# “Cadila Healthcare Limited Q2 FY21 Post Results Conference Call”

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**Moderator:** Ladies and gentlemen, good day and welcome to the Q2 FY21 Post Results Conference Call of Cadila Healthcare Limited. If a participant is connected on the webcast and the audio bridge, you are requested to mute the audio from the webcast to avoid echo or disturbance. To ask a question, participants are requested to click on the link for instructions to dial-in to the audio call to ask the question. Please note participants will have to use their handsets to ask the questions and they will not be able to speak through the web. I now hand the conference over to Mr. Ganesh Nayak - COO and Executive Director. Thank you and over to you, sir.

**Ganesh Nayak:** Good evening, ladies and gentlemen. Welcome to our post results teleconference for the quarter ended September 30th 2020. We wish you and your family are safe and healthy during these 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 Mr. Vishal Gor – Senior Vice President, Corporate Finance.

During the quarter, the spread of COVID-19 continued unabated across the globe and in turn continued to impact the economy and businesses across countries. However, we now consider it as the new normal and by use of technology and newer methods, we continue to endeavour to improve all facets of our business beyond pre COVID levels.

Coming to business, in the India geography, our Human Health business and Consumer Wellness business witnessed an improvement in demand vis-à-vis the preceding quarter on the back of the nationwide unlocking strategy adopted by the government. This kind of improvement is likely to further pick up pace in the coming quarters. Our Animal Health business in India posted strong double digit growth of 20% on a year-on-year basis during the quarter. Our US formulations business continued normal operations as it was not impacted significantly by the COVID outbreak. Business continued to grow in double digits on a year-on-year basis.

During the second quarter of FY21, we posted a consolidated revenue of Rs. 38.2 billion, up 13% year-on-year. Consolidated EBITDA grew to Rs. 8.63 billion, up 36% on a year-on-year basis. Our EBITDA margins improved significantly during the quarters and went up by 370 basis points to 22.6% from 18.9% registered during Q2 FY20. Consolidated PAT including exceptional items for the quarter was Rs. 5.62 billion, up 73% on a year-on-year basis and up 24% on a sequential basis. In line with our commitment to deleverage, I am happy to inform you that we have significantly reduced our net debt by Rs. 27.1 billion in the first 6 months of FY21 which is 40% reduction from the March 20 net debt position. Our net debt as of 30th of September 2020 stood at Rs. 40.3 billion against Rs. 67.4 billion as on 31st of March 2020.

Our India geography comprising of Human Health, Consumer Wellness and Animal Health business grew by 11% on a year-on-year basis, registered revenues of Rs. 15.83 billion during the quarter. The US geography comprising of generics and specialty portfolio registered a revenue of 17.09 billion. The generic business grew by 21% on a year-on-year basis and 6% on

a quarter-on-quarter basis, driven by volume expansion. Our emerging markets business grew by 8% on a year-on-year basis and posted sales of Rs. 2.36 billion. The business grew by 12% in constant currency terms.

Now let me take you through the operating highlights for the second quarter of FY21 for each of our business lines. Starting with our Human Health business in the India geography, the pharmaceutical market in India has moved to positive trajectory and in line with the market, performance of our business also improved during the quarter on the back of steady improvements in demand amidst various unlocking measures undertaken by the government. Overall, Human Health Formulations business posted sales of Rs. 10.87 billion, up 11% on a year-on-year basis.

On the therapy fronts, we gained market share in the gynaecology, pain management, anti-infectives, anti-diabetic and hormones portfolio during Q2 FY21 vis-à-vis the corresponding quarter of the previous financial year. We have maintained our ranking in the key business of gynaecology, respiratory, pain management, cardiology and anti-infectives during the quarter. In the current evolution of prevailing challenges, the trend of improvement which we have experienced during the current quarter is likely to further pick up pace in the coming months. As the Indian economy is gradually opening up with necessary safety measures amidst the pandemic, the quarter gone by saw a revival in growth for our Consumer Wellness business. The business registered a growth of 9.3% in gross sales on a year-on-year basis.

During the quarter, we successfully completed equity fund raising of Rs. 10 billion through the preferential issue and the QIP route. We extend our sincere gratitude to all the investors for an overwhelming response to the QIP issue of Zydus Wellness which was oversubscribed 3 times. Proceeds of the issue were used for redemption of nonconvertible debentures to leverage the balance sheet.

Our Animal Health business in India saw a significant improvement in the performance during the quarter as the business posted a sale of Rs. 1.6 billion during the quarter with a growth of 20% on a year-on-year basis. The growth was driven by good demand and the strong equity that our brand saw in the market. This led to a mass improvement in the profitability of the Animal Health business.

On the US Formulations front, business continued to remain the largest contributor to the consolidated revenues with a 45% share in total revenues during the quarter. During the quarter, we relaunched doxycycline injections from our injectable manufacturing site of Liva near Baroda after site transfer from Moraiya. This is the second injective transfer approval from the manufacturing site of Liva. Till date, we have filed 3 site transfer applications for the injectable products from Moraiya to Liva. We also launched 6 new products during the quarter. We received approval for 10 new products including tentative approvals and filed 5 additional

ANDAs with the US FDA during the quarter. Our cumulative filings include 69 filings for injectable products including that of our partners and our cumulative approvals include approvals for 53 injectable products. Our new product approvals during the quarter include receipt of final approval for Doxorubicin Hydrochloride Liposomal injection. This is the first approval for a complex injectable which has been developed inhouse. Our API business registered sales of Rs. 1.6 billion during the quarter with a growth of 52% on a year-on-year basis.

On the operations and compliance front, we have completed the remediation measures which were required to be taken to address the observations raised by the US FDA in their warning letters issued to Moraiya and we are reaching out to the US FDA for next steps. Operations at most of our manufacturing facilities attained normalcy during the quarter and no significant impact of COVID was observed on the functioning of our plants.

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

**Dr. Sharvil Patel:** Good evening, everyone. I hope you and your family continue to remain safe and healthy during these difficult times.

To begin with, let me give you an update on the various projects initiated by us in different areas of drug discovery and innovation targeted towards the COVID-19 virus. As you know, we have already completed Phase-I clinical trial for our COVID vaccine ZyCoV-D. We have not observed any safety concerns. Cellular and humoral immune response studies are under progress, along with the neutralization antibody testing. For Phase-II clinical trials for COVID vaccine, we have already completed enrolment and dosing of all 1000 subjects. Immunogenicity evaluation is going on at present. From a partnership perspective, we are making conscious efforts to collaborate with various multinational organizations for their COVID-19 vaccine program to make such vaccines available for India and other emerging markets. We will share more details as and when further development on new front happens.

We have also initiated development of our recombinant measles vector construct expressing spike protein of 2019 nCov, which is a is a SARS-CoV-2 during the quarter, which is a second vaccine candidate for COVID-19.

On the NCE Research front, during the quarter we have initiated a few programs targeted at treatment of COVID-19. Our free clinical development is about to be completed for ZYIL1, a small molecule NCE position for management of critically ill COVID-19 patients. A Phase-II clinical trial for Desidustat in the management of COVID-19 is ongoing at present in Mexico.

Coming to our biologics, recently we have completed a Phase-II clinical trial for a pegylated interferon alpha-2b in moderate COVID-19 patients who will be given either a subcut injection of pegylated interferon alpha-2b at a dose of 1 mcg-mg per kg along with a standard of care in the test arm or a standard of care in the reference arm. Each arm has enough subjects. In the arm receiving the pegylated interferon alpha2b, there was a reduction in virus load and also elevation of symptoms faster than the standard of care. The drug is well tolerated without any safety issue. The observations on the study have been recently submitted to the DCGI and further discussions are on.

We have also received regulatory permissions in India to conduct Phase-II clinical trial of adalimumab for COVID-19 indication. We have also developed a cocktail of monoclonal antibodies directed against the spike protein of the virus, SARS-CoV-2 that causes COVID-19. Both the antibodies are neutralizing in nature and directly inhibit the ineffectivity of the virus by preventing its attachment to the ACE2 receptor expressed on the host cell membrane. We plan to complete animal toxicity studies by February of 21 and initiate clinical trials immediately thereafter.

In addition to the projects mentioned above, we have recently also launched Remdesivir injection in India and emerging markets which is indicated for the treatment of COVID-19. We launched this project at the most economical price providing greater access to the therapy and making it more affordable for patients.

With this, let me give you an account of the progress made thus far on different R&D projects other than those targeted to COVID-19. On the innovation front, on the NCEs, our saroglitazar magnesium successfully completed Phase-II clinical trials for PBC indication in the US. The results of the trial would be presented in the late-breaker oral presentation at American Association for Study of Liver Diseases on 16$^{th}$ of November 2020. We have also initiated Phase-II clinical trials for saroglitazar magnesium for NASH and F2, F3 fibrosis in the US and after we received the feedback from the US FDA. During the quarter, we submitted the report of 6-month biopsy result in 16 patients to the US FDA. Patient enrolments is ongoing at present in the US for Phase-II clinical trial for saroglitazar magnesium for NAFLD and PCOS indication. We expect the enrolment to be over by quarter 4 of FY21.

In Mexico, an 18-month paired biopsy randomized for NASH indication is complete, and the results of the study will be available again in quarter 4 of FY21. We completed Phase-I clinical trials in Australia for our NCE molecule targeted treatment for malaria during the quarter.

On the biologics front, patient recruitment has been completed for one of the Phase-III clinical trials of rituximab in India during the quarter. And on the emerging market front, dossiers of adalimumab, bevacizumab, trastuzumab and pegfilgrastim were filed with the regulatory authorities of different countries of emerging markets.

On the vaccines front, we completed Phase-I trial for Hepatitis C vaccine and has received regulatory permission to conduct pre-clinical tox studies for one more vaccine during the quarter. On the 505(b)(2) and specialty initiatives, at present 9 products are under different stages of development. During the quarter, we submitted one pre-IND meeting request for one project and a pre-IND meeting request for one more project from a specialty portfolio. We also are planning to file an NDA for one of our products in the pain management area during the current financial year.

Thank you, everyone and we can now move forward to the Q&A session. Over to the co-ordinator.

**Moderator:** Thank you very much sir. Ladies and gentlemen, we will now begin the question and answer session. The first question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

**Neha Manpuria**: My first question is on the India business. We saw very strong recovery both quarter-on-quarter, year-on-year. Could you give us some color on what drove this improvement year-on-year particularly? Was it driven by COVID portfolio, any color here would be appreciated.

**Dr. Sharvil Patel**: So on the India business, as I said in the last couple of years, we have had very important launches in the chronic spaces and we were the first few to launch some of the gliptins and other molecules and they have done very well. So overall the chronic portfolio has registered a very strong growth. The acute portfolio still remains weak, but it is improving sequentially and because of that, we have seen better traction in terms of overall India growth. So we have done little bit better than market during the quarter.

**Neha Manpuria**: Correct me if I am wrong. The margin was pretty much flat to slightly positive versus our growth seems to be 11% year-on-year. So is it entirely driven because of the chronic portfolio or is there contribution from certain COVID related launches?

**Dr. Sharvil Patel**: COVID portfolio obviously forms the part of some of the growth, but also the specialty cluster has registered a strong double-digit growth.

**Neha Manpuria**: And sir just taking this forward from a point of view of cost, how much normalization in marketing activity have we seen in the India market and therefore to what extent is it reflected in our cost base? How should we look at normalization of marketing activity versus operating cost?

**Dr. Sharvil Patel**: So, because the large part of our expenses are related to the working of the sales representative, so that all has normalized and that has come back to normal in terms of overall spend. The marketing activities are still limited because obviously access to doctors is still not fully there. So we are not yet fully completely back in terms of our full marketing activities, but marketing is always done in terms of, obviously the results that we get. So depending on what we are

seeing, we are focusing on activities on certain types of portfolio which is yielding us results, but I think going forward if the demand again comes back to a normal level, we would see some increase in marketing activity, but that will be a function of obviously growth. But overall, fixed expenses are back to normal largely.

**Neha Manpuria**: So only the marketing portion of it will pick up as things normalize?

**Dr. Sharvil Patel**: Yeah.

**Moderator:** Thank you. We take the next question from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.

**Nimish Mehta:** On the US generic side, can you just let us know what is the outlook on the base business in terms of pricing and also, if you can let us know how has Lialda been performing for us now that there is some more competition?

**Dr. Sharvil Patel:** The base business continues to do well and the pricing is stable so early and obviously it changes depending on the quarter, so right now everything in the base business has grown in terms of volume and we have stability there. Lialda, we are still holding good market shares because of the complexity of the molecule and sourcing of the material, so we continue to see a good traction on it and with limited supply in the market.

**Nimish Mehta:** Understood. Finally, if you can let us know, there are two products that we understand where we already have an approval and the products are also settled from a litigation perspective, but we have not yet launched, those are Silenor brand name and Reyataz, so if you can let us know when the launch time likely to be, that will be great?

**Dr. Sharvil Patel:** Which two products?

**Nimish Mehta:** One is Silenor, I mean generic name is Doxepin Hydrochloride and the second one is Reyataz, the generic name is Atazanavir Sulfate.

**Dr. Sharvil Patel:** So unfortunately, I won't be able to give you immediately, but if Vishal you have with you the details, you can, otherwise we can connect back with you on that.

**Vishal Gor:** No.

**Nimisha Mehta:** No problem, my question is because we feel that this can be probably low competition product for you, so you can tell me probably offline, I will connect with Vishal.

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

**Damayanti Kerai:** Sir, my question is regarding the debt reduction part, so as you mentioned in your opening remark 40% reduction from the March level, so what we understand the proceed from QIP and preferential share would have played a bigger role, but we have seen around more than 350 million kind of debt reduction, at the same time, we have seen significant improvement in the cash and equivalent holdings also, so if you can just elaborate a bit on like what is the fund for this debt reduction which has happened significantly in last 6 months?

**Dr. Sharvil Patel:** Nitin bhai, our CFO can take it. If there are not able to, then I will explain.

**Nitin Parekh:** Rs. 700 crore plus as we have said about Rs. 1000 crores is contributed by the equity raise and Zydus Wellness, the remaining is all internal accruals. So as you know two quarters we have generated enough cash to repay the debt to the tune of about Rs. 1700 crores.

**Dr. Sharvil Patel:** So I would say also good working capital management which led to less number of days and better receivables has also helped, so overall cash management has been very good. Since last quarter, we have been talking about that we have set up a cash manager in the office with better management of that, better realization on products, obviously some lower costs because of COVID and all of that has led to much better improvement in terms of our overall cash which led to good amount of debt reduction.

**Damayanti Kerai:** 21 and say like what is your annual debt reduction target in general?

**Dr. Sharvil Patel:** We will continue to look at that actively and I think we are still seeing some good portals ahead, so we will continue our endeavour on reduction of debt. Immediately, obviously we have achieved a significant milestone. More importantly, we will continue to update you as and when we feel this is a right time.

**Damayanti Kerai:** Final question from my side, any response you heard back from FDA for your request of the Moraiya plant inspection?

**Dr. Sharvil Patel:** No, generally, we don't get immediate responses, but we know that our responses are under review and the FDA has communicated to us that they are in active review, so that is the only update we have as of now and we are hopeful that with the exhaustive responses that we have sent, we will move towards resolution of the warning letter.

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

**Prakash Agarwal:** Sir, my first question is on the R&D side, so we talked about various R&D initiatives both from COVID related vaccines, NCE, injectables, so how do we think our R&D spend is going to be for the H2 as well as next year?

**Dr. Sharvil Patel:** Other than Saroglitazar, we believe that currently we will be around 7 to 8% of revenues in terms of R&D spend and we should be comfortable with that. There are two large items, one is obviously Saroglitazar further clinical trials which will not have a short-term impact in the next 6 months; however, on the vaccine front, once we start the last Phase-III, there may be some largest spends, but we still believe that we would be around 8% to sales for the next two quarters.

**Prakash Agarwal:** And what are the dates in terms of Phase-II and going into Phase-III if all goes well?

**Dr. Sharvil Patel:** For Phase-II, as I said we have finished enrolment for the vaccine. We will have a read out by end of November and immediately, we would apply for a Phase-III permission and we do plan to start our Phase-III in December and again that whole recruitment will take again another 2 months, so by March-April, we should have Phase-III data also.

**Prakash Agarwal:** And secondly, on the US side, so last time we had spoken about in-licensing of few products, so these are development or these are already in development and we have come in between and what is the amount spend, if you could talk about that a little bit?

**Dr. Sharvil Patel:** Product wise, I will not have all the details, but as I said, we have actively a portfolio of 10 to 11 products which are in the in-licensing phase. Couples have already been filed, couple are in the late phases of filing and obviously some are in the stages of taking batches and putting on stability, so they are in different phases. Some are also just next for approval and we are in-licensing them, so they are all different stages of cycle. In terms of breakup, I can may be later on share with you because I don't have the breakup of each and every molecule, but I think they are starting, none of them are at very early stages, barring may be 1, most of them are in stages of either taking executing batches or filing.

**Prakash Agarwal:** No, I am trying to understand like we already have a very rich pipeline across various dosage forms and segments, so would this be differentiated in some manner which we don't have already or how should we think about it?

**Dr. Sharvil Patel:** Yes, they are all different, some of them is where we may have missed first-to-file and we have been potentially be able to in-license that F2F. Some are where there is a source issue, so very few are unknown, very few sources of multi-APIs and we have been able to partner on that and some are to do with complexity in terms of the plant in these dedicated lines, dedicated facilities, which some of the partners do have, so they are all differentiated and one or two of them of them are where we have a gap in portfolio and we have been able to in-license them.

**Prakash Agarwal:** And these are multiple parties?

**Dr. Sharvil Patel:** Yes, they are more than few parties.

**Prakash Agarwal:** And last one on India side, would there be element of generic-generic also in this 11% growth. Clearly you mentioned, chronic is double digit, there is also a COVID-related Remdesivir which is held, but would generics which is about, I think 10% of your portfolio would have led the growth or that was also muted?

**Dr. Sharvil Patel:** Generic was more muted, so if we remove generics, the growth would be better.

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

**Saion Mukherjee:** Sir, can you throw some light on the growth that we have seen in API business and also on the animal health, I mean the growth has been strong, just wondering how sustainable you see those number?

**Dr. Sharvil Patel:** On the animal health side, we have very strong brands in the market and I think very good customer outreach**,** so that has helped us gain momentum. Also, we believe that with the rural economy reviving faster, we have seen better traction for our businesses related to life stock and that business has really outperformed because of the good brands that we hold there and the poultry business is also coming back on track. So actually we believe the growth momentum will continue because one of the businesses is on track and the other is reviving, so the business growth we believe should continue in a fairly good double digit manner and the favorable product mix has also helped us improve margin, so both aspects have overall helped the business really outperform. On the API front, we are not a very large player in terms of third party sales, large part of it is driven by captive demand, but because of the good portfolio that we hold and good cost positions on multiple products of large volumes, we have seen good traction on the API front and the API business will continue to actually drive good double digit growth going forward from the external point of view. Also, it contributes very meaningfully to the internal business, so both ways it has done very well in terms of being able to produce large quantities. Like one example also, if you just say, it is only for internal consumption, but Remdesivir was something that we developed very quickly and we could launch it and that too had much better pricing in the market to make it affordable, so credit to the API teams that they were able to turn around faster and there are multiple other examples which we are seeing both from ANDA point of view or some COVID-related portfolio point of view.

**Saion Mukherjee:** My next question is, you book an export incentive around 45-50 crores a quarter, what is the outlook there and what this number would be going forward in your view?

**Dr. Sharvil Patel:** I would ask Vishal or Nitin bhai to answer that.

**Nitin Parekh:** The government has discontinued the MSME scheme which will impact the export benefits which we get, however, government has already announced a new scheme, the mechanics of

which are being rubbed out by the government in consultation with the industry. Hopefully, early next calendar year, the government will come out with a new scheme and we believe we are yet to see the fine print of that scheme, but we believe this is only a temporary phase and we should not be having any large gap between the current scheme and the next scheme or rather the income which we generate from current scheme and the next scheme.

**Saion Mukherjee:** But in Q3, this number would fall significantly, right?

**Nitin Parekh:** Yes, because for Q3, the government has said the exporter will get on the Rs. 2 crore for the period.

**Moderator:** Thank you. The next question is from the line of Girish Bakhru from Bank of America. Please go ahead.

**Girish Bakhru:** Quickly, on Remdesivir, Sharvil bhai any comments on how is the situation currently? Is there still significant gap between the demand in the supply?

**Dr. Sharvil Patel:** I believe that there is now obviously good amount of suppliers who are available on Remdesivir. We are currently still the lowest price productive patient, so we are still seeing very good demand for it because obviously that becomes a first choice in terms of the product, so we are seeing still good demand and we haven't really done any large export, so we believe that in the export market, some of it also may come up in the future, so we are still building for full capacities and produce as much as we can to sell and so far we are okay if I say further couple of months now and going forward with the next 1 or 2 months. Beyond that, we will have to wait, but because we are the most affordable brand, we believe we will continue to see good uptake on it.

**Girish Bakhru:** And when you say export opportunity, how soon can one actually see a possible export opportunity from this product?

**Dr. Sharvil Patel:** Some we will see starting from October, we are already starting to see some, but we are building onto more opportunities there.

**Girish Bakhru:** And the second question was on the vaccine, you commented that possibly March Phase-III data will be read, is there still a possibility of emergency use approval before March based on what phase till data comes out or do you think that approval is sitting likely after March?

**Dr. Sharvil Patel:** It is a tough one to answer. We would be submitting Phase-II and Phase-III protocol by end of November and I think I can give you more clarity then, but I think it will be the regulator's call to take whether they will approve any vaccines for EUA and if they do, then there would be more than a few vaccines that will get approved, but it is very difficult to say today whether that will happen, so if that happens then we would be there also in the last quarter, but if not then it will be April quarter where more vaccines will come up after full Phase-III.

**Girish Bakhru:** And based on your assessment with the developments that have happened with global trials with AstraZeneca or Pfizer, I mean would you still say that your DNA platform has, let's say better relative safety or efficacy. Is there a possible comparison that you can draw at this stage?

**Dr. Sharvil Patel:** Some of the advantages of our vaccine are, see, we do not have any infectious agents as part of the delivery platform technologies. So when we know that all of these vaccines will be more than single dose and we don't have any active infectious agents present in our vaccine which are there in some of the other platforms, so that is one part of the safety. The second is DNA vaccines have a very clear pathway both by the WHO and the US FDA in terms of what needs to be done for the safety and efficacy. So at least it is a non-pathway that we all are following. Third is because of, it is a highly scalable platform. So that would help us in terms of building for scale and also finding potential third party manufacturer. And the most importantly because of the technology it provides us a product that will be stable at 2 to 8 degrees, so in terms of cold chain regulations and shelf live we would have better, we will be very good at it and that would be an important thing from the logistics point of view because both in terms of shelf life as well as cold chain, this is a much more stable platform compared to some of the others. So all of these will add benefit to it and also because it is scalable, I think something which is important for developing market is cost and I think we should be fairly good on cost also in terms of affordability. The other last part is the platform in terms of delivery because it is an intradermal application. There should be a much easier administration. The need for a training is far limited because it is not an IM injection, intramuscular, but only an intradermal injection. So the whole healthcare professionals or the community which the governments will be using, it will be far more easier to train them or for them to be able to administer this doses.

**Girish Bakhru:** Right, and this 70% increase in the manufacturing capacity for vaccine, is it fungible across all the platforms or is it only DNA vaccines?

**Dr. Sharvil Patel:** This is for the DNA, but there are some other vaccines which in the future which are under clinical, which will also potentially come up for use in the similar investment, in the similar facility that we are building. But you know that we can't do 2 vaccines at the same time. So you have to do one vaccine at a time. Both of the vaccine facilities are dedicated in nature. So if post COVID or if the eventuality of that which we don't see at least for the next 3 to 4 years will remain very relevant. But beyond that, we have few other programs where we will be able to use this capital investment.

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

**Anubhav Aggarwal:** Just one question, taking on the vaccines only, you made a comment that you will be collaborating with MNCs to make their certain vaccines available in India. So are you talking about manufacturing or largely distributing those vaccines in India?

**Dr. Sharvil Patel:** Manufacturing and obviously which would be followed by either giving it back to them and also distributing it.

**Anubhav Aggarwal:** But as you were saying that your current facility is largely dedicated, so that is why my doubt gap was because they are not using that.

**Dr. Sharvil Patel:** While it is dedicated, other vaccines are on different platforms. So they don't compete with this manufacturing facility.

**Anubhav Aggarwal:** So for that you will have to put up another manufacturing plant or how would that go?

**Dr. Sharvil Patel:** We have different platforms of manufacturing which we already have because we do manufacture multiple vaccines. So some of them we have already capabilities to manufacture at small scale and some initial scales and if any of the vaccines are successful, we can scale those up in those plants. So that scale up will definitely be necessary in terms of additional some investment, but we can start the process of tech transfer and scaling up the process and going through the clinical phase for approval while we scale it up.

**Anubhav Aggarwal:** And just one related question on this. So just to put up the scale up process, how time consuming is that process? Is it like 6 month process of less than 6 month or more than 6 months?

**Dr. Sharvil Patel**: Depending on the platform and technology, it varies between 4 to 6 months.

**Anubhav Aggarwal:** And just one another question on Remdesivir, after WHO has made comment, has this really impacted the demand of the drug or is it like the consumption is still increasing very much?

**Dr. Sharvil Patel**: Today, US FDA has just approved it as the first line treatment now instead of emergency use, they have given a final approval to Remdesivir. And currently this is the only line of treatment for moderate to severe patients. So there is no drop in demand yet because this is the only real treatment that is currently working.

**Anubhav Aggarwal:** And one more clarity on this. So you mentioned your price is most competitive. But this is largely a hospital product right now where patient is largely not choosing this. So are you saying that despite being very low priced, your market share is lower because I don't have an idea about how is your market share?

**Dr. Sharvil Patel:** We probably are selling on, I mean one of the largest quantities and you know patients do make a choice because when they know our drug is available at a lower price, they do ask for that. So even if the hospitals don't carry it, the patients who push the doctors to, because this product is now available easily, they are able to source it from a chemist. So it is not that while it is true that some hospitals still carry higher priced product. But the patients are making a choice because

a lot of them are aware of the lower priced product and everybody wants some more affordable good quality product. So we are seeing that traction also.

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

**Surya Patra:** My first question is on the US business front. Let us say, in the recent times what we have seen that Cadila has practically regained the exclusivity in the Lialda as there is no greater competition visible on that product front. So can you give us some sense what inference that given this background because simultaneously with the lower competition in the Lialda, there is an indicative price hike scenario that is also visible. So what inference once would really draw for Asacol HD out of this Lialda background?

**Dr. Sharvil Patel**: I think what one has to understand is, majority of the mesalamine franchises are very difficult to develop and that is why there are very few filers and the second part of it is that even if you have approvals to scale it up and make it at large scales, it has been very difficult and also that has led to obviously while there are lots of generic approvals. There is a still a fair share of market that we continue to hold. You would have seen that even innovator has faced challenges in terms of supply to the market. So these are very complex products to continuously manufacture and we believe we have a very robust process that we have demonstrated over the last few years which is allowing us to remain as a first choice to all the suppliers because of our capability of manufacturing. Also same to do with Asacol, there have been, I believe perceptibly only one critical filer we have heard of and not many people who have been able to file that product. It has similar challenges in terms of manufacturing. So I think these are franchises which are very complex and difficult to manufacture and have the release data which is stable all the time and that is why we believe this is a sticky business for us and which has been serving us good right now. And we will also continue to have at least 3 more mesalamine franchises that we will file, some we have filed, some we will launch. So that portfolio is very good for us. We will have good understanding of the portfolio this franchise and we continue to build on that platform.

**Surya Patra:** Sir, secondly, can I ask about the Tamiflu revenue share at least what is the annual Tamiflu revenue share for the US business because it seems important because given the COVID background, this flu season seems to be a very robust one, as you got the point about the flu vaccine and all that indicating more than 50% kind of YoY jump. So some clarity would be useful there?

**Dr. Sharvil Patel**: So, I cannot give you the numbers. But what I can explain to you on that there are two formats, the capsule format and the second is the oral suspension. Now there is enough competition now on the product in the market and depending on the season what we can say is we are well prepared for the quantities because here you have to prepare quantities way in advance and depending if the season is going to be very severe, then we would see good traction on that

molecule. But it will be very difficult to say yet. We don't have any indication to say how good this season will be and what will be the competition, but it is highly competitive now as a molecule. And depending on the season, we can give you more light by the next quarter, but nothing that we can tell you now.

**Surya Patra:** But whether it is an integrated product for us?

**Dr. Sharvil Patel**: Yes.

**Surya Patra:** Sir, on the domestic formulation business side, so if you can just give a split between what is the mass and what is the Speciality mix for the quarter or for the half year, why because I think the age old concern of underperformance or relatively low growth compared to the industry that is getting addressed starting this quarter. So if you can give some clarity on that front I think that will be helpful.

**Dr. Sharvil Patel**: So again I think, one must understand that while for the 6 months MAT or whatever data we look at, we have always been growing better than market. So we have never underperformed versus market. Even if you take September data also, we are still better than the market, forget internal growth, but also what is reflected in AWACS which even truly reflect everything. So as I told you, I don't have the breakup now, but the speciality cluster and the chronic portfolio has done far better. So the chronic and subchronic. The acute is the one which is obviously not growing and it is having challenges which obviously we understand because of patient footfalls and other things. So once that recovers, we would see some better tractions. Overall, I don't have the split, but I believe it is 60:40, maybe Vishal can provide that to you separately.

**Surya Patra:** Yes, Vishal. Thanks for that. And if you just allow me last one question if I can ask, so regards the COVID portfolio sir, generally, I think Cadila is one company who has built a most expensive portfolio targeting COVID. You are even talking about the second vaccine targeting COVID. So I think, so the aggression on the COVID portfolio front, what is the kind of sustainability of this portfolio that to you visualize whether it is Remdesivir or it is vaccine or the therapeutic medicines that we are currently distributing, marketing or whether even the COVID portfolio has started contributing to the growth of the domestic business. So how should one really see this?

**Dr. Sharvil Patel**: So, I think the way one must look at it is that, you have to obviously be in the market wave and do what the market and drive where the market is driving the growth. So you cannot be complacent to say that we will play in our niche area and not participate in the larger opportunity and we strongly believe that because of our strong R&D capability and platform that we have, we are able to repurpose or bring new introductions whenever needed, whether it is COVID or whether it is something else. So if I start with the earlier part when the gliptins, we were one of the first companies to launch the lowest price gliptin which was teneligliptin and we continue to

perform extremely well on that. We launched Vildagliptin and amongst the 100 plus brands that were launched, we are amongst the top brands in the market in terms of generics. We recently launched an SGLT2 and we were the only company in the market to launch one of the SGLT2. We launched the first in India again two respiratory products with the glycopyrronium base and recently we launched the new one, again we are first in India. It all boards well in terms of the portfolio we are developing, whether it is for COVID or it is not for COVID, but we have now an R&D engine which is delivering first in India launches. We are tracking well because we are launching them at affordable prices and overall momentum has helped us in terms of that. So I think over a period of next few years you will see that the portfolio will have a lot of these kind of new launches, important launches where we also do well in terms of performance and our current strong base of products in the women's health Phase-In some of the other places are doing well in this COVID times also because of the brand recall and other thing. So that is the overall response to it. The only portfolio that requires a lot of effort is the acute portfolio, but overall market is slow and we are not a very strong acute player in some of the anti infectives and other. So that is where we are struggling, but beyond that the other portfolios are doing much better than they were doing before.

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

**Nitin Agarwal:** Sir, on the domestic business, this is the first quarter, a double-digit growth after a fairly long period of time. How sustainable do you think, you know the double-digit growth trajectory is going to be for us as you see the market and the landscape?

**Dr. Sharvil Patel**: It is very difficult to forecast the future in terms of the revival, but we believe at least for the next 2 quarters we are in good place to show good growth on the domestic business and fundamentally with some of the new initiatives that we are taking on obviously important launches, some of the programs doing extremely well and with the whole digital journey that we are taking which will get launched in December, we believe that we are poised to gain a fair share of the opportunity in terms of presence in the doctor's chamber. So I think we are in place to do well in the portfolio that we have which we have identified in terms of mandate brand and next 2 quarters should be good. But I think to speak more further, we don't know yet how to forecast.

**Nitin Agarwal:** We have doxorubicin as being our first complex injectable approval. Now injectables as you mentioned a few times in the past, the critical component of our growth for strategy in the US. How should we look at the whole injectable fees in the US over let us say a year, year and a half in terms of the kind of launch is now that potentially comes to us on this side?

**Dr. Sharvil Patel**: Yes, so we are just starting our initial play on the injectable side. I think we need at least 3 years to make a meaning, 3 to 3.5 years to make a meaningful sizeable business out of it. But all the

elements are in place as I said we are filing important products. Our facilities are compliant and we are getting approval from the regulators. We have been able to inlicense some complex injectables which were not part of our portfolio and all in all, I think from a very small base, this injectables business will become good sizeable business anywhere between $150 million to $200 million in the next 3-4 years.

**Nitin Agarwal:** And last question on the transdermals, what is the visibility of US approvals over the next say two quarters?

**Dr. Sharvil Patel**: So transdermal approvals are contingent on our Moraiya warning letter getting resolved and we believe that once that is there, we should see at least 5 to 6 approvals in the transdermal space and many of them are still limited competition product and we see good opportunity once we are able to resolve our warning letter. We already have the capacities in place, we have everything done. We need to obviously resolve the warning letter, once we see that and see approvals. FY22, you should see good scale up of the transdermal business, but again in the next 2.5 years we would see a good scale up on the transdermal business once we have Moraiya resolution.

**Nitin Agarwal:** And just last one on the US business, is there some element of seasonality in our business wherein second half is because of some products where we have larger seasonality play because stronger than our H1 typically in the US?

**Dr. Sharvil Patel**: Yes, there is, because of the flu season. But it is again very cyclical and it all depends on the season and depends on the competition and pricing. So very tough to say. But only seasonal product now in the portfolio is the oseltamivir, the Tamiflu which we don't know yet as to what could be that opportunity.

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

**Kunal Mehta:** The first question is on NASH, so how do we go about further from here now and pardon me if you have mentioned this in opening comments, so how do we go about for the Phase-III trials for NASH and then what timeframe do these trials would take place in the US?

**Dr. Sharvil Patel**: There are two indications for Saroglitazar. One is the primary biliary cholangitis, it is PBC, again it is one of the indications where there are no approved treatments and the last treatment failed, I mean last clinical program did fail in the Phase-III. So we are working on both the programs. On the PBC as I just stated, we have finished our Phase-II, we have seen very good data and we will be commencing and planning for a Phase-III trial on PBC. It is a shorter trial and with lesser number of subjects. So that potential hits the market much earlier, maybe in 23-24. On the Saroglitazar, we have submitted a Phase 2b protocol with the US FDA and that will be started if

once we get clearance, we will start that program by end of the year or beginning of January. And that will be, if everything goes well, we are looking at in the calendar year 25 for filing for approval, 24 end or 25.

**Kunal Mehta**: So after Phase 2b, the Phase-III trails would be at least, I would say 12 months' timeframe, I mean for the drug like this?

**Dr. Sharvil Patel**: Much more than 12 months.

**Kunal Mehta**: Understood. Second question is on the vaccine side…

**Dr. Sharvil Patel**: If everything goes well, the PBC indication would be the first indication that we will get approval for a launch and the NASH indications will follow post that.

**Kunal Mehta**: So any indication on the size of the PBC market, I mean potential?

**Dr. Sharvil Patel**: It is a very large market and no approved product, and I don't have the exact number, but it is above few billion dollars, in terms of overall size of the market.

**Kunal Mehta**: Understood. And the second question is on the vaccine. So just wanted to understand that once the Phase-II readout comes out and the readout means the targeted outcomes, at least after that, the science of the vaccines is established, right? I mean after that the science of the vaccine because since this is recombinant DNA vaccine, the world is using this route for the first time for building a vaccine. So after favorable Phase-II results, at least the science will not be under question. Is that the right way to put it?

**Dr. Sharvil Patel**: So again a lot of this is for the regulators to take a call on. But we believe the Phase-II will definitely demonstrate clear efficacy outcome if we are able to show that and that should be sufficient from the efficacy point of view. Again, there are other markers like immunogenicity and safety which is based on the type of platform and obviously on the type of products. So that is very difficult to say. But at least efficacy and partly the safety would be established.

**Kunal Mehta**: And just a question related to, I understand this is a bit earlier to get into, but I mean, the numbers which have been thrown around for the pricing of vaccines, especially for the consumption of Indians, I mean for the usage of doses in India, I think it is $2-$3 per dose, these are far different from what the global players are trying to value your vaccine products at. So any ballpark indication of how the pricing would be and what range? Anything would be very helpful on this front.

**Dr. Sharvil Patel**: So again, it is little too early. I can tell you couple of things. One is this, as I said this platform is very scalable. So because we will be able to produce in larger quantities, we believe we will be also competitive in terms of bringing the vaccine to the market. Our endeavor always has

been in this COVID times or in this pandemic is to make sure that we bring any product at affordable prices and definitely we have the same intention in mind when it comes to COVID vaccine.

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

**Prakash Agarwal:** Just wanted to ask on the filing run rate that seems to be, we have been in the range of 25-30, I understand this is COVID world, but what is the expectation in terms of filing for this year and next year?

**Dr. Sharvil Patel**: So this year we will file more than 30 and next 30 to 35 ANDAs and in the next year, we are targeting around 40-45 ANDAs.

**Prakash Agarwal:** And we are 10 as of first half?

**Vishal Gor:** Yes, 10.

**Moderator:** Thank you. So that was the last question in the queue.

**Ganesh Nayak**: Thank you very much and wish all of you a very Happy Diwali and a very prosperous New Year and look forward to interacting with you again in the month of February. Thank you and have a nice evening.

**Dr. Sharvil Patel**: Thank you.

**Moderator**: Thank you very much. Ladies and gentlemen, on behalf of Cadila Healthcare Limited that concludes this conference. We thank you all for joining us and you may now disconnect.