“Cadila Healthcare Limited Q4 FY20 Post Results Conference Call”

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Moderator: Ladies and gentlemen, good day and welcome to Q4 FY20 Post Results Conference Call for Cadila Healthcare Limited. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' and then '0' on your touchtone phone. Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Ganesh Nayak - COO and Executive Director of Cadila Healthcare Limited. Thank you and over to you, Mr. Nayak.

Ganesh Nayak: Good evening, ladies and gentlemen. Welcome to our post results teleconference for the quarter and the year ended March 31st 2020. I do wish that you and your family are safe and healthy during these unprecedented times. 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 Vishal Gor – Senior Vice President, Corporate Finance.

Unabated spread of COVID-19 and the resultant lockdown imposed by the governments across the globe since the beginning of the current calendar year has brought a lot of uncertainties to the business operations not just for us, but for organizations across different sectors. Therefore before moving onto the highlights of the operations for the quarter and the year gone by, let me give you an overview of the actions taken by us to manage our operations in the current scenario and the role played by us to extent the support to the government and the communities at large during these challenging times. In today's prime times for the world, our focus is on ensuring the safety of our employees and all other stakeholders while we ensure that our business operations are run with minimal interruptions as setting up the lights and protecting the livelihood, both are of utmost importance to us. We have taken several steps aimed at ensuring the safety of our employees which include remote working across all the locations, physical distancing at work places, mandated use of protective gears, sanitization of our office premises, plant locations and company vehicles and thermal screening of employees working at our sites.

We have created a group of senior management team to monitor the events happening in the external environment and take suitable preventive and corrective measures to ensure continued safety of the employees and continuity of our business. The team has implemented a business continuity plan across the functions to ensure that the operations continue right through the pandemic situation. We have also established a liquidity management office for monitoring of the cash flows with the objectives of managing and controlling cost, reserving liquidity and sustain the business operations. I am pleased to inform you that our teams across the functions namely manufacturing, quality, regulatory, supply chain, marketing, R&D and other support functions have put in strong collaborative efforts to navigate the business amidst these testing times. All our manufacturing facilities were operating at reasonable capacity utilization even during the lockdown and we have strengthened our supply chain to ensure continued and timely delivery of our products to our customers. There were some logistics related challenges towards

the end of March and during the month of April especially for our India operations; however, the situation has now stabilized to a large extent.

I am happy to inform you that we have been doing whatever possible in this fight against COVID-19. This includes amongst others supplying HCQ tablets to the government, Hydroxychloroquine Sulfate to the government of India and other customers across several countries at very reasonable prices. Manufacturing COVID testing kits for the ICMR partnering with Gilead Sciences for the manufacture of Remdesivir for the Indian market exploring the biologics route to treat the disease with our long-acting biological therapy Pegylated Interferon alpha-2b and working on the development of a vaccine for the virus.

With that, let me take you through the financial numbers for the quarter and the year gone by. During the fourth quarter of FY20, we posted a consolidated revenue of Rs. 37.5 billion, up by 3% over Rs. 36.4 billion reported in the preceding quarters. While the performance of overall business was in line with the expectations during the first 2 months of the quarter, businesses in India and the emerging markets were impacted during the second half of March on account of the spread of the virus and the consequent lockdown imposed by the government of India and other countries across the globe which resulted into disruption of supply of our supply chain and the non-availability of channel partners in the initial days of the lockdown. In the US while the pandemic did not have any adverse impact on the business, our sales during the quarter did not have any material positive impact of panic buying from the customers. Excluding the impact of COVID-19 related disruptions, consolidated revenues would have grown by 10% on a quarter-on-quarter basis. Consolidated EBITDA grew to Rs. 7.91 billion, up 13% on a sequential basis, adding a delta of Rs. 935 million over the previous quarter.

Overall, we expanded our EBITDA market by 190 basis points to 21.1% against the 19.2% registered in Q3 FY20. Volume expansion across the portfolio in the US led to the improvement in the EBITDA margins. Consolidated PAT for the quarter excluding the exceptional items was Rs. 4.3 billion, up 14% on a sequential basis.

Our India geography comprising of Human Health, Consumer Wellness and Animal Health has grown by 6% on a year-on-year basis registering a revenue of Rs. 15.02 billion during the quarter. Excluding the impact of COVID-19 on our business operations and adjusting the base of our Consumer Wellness business for Q4 FY19 on a comparable basis, our business in India, the Indian geography would have grown by 11% on a year-on-year basis during the quarter as the business lost revenues of approximately Rs. 2.2 billion on account of COVID-19 related disruptions. The US geography comprising of generics and specialty portfolio registered a revenue of Rs. 17.6 billion during the quarter, up 5% on a sequential basis. Rest of the world business comprising of multiple emerging markets would have grown by 6% during the quarter on a year-on-year basis after adjusting for the COVID related impact.

On a full year basis, we posted a consolidated revenue of Rs. 142.5 billion, up 8% on a year-on-year basis. Consolidated EBITDA for the year was Rs. 27.8 billion, down by 7% on a year-on-year basis. EBITDA margin for the year stood at 19.5% for the year. Consolidated PAT for the year adjusted for exceptional items was Rs. 14.6 billion, down 21%.

Now let me take you through the operating highlights for the financial year 19-20 for each of our business lines. Starting with our Human Health business in the India geography, the business started to show signs of improvement from the beginning of the financial year on the back of the multiple strategic initiatives undertaken to bring back the growth in the business. During the year, we restructured the portfolio of our 100% subsidiary, Zydus Healthcare Limited which contributes to our 80% of the Human Health Formulations business of the group in India by bifurcating it into 2 clusters namely mass and specialty for us to drive the marketing and promotional efforts in a focused manner. In the case of a mass cluster, the focus will be to improve market penetration by expanding the reach of the products and in case of a specialty cluster, the focus will be on intensified engagement efforts with the key opinion leaders. Efforts were made to create a strategic synergy within the divisions and clusters by reorganizing the brand portfolio to consolidate, sustain and build the existing brands.

During the year, we successfully completed the nationwide implementation of the new salesforce effectiveness initiative which has been developed for second line sales managers and above. The focus of the initiative is on demand generation by improving the sales planning cycle and also improve the quality of interactions between field business officers and business managers. A new model was implemented for improving the forecast accuracy through consensus planning. Now while the performance of the business showed gradual improvement during the first 3 quarters of the financial year on the back of various strategic initiatives and the performance during the first 2 months of the last quarter of the financial which was also as per the expectations, the business was impacted in the second half of March 2020 on account of the spread of the virus and the consequent nationwide lockdown imposed by the government of India in the latter part of March. Overall, the performance of our branded Human Health business remained flat on a year-on-year basis during the fourth quarter while for the full year, the business grew by 6.6%. Excluding the impact of COVID related disruptions, our branded business would have grown by 11% during the fourth quarter and by 10% during the year. As per the AWACS data, the business grew by 11.9% during the year 19-20 outperforming the overall Indian pharma market's growth of 9.8%.

In terms of performance of different therapies, our gynaecological, gastrointestinal and pain management portfolios grew better than the market. Specifically speaking, our gynaec portfolio grew by 12.5% versus the market growth of 6.1, almost twice. The GI, gastrointestinal portfolio registered a growth of 8.6 versus the market growth of 7.9 while the growth in the pain management portfolio was 12.4% against the market growth of 9.3%. On the brands front, our pillar brands having annual sales in excess of Rs. 500 million each and which constitute to 32%

of our branded formulations, the sales grew thereby 9% during the year while the mid-sized brands having annual sales between Rs. 250 million and Rs. 500 million and which constitute 24% of our branded formulation sales grew in double digits with 14% growth during the year.

The financial year gone by was the first full year of confirmation for our Consumer Wellness business as we completed end-to-end integration of the acquired business of Heinz India Private Limited and we are happy to inform you that the integration progressed better than what we had planned or envisaged at the beginning of the year. We continued our thrust on marketing initiatives to grow the categories and increase the market shares of the brands. Overall, Zydus Wellness posted a sales of Rs. 4.9 billion during the fourth quarter with a growth of 22% on a year-on-year basis while for the year, it posted sales of Rs. 17.4 billion, up by 115%.

Financial numbers of the current and previous years are not comparable as the previous year's numbers include the acquired entity's numbers for 2 months. Excluding the impact of COVID-19 related disruptions and adjusting the base of the previous year on account of the Heinz acquisition, the business would have grown by a 11% during the quarter and 10% during the year.

During the year, we restructured our Animal Health business by transferring the entire business including India, US and the rest of the world from the parent company Cadila Healthcare Limited to its subsidiary Zydus Animal Health and Investments Limited on a slump exchange basis to achieve better focus and explore newer strategic opportunities. Overall, our Animal Health business posted sales of Rs. 1.2 billion during the fourth quarter and Rs. 5.15 billion during the year. Excluding the impact of COVID-related disruptions, the business would have grown by 16% during the fourth quarter on a year-on-year basis while the growth for the year would have been 5%. Delayed monsoon and drought-like situation in some parts of the country during the first and the second quarter impacted the annual growth.

Now let me talk you through the performance of our US Formulations business. During the year gone by, the US was the largest contributor to our consolidated revenues with a 45% share. Despite the increased competition and pricing pressure, our US generics business grew by 7% during the year on a higher base of the previous year on the back of increase in the volume share of existing products and the launch of new products. We are now ranked 4th amongst the US generics companies based on prescriptions with a gain of 3 positions from the previous year. As mentioned earlier, the overall business grew by 5% during the fourth quarter on a sequential basis. The growth was driven by increase in volumes, increase in the sales of Oseltamivir on account of the flu season and the launch of 6 new products during the quarter. Excluding the specialty portfolio of Sentynl, the business grew by 6% on a Q-on-Q basis. We launched 30 new products in the US generics market during the year. New launches include Rivastigmine transdermal patch which is the first transdermal patch launched from our own pipeline. During the year, we filed 30 additional ANDAs with USFDA taking the cumulative number of our

filings to 390 and we have received final approvals for 23 new products and tentative approval for 5 new products from the USFDA taking our cumulative number of approvals to 282.

Coming to the emerging markets, we continued to perform well in some of the key geographies of Asia Pacific and Africa regions, driven by volume expansion of our pillar brands; however, performance in some of the countries was impacted on account of increase in the generic competition, a rapid price decline in institutional business and some uncertain regulatory environment leading to significant delays in new product approvals. In order to leverage the market opportunities in the emerging markets, we strengthened the business development efforts with a strong focus on inlicensing and outlicensing activities during the year. We filed 21 new product dossiers from the new manufacturing site at our Myanmar facility for various countries of the Asia Pacific region during the year so as to strengthen the local presence and pursue the regional opportunities in the Asia Pacific region. Overall, our emerging markets formulations business posted sales of Rs. 1 billion during the fourth quarter, down 17% while for the year, the business grew by 5% with the sale of Rs. 8.75 billion. Excluding the impact of COVID-related disruptions, the business would have grown by 5% during the quarter and by 11% during the year as the business lost revenues of approximately Rs. 470 million on account of COVID-related disruptions.

On the biologics portfolio which presently gets clubbed in India and other geographies, it continued its momentum and recorded a sale of Rs. 2,779 million during the year, up 19%.

Now coming to the operations and compliance front, we continue to take all the remediation measures necessary to address the observations raised by the USFDA in the warning letter issued to Moraiya and we also having submitting specific updates to brief them about the actions which having taken by us against the commitments made. Recently, this month itself in the month of June, we gave the fifth update to USFDA with respect to the corrective and preventive actions taken mentioning about completion of a majority of the commitments made and we have requested the FDA for a conference call to discuss the way forward and a desktop audit. As shared with you earlier, we have already initiated site transfers of all injectable products from Moraiya to Liva. In fact, we have launched the first site transfer product from Liva in the month of May last month.

During the year, our oral solid dosage formulations manufacturing facility located at Ahmedabad SEZ received EIR from the USFDA with the voluntary action indicated classification for the facility. The EIR followed by the inspection conducted by the FDA from the 25th of March to the 3rd of April which concluded the one observation. We continue to maintain our successful track record of regulatory compliance at our other facilities as we successfully completed 6 USFDA inspections without any observations in each of these inspections. The facilities which were inspected by USFDA during the year are the Baddi formulations twice, our oncology injectable facility of Alidac Pharma in the Ahmedabad SEZ, the tropical formulations facility

near Changodar and the API manufacturing facilities both at Ankleshwar and Dabhasa. We have also received the EIRs for inspections done at the Baddi formulations facility, tropical formulations facility and the API manufacturing facilities at Ankleshwar and Dabhasa.

Coming to the inspections done by other regulatory authorities are biologics fill and finish manufacturing facility located at the Zydus Biotech Park in Ahmedabad, successfully completed the audits by the regulatory authorities of Sri Lanka, Russia and Mexico while the vaccines manufacturing facility at our Vaccine Technology Center successfully completed the joint inspection by the DCGI and CDL, Kasauli India.

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

Dr. Sharvil Patel: We are happy to inform you that the year gone by has turned out to be a very important and encouraging year for us in perspective of the initiatives taken in the space of innovation. Talking about the progress made on our NCE research first. In the month of March 2020, we received the approval from the DCGI for the new drug application for our lead compound, Saroglitazar Magnesium for the treatment of NASH in India. The drug has become the cost ever drug approved anywhere in the world for the treatment of nonalcoholic steatohepatitis. We also received the approval from DCGI for the use of Saroglitazar Magnesium in the treatment of type 2 diabetes mellitus as an add-on therapy with metformin during the year.

In the month of October 2019, we successfully completed EVIDENCE IV Phase 2 clinical trial for Saroglitazar in US in the patients with NAFLD and NASH, and the molecule achieved the primary efficacy endpoint. A statistically significant 44.39% reduction in ALT was observed in patients treated with Saroglitazar. The EVIDENCE IV NASH trial was a randomized, double-blinded, placebo-controlled study that enrolled 106 patients in NAFLD, including NASH across 20 clinical sites in the United States of America and has very good safety and tolerability**.** In the month of November 2019, we made a presentation for Saroglitazar in NAFLD at American Association for the Study of Liver diseases at Boston and the paper was adjudged as the best of NAFLD/NASH debriefs given by the AASLD. We have also initiated enrolment of patients across several clinical sites in the US and Mexico for an EVIDENCE VII Phase 2 clinical trial for evaluation of Saroglitazar in the treatment of NAFLD in women with polycystic ovary syndrome which is PCOS during the quarter. Additionally, we are also having an approval from the USFDA to conduct Saroglitazar trails in hepatic impairment, 100 patients and renal impairment, 32 patients indication. These studies will help us understand the pharmacokinetics of Saroglitazar in mild, moderate and severe hepatic impairment patients and severe renal impairment patients. Saroglitazar has shown a 48% reduction in alkaline phosphatase and 63% reduction in gamma-glutamyl transpeptidase in 6 completed PBC patients. The study was an open labeled study conducted in Mexico.

Recently, on June 9th 2020, Nature which is the world's leading multidisciplinary science journal published an article on our lead molecule Saroglitazar highlighting that the PPARalpha/gamma agonist improves insulin resistance and steatohepatitis in a diet-induced animal model of non-alcoholic fatty liver disease.

Coming to our other molecules in NCE pipeline, Desidustat, we initiated Phase-III clinical trials in India targeting anemia both in dialysis and non-dialysis dependent CKD patients. Additionally, Desidustat, HIF-PHD2 inhibitor is also being filed in US for myelodysplastic anemia. This is the most prominent feature of a large bone marrow disorder called myelodysplastic syndrome. The disorder affects how bone marrow stem cells produce and release new blood cell. 60,000 patients in USA and 14,000 patients in Japan are living with this disease. Desidustat is also being perceived in USA for chemotherapy-induced anemia. Chemotherapy-induced anemia occurs frequently in patients receiving myelosuppressive chemotherapy and this inhibits work by maintaining increasing levels of haemoglobin oxygen carrying capacity, iron regulation as well as reducing inflammation in these groups of patients. Desidustat is also being evaluated in moderate COVID patients that attacks with the novel Corona, pneumonia, COVID-19 will cause less and less haemoglobin that can carry oxygen and carbon dioxide. The lung cells have extreme intense poisoning and inflammation due to the inability to exchange CO2 and oxygen frequently which eventually results in brown-like lung images. Iron dysregulation is also noticed in subjects with COVID-19. Desidustat regulates HIF which in turn results in increasing EPO and inhibition of hepcidin thereby relieving the symptoms in COVID patients.

In February 2020, we have out-licensed the rights of Desidustat in China to CMS, China Medical System. This will boost our overall commercializing strategy for anemia drug Desidustat being developed for chronic CKD patients. The deal provides us access to markets in Greater China, mainland China, Hong Kong special administrative region, Macau special administrative region and Taiwan which have significant number of CKD patients. We have also received an approval from DCGI to initiate a Phase-I clinical trial for our new molecule, ZYBK2, an another investigational drug for treating rheumatoid arthritis.

During the pandemic of COVID-19, various nations and organizations are exploring novel drug molecular entity for treatment of COVID-19. Also, there is a huge interest in repurpose drug for the treatment in COVID-19**.** We have also followed similar approaches and have taken multiple initiatives for tackling pandemic of COVID-19. As a healthcare organization, we have initiated across the spectrum from prevention to treatment of COVID-19 using a diverse set of capabilities and small molecule therapeutics, biologics testing and even used a range of wellness products for sanitization and immunity enhancement.

Now talking about the biologics front, in a bid to provide treatment options against novel Coronavirus, we have explored multiple options and portfolio for biologics products and based

on available evidence, have selected the long-acting biological therapy of Pegylated Interferon alpha-2b as a product for treatment of COVID-19. The treatment has emerged after recent research conducted in the US which showed that Interferon alpha significantly reduces novel Coronavirus titers in vitro. A clinical study in China shows shortened duration of viral shedding in the patients. The DCGI has approved a clinical trial study proposal for usage of Pegylated Interferon alpha-2b in treatment of moderate cases of COVID-19. We will attempt to go ahead with the study of this product in moderate cases of COVID-19 in Mexico where we are now awaiting COFEPRIS approval. We are also working with the USFDA to open an IND for Pegylated Interferon alpha-2b in mild cases of COVID-19. Overall, we hope Peg Interferon alpha-2b proves to be an important biological for the treatment of COVID-19 patients and could provide a hope in the current pandemic.

On the biological front, we achieved significant milestone as we received the first marketing authorization in India from DCGI for a novel biological RabiMab. The product will be launched under the brand name Twinrab in the month of June and is indicated in combination with Rabies vaccine for rabies post-exposure prophylaxis. This product is also highlighted a commitment to bring forward novel NCEs and novel biologics from lab to market to meet the unmet medical needs. Also, this product very well complements rabies vaccine.

On the international front, RabiMabs has got orphan drug designation from the USFDA during the year in May 2019. Also, we are in advanced stages of discussion with one of the largest Chinese players for an arrangement of commercializing this product in China due to the large unmet medical needs in treatment of rabies. We have also initiated a Phase-III clinical trial for our antibody-drug conjugate and Rituximab during the year**.**

Coming to the biosimilars candidate, we have 7 products under early stage of development, of which we have completed preclinical toxicity for one and initiated another preclinical for one more product during the year. On the emerging market front, we continue to file our biosimilar product in all of these markets with 5 new dossiers during the year. Also, we expect an area of approval for biological products on emerging markets in the coming year. In Russia, we are expecting approval of 2, 3 products by the 2020 year end.

Talking about vaccines, in the vaccine space, we have an organization that has been on the forefront of development of key vaccines like VaxiFlu, which was the first H1N1 vaccine. We have been pioneers in vaccine space with multiple vaccines for diseases like rabies, Hep B, measles, mumps, rubella, varicella, influenza and typhoid. Now in the current pandemic, we have initiated a fast-track research program with multiple teams in India and Europe for developing a vaccine for COVID-19. The first approach deals with the DNA vaccine against a major virus membrane protein responsible for entry of the virus into the cell. The immunization potential of this DNA vaccine has been evaluated in suitable annular models in dose changing studies using different formulations and is found to be elicited strong immune response. At

present, pre-clinical toxicological study in animals is underway to ensure safety of the vaccine. Hopefully, by next month, we plan to initiate and adapt a clinical trial for the DNA vaccine candidate and we are working closely with the Indian regulator to fast-track this program in order to use novel and adaptive approaches in clinical trial to speed up the approval process of the vaccine program and we hope to achieve rapid breakthrough on the same at par with other COVID-19 developers across the world. This would enable us to serve the Indian population at the earliest and provide hope and respite from the current crisis of the COVID-19.

We also have a second approach where we are working on as a follow-on approach. We successfully also completed Phase-II, III clinical trials for our pentavalent vaccine and waiting market authorization. Also, our Hep B vaccine has received market authorization and we are initiating our Phase-II, III clinical trials for our CD vaccine very soon. We have also completed Phase-I trial for our inactivated Hep A vaccine and a Phase-I clinical trial for recombinant Hep B vaccine.

From the business perspective, vaccine is going to be an integral growth driver for us with a diverse portfolio of vaccines in a development pipeline. For a couple of vaccine candidates in our portfolio, we are also in process of applying for prequalification to WHO so that we can expand and establish our presence of supply of these vaccines to procurement agencies like GAVI and PAHO.

Coming to the 55 b (2), an in-licensing initiative, we have developed the portfolio of innovation 55 b (2) product. The portfolio comprises of novel concept offering incremental innovation and fulfilling existing unmet medical needs. Our focus is to enhance patient ease and offer better treatment options to physicians. During the year, we submitted 3 INDs with the USFDA for our inhouse 55 b (2) program. We are also exploring potential strategic collaborations and licensing opportunities to grow our tech business through an inorganic route. At the global level, business environment remains increasingly challenging on account of pandemic and the measures taken by the countries to contain its spread. We are finding newer ways of managing our business and have been working on changes in the business model including increased use of digital technology so as to adapt ourselves to the new norm imposed on us by all of us by the pandemic. We remain hopeful to continue to grow amidst these testing times and emerge as a strong player.

Thank you and now, we can start the Q&A.

Moderator: Ladies and gentlemen, we will now begin the question and answer session. We take the first question from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Sir, first question is just on understanding that India, an emerging market has been little weak due to the COVID situation and US, you mentioned that you have seen a volume uptick which has led to better gross margins, is that a correct statement?

Ganesh Nayak: Yes.

Prakash Agarwal: So you are attributing the better gross margins to largely the US business which has done better volumes?

Ganesh Nayak: Yes.

Prakash Agarwal: Can you share outlook for the US business for next year and did we have any COVID related supply opportunity in the Q4 or in the upcoming quarters?

Ganesh Nayak: No, we do not have any opportunity. In fact, we made sure that we were not forced to do that. And as far as the guidance is concerned, under these circumstances, we do not feel it appropriate to do so.

Dr. Sharvil Patel: But from what you just said and Mr. Nayak said, we have no significant sales because of COVID, it is normal sale that we have for the quarter and our trajectory looks good for the US.

Prakash Agarwal: And second question is on the peak cash flow done for the year and I see there is a net debt reduction of about 400 crores. Would that number be correct and what is the outlook for 21 for net debt reduction please?

Nitin Parekh: Prakash, actually the net debt reduction would have been even higher in March, but we paid an interim dividend of about Rs. 450 crores including the dividend distribution tax. That not being there, our net debt reduction would have been even higher by Rs. 450 crores. So for FY21, subject to COVID related impact on business margins and cash flow, our plan is to reduce the net debt by about Rs. 800 to Rs. 1000 crores.

Moderator: Thank you. We take the next question from the line of Kunal Damesha from Systematix Shares. Please go ahead.

Kunal Damesha: So now that we have segmented our India formulation business into mass and specialty, could you provide some color in terms of revenues of mass segment versus specialty segment and the kind of field force we have in both of those?

Ganesh Nayak: It is 55 broadly on the mass and 45 on the specialty.

Kunal Damesha: And on salesforce, similar proportion?

Harish Sadana: Salesforce could be around 60-65% on mass and specialty it could have been lower it is around (+35).

Ganesh Nayak: Exact numbers Vishal will give you later on, but broadly it should be about Harish just mentioned.

Kunal Damesha: Thank you for that. And going forward, what would be your focus, let us say, are we planning to hire more salesforce into specialty or the focus would be mass, some outlook in terms of India formulation from next 2 to 3-year perspective?

Ganesh Nayak: There have been quite a few learning in the last 3 months because of this COVID thing and one is in terms of total manpower, we will have to really think, we are talking about an increase, but obviously, the focus is going to be more on the chronic segment.

Dr. Sharvil Patel: So let me also explain to whatever they said. So one is mass with appropriate fieldforce we have, we feel they have enough penetration possible in terms of reach, so that will help us in terms of gaining more prescriptions. And on the specialty front, it is going to be more focus and driven largely by scientific medical detailing and new launches. So I think both, we do not require any additional salesforce or fieldforce in the future.

Kunal Damesha: And secondly on the Saroglitazar, what is our plan forward for US? Now that we have Phase-II trial, have we started Phase-III trial or are we partnering?

Dr. Sharvil Patel: We are finalizing the total cost for Phase-III and we will be going to the FDA**.** We were hoping to do so in quarter one, but maybe it will be in quarter two where we will reach the FDA for Phase-III protocol.

Kunal Damesha: And then commercialization, will we be doing it on our own or will be partnering?

Dr. Sharvil Patel: That is too early to decide, but we will look at all options.

Kunal Damesha: And the cost of the trial, how much it would be?

Dr. Sharvil Patel: We have not got an estimate yet.

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

Anubhav Aggarwal: One question that you mentioned that in this quarter, if everything was normal, we would have grown 10% sequentially so that gives out roughly we had lost about 250 crores sales in this quarter. I just wanted to understand if the sales would have come, how much EBITDA would have extra come in because on the total margins that we reported, it does not look like a large part of, what I am trying to say is that on the cost side, so if some of the sales has not come in, is it that some of the cost also has not been booked yet, if the 250-260 crores would have come in, what kind of EBITDA would have come in?

Ganesh Nayak: So in that case, our EBITDA would have been higher by about maybe Rs. 80 – Rs. 100 crores.

Anubhav Aggarwal: And second question I had about the US market, how are you seeing the market right now? Are some of the global companies because of the social distancing norms still facing production issue, so are there significant amount of opportunities in the market to gain market shares on the volume for the regular products or you are not taking them because you are not sure on the COVID situation right now**.** What is the scenario right now?

Dr. Sharvil Patel: So as we already spoke about earlier, for the financial year we have had volume gain that has happened and we continue to see those opportunities on our base business to increase volume. I do not think it is because of only COVID, it is multiple reasons in the supply chain, higher risk of supply from intermediates and APIs from certain regions, issues related to plants and compliances and also supply chain efficiencies. All of that have led to our ability to garner more share and we are still seeing opportunities to gain more share with new things happening all the time. So the NDMA issue happened with the whole sartan family. You hear similar things happening with Ranitidine, you hear similar things now with metformin and so we are capitalizing on all of these opportunities and also seeing opportunities on product because many of our products we do are very difficult to manufacture. So we are seeing volume gains there as well through one-time buys also.

Moderator: Thank you. We take the next question from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: Sir just on the innovation program front, since it is a full year, can you just give some clarity that, from all these efforts whether we talk about NCE or vaccine or biosimilar, all put together what would be our global revenue let us say and against that, what would be the cost that we would be incurring annually on that front? And if you can share how this structure cost wise towards this innovation program can change in the current year FY21?

Dr. Sharvil Patel: Let me explain to you for the cost part of it. So our guidance that we are comfortable between 7-8% of our spend on R&D from revenue and that is what is our guidance going forward that includes small molecule R&D, biologics, vaccines and formulations R&D as well**.** If you look at it, half of it goes into US formulations research and the rest of it is into the biological vaccines. So that is how the breakup of spend. Now with respect to outlook on these, these are all proprietary, new chemical entities. If you look at our biosimilar business, start of the business. So we see that scaling up in the future. Vaccines is also, we have a large pipeline of vaccines coming up. So good commercialization and value creation will happen in the year 22-23 and that is where you will see large scale revenues from all of these products.

Surya Patra: Whether you have mentioned that specific revenue number for the entire…

Dr. Sharvil Patel: We have not given specific guidance, but we will give it when we are nearer to those financial years.

Surya Patra: So any revenue that we are currently making sir, I just wanted to have that. Since it is a full year closing, so are you sharing any specific revenue number out of this entire effort?

Dr. Sharvil Patel: So I already gave you on the biologic front.

Surya Patra: I missed it, so it is not audible. So can you please repeat sir?

Nitin Parekh: Surya, it was Rs. 278 crores for biologics and vaccines as of now is less than Rs. 50 crores.

Dr. Sharvil Patel: Saroglitazar that is still pretty soon.

Surya Patra: Obviously we have because of the strategic initiative that we have taken on the domestic formulation side by splitting the business into mass and brand efforts and so what is the key objective that we have been targeting before deciding about this policy and after completing one year on this front, so what real achievement that we have witnessed for that particular initiative, that is one. And secondly also, if you can share something more on the consumer business. After first year of complete integration and on a like-to-like comparable basis, what growth at 21% that we are witnessing for this fourth quarter that seems really interesting. So anything that you have seen, any contribution meaningfully coming because of the Heinz acquisition or it is your internal portfolio that is really contributing to this 21% growth despite the COVID impact?

Dr. Sharvil Patel: We have explained earlier that with respect to our India formulations business, we have created two different portfolios where they will have two different marketing strategy. One is to create a reach and depth and also use the trade channel effectively and push and build our portfolio there. And then other is to create a specialization in different therapies and look at chronic long term prescriptions with good adherence and with very strong scientific marketing skills. If you look at the businesses, what has happened for this is that if you see our focus on large brands and upcoming brands, we have had very strong growth on both of those lines. As a part of the restructuring, we had discontinued a large number of SKUs which has brought in clear focus on the brand which has been shown in terms of two-third of our business having good growth going forward. So that has been the broad strategy for this and we are seeing good traction till March which then we had a problem post March 20th, but things are recovering now. In terms of our consumer business, the integration went off much better than we expected. We have improved our distribution rates and we still have long way to go. We have doubled our distribution and for the year end, we should be able to do that. That is helping the brand, the right marketing approach for some of the brands will help. So it is not only Zydus Wellness erstwhile but Complan, Glucon D, Nycil have all done very well and even in the difficult times right now, some of these brands are still doing extremely well.

Surya Patra: Just if you can share what was the mix of this mass and specialty in the domestic formulation in the previous year?

Dr. Sharvil Patel: That I don't have data right now.

Moderator: Thank you. We take the next question from the line of Damayanti Kerai from HSBC Securities. Please go ahead.

Damayanti Kerai: My question is regarding your CAPEX budgets. So sir, since last 3-4 years we are seeing consistent spend of around 8 to 10 billion. So can you specify where our major CAPEX is going? Like, how much is routine and where all we are spending and what are we expecting for FY21?

Nitin Parekh: So, large part of the CAPEX has been on expansion of our existing facilities and setting up newer facilities mainly for our US market. About 80%-85% will be for that and remaining 10% to 15% will be maintenance CAPEX. And we expect that in financial year 21, we would be spending about 600-700 crores kind of CAPEX.

Damayanti Kerai: So, we are adding on new plants as well as expanding capacity mainly for the US market in last few years, that is what you mentioned, right?

Nitin Parekh: Yes.

Damayanti Kerai: My next question is regarding your status of Remdesivir with DCGI. When we are expecting any update to come there?

Dr. Sharvil Patel: So I think we will be ready to sell products by end of July.

Damayanti Kerai: Okay. And once we get the approval, we can immediately start supply, right?

Dr. Sharvil Patel: Yes, but that approval will be probably by mid July or so.

Damayanti Kerai: Okay. And though like you mentioned there were no COVID specific supplies during fourth quarter, but how about the Hydroxychloroquine supply, like, haven't we seen anything incremental coming there and what is the status right now?

Dr. Sharvil Patel: So in US, we have a very large market share on Hydroxychloroquine. We almost controlled close to 40% share and we continue to do well and we have gained some customers in US because of that. So that is a good part of it, but it is not very significant and in India, we have done institutional sales to government authorities to the tune of about 8 crores sales.

Damayanti Kerai: Sorry, you said 8 crores sales we have done in India?

Dr. Sharvil Patel: Yes.

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

Sameer Baisiwala: At what level of manufacturing utilization are you, if you were to compare now versus pre-COVID, say Jan-Feb?

Dr. Sharvil Patel: We are almost at same levels now, better sometimes actually.

Sameer Baisiwala: Okay, great. And second question is, Sharvil bhai, how do you think about a year plus later when Asacol HD goes generic and that could be a sort of a big dent in the US revenues. So looking out 1 to 2 years, how do you expect to make up for that or should we expect YoY decline going forward?

Dr. Sharvil Patel: So, one is I said we have a large portfolio of injectables coming through which will more than make up for the gap of Asacol and also there are important oral solid launches. So with the large number of important launches in transdermals also and injectables which will be the largest part, it will be I think more than sufficient to cover up the deficit if there is competition and also we have had very successful inlicensing activity happening which we feel confidently that we can also add more portfolio to beyond what we have been developing and in the next 1 or 2 years you will hear of some very critical launches there as well.

Sameer Baisiwala: That is great. And just talking on the US market, what are you seeing on the pricing side because when there are supply chain disruptions with competition, one would get volume plus also pricing opportunities. Are you seeing that?

Dr. Sharvil Patel: We are seeing volume opportunities. So it is case to case basis. There is still price erosion in the market, but it has come down to low single digit. But we are seeing opportunities in improving margins somewhere and we are also seeing volume share gains. So currently, we are seeing the situation as such that if you have the right product portfolio, you can gain share.

Sameer Baisiwala: Okay, great. And one final question from my side, if I may. What is the outlook for HCQS for COVID use, both domestic as well as exports. Do you think you will be maintaining this momentum or is sort of fading down as you know various agencies have various things to respond and you had mentioned that you are going to expand 3-4 tons to about 20 tons a month. So where are you on that?

Dr. Sharvil Patel: So, for April-May-June, we have produced 20 tons and we have been consuming all of that. And we are still seeing traction on Hydroxychloroquine for different markets. So one good part of it is that we have contracted business in the US and we have gained additional contract also on Hydroxychloroquine. So we can see some stickiness to the business for the US, which could

almost be close to half of our overall volume. And the rest, India still continues usage of Hydroxychloroquine and some markets and some countries regulatory bodies still authorize and use HCQ, so that still is ongoing.

Moderator: Thank you. We take the next question from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: Sir, on the India business, Rs. 2.2 billion of loss sales in the fourth quarter. In this, because the supply chain should be looked it as deferred sales probably that sales coming into first quarter, you don't think that will happen? And my second question is, obviously April and May were weak, how are you seeing the domestic market trend going through now in June?

Dr. Sharvil Patel: So I think the loss of sale mostly was because we could not bill our book. So lot of that has happened in the next following months. But at the same time, we are seeing demand erosion also in the pharmaceutical market and I guess we all know the reasons for it less OPD, less practice leading to some of that and so I think there is a whole mix of portfolio that has changed. You can see that in April-May, chronic still continue to do better. But it had slowed down in June as well. But some of the other therapies that was slowed down have picked up in June. So it is a mix bag. But overall there is a contraction in demand that has happened. For Zydus, what we have tried to do is in these times tried to find new opportunities, so we have done couple of new brand launches which are doing well and so I think we are finding opportunities where we can and with some normalcy of fieldforce working, we can see demand is picking up again, but I would say it is still too early to say whether there is any recovery. I think maybe in July we can give you a better idea. So far it has improved from April and May, but it has not come back to normal.

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

Nitin Agarwal: Sir, on the biologics business, I mean are we still up, when we are looking at the scale of FY23, this is largely going to be a ROW market driven business for us or how we are looking at this whole biologics piece over the next 3 to 5 years?

Dr. Sharvil Patel: It is only India and emerging markets, minus US, Europe.

Nitin Agarwal: And what kind of opportunity, I mean when you dimension the market, what kind of a portfolio are we looking at? Are we looking at a portfolio of some 10 products or thereabouts or across markets or is there any broad view of how we are looking at this business?

Dr. Sharvil Patel: So, we have filed about 9 to 10 products and in the next 3 years, we would at least file another 4 products minimum. So we would look at, if you say till 2023 we look at a basket of between

12 to 15 molecule of biosimilars and we are looking at from the India and emerging markets creating a value of around 150 to 200…..

Nitin Agarwal: And sir, secondly you mentioned about the in-licensing effort in the US, this is towards the specialty side of the business or this is also on the generic side from new products that you licensed in the US?

Dr. Sharvil Patel: Currently the in-licensing is largely driven by generics but more difficult to do generics. So very limited competition.

Nitin Agarwal: So, your partnership products with other partners who are developing products for you, how does this structure work sir?

Dr. Sharvil Patel: Jointly developing or they have developed and we have partnered.

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

Tushar Manudhane: Sir, just on this biosimilar front, typically as you are seeing with the other companies, the focus is not just India and emerging but as well as the developed market in terms of regulatory because the development work remains more or less similar. So any particular reason why we are focusing as of now only on India and emerging market?

Dr. Sharvil Patel: So, our view to this is for developed markets, I believe the risk is very high. The development in terms of clinic and all are very high and the market formation is difficult because of the way the whole structuring happens on biologics. So I think our view has always been that unless we find our commercial partner who is strong enough to build that, we would not want to venture out on our own. So we would mostly look to see if we can partner our biosimilars business in these markets because you need a lot of capabilities to sell and until we are able to do that, we don't want to partner or have a program for US and Europe as of now. Now we will evaluate closely and see if in the second wave of products, if there is some stabilization and genericization of this, then we will look to nominate some programs.

Tushar Manudhane: Got it, sir. Understood. And just secondly, if you could just also qualitatively help us understand the profitability in mass and specialty separately? Is it at a similar margins or different?

Dr. Sharvil Patel: I don't have it off me unless Harish or Vishal have it?

Harish Sadana: Tushar, is the question related to US specialty?

Tushar Manudhane: No, domestic formulation mass and specialty.

Harish Sadana: Specialty margins are better than the mass margins.

Tushar Manudhane: The gap is quite big, is that safe to assume?

Harish Sadana: Though it depends, you are taking of net margin or gross margin?

Tushar Manudhane: EBITDA margin.

Harish Sadana: I think we can give it to you offline , we don't have it offhand. But my view is, we can send it to you later.

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

Kunal Mehta: Sir, I have a simple question. When I look at the investments which we have been making in the last 3-4 years, so we have invested and likely so we have invested considerable amount in building up our manufacturing capacities as well as different type of initiatives which are going to tune our growth in the next few years. So I just wanted to understand, when we look at this year end closing, what objectives do we have in terms of improving the return on capital which at the present is a bit surprised because of the capacities which are not yet utilized, so how would you look at it from a return on capital improvement perspective?

Dr. Sharvil Patel: So some part I will add and then Vishal can talk if needed more. I think what you have to on the return on capital employed, I think couple of things that are important. One is, for our oral formulation side, I think we have good capacity utilization. We had a new site in SEZ which is now scaling up, so there is good utilization. We still have a whole block of unutilized assets which is mostly do with injectables which is our Liva facility and Alidac facility. Now, we also mentioned that we have our first approval from Liva and we commercialized it and we are seeing good traction for these injectable facilities to be operationalized in a significant manner and then the return on capital employed will improve significantly for that. In the coming year, our whole asset block on transdermal will improve, but not this year, but in the coming year. So there you would see which are still unutilized assets which need to get used and with larger revenues from biologics and vaccines, that improvement we will see. So I believe in the existing investments that we have made, I think we are on track to see visibility for better return on capital employed with respect to this facility. Other may be Vishal or Nitin bhai, if you want to add.

Vishal Gor: Yeah, as we have mentioned our CAPEX going forward is going to be lower than what we used to spend till now and with that, we expect our ROI to be better compared to what we had in FY20.

Kunal Mehta: Okay, sir. And the second question I have is that, pre-COVID we had a timeline that till June if we are able to get Moraiya cleared, you would not have any progress with respect to supplying

our products from this facility based on the commitments which we have. So sir, what is your view right now because for the next 6 months it would be difficult to get our plants inspected and get it cleared unless remote inspections they come up with the guidance for that. So how will you look at the supply commitments if you have from Moraiya and how are you going to service those commitments?

Dr. Sharvil Patel: So, first thing, for Moraiya, for existing supply commitments for approved products, we don't have any concern on an ongoing basis at all and it continues to do well. As I said, we had earlier communicated also that we would finish our remediation by end of June and today, the majority of our all remediation is over and we are going to request the FDA for a teleconference and request for a desktop of audit or any form of audit. So that is our next plan. So what we have earlier committed is, we would try and finish our commitments by end of June and request for reaudit and if everything goes well by end of the year, for calendar year, we would see an audit and resolution of the same and that is what we are building for.

Kunal Mehta: So, if the clearance does not come to December, we are not subject to or vulnerable to any failure to supply problems which we are going to…

Dr. Sharvil Patel: No.

Kunal Mehta: Okay. And the last question I have is on the injectable side. So to the good extent the improvement in utilization of our assets is based on the launches which we are going to do for the next 3 years in injectable portfolio. So can you give us an understanding of in the US business what is the present contribution of injectables at the present and what are the launches in terms of number of launches which you are going to have over the next 3 years?

Dr. Sharvil Patel: So, the current contribution is negligible. So it is not significant. Do you have the number of filed products?

Vishal Gor: The total number of filings are 32.

Dr. Sharvil Patel: And we have some inlicensing portfolio as well. So over the next 3 years, we will have at least around 50 launches.

Kunal Mehta: 50?

Dr. Sharvil Patel: Yeah.

Kunal Mehta: On injectables?

Dr. Sharvil Patel: Yeah, I am only talking injectables.

Moderator: Thank you. We take the next question from the line of Vibha Ravi from SCRIP Intelligence. Please go ahead.

Vibha Ravi: I just have one question. So do you see an opportunity for the Dexamethasone on the lines for HCQ?

Dr. Sharvil Patel: What we can say is as we had HCQ a good supply chain and we contribute a large part of Indian formulations market and we are geared up to supply if the use is accepted by the authority, both India and outside as well.

Vibha Ravi: So exports right now are pretty small component, right?

Dr. Sharvil Patel: Yeah, it is only India right now.

Moderator: Thank you. Well, ladies and gentlemen that was the last question for today. I would now like to hand the conference over to Mr. Ganesh Nayak for his closing comments. Over to you, sir.

Ganesh Nayak: Thank you very much and have a nice evening and look forward to interacting with you during our next quarterly telecon. Thank you.

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