D expenses. As we come later on to a larger Phase-III, maybe a post 24-25 we can give different guidelines. But with the commensurate growth in revenue and opportunities we still believe that we can maintain an R&D around 8% of overall revenue.

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

Tushar Manudhane: Sir, just on this ZyCoV front, while currently the supply rate can be one crore per month and considering, checking with the industry expert it suggests that the contract manufacturing capacity is kind of chockablock for other vaccines. So how do you see the availability of the capacity for our product?

Dr. Sharvil Patel: We have completely built our capabilities to product both drug substance and drug product and the devices. So, we don't have a concern anywhere between 1 to 2 crores and for additional capacities we are already looking at licensing technology to at least one company immediately. But potentially one or two more. So, we believe we could have an echo system of at least 2 to 3 other contract manufacturers who will be able to produce this vaccine and that is the current plan for the medium term.

Tushar Manudhane: Sir just on Virafin, just to understand why we protocol through state government route rather than going through ICMR or the Central Government route?

Dr. Sharvil Patel: We will work on all of that, including ICMR, but we have just given you an update of what has come first. So as a part of our ongoing process with the experience, we will obviously work towards the drug being involved in part of this overall protocol as well. But already through states we have gotten success. Our major institutions also like in AIMS and some other institution they have seen good usage of it now.

Tushar Manudhane: Understood, sir. And just lastly on the domestic formulation front, while the digital use has enhanced, is being enhanced due to this pandemic situation, but how do you see this cost saving over FY22 as well because of increase use of digital tools.

Dr. Sharvil Patel: So, I don't think digital will show any cost savings at least for the next 1 to 2 years. This whole ecosystem has to be built, the user and the customer has to find it comfortable to move to a new way of working and new way of using it. So, I think this is a medium to long term investment in the digital space, we don't believe you will see its success overnight and immediately and we don't commensurately see any immediate cost savings on that. What we hope to see is higher productivity by the teams, better reach that we can create through this and larger reach that we can create for more brands of the company and also dissemination of more scientific data for proprietary product that we will be launching. And our end goal is to make sure that we look at the disease management and how do we show compliance to the patient in terms of the dosing and the requirements that are there. So that is our overall game plan in terms of how do we improve better disease management for the disease that we are targeting for and make it more complaint, so that we can see better patient outcome. But it is not something that can be achieved in a period of next one year. It is a 3 year-5 year journey now.

Moderator: Thank you. The next question is from the line of Kunal Dhamesha from Emkay Global. Please go ahead.

Kunal Dhamija: So, first housekeeping question on the vaccine front. So there is some confusion regarding what dosage regimen will we be applying for approval, whether it would be 2 dose, or whether it would be 3 does. Because our Phase-III 3 dose regimen and some talks about applying for a 2 dose regime. So, can you please clarify that?

Dr. Sharvil Patel: So I think on study, we have clinical studies, one is the large Phase-III study which is a 3 dose study, for which we are waiting for the efficacy data. We have also at the same time done an abridged study for a 2-dose regimen for the same vaccine for which also the data potentially will be coming in the next 10 days. So, looking at both of that we will make a final call with the regulators in terms of which could be the best mode to move forward, whether it will be a 3 dose or a 2 dose. But currently the body of evidence is largely based on the 3-dose vaccine and once we see our data for 2 dose, we can give you further update which will happen in a very near future.

Kunal Dhamija: And secondly on the Saroglitazar trials for the PBC, so you suggested the trial would start in August. So, are we still sticking to the launch of the product by FY24 for the PBC indication in the US market?

Dr. Sharvil Patel: FY25, we said in the end of calendar year 23, we may potentially file for NDA. So, it will be late, it will be at least not before FY25, in the year of FY25 we can see the launch.

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

Sameer Baisiwala: Just picking up from the previous participant. If it does turnout to be a 3-dose regimen, is the COWIN app enables for that and do you see a lot of administrative issues around it?

Dr. Sharvil Patel: So, currently from whatever we have understood, it should not be a challenge and with both the state government or the central when we have discussed, they already are fully aware of it being currently a 3-dose regimen. So currently it is not the challenge.

Sameer Baisiwala: And sir, can you talk a bit more about the order book that you have, either domestic or exports, do you think your one crore per month can easily get absorbed or do you think there can be some challenges and your thoughts on the pricing?

Dr. Sharvil Patel: So, I think it is an evolving area. If I can answer, if you talk about it for the next 4 months to 6 months, we have the potential to sell more than what we have, significantly more and so I don't think the concern today is about being able to make the vaccine available. It is to make sure how much we can produce in a compliant manner. So, I don't think the demand is the issue for the current period of time for at least till December. On going forward, I think it will all depend on the result of the products, the pricing of the products, the efficacy and safety which will all matter and this potentially all vaccine potentially need maybe looking at an option of whether there will

be a booster dose that would be required annually or in some form. I think the vaccines will be an important aspect of the overall future in terms of how it is administered on an annual basis. But I think today we have more orders than what we can commit too in terms of manufacturing. So, order book is very good. On the pricing front, we have always committed that we will bring the vaccine at an affordable price. And our effort is on that and as soon as we are filing for our emergency use and on the way of approval, we will also announce our pricing.

Sameer Baisiwala: And just, how to think about this going into 2022 I asked this because, if you see everyone's scale up plans, it seems like right now there is a lot of shortage. But in 2022 there will be a massive supply. So I think everyone is doubling or tripling the capacities between Sputnik and the other two. So, do you think there will be a business case for you, going into 2022 and beyond?

Dr. Sharvil Patel: So, Sameer, I think that is a question obviously which we all think about. There will be multiple point to it. One is to vaccinate good part of our, the global requirement for vaccine is still very large. And it will be dependent on multiple things. One, including access and pricing and cold chain and other logistics related to it. So, I think the pricing will play a critical role in terms of how these vaccines play out in the long term. I strongly believe that for treatment, for COVID and vaccination related to that, it could potentially become part of the annual vaccination program, but only time will tell whether that would be the need. We have seen data of whatever is published so far of talking about antibodies going down between 3 months to 6 months to 7 months. So, assuming that you need to take a booster shot, we know that the vaccines will be required on an ongoing basis. So that is one data point. The second is pricing and access in terms of cold chain and other thing which would also play a critical role in terms of what in need available. And finally, obviously the data on safety and efficacy for the long term will matter. So, I think there are many moving parts to it and only then we will be able to figure out finally what happened. But I believe that when you talk about global vaccination and continuous vaccination then pricing becomes very critical and at least we believe that our technology offers us to product vaccine at a lower cost which can be beneficial.

Moderator: Thank you. The next question is from the line of Naveen Baid from Aditya Birla Capital. Please go ahead.

Naveen Baid: My question is, the Phase-III clinical trials, the results from the Phase-III was supposed to be published somewhere middle of April or end of April, but they seem to have gone on well into June now, I mean as per your comments. Any specific reason why the Phase-III clinical trials have taken 40-45 days extra. specially since the endpoints were defined at the start.

Dr. Sharvil Patel: When you talk about efficacy you have to hit an event number, event number of interim maybe 79 on total event number of 158, which is you need these many number of people to become positive. So that is a statistical, we are all guessing as to by when we will achieve that kind of number. So that is not something that can be hard planned weekly. We were hoping that we

would get it see it by end of May. Now we are potentially thinking that with the ongoing trend it can be seen by 1st week of June maybe.

Naveen Baid: Sir, as a corollary, can I assume that maybe the vaccine is showing higher efficacy and that is why you are taking slightly longer to reach the end point considering that the pandemic is raging across the country?

Dr. Sharvil Patel: No, I don't think one can assume that. I would wishfully like to but I don't think that is right. It is just sometimes takes time. It is difficult to plan statistics on a weekly basis. So, in a month we know we achieve it, but every week, how many positive cases we will get is very difficult to predict.

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

Charulata Gaidhani: My question pertains to the innovative products for COVID like interferon, how is the acceptance across India and what kind of revenues do you anticipate from if not interferon the entire innovative products for COVID?

Dr. Sharvil Patel: With the launch of interferon, we have seen very good use and repeat purchases by all major institutions that we have supplied into. As we are able to make more supplies available obviously we will go for larger supplies to state government and larger institutions as well and make it then also available in the retail as we have proper stocks, so that we don't run into wrong practices related to the use or misuse in terms of the drug**.** So that is our endeavor right now and currently whatever we are able to produce, we are able to make it available and we are able to make it available to the patient. We are looking to scale it up by four times or what we need today and we are on track to do that for June and we are still seeing good demand with the amount of cases even if 7% to 10% of these people become eligible for it. This will become an important treatment for the patients for early use, so we are seeing good traction for this molecule and it will continue to do well. With regards to other products like Remdesivir and others we are still seeing uptake. We are the most accessible fully priced Remdesivir. We are at 1/5th of most of the company. So that again is doing very well and it continues to be made available as and where it is needed. So overall this quarter because of the clearly large positive rates that are seen in the country, we have seen very good traction for all our COVID portfolio.

Charulata Gaidhani: How much contribution would you expect from the new products from India?

Dr. Sharvil Patel: From this portfolio for the current quarter will be significant. And for future it will be still very difficult to answer. But for the ongoing quarter, it is critical, it is significant because of the number of cases in the country.

Charulata Gaidhani: And my second question pertains to the animal health transaction. By when would you expect the money to come in?

Dr. Sharvil Patel: We expect the transaction to be completed within a period of 90 days, in all probability earlier than that.

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

Surya Patra: Just one question about the, the 20 products license impact what you have mentioned, out of it 7 have already been signed and you are indicating this is all about your expectation of building a specialty portfolio in the US. So, if you can add some more color to that, that would be useful.

Dr. Sharvil Patel: So, the 20 products that we have licensed for are mostly driven towards complex injectables where you will see, where they are difficult to produce and limited competition. Also, some products where we potentially didn't have the capability to do it in small molecules space and that also we have been able to license where we can be amongst the first generic or with some exclusivity. So, it is a mix of those high value products where we sometimes are late or don't have the capability to do so and we have been able to partner it in and build this franchise on complex injectables, largely complex injectables, but also some small molecule oral solids also.

Surya Patra: But is there any timeline that you can indicate right now sir, for whatever portion of the portfolio?

Dr. Sharvil Patel: Like I said, we launched Fondaparinux last year. This year we are saying we will have another complex injectable launch which will be critical. As and when these come up for critical launches, we will definitely make you all aware of it as soon as we can, but currently for business reasons we can't make some of these things known right now.

Surya Patra: And is it fair to believe sir, the sequential decline in the US business what we have seen, it is entirely because of the weak flu season and specific to the fourth quarter that way?

Dr. Sharvil Patel: Three reasons for it, one we said that offtake on Asacol did slow down, with flu season definitely is nonexistent. Third is we did face pricing challenges on some of our base products which obviously will lead to erosion in value. So, all of those 3-reason led to lower, but the other two are the larger part.

Surya Patra: And since Asacol is an important product, so if you can just add some more color to that? What is the kind of challenge and how sustainable, you have mentioned that it can continue for this quarter as well, but still?

Dr. Sharvil Patel: There is no challenge. We are the only generic in the market. It is only question of offtake which can be, for two reasons, one is inventory adjustments that happen by the distributors and the

second is overall in the US prescriptions came down and so did Asacol prescriptions come down. So both of those are the reasons for lower off take.

Surya Patra: Just last question if I may. On the margin front, we know that this COVID portfolio could really surprise FY22 earnings in a big way. But on the core business front, what margin visibility or trajectory that one should really expect for Cadila?

Dr. Sharvil Patel: Again, without COVID portfolio also our gross margin profile is actually much better than the COVID portfolio. You will see that in most of the portfolio that we have launched for COVID we are one of the most accessible products or lowest price products, but our interest here is to make sure that we can make this drug affordably available to the patients at large. So, this is a conscious effort by the company to not charge what we would normally charge but significantly reduce the pricing. So on the gross margin front overall business delivered better gross margins, our base business minus COVID also did extremely well and overperformed and so in the animal health and the consumer health and the pharma business. So, it was an overall good performance by the whole India geography and not driven by COVID. So, COVID does add to the profit, but the profitability is lower compared to the base business.

Surya Patra: For the outlook price, if you can just provide some sense of what would drive that and what margin trajectory for the base business that we should expect because there are so many things happening in profitable progress in the domestic business and US is obviously getting the benefit of the export opportunity and you have exited out of the animal business which was not that great or not fitting to the long term strategy. So given all these, the base business itself looks positive sequentially in terms of profitable progress.

Dr. Sharvil Patel: As I said, one is the India geography overall has more than 50% contribution to the quarter. The branded portfolio has done significantly well. Our consumer health business also has delivered very strongly. The second part is our portfolio, so the gross margins are good because the product mix has been very good. The second part is, we always said that we are looking at around 22% margins for EBITDA on a sustainable basis. However, because of COVID we would see some better result for the coming quarter because obviously a larger sale of COVID products. But by and large because of better utilization, better cost management and making sure that we improved our health on the overall front by reducing the non-viable product and now the proprietary products and IP driven products also contributing, biosimilar contributing, all of that is improving the profile of the branded business.

Moderator: Thank you. The next question is from the line of Jatin Karani from Samattva Advisors. Please go ahead.

Jatin Karani: I just had a question on, you mentioned there is another vaccine candidate that is under clinical trials. So just wanted to understand the thought process behind this second candidate that we have, why are we pursing that considering we on Phase-III of main candidate, and as far as

ZyCoV-D is concerned, can you give some color on what kind of logistics are required for this as well as administration still happen at the hospital level, right?

Dr. Sharvil Patel: So, I will answer the second question first. On the logistics and supply part of the ZyCoV-D it has some of the least challenges because it is thermostable. It is stable at 2 degrees to 8 degrees and it is stable at 25 degrees for more than 5 months now. So, logistically it would be definitely something that would be not a significant challenge compared to other vaccines and potentially will lead to less wastage or less all of those concerns related to mishaps in cold chain, because it is very stable. And obviously it will be given at medical centers supervised by the nursing staff or whoever is. The good part of this vaccine is that it is intradermal application. So, it has lot of benefit compared to the intramuscular injections that are given for other vaccines. And that benefit will definitely play out in terms of the acceptability of this vaccine when it gets rolled out into the general public. With respect to the other vaccines, when we were in the development phase of COVID we were obviously wanting to work on beyond one strategy. So we have two opportunities, one was the DNA platform and one is a measles vector based platform. We believe that going forward, the whole virus understanding is evolving. We also know that there are other challenges that can be posed and so I think from our point of view we believe that it is prudent for us to have work on at least more than technologies and we do have the capability to do so also. So, we are going to move forward in a not as aggressive manner as we moved for the DNA vaccine, but definitely do the animal studies and maybe certain Phase-I studies to see if the new generation vaccines could potentially be better than the current vaccine. And that effort is an R&D effort which will continue. So we would want to bet on more than one vaccine and we are making an effort to see whether the second platform is equally good or has some other advantages.

Jatin Karani: And sir, as far as the ZyCoV-D is concerned, I understand you are also doing trials, as you mentioned for 12 to 18 years old, so will that makers of first vaccine, if once it gets approved, we will be first vaccine that is applicable for children?

Dr. Sharvil Patel: Actually, definitely has the potential because we are covering more than 1000 children. So, it definitely will have that opportunity and as I said this vaccine is a needle free application. So, it will be far more suited for children because of the worry of giving needle injections and other things. So, it doesn't have any onset of pain. It doesn't have site reactions, on-site reactions that happen with many intermuscular injections. So, it would be far more suited for children also and that is why we were approved to do a study in children because of the platform and the safety of this platform and obviously the way of administering it. So, we are hoping that once we see the body of evidence and if it looks good it will potentially be approved for children also.

Jatin Karani: And as far as our capacity, you mentioned we will be starting off with one crore per month capacity which at some point will be ramped up to 3 crores a month, right, that is what we are planning. So, what would be the time frame for this ramp up?

Dr. Sharvil Patel: So, initially we will be producing about one crore doses per month. First, the partnerships, in the next four months we can probably improve it to another 15% more and then if we are able to do any further some incremental investment, we can then double our internal capacity, which would take around 6 months.

Jatin Karani: And sir, can you give us some color on, what would be the margins for this kind of a product? I understand we will have a very affordable product, but even at an affordable price point, what could be, some guidance on the margin?

Dr. Sharvil Patel: So, it is currently not easy to answer that. Definitely it will have, we have put in a lot of money and investment behind it. Yet, we will also make sure that it is made affordable. So, it will definitely be profitable, but it is very difficult to say yet because we are still in the scale up space to producing up to one crore doses and all of that and once we are able to do that and then obviously the pricing, then finally we can give you that answer. But at least as of today it is a little pre mature for us to give you margin outlook.

Moderator: Thank you. The next question is from the line of Kunal Dhamesha from Emkay Global. Please go ahead.

Kunal Dhamija: Sir, on the vaccine front, have we reached the interim event data or are we still waiting to reach interim events?

Dr. Sharvil Patel: We are waiting for the interim event data.

Kunal Dhamija: And that we expect to happen in by next couple of weeks, right? And will we be able to file?

Dr. Sharvil Patel: My best estimate is in the next 10-15 days maximum, yes.

Kunal Dhamija: And based on that will we be able to file for the emergency use authorization?

Dr. Sharvil Patel: Yes.

Moderator: Thank you. The next question is from the line of Ranveer Singh from Sunidhi Securities. Please go ahead.

Ranveer: Ranveer here. Sir, one question on trastuzumab ADC, can you give some outlook what would be, what kind of market is currently existing or what is the revenue potential we see from this product?

Dr. Sharvil Patel: The potential of this molecule is very good. We are aspiring to achieve a 50 crores number in the next 12 months - 15 months and that is what we are moving towards, but it is definitely a 30 plus crores opportunity in the short term. So, it will be a sizeable new introduction for us because it will be an accessible, today the cost of treatment for this is very expensive and we believe the

affordability that we have brought for this medicine and the science behind it, it has a potential to be a very important biosimilar launch in the oncology space.

Ranveer: Sir, wanted to understand some data, you mentioned sir roughly 2 lakhs patients are currently on breast cancer and I think most of them might be using this trastuzumab. Going by this even 10,000 patient some more than 30 crores kind of market size. So, of that two lakhs, can we get more than 10%-30% kind of market share in terms of patient pool?

Dr. Sharvil Patel: We will definitely get more than that.

Ranveer: And another book keeping question, other income is negative. So, what is the reason in Q4?

Vishal Gor: Actually, we have an agreement with another joint venture partners and that is accounted as forward contract because of the certain terms of that agreement. Under that forward contract we had a loss on fair valuation which even though we were having gain. So, the cumulative loss for the year has been accounted for as negative amount in the other income side. And that amount is about Rs. 49 crores for the quarter.

Ranveer: And the last one, this quarter we have various strong boost from wellness business and some COVID related portfolio also. Just if I remove that your wellness business from the overall consolidated number, actually we have seen a degrowth. So apart from US India should have, we are expecting India to give better performance ex wellness. So, in India business also apart from COVID, the base portfolio we have seen weakness there?

Dr. Sharvil Patel: I don't think you got the numbers right. India business for quarter four has shown very good growth. So, I don't know where you got saying it is negative. All these businesses have delivered double digit growth.

Ranveer: So, going forward basically that I wanted to understand is the base business, because COVID I understand this is the gravity of pandemic will definitely reduce going forward. So base business can we see some 2 years - 3 years down the line growing at least in double digit or higher double digit kind of number, in India perspective I am asking.

Dr. Sharvil Patel: Yes, we have definitely we have said that the base business has done extremely well and will continue to do well even in the quarter it has grown at 15% and if you take the branded market only, it has grown at 16%. So, the base business has done extremely well, even the emerging market business has a strong double-digit growth. So I think overall other than US, all businesses have delivered strong double digit growth and they continue to do so and they were all driven by base business. Because in the last quarter there was no impact of COVID product in the business.

Moderator: Thank you. Ladies and gentlemen, due to time constraint we take that as the last question. I would now like to answer the conference over to Mr. Ganesh Nayak for closing comments. Over to you, sir.

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

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