“Cadila Healthcare Limited Q3 FY '21 Earnings Conference Call”

February 05, 2021

MANAGEMENT: **DR. SHARVIL PATEL - MANAGING DIRECTOR, CADILA HEALTHCARE LIMITED**
MR. GANESH NAYAK - COO AND 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 Cadila Healthcare Limited Q3 FY '21 Earnings Conference Call. If a participant is connected on both the webcast and the audio bridge, you are requested to mute the audio from the webcast to avoid echo. To ask a question, participants are requested to click on the link for instructions to dial into the audio call.

I now hand the conference over to Mr. Ganesh Nayak, COO and Executive Director from Cadila Healthcare Limited. Thank you, and over to you.

Ganesh Nayak: Good evening, ladies, and gentlemen. Welcome to our post results teleconference for the quarter ended December 31, 2020. I do wish that you and your family continue to remain 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.

While 2020 turned out to be one of the most challenging years for people across the globe on account of the unabated spread of COVID-19, 2021 offers new hope to humanity as various countries have now seen success in the development of vaccines to combat the pandemic.

With that, let me take you through the highlights of the quarter gone by. During the third quarter of FY '21, we posted consolidated revenues of Rs. 38 billion, up 4% year-on-year. Consolidated EBITDA grew to Rs. 8.07 billion, up 16% year-on-year basis. Our EBITDA margin improved during the quarter as it went up by 210 basis points to 21.3% from the 19.2% registered during Q3 FY '20. Adjusted for loss of export incentive revenues, our EBITDA margins would have been in line with that of the preceding quarter. Consolidated PAT for the quarter was Rs. 5.27 billion, up 41% on a year-on-year basis and up 11% on a sequential basis. The quarter gone by turned out to be an encouraging one for our India business, which comprises human health, consumer wellness and our animal health business, as the business grew by 20% on a year-on-year basis, registering revenues of Rs.16.43 billion and drove the overall performance for the quarter. The US geography, comprising of generics and the specialty portfolio, registered revenues of Rs. 16.03 billion during the quarter. Our Emerging Markets business grew by 11% on a year-on-year basis and posted sales of Rs. 2.93 billion. On a sequential basis, the business grew by 24% during the quarter.

Now let me take you through the operating highlights for the third quarter of FY '21 of our business lines. Starting with our Human Health business in the Indian geography, the pharmaceutical market in India showed further signs of improvement as it grew by 6.4% during the October to December 2020 quarter after registering a flattish performance during the July-September 2020 quarter. Performance of our business also improved during the quarter on the back of steady improvement in demand amidst various unlocking measures being undertaken by the government. In fact, we were the second fastest-growing company among the top 10 Indian pharma companies during the quarter gone by. Our specialty cluster grew faster vis-à-vis the

mass cluster, and in turn, led to a better performance vis-à-vis the market. Overall, our Human Health Formulations business posted sales of Rs. 11.04 billion, up 21% on a year-on-year basis. Branded generic business grew by 24% on a year-on-year basis. On the therapy fronts, we gained market share in pain management, anti-infectives and the antidiabetic portfolio during Q3 FY '21, vis-à-vis the corresponding quarter of the previous financial year. We have maintained our ranking in the key therapies of gynecology, respiratory and pain management during the quarter. On the back of continued revival in the economy and with the festive season kicking in during the quarter, our Consumer Wellness business witnessed a strong surge in the revenues with the majority of the brands growing in double digits. Overall, the business grew by 16% on a year-on-year basis, driven by healthy double-digit volume growth. Our Animal Health business in India saw another quarter of robust performance as the business posted sales of Rs. 1.63 billion with a growth of 17% on a year-on-year basis. Implementation of digital initiatives, along with focused efforts to enhance customer connect led to the improvement in the growth of the business. Our US formulations business posted sales of Rs. 16.03 billion, down 4% on a year-on-year basis. We launched 7 new products during the quarter. These include the launch of doxorubicin liposomal injection, which is the first complex injectable developed in-house. We received approvals for 9 products, including 4 tentative approvals, and filed 10 additional ANDAs with the US FDA during this quarter. New product approvals for the quarter include three first cycle approvals. Cumulative first cycle approvals for the year 2020 now stand at 7. During the calendar year 2020, we received approvals for 38 new products, which is the second highest number of ANDA approvals received by any generic company across the world. Our cumulative filings include 71 filings for injectable products, and our cumulative approvals include approvals for 56 injectable products. This concludes the business review. I would now request Dr. Sharvil Patel to take you through the progress and initiatives in our innovation program. Thank you.

Sharvil Patel: Thank you, Dr. Nayak, and good evening, ladies, and gentlemen. As you know, there are continuous efforts to combat the COVID-19 pandemic. We completed Phase-II clinical trials of our first-in-class plasmid DNA ZyCoV-D during the quarter gone by. The trials were conducted in over 1,000 healthy volunteers. As part of the adaptive Phase-I/Phase-II study, the vaccine was found to be safe and elicited strong immune response. We also initiated a Phase-III trial for the ZyCoV-D vaccine now. The trial is progressing very well, and we will be conducting it in around 30,000 volunteers across 60 sites in the country. We are expecting to complete the recruitment of 30,000 volunteers by end of February. As you are aware, we are putting up a plant for the production of ZyCoV-D vaccine. The plant is expected to be ready for commercial production by the first quarter of FY '22. The designated capacity of the plant is equivalent to 120 million doses. During the quarter, we also submitted an application to the RCGM to carry out the preclinical and safety toxicity studies of our recombinant measles vector vaccine, which is the ZyCoV MV vaccine, which is a second vaccine candidate for the COVID-19. On the NCE research front, during the quarter, we successfully completed Phase-IIb trials for Desidustat for the treatment of hypoxia in hospitalized patients in Mexico.

Coming to Biologics. We have initiated Phase-III clinical trial in India for our Pegylated Interferon alpha-2b in 250 patients. So far, we have recruited 115 patients, and the trial is moving along smoothly. We submitted an IND application to the US FDA for our Pegylated Interferon alpha-2b for the treatment of COVID-19 patients. We are also developing a cocktail of monoclonal antibodies targeted towards the spike protein of the SARS-CoV-2 that causes the COVID-19. Regulatory permissions to start the toxicity studies were obtained and the toxicities have been initiated. The studies will be completed by March 2021, and the clinical trials will thereafter be initiated.

With this, let me give you an account of the progress made so far on the different R&D projects, other than those targeted towards the COVID-19. I'm very happy to say that the saroglitazar magnesium has been granted orphan drug designation by the US FDA for the treatment of patients with primary biliary cholangitis. This follows the granting of the Fast Track Designation by US FDA to the molecule for PBC in December 2020. During the quarter, we also received approval from DCGI for saroglitazar magnesium for the treatment of nonalcoholic fatty liver disease, NAFLD, in India. The molecule becomes the first medicine for the treatment of NAFLD. On the Desidustat, which is our second NCE molecule, we have completed large-scale recruitment of patients in the Phase-III clinical trial in India for the treatment for anemia in dialysis and non-dialysis-dependent CKD patients. In fact, we recruited a large number of patients despite the challenges posed during the COVID-19 pandemic. 392 patients were recruited who are suffering from anemia and were on dialysis for the Phase-III trial, also known as the Dream-D trials, and 588 patients were recruited who are suffering from anemia and who are not on dialysis for the Phase-III trial, also known as the Dream-ND trial. We have received regulatory approvals in India also to initiate Phase-I clinical trial for a new chemical entity ZYIL1, a novel oral small molecule candidate targeted at selectively suppressing inflammation caused by NLRP3 inflammasomes.

In order to provide a remedy for malaria, we have been developing a molecule which is fast-acting and effective against both plasmodium falciparum and P vivax strains of malaria parasite. Phase-I study in healthy volunteers has demonstrated long half-life and potential for a single dose to cure malaria. We now plan to pursue the development of this molecule in close consultation with the global regulatory agencies. On the biologics front, we received marketing authorization for 1 biosimilar in India and completed preclinical toxicity study for another biosimilar during the quarter. Talking about our vaccine portfolio, we successfully completed a Phase-II/III trial for tetanus diphtheria, the TD vaccine in India during the quarter. On a 505(b)(2) initiative, during the quarter, we submitted an NDA for one product from our specialty portfolio. We continue to explore potential collaborations and licensing opportunities to grow our specialty as well as complex generics business. Till date, we have successfully in-licensed 16 products to build the product of complex generics. This includes true products where we are likely to hold an exclusivity, first-to-file status and are likely to have a 180 exclusivity upon launch.

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

Moderator: Thank you very much. The first question is from the line of Saion Mukerjee from Nomura. Please go ahead.

Saion Mukherjee: Sir, just wanted to understand the India growth, if you make adjustment for remdesivir and other COVID related drugs, what is the underlying growth? And also related to that, given the fall in COVID cases, is there any stock return that we may have to book in the next quarter? I just want to get your views on that.

Sharvil Patel: So, with regards to your second question, we don't expect any stock returns for our remdesivir. Obviously, the cases have come down and that, accordingly, the volumes have come down. We still have a healthy volume mix for export. So, we still continue to see good traction on remdesivir. In India, as I said, certain therapies have done very well. And so the specialty play, especially the diabetes franchise has done very well and overall internally grown at good market shares. And so has our respiratory portfolio, which has improved significantly. However, it doesn't reflect right now in the IMS or AWACS right now. So, the specialty portfolio is doing well. And pain, we have gained good share in the pain management area. So that's boding well for us. And a lot of new introductions both in the diabetic franchise and in the respiratory franchises are doing well.

Saion Mukherjee: Sir, would you say, adjusted for COVID related drugs because that seems to be quite lumpy. So, it would be single digit, mid-single digit, some kind of indication if you can provide.

Sharvil Patel: We don't give a breakup like that, but I can at least tell you that for the quarter gone by and if you look at the top Indian companies and if you look at the external factor, we were the second fastest growing company. And that doesn't cover largely the COVID portfolio because it is obviously hospital driven.

Saion Mukherjee: Sir, just a couple of more on the saroglitazar for fatty liver, what's the kind of potential you see how large it can be for this particular indication in India?

Sharvil Patel: You're talking for India or global market?

Saion Mukherjee: You got an approval from DCGI, right, for India market?

Sharvil Patel: Yes. So, India, it's a very large opportunity. Today, the prevalence of NAFLD and NASH is very high. And obviously there is not enough diagnosis and treatment available. So obviously, we have recruited a lot of patients when we got approval for TG and treatment for triglycerides or high triglycerides. But now with this indication, we will see a longish therapy in terms of usage. And we are expecting and our vision and our plan is that this will become the largest selling molecule in Zydus in the next 3 years to 5 years.

Saion Mukherjee: And sir, just one last question, if I can just ask on the US progress or you've got the orphan drug designation. So, what's the timeline? What's your plan? Are you looking for a partner? If you can share something on the timelines and what we should be watching out for this particular molecule for US?

Sharvil Patel: On US front, we have 2 indications, PBC and NASH. On PBC, we believe that we can complete everything and enter the market somewhere in 2023 and by NASH, we hope to enter by 2025. There have been recent updates by the FDA, which may help us push this timeline better for NASH earlier, so we are very excited about the recent developments with the US FDA. Both the FDAs blessed our work in terms of our protocol. So, we are starting our trials very soon. On PBC, it's a very interesting area. Again, no approved drugs. And because of the need of the treatment, we got orphan drug as well as priority Fast Track Designation. So, I think we are very excited about it. We feel we can commercialize this ourselves. It doesn't require a large footprint. We are working towards that capability. At the same time, we will continue to also look at options of finding the suitable partners. If we feel that if that option works out better for us. But currently, we are committed to launching these molecules ourselves. And we can see the opportunity size by 2026 for PVC itself is $10 billion in terms of market size. So, it offers a very large opportunity for us. And if we are able to get a decent market share being among the first wave of launches, it would bode well for the molecule. And when we get through with the NASH study, then it opens up even 2 to 3 times larger market size for it. Which will also require a larger reach, and so we're working separately on that as well.

Saion Mukherjee: And sir, how much investment would be required for the remaining development studies before you file the NDA?

Sharvil Patel: We have still a runway of 3 to 4 years to do the investment, and we are planning, the whole clinical work is being planned by our internal teams. So, it is very well managed and we will manage it in the assumptions that we have made in terms of 8% to 9% of our overall spend on R&D.

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

Kunal: First question is on the vaccine. So, for the Phase-III trial readout, is it based on the number of events or do you have a fixed readout on particular day after the second shot or the third shot?

Sharvil Patel: So currently, it is based on the number of events, 158.

Kunal: So now that we are seeing the cases in India is reducing, so does that mean that it might take longer than what we initially expected readout so because cases are reducing, so it might take no longer time to read that event number, right? Or you are still switching to the March end readout?

Sharvil Patel: No March end, we won't have the readout. March end, say when we hope to complete first dosing, we are a 3-dose vaccine. We expect a readout in the first quarter of the next financial year, not in March.

Kunal: And how much would have we invested on this vaccine in terms of R&D and CAPEX?

Sharvil Patel: So, all of the investments so far we have done it through, obviously, internal plants. So, it's sizable. I think in the end we will end up investing anywhere between 150 crores to 250 crores, overall for capital investment, R&D and other things.

Kunal: And then this plant would be used for any other vaccine, right?

Sharvil Patel: No. Over a period of time, it can be used for other platforms. But currently, it is planned for COVID only.

Kunal: And second question, basically is, if we are to target some of the emerging markets for the vaccine, what will it require? And have you started any work on that? Like will it require bridging studies or maybe full-fledged studies and have we started the processes?

Sharvil Patel: So, it's an important question. We strongly have always believed that this platform offers the most safe and efficacious way of handling such a large pandemic and we are very happy to see the strong response we are getting from different countries. So, a lot of the countries are ready to accept Phase-II data and get approval. So, we have almost all countries accepting a Phase-II trial data for market authorizations. Some will do local studies if necessary. Today, in terms of our opportunity size, we have orders far more than what we can make in terms of what we have committed to. So, we have to, now, work on prioritization of supply and prioritization of manufacturing because we have more orders than what we can make.

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

Prakash Agarwal: Sir, first question on the US, I missed your opening comments. There's a Q-on-Q decline. And you also mentioned on the pipeline, you have 16 complex generics. So, what explains the decline given that you had doxil launch and so if you could help us understand that? And some commentary in terms of complex generics and when would this be monetized?

Sharvil Patel: The decline for the quarter is on account of 2 things. One is, obviously, we did have a flu season as it was predicted also. Also, there was some inventory correction that happened on few products as the year ends in the US for the buyers. So obviously some orders were, I would say, delayed from that point of view. We don't have any change in market share, so we continue to hold on to strong market shares. On our main compound, Lialda, we maintained still strong market shares of about 55% and it stabilized. What we did not see is onetime opportunities on

this molecule and some because of the year-end. So that we hope will start coming in from the next quarter. In terms of future outlook, we believe that quarter 4 will be trending towards similarly anywhere between $215 million to $220 million. And with the ramp-up happening in quarter 1 of the next financial year, we see a significant uptick in our value from a quarter-on-quarter point of view. And that is because of impact of new launches that are happening now and in February onwards.

Prakash Agarwal: But you mentioned Q-on-Q because of flu season, I think. Q2 wouldn't have any flu season. I was understanding why the sales declined Q-on-Q?

Sharvil Patel: No, Q-on-Q, there is no flu season. I'm just saying, I'm comparing it versus last year.

Prakash Agarwal: Your Q-on-Q decline is largely due to inventory correction?

Sharvil Patel: Inventory correction and not enough onetime buyers.

Prakash Agarwal: And secondly, sir, on the cost side, if you look at it, clearly you are doing R&D initiatives, R&D cost has gone up. But if we do the math ex R&D, your cost is substantially controlled. So how do we see this going forward, especially going into fiscal '22 and Q4, given the marketing, all the companies are talking about that marketing promotions are coming back to normalcy. How should we see that in Q4 and '22?

Sharvil Patel: There are 2 different markets, right, I think US business, there was no curtailment of cost or anything. I mean the business continued without any hiccups. In fact, we improved our supply chains and everything. When it comes to India business, our one large part of the business, which is at Consumer Health, obviously, it went through a good amount of marketing investment. So, it's come back to its normalcy in the last quarter. So, it's already achieved that. When it comes to India formulations business, we are at 70%, 80% or 80%, 85% of what we used to spend. So, we are back to normal in terms of what we used to spend. And I'm very happy to see that there was a good growth all around the business, whether it was Animal business or Consumer Health or Wellness and India Formulation. So going forward, we think our costs have normalized. Our next year growth on cost will be obviously a little higher than this year, but overall we would see good margin improvement on some of our businesses on India front.

Prakash Agarwal: But there will be growth on the cost side, right? I mean, currently, you are around 19% of sales. There would be a 50 to 100 basis point increase or no?

Sharvil Patel: Nitin or Vishal, do you want to take that question?

Vishal Gor: So yes, there would be some increase in the expenses, but we don't foresee that the expenses would still be in the pre COVID level, because whatever initiatives we had taken while we were

in the lockdown, we hope to continue them and build on them further. So, we don't foresee the expenses to be coming back to the pre COVID levels.

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

Anubhav Aggarwal: Just one clarity on the Phase-III trial that you talked about. So, what percentage of the volunteers you have already recruited out of 30,000, let's say, like 50%, 60% or 70% already done? And how many of them you have already started giving the first shot?

Sharvil Patel: Our view is in the next 10 days; we would have had about 15,000-plus people who would have finished first dose. And end of the month, we are confident that we can complete most of the recruitment by first dose.

Anubhav Aggarwal: The first dose would have been given to all 30,000 by end of February? That should be the assumption.

Sharvil Patel: Yes.

Anubhav Aggarwal: And one question was on the tax side. Nitin bhai, on the budget proposal, goodwill amortization was excluded. And we see in Zydus Healthcare, we almost have a 460 crores amortization of goodwill each year. So, would there be impact on Cadila Healthcare's overall taxation because of this?

Nitin Parekh: No. Until financial year 24-25, we don't envisage any additional tax outgo because of proposed change in goodwill depreciation.

Anubhav Aggarwal: Not even the cash tax…

Nitin Parekh: No. Because we have unabsorbed depreciation, if you talk of Zydus Wellness specifically. And we have MAT credit and also we have API benefit in Sikkim for both Zydus Wellness as well as Zydus Healthcare.

Sharvil Patel: So, Anubhav you specifically asked about Zydus Healthcare, and you quoted a number of 460 crore in depreciation. In fact, in Zydus Healthcare, till 2027, we don't expect any cash outgo on account of tax because of the other things which are available to us, which Nitin just spoke about.

Anubhav Aggarwal: And one question I had on the India business. So Dapagliflozin that we have launched, just trying to understand that can this product of Cadila Healthcare is something like 40 crores - 50 crores in, let's say, 2 years from now in fiscal '23 as a whole, because the market is growing very fast and very competitive price?

Sharvil Patel: Definitely. It will be a very good product. Obviously, we were the first to launch the single product, and we'll soon be launching the combination also. And we have got good traction, so we will see this become a large opportunity in the range of 40 crores to 50 crores as you mentioned. We also have at least 2 more introductions coming this year, which will be in that bracket of large, I would say. We have one monoclonal therapy coming, which will also be in the 40 crores to 50 crores range in one year's time. We also have a few COVID products coming, which are very essential in terms of preventive, and we believe those could be very large also for the given year.

Anubhav Aggarwal: And this COVID drug that you're mentioning, is it prescription, sir?

Sharvil Patel: Well, it will be prescription, but some part of it will be OTC. We will also be coming out with a testing kit, which will be the first in India, which will be only saliva based, at-home use.

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

Surya Patra: Sir, just on the vaccine side, possibly I missed your comment a bit. You said about an additional plant that you are setting up for vaccine, this ZyCoV-D vaccine, with 125 million capacity, but we already have a capacity of 100-odd million vials, right? So, the cumulative capacity of around more than 200 million, is that the capacity that we are targeting for this?

Sharvil Patel: No, it's not the right interpretation. Our new facility will have the capacity to produce 120 million doses. Our current plants, the current smaller plants can only produce about 10 million to 20 million doses. And we are also finding right appropriate CMOs to additionally produce 50 million to 70 million doses, and that is under the work.

Surya Patra: So then the plant approval and validation, all that process will also take time. Is that the right understanding?

Sharvil Patel: All that has been planned for, and we are ready for commercialization from April. I mean, from manufacturing, not commercialization, sorry.

Surya Patra: In fact, so far as the COVID portfolio for us is concerned, see, whether the export revenue of this COVID portfolio is higher than the domestic revenue as of now?

Sharvil Patel: Currently, largely it is domestic. We don't have major export revenue on COVID portfolio.

Surya Patra: Not even for remdesivir?

Sharvil Patel: Not significant.

Surya Patra: Third question on the Revlimid, sir. Having seen settlement by your competitors, you are also a potential player to participate in that Revlimid opportunity by settling. So can you share your thought process on that opportunity?

Sharvil Patel: So, this is under litigation. So, at this point, I won't be able to share anything more. As soon as I'm able to give any updates, we will apprise you of it.

Surya Patra: And regards the US pipeline, we have been talking about the in-licensed product opportunities. In fact, last quarter, it was somewhere around 14-odd in-licenses that you are talking about. Now you have added a couple more. So, can you give some additional color how this pipeline would be contributing starting FY '22?

Ganesh Nayak: So again, so for the in-license portfolio, all of them are either fall into the complex, all of them fall on the complex category. Some of them is where we had missed the first-to-file opportunity and we were able to in-license them and we remain first-to-file with the partner and amongst limited players. A good amount of this portfolio is injectable. They form part of the **(34:41) __** process, the API is complex or the formulation is complex. So complex carbohydrate chemistry kind of APIs, peptides and other things. So that is the kind of portfolio that we have. We still have a pipeline of another 11, which we are in phase of licensing in further. In FY '22, we believe we would see some important launches through this. And as those launches come upon, we'll specifically speak about those launches. But right now, I cannot give you a specific answer on any particular launches. But definitely, this portfolio is going to be very valuable, nearest from a point of view that we don't put capital investment behind it. Derisk because we have been able to file on time earlier than what we would have internally developed. So, it's an additive for us. And we have one success so far, which is one of the products that we had launched on the injectable side, Fondaparinux, which was an in-licensed product. You will see similarly those types of products coming through in the next 2 years to 3 years.

Surya Patra: And is it fair to believe that the growth momentum in the US portfolio or US business in FY '20 would be kind of a relatively much better than the recent trend, what we have been seeing?

Ganesh Nayak: So FY '20, you're saying?

Surya Patra: FY '22.

Ganesh Nayak: FY '22, with the important launches that we have planned, yes, we are looking at continuing to grow this. We believe we can still do a high single-digit growth. But going forward, with the portfolios coming through, we can see a better trajectory of growth in the coming year.

Surya Patra: Just last one question, sir, on the R&D side, with the multiple projects progressing simultaneously, there is a kind of a pickup in the R&D spend front that we are witnessing this quarter. But do you see there could be a kind of increasing trajectory that one should see on the

R&D spend front? Or what is your thought process there? And how would that be impacting the overall margin performance?

Sharvil Patel: So, R&D is a very important growth driver for the organization. So that has always remained very critical for us. And while we have to manage both the expectations of internal development as well as margins, we believe that we will be in FY '22 also around 8% of our overall revenue as R&D, including all of the major developments that we have.

Surya Patra: This quarter is a kind of an aberration in terms of incidence?

Sharvil Patel: Every quarter-on-quarter will change, but overall, our guidance is that we will be around 8%.

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

Sameer Baisiwala: Sir, any update on Moraiya and your expectation? When can FDA come; first half, second half this calendar year?

Sharvil Patel: Not really. We don't have any update on Moraiya. As I said, we did complete our correspondence with the FDA, and we received that acknowledgment. I believe our next phase would be to receive any kind of response from the FDA with our responses that we have filed with them and whether they found them appropriate or whether there are any deficiencies further. But we await to those kinds of communication, until then we don't have any other view other than that. We do see for new products in other plants getting approvals through desktop audit. But for Moraiya, we don't have any update yet.

Sameer Baisiwala: So, if another 6 months, 12 months pass by, then does all the remediation work or CAPA work done, does it start losing relevance because it was implemented quite some time back at the end of this time?

Sharvil Patel: So, the 2 large parts of the remediation work, one was related to injectables. And as we have stated before and we have, I mean, communicated to the FDA also, so we have stopped all injectables at Moraiya. So with that time point of view doesn't change because, I mean, that one part of our complexity has been removed. The second was to do with cross contamination, and we have taken the right CAPAs and we appropriately completed all of that. We have been in the market for so long. We haven't had any major recalls only because, obviously, we have not had any contamination or anything. So, I think we are on track in terms of the remediation. I don't think time will change it, but it will not become ineffective because of time.

Sameer Baisiwala: Sir, on saro, any color you can share, what is your expectation of what the adoption can be in India in year 1, year 2?And second just to that, I mean, it's approved here in India and you're working Phase-III in the US, is it a theoretical possibility that it gets approved in India but doesn't

get approved in the US?I guess what I'm asking is, is that technology is a leap of faith or it's pretty much a done deal for the US?

Sharvil Patel: In India, we are very, I would say, ambitious in terms of what we want to achieve because this is the first treatment available, and it's a single dose. So, the pill burden doesn't exist, and it has multiple benefits beyond, obviously improving the liver profile. So, as I said, we believe this can be easily a 250 crore plus molecule for us in India. And that is how we are building for that. Internationally, because, see, our data on PBC, which is a Phase-II readout, is almost an equivalent to an efficacy trial. We have a very large data on safety that we have created. In India, we, on NASH, specifically, we have biopsy related data. So, I believe that it's, in our view, while it's a process of drug discovery and anything can happen. But on PBC, we are extremely confident that with the data that we have seen both in India and Mexico and in US, in Phase-II, we are very confident that this can move with very little chances of failure to approval post our successful Phase-III. On NASH, it's a difficult field. And the onus is, I mean, there's a lot of expectations on what is expected in terms of outcome. With the recent guidance of the FDA, I think it's very positive for the people who are working on this indication. So again, we have very strong data in India and in other countries. So again, we are very optimist on that. But definitely, if you say chances on PBC are almost certain, on NASH, as we move forward, we can talk more about it, but our Phase-IIb was very good. So, we believe that we are on track for this product to become approved for both indications. But obviously, there are always challenges, and one must not take this for granted.

Sameer Baisiwala: I just have one more on the same, saro. Is the primary endpoint, call it similar, that the regulator wants in India versus what they want in the US or they are 2 completely different things?

Sharvil Patel: So, there are 2 areas, right? One is the NASH score, and one is the fibrosis score. Yes. So NASH and fibrosis. There are 2 options. The higher end of the spectrum is to get a reduction in fibrosis from F3 to F2. And the broad-based more indication is the NASH score, which is just a reduction in NASH score. So, on both those parameters, India and US have similar outcomes. It's just that in US, they do expect a pre and post biopsy. In India, we did a post biopsy. So obviously, it has to be done. So, it's very similar, I would say.

Sameer Baisiwala: Just one final from my side if I may. And I think the previous speaker already asked you. Sharvil, is it fair to think that you'll be in the first wave of market formation?

Sharvil Patel: I can talk about it once we come closer to the trial getting over, and we'll definitely give a proper update on that.

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

Harith Ahamed: So on Desidustat, you disclosed today that you've finished patient enrollment in the anemia in CKD indication. So, could you give some timelines around these trials? And I see that these are US registered trials. So, the question is whether you'll be able to make a US NDA filing with this trial data, assuming the trial data is positive?

Sharvil Patel: So, on Desidustat, we have the indication that we are working for in India is not the indication we're working for in the US. The indication for India and China is similar. And I'm very happy to say that on the India front, we have completed enrollment and looking at the Phase-II data, similarly, we are able to show good data. This could be potentially one of the first molecules to get approved as an oral drug for anemia for CKD patients and non-CKD patient. The opportunity size, again, this is a 100-plus crore opportunity for us in terms of commercial potential in India. Similarly, in China, which is probably the closest largest market for CKD and kidney dialysis patients, again there we have tied up with CMS, and that is also moving on very well. So that has to do with these 2 markets and these are not regulatory filings for the US. For US, we're working on an orphan-like indication for people where we started a trial on chemotherapy-induced anemia, and we are targeting those patient subset, and we believe that could be a much better value driver for us in the US market.

Harith Ahamed: Any reasons why we're not targeting the anemia in CKD indication in the US. My question is in the context of……

Sharvil Patel: It doesn't make sense, because by the time we get approval, there could be a product that is already generic. So, then you don't have the value driver for it.

Harith Ahamed: And on saroglitazar, you alluded to a 2023 launch in the PBC indication. So, have we started the Phase-III in PBC and if you could also help us with the competitive dynamics in the PBC market in the US? There is UCB and quite a few other candidates that I'm seeing including other PPAR agonists in development. So how are we positioned versus some of these other drugs in terms of developmental timelines in PBC?

Sharvil Patel: I think we have the potential to be in the first wave of launches in the US, and that's what we are targeting for saro for PBC. Getting a priority, sorry, Fast Track Designation will help us move the parallel submission faster.

Harith Ahamed: And on the Phase-III timelines?

Sharvil Patel: As I said, Phase-III, we are already going to start like in the next month or so.

Moderator: Thank you. The next question is from the line of from Vishal Manchanda from Nirmal Bang. Please go ahead.

Vishal Manchanda: I have a question on saroglitazar. Just wanted to understand how saroglitazar is currently in the domestic market. And how fast is it growing on a Y-o-Y basis?

Sharvil Patel: Saroglitazar in India in the current earlier indication of triglyceride has done extremely well. We have more than 1 million patients who have been on the treatment. And we are seeing strong double-digit growth year-on-year on this molecule. And with these new indications, obviously, this will increase significantly. We are targeting it to gastro and to another important practitioners and we are seeing very strong traction and with the amount of publication and data that has now been published on saro, we will see this molecule as a potentially large blockbuster molecule for the company in the coming year.

Vishal Manchanda: Would this figure among your top 20 brands now or not? Not so far?

Sharvil Patel: Not yet. I don't think it is in the top 20 yet. I don't have the data, but I can come back to you on that.

Vishal Manchanda: And just one more on saroglitazar in PBC. So, in the Phase-II trials, there were incidences of drug-induced liver injury at the 4 mg dose. And we have seen similar cases with other PPAR agonist that are under development, but competitors have been able to address it using a lower dose. So, have we kind of seen a similar situation with saroglitazar?

Sharvil Patel: No, we don't have that issue. We are not a typical PPAR, and we don't have that concern in our Phase-II data.

Vishal Manchanda: And just on the tax rate, what would be the annual effective tax rate?

Nitin Parekh: So, it should be in the range of 20%, 21%.

Vishal Manchanda: And this should remain so in FY '22 as well?

Nitin Parekh: Yes, we believe so.

Moderator: Thank you. The next question is from the line of Abhishek Sharma from Jefferies. Please go ahead.

Abhishek Sharma: Sir, just a couple of questions on saroglitazar again in PBC indication. If you can just share with us top line headline results from the proof-of-concept study, what were the endpoints? Did you look at reversal of liver damage or was it restricted to symptomatic relief? In Phase-III, what number of subjects in duration are you looking at?

Sharvil Patel: So, Abishek, it would be very difficult for me to off the hand tell you those answers, but I'm happy to set up a separate time to give you those specific answers.

Abhishek Sharma: Alright. But just on Phase-III, have you had a discussion with FDA in terms of number of subjects that you're planning to recruit?

Sharvil Patel: Yes, we have had the correspondence with the FDA, and we are aware of the number of subjects we need to do. But off hand, I don't have that exact number, so I won't be able to give it to you.

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

Kunal Mehta: Just coming to PBC for saroglitazar. Sir, could you please help us understand how long do you expect the Phase-III trials to go on for this molecule? I mean, you mentioned that we are planning to start next month and the closest launch that you mentioned could be in calendar year '23. So how long do you expect the trials? And after that, what are the milestones one would expect to monitor?

Sharvil Patel: For saroglitazar, we believe commercialization is potentially in calendar year '23. So that's what we are targeting for PBC. And for NASH, we have hope to file by end of '24 or in some part of '25.

Kunal Mehta: Absolutely, sir. And this trial for PBC would last for a year or so or more than that?

Sharvil Patel: Yes.

Kunal Mehta: And just the second question for my end, I wanted to understand, in terms of the launches planned for the US for the next year, financial year '22, could you give us an understanding of how many launches are you planning for this for the next year?

Sharvil Patel: In the next year in the US, we are planning for 40-plus new launches. And out of that, we have at least 8 or 10 molecules, which are high value.

Kunal Mehta: And just a last question from my end. I mean this is something I wanted to understand a bit regarding the whole mesalamine franchise, just wanted to understand, you've seen our share drop and then recover back very strongly. And I think even Lialda and both Lialda and Asacol HD and I'm sure there are a few other products also on the mesalamine side in the pipeline. Just wanted to understand the complexity here in terms of this whole product basket, which prevents other players in the market to gain meaningful share in this product. So just could you just help us understand what is it which makes it difficult for other players to gain the better and higher shares in this molecule. What is it working in our favor for this molecule, the whole mesalamine basket?

Sharvil Patel: I think the whole mesalamine basket, the first and most critical thing is API. And API forms a very critical part of the formulation. And the second aspect of it is that to produce at such large

scales, it's a very sensitive product in terms of having the right processing parameters to make sure that you have the right dissolution results. So, it is very tricky there, and that's why the scale-up has been very difficult for this. We have been obviously working for now 12 years. So obviously, we have a lot of learnings during the way. And this product did take us a very long time to get approval in this whole franchise. So, we have learned it over a period of time. So, I mean, it does require a lot of capability and it takes time more than also capability. And as I said, API forms a very integral part of the whole value chain.

Kunal Mehta: We had 2 entities, which were catering to the transdermal side where I think because of Moraiya resolution pending, the transdermal launches have got stuck in that. So, could you give us a quantum of the cost of these 2 entities? I mean, the operational costs, which are hitting the P&L, but right now, there is no revenue corresponding to these on a quarterly basis?

Nitin Parekh: Yes. I'll get back to you on the specific numbers. I'm not carrying those numbers right now.

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

Kunal: The first is how much R&D would we be spending right now on the specialty or, let's say, innovation effort, including vaccines **(Inaudible) 57:25?**

Sharvil Patel: We don't give individual breakups on overall our different franchises. But as I say, overall cost of R&D is 8%. But segment-wise, we don't give updates.

Kunal: Because it is expected to become an important segment for us and hence, I think, some details would be included. In terms of overall, what are we spending on the innovation **(57:56) ___?**

Sharvil Patel: So that said, right, 40% to 50% is on generics portfolio and the remaining over a period of time, equal proportion on the generics and 505(b)(2) versus the NCE and biologics and vaccines driven portfolio.

Kunal: And secondly, with this vaccine plant that we are planning to set up, that does not change our CAPEX outflow, right, significantly?

Sharvil Patel: The vaccine plant is under construction and will be commissioned in April. So, it is as part of our CAPEX plan currently.

Kunal: And what is our CAPEX for this year and for next year, what would to the CAPEX?

Nitin Parekh: It should be in the range of 700 crores to 800 crores basis, both the years.

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

Ranvir Singh: Sir, on vaccine side, do we work on pneumococcal vaccine also?

Sharvil Patel: Yes, we are.

Ranvir Singh: Because I was asking in this context that in this budget, government mentioned pneumococcal vaccine to roll out all over India. So, do we see any opportunity there? Or it will take some time to actually launch this work?

Sharvil Patel: Some time, we are in the development phase. We are working on the next generation of the pneumococcal vaccine, which covers the largest number of streams. And that's our development plan. And one other important vaccine, which has become very relevant is our flu vaccine, because we are the only Indian company who have quadrivalent flu vaccine. So that is an important vaccine for the future as well.

Ranvir Singh: So overall, vaccine portfolio, we have been talking about this to be a sizable business going forward. So, what's the current contribution and how it should pan out in the next 2, 3 years? If you could give, excluding this ZyCoV-D?

Sharvil Patel: Currently, it is not very large. It's about 70 crore kind of franchise. But without the COVID, we are hoping that by '24, '25, we hit a $125 million revenue for this.

Ranvir Singh: Excluding COVID vaccine?

Sharvil Patel: Yes. COVID is very large.

Ranvir Singh: And on saroglitazar side, in US initially we started with dyslipidemia also and later we suspended it. So, do we have any plan to work on this indication also?

Sharvil Patel: So, in US, we have always worked on NASH and then we added PBC, not on dyslipidemia. It was an indication for India.

Ranvir Singh: Yes. So that, I wanted to understand. So, we started, then we suspended it, sir, because that was not successful or want to put our resource in PBC because their prospect was better, so that was the reason?

Sharvil Patel: So two things. One is, obviously the prospect on NASH is far better. The second is some of these require, if you see the large outcome trials, which would be very long and painful. So, we have to prioritize where we see the maximum value is.

Ranvir Singh: And the last one, on ZyCoV-D, you see in first phase the way vaccination is happening in India. I think by the time we will be ready with the vaccine; a sizable population would already have been given the vaccine. So, do you see that the opportunity size of which earlier we anticipated has considerably reduced?

Sharvil Patel: Not yet. I mean, I don't know. But if you assume even 30%, 40% of the population getting vaccinated, you need at least 150 crores plus doses. So obviously it's not a small number. And this will definitely become a vaccine that will be required on some frequency basis. You can already see where a lot of places there are talking about annual vaccination requirements. So, it could become part of the annual vaccination. So, I don't think this opportunity is limited. And there's no way the demand can be met through in a period of a few months. Any global vaccination program, even the most successful ones, have taken 10 years. With all the might and resources that everybody, all of us will put in, we don't believe this can happen in a period less than 3 to 5 years. So, it will be very wrong to assume that we'll be able to vaccinate large part of the population in a few months.

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

Nimish Mehta: Just one question on US when we are likely to launch this product, the doxepine hydrochloride, branded as Silanol and **(Inaudible) 63:47** hydrochloride. I understand in both these products, we have settlement. And in Silanol we also have a tentative approval and also want to know whether these are important products or not?

Sharvil Patel: They are important products. The new launches in quarter 1 and quarter 2.

Nimish Mehta: And next, on the India formulation, actually I miss some of the initial comments. What is the ex COVID formulation growth in India? And what do you think is the outlook on remdesivir outside of India, especially next year?

Sharvil Patel: So obviously, there's a major concern outside of India versus India when it comes to COVID right now for the current time. However, the markets are limited in terms of what is available for Indian companies in terms of part of the licensing agreement. So, we still see some good opportunity for some of the markets, and we believe we will get good share when it comes to those markets. They don't form part of the largest market-shaping opportunities. But whatever there is, we would see at least a good amount of traction. As and when we get good opportunities, we will obviously keep people updated. India, on the India front, remdesivir, obviously, the cases coming down. Remdesivir sales are not as large as they used to be, and they have tapered off every month. For us, on our domestic business, as I said, in terms of our execution, other than anti-infectives where we did well from the market point of view, but internally, obviously, we didn't have good growth. But on the cardio-diabetes portfolio, on the respiratory portfolio, pain,

and inflammation, we did very well. We are seeing good recovery on gastro, and we hope we can come up similarly also on gynec and derm. So, we have those 2 therapies still need to come up. But by and large, the specialty portfolio has done well.

Nimish Mehta: But what could be the number, ex COVID formulation growth, Y-o-Y this quarter?

Sharvil Patel: We are not giving ex COVID numbers.

Moderator: Thank you. The next question is a follow-up question from the line of Anubhav Aggarwal from Crédit Suisse. Please go ahead.

Anubhav Aggarwal: My question is on the vaccine front. When you're almost guiding that without COVID, this can become a 1,000-crore business at some point in time in the medium term. I'm assuming a good part of this will come from the WHO contract. So, I'm just trying to get an update there, what is the trigger for that large portion of revenue to start flowing in?

Sharvil Patel: That is FY '23 onwards and '23, '24 will be those years when we can see prequalification through and obviously, the tenders through. So, that will be in calendar year '23 and calendar year '24, largely calendar year '24 when you will see the major triggers, for WHO global PQ and obviously, getting the fund**.** We are targeting a 10%, 12% share. So, we're not targeting a very large share. But if we get that 10% to 12% share on the 2 of them we are targeting and some other niche vaccines like varicella and others in some of the private markets, we can see us achieving those numbers.

Anubhav Aggarwal: And what will be split of these 1,000 crores, roughly, how much of the domestic versus export?

Sharvil Patel: I do have that projections, but top of the mind, obviously, I'm not able to recollect. But I can share that with you separately.

Anubhav Aggarwal: Say, like 30% domestic or 50% domestic. So, which will be more? Exporting more or the domestic will be more?

Sharvil Patel: Export will be definitely more followed by Indian public and private will be similar.

Anubhav Aggarwal: And just last question from my side on the cost front. Over the last 6 months, besides the saving on the promotion cost, more digital initiative, any other cost initiatives, which have been very significant in the organization which could have helped the margins for the company?

Sharvil Patel: We continue to work on cost, both operational cost and obviously input cost. And there, we have consistently, every year, we have demonstrated good savings. So, I still believe that we will continue to add almost 1% margin improvement because of these initiatives. And we would now have new investments in front-end on the digital front. So that is something that we are poised

to do. Because we believe that maybe slowly but steadily, one needs to build a strong digital outreach program for the medicine side, and that is what we are endeavoring towards building.

Anubhav Aggarwal: This is towards the doctor side?

Sharvil Patel: Yes, doctors and also patients then. We are looking at both.

Anubhav Aggarwal: Sorry, can you explain what do you mean by digital outreach to patients?

Sharvil Patel: We strongly believe, as a pharmaceutical company, we have to look at health outcomes and reduce disease progression as well as show positive outcomes. So, on certain therapies, we are building our capabilities to be able to work with the medical practitioner and most importantly, patient to make sure that we can reduce the disease progression or show better outcomes, and that is what we are working towards. And so those will be specific to therapies like NASH, specific to COPD, then obviously, some specific in cardio-diabetes side, renal side. These are the therapies that we are targeting to give patient support in every form to make sure that the outcomes are better.

Moderator: Thank you. The next question is a follow-up question from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: Is there any reduction in the debt, even during this quarter beyond the 1,500 crore what you have done in the previous quarter?

Nitin Parekh: So, Surya, I'll answer that question. As on 31st of December, our net debt stood at Rs. 3,800 crores, which if you compare with the September 30, which was at Rs. 4,030 crores, so almost a reduction of almost Rs. 200 crores plus. And if you look at it from March end number, there's a reduction of almost Rs. 2,900 crores plus.

Surya Patra: So that means whatever guidance or the indication that we have been giving around 2,000 crores, that has been done?

Nitin Parekh: Yes. Largely done or maybe more than that actually.

Moderator: Thank you. Ladies and gentlemen, that was the last question for today. I now hand the conference over to Mr. Ganesh Nayak for closing comments. Thank you, and over to you, sir.

Ganesh Nayak: Thank you very much and look forward to interacting with you again in the month of May for our last quarter FY '21 Results. Thank you, and good night.

Moderator: Thank you very much. Ladies and gentlemen, on behalf of Cadila Healthcare Limited that concludes today's call. Thank you all for joining us, and you may now disconnect your lines.