# “Cadila Healthcare Limited Q1 FY21 Post Results Conference Call”

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**MANAGEMENT:** **DR. SHARVIL PATEL – MANAGING DIRECTOR, CADILA HEALTHCARE LIMITED**
**MR. GANESH NAYAK – CHIEF OPERATING OFFICER & EXECUTIVE DIRECTOR, CADILA HEALTHCARE LIMITED**
**MR. NITIN PAREKH – CHIEF FINANCIAL OFFICER, CADILA HEALTHCARE LIMITED**
**MR. HARISH SADANA - CHIEF STRATEGY OFFICER, CADILA HEALTHCARE LIMITED**
**MR. VISHAL GOR – SENIOR VICE PRESIDENT-CORPORATE FINANCE, CADILA HEALTHCARE LIMITED**

**Moderator:** Ladies and gentlemen, good day and welcome to the Q1 FY21 Post Results Conference Call for Cadila Healthcare Limited. As a reminder, all participants' lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference, please signal an operator by pressing '*' and then '0' on your touchtone telephone. Please note that this conference is being recorded. I now hand the conference over to Mr. Ganesh Nayak – COO & Executive Director of Cadila Healthcare Limited. Thank you and over to you, sir.

**Ganesh Nayak:** Good evening, ladies and gentlemen. Welcome to our post results teleconference for the quarter ended June 30, 2020. I do wish that you and your family are safe and healthy during this time of the pandemic. 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 & Mr. Vishal Gor – Senior Vice President-Corporate Finance.

COVID-19 is one of the most complex health care challenges of our times, and the world is still grappling with it. On the one hand, we had an urgent task of ramping up production of drugs for COVID-19 and other essential drugs. And on the other hand, we face challenges of people not being able to come to work and other logistic hurdles. We fought the battle on many fronts and have contributed with therapeutics, preventive vaccines, diagnostics and essential personal safety consumables.

Motivating people to resume work after the lockdown was quite a task. 15,000 people in manufacturing, quality and research were required for us to work at full throttle. The concerns have to be addressed, and assurance was needed to be given that they were safe at work. We engaged with these employees and their family members to allay their fears. Stringent measures in the form of maintaining adequate social distancing at workplaces, thermal scanning and providing PPE kits have been put in to safeguard our employees.

On one side, all these initiatives helped us in keeping the momentum across the value chain and continue our operations with minimal disruptions. And on the other side, the agile decision-making coupled with focus on execution helped us in finding solutions in line with the progression of the pandemic.

From diagnostic kits to portable oxygen cylinders to UV sanitizers, alcohol-based sanitizers brands such as Nycil Sanitizer and Happy Hands and immunity boosters like SYMUNE, an ascorbic acid and zinc combination; and Supermune, a herbal combination of multivitamins, multiminerals and zinc, Zydus today provides a range of products wheel to fortify and safeguard oneself against the pandemic. In addition, all of you are also aware of our ongoing COVID vaccine program and the studies for evaluation of pegylated interferon alpha-2b as a possible treatment for the disease, about which Dr. Sharvil Patel will talk later.

Coming to business. Though we began the quarter on a quiet note, business started to recover as the quarter progressed, which led to some improvement in the month of May, and the month of June was even better. And as a result, during the first quarter of FY '21, we posted a consolidated revenue of Rs. 36.4 billion, up 4% year-on-year. Our U.S. generics business grew by 25% on a year-on-year basis on account of volume expansion and new product introductions. Consolidated EBITDA grew to Rs. 8.15 billion, up 24% year-on-year. Our EBITDA margin stood at 22.4% during the quarter, which was higher by 360 basis points as compared to 18.8% registered in Q1 of FY '20 and by 130 basis points compared to the 21.1% registered in Q4 FY '20.

Other expenses have degrown during the quarter due to lower spending on marketing and promotional activities and reduction in administrative expenses. Consolidated PAT for the quarter was Rs. 4.54 billion, up 50% on a year-on-year basis and up 16% on a sequential basis. Our net debt as on the 30th of June 2020 stood at Rs. 52 billion against Rs. 67.4 billion on the 31st of March 2020.

Our India geography, comprising of human health, consumer wellness and animal health business registered a revenue of Rs. 14.86 billion during the quarter. India human health formulations saw reduced number of prescriptions and a fall in patient footfalls. The U.S. geography comprising of generics and specialty portfolio registered a revenue of Rs. 16.23 billion during the quarter, down 8% on a sequential basis. Excluding Sentynl, the business was down 7% on a Q-on-Q basis.

The degrowth was mainly on account of substantial reduction in sales of seasonal products, mainly Oseltamivir capsules and suspension. Our rest of the world business grew by 8% during the quarter on a year-on-year basis. Despite the COVID-19-related disruptions, the business registered significant improvement in the performance vis-a-vis the preceding quarter.

Now let me take you through the operating highlights for the first quarter of FY '21 for each of our business lines, starting with our human health business in the India geography. The pharmaceutical market in India showed gradual recovery during the quarter as the market grew by 2% during the month of June after degrowing 11% and 8% in the months of April and May, respectively. In line with the market, performance of our business also improved gradually during the quarter as the demand started to show some early signs of recovery with doctors partially restarting their practice.

This trend is likely to pick up pace in the coming months. Overall, our human health formulations business posted a sale of Rs. 8.29 billion, down 11% on a year-on-year basis. Large brands having annual sales in excess of only Rs. 250 million performed better than the overall portfolio. Zydus Healthcare Limited, which spearheads our branded mass and specialty

formulations business in India, de-grew by 5.9%, excluding the discontinued brands, as per AWACS, which was in line with the overall market degrowth.

On the therapy front, we gained market share in gynecology, pain management and antidiabetic portfolios during Q1. In the gynecology segment, we have improved our rank from the third to the second; while in the respiratory, cardiac and GI and anti-infective therapeutic areas, we have maintained our ranks. With the demand-generation activity gradually returning to normal, we are hopeful of regaining lost ground in the coming quarters.

Like the India human health business, consumer wellness business also registered a gradual improvement on a month-to-month basis after the quiet start. We posted sales of Rs. 5.32 billion during the first quarter, down 12% and a net profit of Rs. 892 million, up 11% on a year-on-year basis.

Our animal health business in India recovered from the effects of COVID-19-related disruptions as the business posted sales of Rs. 1.25 billion during the quarter with a growth of 4% on a year-on-year basis.

Now for the performance of our U.S. formulations business during the quarter gone by. The U.S. was the largest contributor to the consolidated revenues with a 46% share. During the quarter, we relaunched Succinylcholine Chloride Injections in the month of May 2020 from our alternate injectable manufacturing site of Liva near Baroda after the site transfer from the Moraiya formulations facility.

We also launched 3 new products during the quarter. We received approvals for 12 new products, including 4 tentative approvals. And we filed 5 additional ANDAs with the USFDA during the quarter. Recently, in the month of July, we successfully completed the site transfer of Doxycycline Injections as we received an approval for our supplemental abbreviated new drug application from the USFDA for the manufacturing of this product from the injectable manufacturing facility of Liva.

Our API business registered sales of Rs. 1.31 billion during the quarter with a growth of 89% on a year-on-year basis.

Before I conclude, on behalf of the organization, I must say that one of the most important learnings during this lockdown has been that there are better and more agile ways of doing business. From connecting with customers and business partners through digital means to working from home while maintaining the same level of efficiency were important lessons of this pandemic. We intend to continue these efforts of finding innovative and cost-effective ways to enhance productivity and drive revenue growth using newer technology tools.

To this effect, we have already launched an enterprise-wide cost-transformation initiative, working on the principle of zero-based budgeting.

I will now request Dr. Sharvil Patel to take you through the progress on initiatives of our innovation program. Thank you.

**Sharvil Patel:** Thank you, Dr. Nayak, and good evening, ladies and gentlemen. Again, to reiterate Dr. Nayak's point, I hope you and your family are safe and healthy during the health crisis that you all are going through. In the midst of this challenging times, we have been able to continue the momentum in the innovation and drug discovery space during the quarter after attaining significant milestones during the previous financial year. Let me give you an account of various actions that have been taken in different areas of drug discovery and innovation.

Talking about our progress on the NCE research, recently, in the month of July, we are very happy that we have received an approval from the COFEPRIS, which is a Mexican Drug Regulator for a study of Desidustat in the management of COVID-19. The attack of the COVID-19 causes less and less hemoglobin that can carry oxygen and CO2. The lung cells have been reported to develop extremely intense poisoning and inflammation due to the inability to exchange CO2 and oxygen frequently.

Our molecule Desidustat mimics the physiological effect of high-altitude oxygen deprivation. At higher altitudes, the body responds to lower oxygen availability with stabilization of Hypoxia-inducing factor, and this can lead to increased red blood cell production and improved oxygen delivery to tissues. With this in knowledge, recently, we have now also got an approval from the USFDA to initiate Phase-I clinical trials of Desidustat for chemotherapy-induced anemia.

On Saroglitazar Magnesium, we are happy to inform that the Phase-II double-blinded, placebo-controlled clinical trial for the orphan-like indication PBC in the U.S. has been completed. And we shall seek the USFDA's approval for subsequent phase of clinical trials.

On the biological front, we have received an approval from both the Drug Controller General of India and the Mexican Regulatory Authority to conduct clinical trial for our Pegylated Interferon Alpha-2b to treat novel Coronavirus. At present, clinical trials in India and Mexico are underway for this molecule. We are in the process of filing an Investigational New Drug with the USFDA for Pegylated Interferon Alpha-2b for the treatment of mild cases of COVID-19.

On the emerging market front, we expect to see an array of approvals for our biological products in the next 6 to 9 months, which will pave way for our biosimilars entry into the emerging markets.

Talking about vaccine, we have now successfully completed Phase-I clinical trial for a ZyCoV-D, our plasmid DNA vaccine to prevent COVID-19. The doses of the vaccine administered to healthy volunteers in the Phase-I clinical trial, which began on 15th of July, have been well tolerated. Previously, the vaccine was also found to be safe, immunogenic and well tolerated in the preclinical toxicity study. The vaccine was able to elicit high levels of neutralizing antibodies in the animal model.

We will now commence the Phase-II trial from the 6th of August, which will be conducted in over 1,000 healthy volunteers as part of our adaptive Phase-I/Phase-II dose-escalation, multicentric, randomized double-blinded, placebo-controlled study. The Phase-II trial will be evaluating the humoral and cellular immune response for the vaccine candidate, in line with the current global trial protocols approved globally.

Coming to the development of other vaccines, we have also received marketing authorizations in India for the Pentavalent Vaccine, and the Haemophilus Influenzae Type B Conjugate Vaccine during the quarter. We have also received regulatory approvals to conduct Phase-II/Phase-III clinical trials for our Diphtheria and Tetanus Vaccine during the quarter. This marks an important movement for our development of vaccine.

Coming to our stages of 505(b)(2) and other special initiatives, we are developing a portfolio of branded specialty products, comprising of novel concepts offering incremental innovation with an aim to fulfill unmet medical needs to enhance patient ease and offer better treatment options to physicians. Some of these programs have a focus on orphan and rare diseases. At present, 9 products are under different stages of clinical development, and we are planning to file an NDA for one of the products in the pain management area in the current financial year.

During the quarter, we conducted 3 IND meetings for 2 products and have also submitted an orphan-designation request for one of the molecules. We are continuing our effort to seek potential strategic collaborations including inorganic opportunities to further build on to our specialty business.

In addition to building the specialty business, we are also working on expanding our presence in the complex generic space. And till date, we have already in-licensed 14 products with brand value in excess of $15 billion. To augment our presence in this part of the business, further 10 more licensing deals are under discussion with near-term commercialization opportunities.

Thank you. And now we move over to the Q&A session. Over to the coordinator for the Q&A.

**Moderator:** Thank you very much, sir. Ladies and gentlemen, we will now begin the Question-and-Answer session. Our first question is from the line of Mukesh Prajapathi, an individual investor. Please go ahead.

**Mukesh Prajapathi:** My question is that, how is the price rationalization, margin realization in the US, sir?

**Sharvil Patel:** So the U.S., the pricing has been very stable. And our guidance for U.S. generics price erosion is that it would be in the low single digits.

**Mukesh Prajapathi:** Right. So are we expecting that there will be upward price margins, in particular U.S. export, looking towards the condition across the world?

**Sharvil Patel:** I would say it really depends on what kind of supply chain disruptions that are there, but on a normalized basis, we have seen that the price erosions are in the mid to low single digits. So I think that would be our current guidance for the future unless there are some disruptions.

**Moderator:** Thank you. Our next question is from the line of Tarang Agrawal from Old Bridge Capital. Please go ahead.

**Tarang Agrawal:** Congratulations on strong performance in the U.S. formulations business. On this business, I have queries relating to the injectable space, sir. I just wanted to understand what would be the size of the injectables business in FY '20?

**Sharvil Patel:** So it is very small. Vishal, I do not know if you have the number, you can give, but it is not any meaningful number right now. The large part of our injectables buildup is going to happen in the next couple of years. We have earlier elucidated to the point that we have a very large injectables franchise that we have been developing including complex injectables. So we have a portfolio of 45 products that are filed and another 30 under development.

And we believe that in the next 2 to 3 years, we will have at least 20-plus injectable products, which will have good value proposition in terms of limited competition and complexity, which will help us build our overall injectables franchise.

**Tarang Agrawal:** So out of your maybe 108 pending ANDAs as on 31st March '20, 45 are injectables. Would that be the right way to look at it?

**Ganesh Nayak:** No, it is less, there are oral solids as well.

**Sharvil Patel:** So some of them are approved under Moraiya. So Moraiya products are getting site transferred to Liva. So it would not mean they are under approval. A lot of them are approved, but they are obviously under the site transfer process.

**Tarang Agrawal:** And what is FY '20 size of the business?

**Ganesh Nayak:** So it is less than $15 million.

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

**Prakash Agarwal:** This is Prakash. So my first question is on the R&D side. Just wanted to check on the R&D as a percentage to sales. So what is the plan ahead for this year and next year? And how do we think the split is going to be, given that our complex generics as well as innovative initiatives are increasing? So what is the current split? And what it could be year after?

**Sharvil Patel:** So our guidance continues that we will be between 7% to 8% of revenue as the R&D spend, which will be divided sort of largely into our generic portfolio, followed by the NCEs and then biologics and vaccines.

**Prakash Agarwal:** Could you help us with the breakup, sir?

**Sharvil Patel:** I would say about 60% is on generics ANDAs, and the rest is divided between the NCEs, biologics and vaccines.

**Prakash Agarwal:** Okay. And this includes the current COVID-related initiative, Phase-I/Phase-II that you are doing.

**Sharvil Patel:** Yes.

**Prakash Agarwal:** And this will likely to continue next year as well?

**Sharvil Patel:** Which part?

**Prakash Agarwal:** The 60:40 split?

**Sharvil Patel:** I think there will be a little increase on the NCE front, but by and large, I would feel that we will be at best 50:50, if not 60:40.

**Prakash Agarwal:** And secondly, the gross margin has improved, but EBITDA margin improved largely due to cost savings. So what has led to this kind of gross margin expansion? And secondly, what has been the FCF and debt reduction for the quarter?

**Sharvil Patel:** Gross margin has been because of better product mix in India business, which has helped our gross margin, and also the U.S. business has done well. So those 2 businesses have led to better gross margins. Other than that, Vishal, if you can answer the other question.

**Vishal Gor:** So Prakash, are you referring to the gross margin on year-on-year basis or quarter-on-quarter basis?

**Prakash Agarwal:** On the gross margin, he clearly explained. The other one was on the FCF and debt reduction, sir, for the quarter.

**Vishal Gor:** So debt reduction, Mr. Nayak, in his opening remarks, has already mentioned that our net debt is about Rs. 5,200 crores vis-a-vis Rs. 6,700 crores in March '20. So on a net basis, there is a reduction of Rs. 1,500 crores. But on an annualized basis, we believe we should be in a position to reduce the debt by Rs. 1,000 crores.

**Prakash Agarwal:** Okay. So this quarter was Rs. 1,500 crores reduction?

**Vishal Gor:** Yes.

**Prakash Agarwal:** And this is a function of what? I mean?

**Vishal Gor:** Yes, better control on the working capital as well as some timing differences in terms of business in different geographies.

**Sharvil Patel:** Better receivables and working capital management.

**Moderator:** Thank you. Our next question is from the line of Surya Patra from Phillip Capital. Please go ahead.

**Surya Patra:** A couple of things. Just on the in-licensed product opportunity that you have mentioned, you have already seen license something like 14-odd products, having a business potential of Rs. 15 billion and 10 more that you are adding. Can you give some clarity whether these are like currently into the business already and contributing something and the potential of what you are indicating or it is entirely futuristic kind of initiative?

**Sharvil Patel:** No, these are already products that we have in-licensed which are either filed and yet to be approved or to be filed. Most of them are complex technologies. And some of them which are to do with first-to-file where we did not have that in our pipeline, and we have been able to partner in first-to-file with limited competition.

So most of these releases are either where we have significant advantage because of some chemistry and API, complex carbohydrate chemistry, where there are some injectables which require dedicated resources. So they are with a limited competition. But some are filed, and some are yet to be filed. So these are all for future projections.

**Surya Patra:** Okay. So then in the R&D spend so whether any cost is likely to be incurred on these assets and whether that is part of the R&D that we are talking about and when from these assets can start contributing? Any color on that would be helpful.

**Sharvil Patel:** So most of these assets will be commercialized in the next 3 years. So they are not beyond that. They are in therefore for the next 3 years.

**Surya Patra:** Okay. And any costs that would be incurred on that, sir?

**Sharvil Patel:** Yes, Vishal can give the technical breakup of it. But yes, the costs that are mostly incurred are during approvals and the launch.

**Surya Patra:** Okay. And my second question is on all of your portfolio that you have created I think you are one of the companies having the entire portfolio of products targeting COVID, whether it is vaccine or it is product and all that. So now it seems that, okay, COVID is going to be there in the global system for some time. So in terms of business, have you seen any opportunity during this quarter because of the COVID from any of your product?

Or what business progress or what incremental business that you are anticipating out of all your kind of COVID initiatives, whether it is vaccine or it is the test diagnostic kit or it is the existing product or the future products that you are trying to do the clinical trials. So anything on that front would be kind of useful.

**Sharvil Patel:** So we are working on multiple fronts. I can give you some example of some of the things. On the diagnostic tests, we are currently able to commercialize about 2.5 lakh to 3 lakh tests commercially every month. On the vaccine front, we are committed to being able to produce 100 million or 10 crores doses annually. That is the capacity that we are planning for the vaccine. So if we meet our clinical end points and safety and immunogenicity results, that is a large and sizable opportunity for the coming future.

And we are also working on some of the biologicals, which are important as therapeutic treatments, which were the Pegylated Interferon has enrolled the case for Phase-II and almost about to complete that. So some of those will again have meaningful opportunities in the future. And we will also be launching Remdesivir, which will add to our for further revenues in the coming quarters.

**Surya Patra:** Okay. But this is very difficult to really give an indication about potential business that we can gather out of the entire initiative targeting COVID?

**Sharvil Patel:** It is large and meaningful. If the commercialization comes, I think we can give a better estimate. Right now, it would be too early to give those estimates but knowingly any case that gives a proof of COVID has a good commercial potential if you have limited competition.

**Surya Patra:** Okay. Just last question, if I may, sir. In the opening remarks, Mr. Nayak has indicated about the additional costs continuing. So if you can just add what incrementally that we are doing to contain the cost? Although we have already been segregated our initiatives, our domestic business into mass and the branded, and we are anyway rationalized some of the cost there. But now you are talking about additional incremental kind of cost measures. So can you talk something more on that?

**Sharvil Patel:** Yes. I think the whole crisis in COVID has obviously given us a lot of positive lessons. The first is the whole use of digital technologies, we believe, can enable us both in the operations and in the front-end side to improve on productivity by improving throughput as well as improving our costs. So I think that is one big initiative that we have taken. And we believe through the means of digital, we can go forward and reduce cost and improve productivity.

The second is we are adopting zero-based budgeting for many of our established businesses because I believe going forward, there will be new ways of engagements. So we are adopting that for the future, and we believe we can bring good cost savings from that. So a large part of it is going to be driven from operations, everything driven towards productivity, which will lead to benefit. And also, there are some costs we believe because of digitization, related to travel and other expenses, which will all be curtailed for the future.

**Moderator:** Thank you. Our next question is from the line of Kunal Dhamesha from Systematix Group. Please go ahead.

**Kunal Dhamesha:** So the first question is again on the India business. So what was the percentage of our branded as well as the trade generic business for this quarter? And have you seen any dichotomy in terms of growth in both of these engines? And secondly, on the vaccine Phase-I. So how many patients were enrolled? And on Phase-II trial, what is the time line in terms of enrollment and then whether we will be having any early data which any time in point we will be releasing. So any color on that would be useful?

**Sharvil Patel:** So I will take the second question first on the vaccines. We are starting our Phase-II trial where we are hoping to enroll 1,000 patients, 1,000 healthy volunteers. And we believe we will be able to complete that by October. So that is our time line. And as and when we see the recruitment improving, we will keep everybody updated. So that is our current time line for this vaccine trial that is ongoing.

With regard to the formulations business, we have I think, Vishal, if you can give the breakup of GX and the branded. I think it is about 10% Gx? Vishal, how much is Gx as part of the overall?

**Vishal Gor:** Yes, it is about 10%.

**Sharvil Patel:** Yes. So I would say the branded side has done better than the generic side on a comparable basis.

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

**Sameer Baisiwala:** Sir, is it possible to give some more color around Rs. 1,500 crores debt that you have managed this quarter? Very impressive. But if you can break it down, how much was receivable, internal accrual or some other head that you had?

**Nitin D. Parekh:** So Sameer, Nitin, here. So basically, as you know, in different businesses especially in US business, the targets have different kind of tenure period depending on the primary sales and secondary sales. So with the kind of approach in terms of liquidity management that we did, we have been able to get better collections in our sales for certain months. Also in India and other geographies, we had stringent controls in terms of management of inventory receivables etcetera. And also certain postponement of certain programs, including CAPEX for a limited period of time that was in light of exigencies during lockdown. So that has helped us in terms of about Rs. 1,500 crores of net debt reduction during the quarter. However, on annual basis, some of these would be of reversing nature, especially in terms of receivable part in U.S. and therefore, we, on a conservative basis still believe that Rs. (+1,000) crores kind of reduction for the entire year would be possible.

**Sharvil Patel:** And so if I can add to what Nitin Bhai said. We have set up a cash management office to manage our daily cash flows and everything as part of the response to the COVID. And what we have seen is because of that other than U.S., which is sort of cyclical, we have seen better receivables and much better healthy receivables than sales in the months gone by. So that has also helped our cash position. And obviously, CAPEX is delayed for want of issues related to availability of doing some of those.

**Sameer Baisiwala:** Okay. And our year-end target is Rs. 1,000 crores down from June end or from March end?

**Vishal Gor:** From March end. Yes. So as Nitin bhai said, some of the things, which will be reversing in the time to come, including higher collection in U.S. compared to the sales. So by March '21, we are expecting to reduce the net debt by Rs. 1,000 crores compared to March '20.

**Sameer Baisiwala:** And what is the update on Moraiya?

**Sharvil Patel:** So Moraiya, we have completed all our remediation, and we have written to the FDA requesting them to start the review and request for desktop audit if possible.

**Sameer Baisiwala:** Sir, the expectation earlier was to get it resolved in the current calendar year. Does that still stand?

**Sharvil Patel:** We are hopeful that I mean, before COVID, we were hoping for an inspection by end of this calendar year, which would have meant that by first quarter of next calendar year, we could have seen resolution provided we had a successful audit. So now in response to what the way the FDA looks at the review, it will all depend on that, but we are still hopeful that we can stay with those time lines, but it is still unknown right now.

**Sameer Baisiwala:** Okay. And sir, on HCQS, was it a big incremental part of the driver for this quarter? I mean not your regular base business but just the COVID indication?

**Sharvil Patel:** Yes. So we did have higher sales for HCQ so some part in the U.S., which is our new contracted business that we have. And also the state and central government sales that we did in the quarter, which still continues in this quarter.

**Sameer Baisiwala:** Sir, the reason why I am asking is this may be transitory, may not be so is that a big number of Rs. 100 crores, Rs. 200 crores or a smaller number?

**Sharvil Patel:** No. Vishal can answer, but it is not that big.

**Sameer Baisiwala:** Okay. Vishal, any color you want to add?

**Vishal Gor:** It is less than Rs. 100 crores, incremental sales.

**Sameer Baisiwala:** Okay. Good. Sir, maybe with your permission, my final question on 45 injectables. And that is quite important for your growth story next 2 years. So just wanted to understand how many of these are approved. And how many of them are presently tied to Moraiya versus the new site Liva? So just clarity on this would be very helpful.

**Sharvil Patel:** Yes. So I would not have it off hand on me, Sameer, but I will definitely make sure that Vishal gives you the ones which are in Moraiya, which are getting site transferred and other facilities where we have filed the products from of this 45 and the remaining that we have to be filing, which is another 30, which is under plan. Some of these are partnered in also filed and to be filed.

The good part, I can only say for this is that our big manufacturing facility, which was Liva, while it got audited which was an audit that got completed successfully, but we have also through we believe got Doxycycline, which is on a new line, which gives us the confidence that we will get further site transfer approvals from now two lines instead of one line because only one line was inspected earlier, but the second line approval has also come through. So that would mean that Liva will see further ramp-up of site transfers from Moraiya.

**Moderator:** Thank you. Our next question is from the line of Harith Ahamed from Spark Capital. Please go ahead.

**Harith Ahamed:** On the COVID vaccine, you mentioned that you finished Phase-I and then you are about to start in the process starting Phase-II. So in the Phase-I study, was there an immune response that you were able to monitor in terms of utilizing antibodies or any other cellular response? Or is it a part of the Phase-II trials?

**Sharvil Patel:** No. As part of Phase-I, we will look at initial results, but large part of that data will come from Phase-II. The Phase-I is initially set up for making sure that the safety protocols and the safety is seen. So the following results, which you are talking about, you will see in the next 4 to 8 weeks with that data.

**Harith Ahamed:** Okay. And on the Saroglitazar, you were planning Phase-III trials in NASH indication in the U.S. Any updates around that?

**Sharvil Patel:** Yes. So we believe that we are still committed to, in the coming quarter, to go to the FDA with our next clinical trial protocol for NASH as well as also working because we have completed our PBC Phase-II enrollment also. So we will actively be also working on how to take it forward for PBC as well. So two indications. In the next 3 to 6 months, we will be taking FDA's advice on that.

**Harith Ahamed:** Okay. And any progress on the partnership plans for these trials?

**Sharvil Patel:** Partnership is still we have not officially started any discussions on partnership. We are still working with a consultant to help us formulate our plan. And once the whole plan is formulated, then we would reach out in terms of partnership or any other model, which will help propel this trial forward.

**Moderator:** Thank you. We will take our next question from the line of Sapna Jhawar from Dolat Capital. Please go ahead.

**Sapna Jhawar:** So my question is pertaining to the annual report, specifically on the other expenses side. We have seen two heads. One, the miscellaneous expense and second, the legal and professional fees increased rather high. And the miscellaneous expense has probably increased to around Rs. 800-odd crores now. Any breakup there would be helpful?

**Sharvil Patel:** Yes, I think we will give that to you off-line.

**Sapna Jhawar:** Sure. And the second question, with regards to the COVID trials and the entire range that we have done so far, can you guide us the amount of investment that has gone through these trials so far? And how much do we intend to spend more over here?

**Sharvil Patel:** So we do not give plans on individual programs. The substantial part of investment is still to be made. I would say only initially, 15% to 20% of investment is made. But now we have to

make two investments. One is obviously the larger trial and followed by investment in manufacturing as well.

**Sapna Jhawar:** And this would I mean, I am assuming a large part of these trial expenses would be carried only in the R&D side? Or we will be recapturing in some other line items as well?

**Sharvil Patel:** No, it is in R&D.

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

**Nitin Agarwal:** Sir, on the U.S. business, we have seen a QoQ sharpish decline in the business. Can you help us understand the drivers in terms of what sort of led because what our understanding was that there is no seasonality in our business and sort of largest one-off on sales in the Q4 U.S. sales. And clinging to that, how should we look at U.S. sales progression through the quarters now for the year?

**Sharvil Patel:** So the main seasonality that we see for the U.S. business is because of the Oseltamivir capsules and the suspension, which is highly seasonal and which is one big gap that is always there between quarter 4 and quarter 1. So the majority of the drop is because of that and the new product. But beyond that, I think it is just a question of we get a lot of onetime buy opportunities.

And while we completed a lot of them in the quarter 4, we believe now in the coming quarters, we have built up some further inventory, so we will further get those opportunities. So our guidance for the financial year is we will definitely grow in mid to high single digits for the generics business in the U.S., and we are on track for that.

**Nitin Agarwal:** Okay. And then secondly, in terms of on your emerging market business, the biologics approvals and all that you talked about, the impact of that, will it be visible, start getting visible from this year? Or it is going to be more like a FY '22 onwards opportunity?

**Sharvil Patel:** Meaningfully FY '22, but we have good traction going on. I think the key milestones will be the approvals in many of these markets. Which once we get, we will obviously inform, which will be able to then predict the sales. So as I said, the critical approvals we are hoping for are from Russia, from Latin America, Colombia and Mexico. So those three are in debt, and we are very hopeful that they will come through in the next 6 months, which will then lead to meaningful sales in the coming year.

**Nitin Agarwal:** And sir, how many biologics are we looking at on average across these major geographies to come through? And secondly is the fact that we are not filing these biologics in U.S. or not

looking to get any approval right now, is there a hindrance in getting approvals to this geography?

**Sharvil Patel:** So in the geographies that we have filed, we do not believe they are invested because at least all the geographies that we have filed for, we already have been audited in terms of our plant, both formulations and API. So we are regulatory-wise clear in terms of our capabilities on the manufacturing side.

Now on the review of the dossier, I think we are in the final stages in many of these markets. In some of the markets, we have also done local studies as is required. So I think we are comfortable with some of our biosimilars in many of these emerging markets. The advanced markets where we have not filed it because, obviously, we do not have the EMA approval.

So we do not have current plans to take them for that route. We are taking a next wave of biosimilars for the developed market. But in the first wave, it is only limited to markets in Latin America, some markets of Africa and North Africa, the Middle East and Southeast Asia.

**Nitin Agarwal:** So will you be able to name some of these important or largest biosimilars you are looking at?

**Sharvil Patel:** So we are looking at PEG-G-CSF, Trastuzumab, Bevacizumab, Adalimumab and followed by Rituximab and follicle-stimulating hormone are in the first wave of product and parathyroid hormone are in the first wave of products that we have filed or are filed and moving forward. In the next wave, you will see Rituximab and Xalone in the next wave of biosimilars.

**Moderator:** Thank you. Our next question is from the line of Arvind Kothari from Niveshaay. Please go ahead.

**Arvind Kothari:** Thanks. All my questions have been answered.

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

**Anubhav Aggarwal:** Yes. First one, clarity on the injectables. Before we had the issue at Moraiya, we were doing roughly about $50 million from the injectables sales. So if you assume no more approvals for us, that is the first goal post for you to get to $50 million in injectables?

**Sharvil Patel:** So this year, definitely, we will try and achieve those numbers. But in the next 2 years is where the large part of the portfolio comes. So then we are talking about larger value, as I said, we believe our injectable value for FY '24 is between $150 million to $200 plus million.

**Anubhav Aggarwal:** Okay. Sure. And one clarity on the vaccine. Now by the time your Phase-II will be done, this year October, we will have Phase-III for some of the global vaccines, which have been done.

So how would you evaluate the path forward? Would you evaluate your candidate versus them? Take your call on to whether to proceed or not? How are you thinking about it?

**Sharvil Patel:** Well, it will all depend on the data that we get. I mean I think globally, it is very clear that there cannot be a single vaccine that can solve the issue that we are currently facing. So there will be multiple vaccines that we believe are moving forward, which will be approved. And also the kind of requirement that would be there in terms of at least sometimes 50%, some people say larger immunization required, I believe there will be multiple vaccines that will be approved and will be available.

And depending on the results, obviously, the success will be there. We are planning for 100 million dose capacity and that we believe if our vaccine is successful, this is the kind of investment that we are planning for. Obviously, if their vaccine data is very good, which we believe will be, then we will look at how do we further build up on that capacity through partnerships.

**Anubhav Aggarwal:** Sure. That is helpful. One clarity on the point which you mentioned over the India business earlier, the use of digital media and this drive higher sales productivity. I just want to clarify here, is the use of digital is this are you referring to promotion to doctors? Are you referring to monitoring the costs and better sales force more effectively? In which one segment are you there?

**Sharvil Patel:** This we are doing everything. So it will be a doctor-patient connect, and we bring some solution that can be independent. We are talking about how do we do better scientific medical education, which is the large part of what we do in a more faster and agile manner. And we are looking at how do we reduce doing better frequency of calls and more precise calls, which will improve productivity of our sales reps and also reach a larger audience through the digital platform. And also, which would lead to lesser travel and lesser other costs.

**Anubhav Aggarwal:** Sure. Okay. Maybe after a couple of quarters, I will just stay with you again on this because right now, it is very fluid time line how this activities are. My view was this is so dependent on what other players are doing. Maybe the market move towards you then it is much easier. Internally you can adopt more and more digital, that the doctors are attuned to talking more on digital. I was not sure about even now?

**Sharvil Patel:** That is the big question, and that is, as you said, it is only time will tell. So we are making a very honest attempt that we are building a group for the doctor. And we make sure that our final outcome is how do we get better patient outcome. And if we are able to build a meaningful digital tool to address that, I think we will see success. But yes, we are going ahead with it. We will be launching it very soon, but the proof of the results will be, obviously, a few quarters from now.

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

**Nimish Mehta:** I just wanted to know how big do you think in the market for Remdesivir in India and other countries where we have a license?

**Sharvil Patel:** I do not think I can fully estimate that. But today, there is a significant shortage on Remdesivir. And this is a lyophilized injectable product and a very large vial size and volume, which leads to lower capacity. So I believe whoever has significant capacities will be able to do well. What we believe is we should be able to sell out most of our capacities. I feel the advantage for us is that we manufacture our own API, and we manufacture our own finished dosage from formulations.

And we have four facilities that can manufacture lyophilized products, and we are going to do with through all four facilities. So we are building significant size and scale, and we are backwardly integrated completely. So we believe we will create a meaningful availability of the product, which is the need of the hour. Today, the major concern is both access and affordability of this molecule. We hope that by coming to market, we will be able to address both.

**Nimish Mehta:** So I understand the prices also will come down basically as more and more players are coming. But I mean, just to share Remdesivir I mean, I understand it is a fluid situation. But some ballparks for Indian markets would help and also how big is our export opportunity vis-a-vis other Indian opportunity? I mean, do you think that there is a meaningful I mean there are about 127 countries included. So can this be bigger than the India opportunity that we are envisaging?

**Sharvil Patel:** I think currently, it is difficult to predict the opportunity. We are in the midst of discussing that and working out with different partners because you have to go through a regulatory process also, while it may be abrupt and short. One thing is very clear. This drug is not easily available. And because it is a difficult technology, it is not easily scalable in different countries.

So India can definitely play a meaningful role in creating and not only for India but for other countries where the need is and India is a large manufacturer of some of these things. So we believe it is a meaningful opportunity, but to give an estimate, I mean I believe with the current need of it, we probably, whatever you can make, one should be able to sell. But we have to wait and see how the market forms.

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

**Neha Manpuria:** My questions have been answered. Thank you.

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

**Kunal Mehta:** You mentioned the number of $150 million for injectables. So I was just trying to confirm, this is the potential sales to your P&L. That is correct?

**Sharvil Patel:** Yes.

**Kunal Mehta:** Yes. So sir, when I look at the injectable space, between 2022 to 2024 we are going to see a good number of products losing exclusivity. So just wanting to understand the launches which you are talking about while you build up your injectable business, are those really aligned to those LOEs? Or you are also talking about launching a lot of existing new products and including onco injectables also?

**Sharvil Patel:** So definitely, there are onco injectables. And on the injectables front, there are a lot of injectables, which complex chemistries that there are no patents, so there are no generics. So you can say a lot of our in-licensing opportunities have been products where there are no generics without any LOE left. So large part of them are those. Some of them are where there are huge shortages in the U.S. market.

So we have identified those types of products. And then there are certain products, which we believe are good volume products, which if there is any disruption, we can see some meaningful gain. So it is a mix of portfolio. We have an oncology injectable site, which is approved by the FDA. We have a Liva site, which is approved, and we have one more injectable site, which has also approvals. The three of these sites and through our partners in products will help us achieve these revenues.

**Kunal Mehta:** Sir, second question I have is on the API side where we have seen almost the entire industry now report very strong business momentum in this segment. So would you look at external APIs as a lever of growth going forward for the next, at least, few quarters until we see? I am sure you must be seeing good inquiries about the APIs you have on your portfolio. As a Board, will you take a decision to allocate more capacities for external sales provided the pricing is in your favor?

**Sharvil Patel:** Yes. So I think our API business has turned around and started to do well from merchant sales point of view, and with the kind of products that we have planned for in terms of good capacities and good capabilities, we will see a good momentum for our own API business in terms of third-party sales. And we see good momentum for it as this quarter has also good results. With the kind of orders that are in hand, they should continue to do well in the coming quarters as well.

**Kunal Mehta:** Okay. And the final question from my end is, we have our facility here, the investment facility for Transdermals. So just wanted to clarify, is this only Transdermals or can you manufacture the whole topicals category in these products? And are the filings covering Transdermals where generic is essentially very rare? Or we are covering all basic products on the topical side also?

**Sharvil Patel:** No. So our Transdermal facility, we have 3 facilities. One is in Moraiya. In the oral solid, we have a plant in plant. We have a Zydus Technology facility in SEZ, and we have one facility in U.S. near Baltimore. So those are our 3 Transdermal facilities, which cater to Transdermal products, and that can only cater to Transdermal products.

**Kunal Mehta:** So you do not have topicals or manufacturing in those plants?

**Sharvil Patel:** Topical is a different facility, which is also approved, and we sell our topicals through that facility.

**Kunal Mehta:** Could you just help me understand which is the type where we are strong, is it topicals?

**Sharvil Patel:** It is in Changodar.

**Moderator:** Thank you. Our next question is from the line of Krishna Prasad from Franklin Templeton. Please go ahead.

**Krishna Prasad:** On the vaccine front, how large will the Phase-III have to be? Is there a sense that you have now?

**Sharvil Patel:** It is too early. Obviously, the Phase-II will also lead to some better understanding, but we believe it will be between 5,000 to 10,000 patient study.

**Krishna Prasad:** Okay. And in terms of delivery of this DNA vaccine, is it just a regular injectable? Or you will need a device or something to improve the efficacy.

**Sharvil Patel:** We are trying out both regular injectable, and we have also added a device for better delivery. And we are trying trial and the trials are going on for both.

**Krishna Prasad:** Okay. And the Phase-II would tell you what would be the route?

**Sharvil Patel:** Yes. It will very clearly tell which dose because we are trying multiple dose and multiple delivery platforms.

**Krishna Prasad:** And would you share the Phase-I efficacy data at some point whatever you have generated so far?

**Sharvil Patel:** Definitely. Once the data will be out, we will be definitely sharing it.

**Krishna Prasad:** Okay. And that you said is in 4 to 6 weeks, right? That is what you mentioned before.

**Sharvil Patel:** Yes. So it will depend on the completion of all cohorts. And once we have results of all cohorts, we will definitely share it.

**Krishna Prasad:** Understood. Just on injectable side, I think you mentioned you will get to 160 million to 200 million by FY '24, right? I mean, if my understanding is correct. So how are you thinking about this trajectory? Like is it like going to be somewhat more front-end or more equal? Or are some of the larger products really more back-ended?

**Sharvil Patel:** So I mean, you would see meaningful increases in the next year, but more importantly, it is FY '23, FY '24. So the last 2 years where you will see this significant scale up because large part of the complex products are something that we are filing now or have filed. So because they are complex, we believe at least one CRL, which will mean at least a 14 to 16 month approval cycle. So looking at all of that, we are looking at FY '23 and FY '24 as a meaningful ramp-up to the injectables business.

**Krishna Prasad:** Sure. And just last question, sir. On the injectable side, we are seeing almost every Indian player kind of build capacity. I know it is today very attractive, but I am just wondering how are you thinking about the medium term? And for example, you have done a great job in oral solids and remaining competitive. How are you thinking about for more similar kind of strategy in the injectable side?

**Sharvil Patel:** So it is a couple of strategies. I think what is maybe a little bit unique for us, and maybe that is also because we were late to the game also is that we have these three strong manufacturing footprints, which is what we feel we will consolidate. And there could only be further incremental investment but not any meaningful more investment. And whatever we have planned for, we have sufficient capacity for the next 4 to 5 years.

What we are now doing is, we are switching up a lot of partnerships in in-licensing a lot of injectables because the kind of injectables that are differentiated and high value would mean dedicated capacities and dedicated capital investments. And I think to do everything and build every product requiring a separate kind of line and a separate kind of scale and the whole system was becoming very expensive. So we have formed meaningful partnerships from Europe and some parts of Asia, where we have been able to in-license complex injectables.

A lot of these injectables are also mean complex carbohydrate chemistries, which means the APIs are very difficult to find. And we have forged very good relationships there. So I think our model is in a way derisked because we are not relying only on our plants. We are spread in

terms of our partnerships in Europe and there, and our own plants, which will deliver some of the base volumes and some of the important launches that will come up.

So it is diversified in its risk, which is the biggest challenge when it comes to injectables. And we have formed a meaningful partnerships where companies have demonstrated successes in Europe or some other markets. And we are bringing those products to the U.S. So I feel it is a well-balanced strategy. Obviously, time will only tell how successful we are. But I am very excited about how we have been able to form some of these partnerships.

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

**Tushar Manudhane:** So just on this desktop inspection, it has been now almost 3, 4 months, in fact, start of the COVID has helped not just Cadila, but other companies to pursue a desktop audit. But is there any guidelines given out by USFDA, which can give some clarity in terms of when can this happen?

**Sharvil Patel:** So there are no clear guidelines. There is a view of desktop audit and the FDA is conducting desktop audits. So that is what I can say. Our Liva approval of the new product Doxycycline is through a desktop audit.

**Moderator:** Thank you. Ladies and gentlemen, due to time constraints, that was the last question. I now hand the conference back to Mr. Ganesh Nayak for closing comments. Over to you, sir.

**Ganesh Nayak:** Thank you very much. Stay safe, and look forward to interacting with you again in the beginning of November. Thank you and good night.

**Moderator:** Thank you, members of the management. Ladies and gentlemen, on behalf of Cadila Healthcare Limited, that concludes this conference. Thank you for joining us, and you may now disconnect your lines.