BSE Limited 1st Floor, P. J. Towers Dalal Street Mumbai–400 001 Code: 532321	**National Stock Exchange of India Limited** Exchange Plaza, 5th Floor, Plot No. C/1, G Block, Bandra-Kurla Complex, Bandra (East) Mumbai–400 051 Symbol: CADILAHC
Date: February 10, 2022	
Sub.: Transcript of Company's Q3 FY22 post results conference call	

Dear Sir / Madam,

Please find attached the transcript of the Company's Q3 FY22 post results conference call held at 4:30 p.m. on February 3, 2022.

Please find the same in order.

Thanking you,

Yours faithfully,
For, **CADILA HEALTHCARE LIMITED**

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

“Cadila Healthcare Limited Q3 FY'22 Post Results Conference Call”

February 3, 2022

MANAGEMENT: **DR. SHARVIL PATEL - MANAGING DIRECTOR, CADILA HEALTHCARE LIMITED**
MR. GANESH NAYAK - EXECUTIVE DIRECTOR, CADILA HEALTHCARE LIMITED
MR. NITIN PAREKH - CHIEF FINANCIAL OFFICER, CADILA HEALTHCARE LIMITED
MR. VISHAL GOR - SENIOR VICE PRESIDENT, CORPORATE FINANCE, CADILA HEALTHCARE LTD
MR. ALOK GARG - SENIOR VICE PRESIDENT, MD OFFICE, CADILA HEALTHCARE LTD

Moderator: Ladies and gentlemen, good day and welcome to Cadila Healthcare Limited Q3 FY'22 Post Results Conference Call. As a reminder, all participant 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 call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Ganesh Nayak, Executive Director at Cadila Healthcare Limited. Thank you and over to you, sir.

Ganesh Nayak: Thank you. Good evening, ladies and gentlemen. Welcome to our post results teleconference for the quarter ended December 31st, 2021. I do wish that you and your families are keeping safe and well. For today's call, we have with us Dr. Sharvil Patel, Managing Director; Mr. Nitin Parekh, Chief Financial Officer; Mr. Vishal Gor, Senior Vice President, Corporate Finance and Mr. Alok Garg, Senior Vice President from the Managing Director's Office.

I'm sure you would have gone through the quarterly results' investor presentation which we have posted on our website and filed with the stock exchanges. The quarter gone by was yet another quarter of robust performance for our human health formulations business in India. The branded generics portfolio delivered a strong double digit growth during the quarter. In fact, this is the fourth consecutive quarter of strong growth for our branded formulations business in India. With the reduced need of COVID related medicines in India during the quarter, COVID related opportunistic portfolio recorded a decline in the revenues during the quarter both on a sequential and on a year-on-year basis. The consumer wellness business maintained its leadership positions in 5 out of the 7 brands in their respective categories. Overall, the India geography which contributed 41% to the consolidated revenues during the quarter, posted a growth of 12% on a year-on-year basis excluding sales of COVID related products, generic portfolio and divested products. Contribution of the India geography in consolidated revenues has gone up to 41.8% during the April-December 2021 period from 37% during the April-December 2020 period.

With that, let me quickly run you through the financial numbers for the quarter gone by. During the quarter we posted a consolidated revenue of Rs. 36.55 billion up 1% year-on-year. Excluding the COVID related revenues growth was 5% on a year-on-year basis. Consolidated EBITDA for the quarter was Rs. 7.5 billion and the EBITDA margins were at 20.6% vis-à-vis, 21.1% recorded during the corresponding quarter of the previous financial year. Despite reduction in the Mesalamine revenue in the US and decline in the COVID related revenues during the quarter, various cost optimization and efficiency enhancement initiatives helped us contain the EBITDA margin decline by only 50 basis points. Consolidated PAT for the quarter stood at Rs. 5 billion with a flat growth on a year-on-year basis. This is after adjusting profits from discontinued operations in Q3 FY'21.

Now, let me run you through the operating highlights for the third quarter of FY'22 for each of our business lines. Starting with our human health business in the India geography, the human health formulations business recorded sales of Rs. 10.8 billion during Q3 FY'22. Excluding sales

of COVID related products, generics portfolio and divested products, the branded business growth was 17% on a year-on-year basis. The growth was driven by volume expansion in the existing products and key new product launches made over the last 12-months and improved realizations. We gained market share in our core therapies of the anti diabetic, cardiovascular, gynecology and anti-infective therapeutic areas during the quarter on a year-on-year basis. During the quarter, Lipaglyn catapulted amongst the top 100 brands and was ranked 92nd in the India pharma market. This is a jump of 183 ranks, that is from 275 to 92 during the current quarter. On the super specialty front, we continue to retain our leadership position in the nephrology segment. In the oncology space, we are the fastest growing company in India. Consumer wellness business posted revenues of Rs. 3.8 billion with a growth of 2% during the quarter. Lower growth in sales is largely due to two reasons. Firstly, due to the high base during the previous year comparable period which was accentuated by a slowdown in rural growth. Secondly, as we are implementing a continuous replenishment process internally as part of the integrated business planning tool, we have reduced inventory both internally as well as in the trade channels. This would help us operate with leaner inventory and better availability of fresh stocks with the consumers. To counter commodity inflation, the price hike taken in key brands towards the end of Q2 FY'22 helped in protecting the gross margins during the quarter.

Now, let me take you through the performance of our US formulations business. The US geography comprising of generics and specialty portfolio posted sales of Rs. 15 billion during the quarter. The business managed a flat growth despite continued pricing pressure in the market and decline in sales of Mesalamine products. We gained volumes in other existing and new products. We received 9 new product approvals including 5 tentative approvals and launched 3 new products during the quarter. New approvals and launches for the quarter included Nelarabine injection for which we are granted a 180 days of exclusivity. This product was launched immediately upon approval. We filed 12 ANDAs during the quarter and amongst them is a first drug device combination product on NCE minus one date. Apart from this, two products are single sourced products and two others are limited competition products. We intend to prioritize products where we plan to gain volumes and also maintain safety stock of products where we foresee some opportunities to open up in the market.

At consolidated level, the emerging markets business posted sales of Rs. 2.9 billion down 1% on a year-on-year basis. Excluding the COVID related portfolio, the business posted a growth of 7% during the quarter. Due to its presence in diverse geographies, the business managed to overcome challenges emerging out of political and economic uncertainty in some of its markets as these were offset by strong growth in some other markets. As shared on previous occasions, we continue to work on various efficiency enhancement initiatives to improve operating margins. To reiterate, the zero based budgeting approach will lead to margin improvement during the current calendar year. Advanced digital and analytics tools being implemented in manufacturing operations is likely to enhance compliance and efficiency through simplification. Both these initiatives put together are expected to improve our overall operating margins by 80 to 100 basis points. It was our priority that our employees feel safe and supported during COVID.

In addition to implementing work-from-home, we provided teleconsultation and telemedicine facilities so that all our employees irrespective of their location could benefit. For employees attending office and at our manufacturing sites, strict protocols were followed for regular sanitization of the premises and limiting human-to-human interaction. We also provided special compensation to families of employees who unfortunately succumbed to the pandemic. I am pleased to inform you that our group has been selected as the Best Pharma Company to work for in the Large Company category for the year 2021 at the Employee Choice Awards by AmbitionBox. Our CSR initiative at Dahod bagged the Gold Award at the CSR Times Award during the quarter. Zydus Medical College and Hospital, Dahod won the Gold Award in the corporate healthcare sector at CSR TIMES Award. This was in recognition of the various initiatives in the healthcare support programs carried out in the rural area of Dahod. The criteria for the awards were impact, reach and sustainability. The award saw participation from across industries and 138 corporates participated in this. This concludes the business review. I will 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, everyone. As you know, post the receipt of emergency use approval from the DCGI for our COVID-19 Vaccine ZyCoV-D during the previous quarter, we have received an order from the Government of India to supply one crore doses of the vaccine. As informed by us yesterday we have already started the supplies of the vaccine to the government of India against their order. As you are also aware we have entered into an agreement with Shilpa Medicare Limited for production and supply of drug substance of ZyCoV-D from their manufacturing facility. Supply of commercial batches of drug substance from their facility shall begin from the current month which will help us improve our demand supply. I am happy to inform that The Lancet has accepted our submission of interim analysis of the phase-3 clinical trial results of ZyCoV-D vaccine for publication which is the largest clinical study done on Indian patients.

On the global front, we entered into a manufacturing license and technology transfer agreement for the vaccine with Enzychem Lifesciences of South Korea. The partnership will lead to manufacture of over 80 million doses of the DNA vaccine in the year 2022. These doses will be supplied in South Korea and number of countries in Latin America and Asia. We have also made good progress on the NCE research front. We have initiated a global pivotal phase 2(b)/3 adaptive trial which is the EPICS-III trial of Saroglitazar Magnesium to evaluate the efficacy and safety in patients with primary biliary cholangitis which is PBC for the US market. The trial will be conducted on 192 subjects over a period of 52 weeks. The results of the phase 2(a) EPIC trial which were published in the journal of Hepatology, a strong peer reviewed journal has demonstrated that the molecule holds immense potential base on its safety and efficacy profile. Just to refresh your memory, Saroglitazar has also been given an orphan drug designation and a fast track designation by the US FDA for the indication of PBC. From the month of October, we have also initiated enrollment for patients for the EVIDENCE X another global pivotal phase 2(b) trial for Saroglitazar Magnesium to evaluate the efficacy and safety of the molecule in

subjects with Nonalcoholic steatohepatitis which is NASH and the fibrosis indications. The two clinical trials are underway in the US, one for NASH and one for PBC. Study of Saroglitazar Magnesium for PTMS, which is post transplant metabolic syndrome in the US reached the targeted number of patients 15**.** we shall now be approaching the US FDA for a possible unmet medical need indication viz. post transplant NAFLD. We have also completed the study for Saroglitazar Magnesium with respect to hepatic impairment. We shall soon be submitting these results to the US FDA.

Coming to other new molecules in our NCE pipeline, we are extremely pleased that we are able to submit the new NDA, the new drug application to the drug control general of India for Desidustat which is an oral small molecule hypoxia inducible factor prolyl hydroxylase which is the HIF-PH inhibitor for treatment of anemia in patients with chronic kidney disease (CKD), both on dialysis and not on dialysis. This molecule will further consolidate our leadership position in the Indian nephrology market. As per the study conducted by Lancet in 2020, 114 million people in India, another 132 million in China, 38 million people in the United States, another 21 million in Japan and 41 million in Western Europe are estimated to be living with this chronic CKD illness. This underscores its strong global potential and you know we have already partnered for this drug's clinical trial in China as well.

For our novel antimalarial compound ZY19489, which is developed together with the medicine for malaria venture, we have received an orphan drug designation from the US FDA during the quarter. This is active against all clinical strains of plasmodium falciparum and plasmodium vivax including all the drug resistance strain. The phase 1 study of the molecule has demonstrated a long half life and a potential for a single dose cure for malaria. This molecule is a potential single dose radical cure for malaria for the developing countries where majority of the malaria cases and deaths are recorded and we are very excited with the progress of this molecule which has now entered phase 2. With respect to another molecule, ZYIL1 which is a novel oral NLRP3 inflammasome inhibitor, we have received a regulatory permission to initiate phase 2(a) clinical trial in patients with Cryopyrin-Associated Periodic Syndrome which is CAPS in Australia. CAPS is a rare lifelong auto inflammatory condition caused by the NLRP3 activating mutations and is classified under the orphan diseases. This molecule has been found to be safe and well tolerated in our phase 1 trials and as I said will enter now the phase 2 clinical trial.

On the biosimilar front, we have successfully completed phase 3 clinical trials for one monoclonal antibody and have received permission from the DCGI to initiate phase 3 clinical trial for one more monoclonal antibody in the field of cancer during the quarter. With respect to molecules in early stage of development, we have also submitted an application to the RCGM to conduct pre-clinical toxicity studies for one more biosimilar. On the novel biologics front, for a current lead NBE program, a humanized monoclonal antibody designed to downregulate the alternate complement pathway, we have completed a critical non human primate PKPD study and established that the molecule has significantly good PKPD and safety profile. With this we

shall be starting our animal tox study soon and potentially see this as an important molecule again in the orphan and rare diseases side.

On the 505(b)(2) initiatives, as you know in the month of October our wholly owned subsidiary Sentynl Therapeutics and its licensing partner Cyprium Therapeutics announced positive results from an efficacy and safety analysis of data from two completed pivotal studies in patients with Menkes disease treated with our copper histidinate product. Making further progress towards the filing an initial module of the NDA of CUTX101 was filed with the US FDA during the quarter. This is a rolling submission and we are likely to see an approval by end of this calendar year. Menkes disease again is an orphan drug indication.

Coming to the pipeline of other 505(b)(2) products, we have received a clearance from the US FDA for an Investigational New Product (IND) application which was filed for a pain management product. The NDA for this product is expected to be filed by the end of the current financial year. We concluded a pre NDA meeting with FDA for two more products in the area of metabolic disorder and also submitted a pre IND meeting request for one more product in the orphan drug space. It is our endeavor that while we continue to grow our existing base business in India and other markets, we efficiently add more new generic products and leverage our strong R&D infrastructure to create novel assets that will make us future ready.

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

Moderator: Thank you very much, sir. Ladies and gentleman, we will now begin with the question-and-answer session. The first question is from the line of Tushar Manudhane from Motilal Oswal. Please go ahead.

Tushar Manudhane: Just on the vaccine front, the order with respect to the government of India will that get completely manufactured in fourth quarter itself or it will flow through in first quarter of FY23?

Sharvil Patel: It will flow through in the first quarter as well.

Tushar Manudhane: And secondly on this tie-up with Enzychem Lifesciences, what are the steps in terms of getting the regulatory approval from those countries and then subsequent commercial manufacturing that is first and how will the pricing play out?

Sharvil Patel: Currently, we are going to help them with the tech transfer of the technology, they already do have capabilities to produce recombinant DNA kind of product, so we will be transferring the technology. Once they have scaled up the technology and they will be able to use our clinical phase 3 data from India and work with the Korean regulators for getting an approval is our current understanding and we are required to do some post marketing data as well or a bridging study. It is still a little early to say all of this, but the responsibility for moving the work ahead is from them.

Tushar Manudhane: But considering these milestones, still 80 million doses in 2022 looks visible?

Sharvil Patel: That is their current estimate that they have been able to give us.

Moderator: Thank you. The next question is from the line of Neha Manpuria from Bank of America. Please go ahead.

Neha Manpuria: The first question is on the US business, the flat number quarter-on-quarter, is it fair to assume that this included the seasonal uptake that we usually see because of flu in the US and just on this one, if you could highlight what the base business erosion was due to Asacol and without Asacol?

Sharvil Patel: Two points, one is, we have no seasonal business because we don't, this year, the flu season has not been there in the US and we didn't have any new business on Oseltamivir, so there is no seasonal business which was there earlier, but not there this year. Also, with respect to the loss in share on Mesalamine is on Lialda, Asacol is still without any competition in the US.

Neha Manpuria: You had indicated some loss in volume in Asacol, so that stabilized, right, you are not seeing any further?

Sharvil Patel: Yes, that has now stabilized, because this started almost in quarter 3 of last financial year.

Neha Manpuria: And what was the base business erosion sir, in that case, the price pressure that you have mentioned?

Sharvil Patel: I don't have it exactly right now, but the base price erosion is around the single digit right now. This is excluding Lialda. Lialda has had higher erosion, but on the base business, it is low single digit.

Neha Manpuria: And my second question, I think in your opening remarks, you made a comment about improving margins by about 80 to 100 basis points, I missed what would drive these improvements, if you could give some color on that please?

Sharvil Patel: We have 3-4 initiatives every year and this is the part of the programs that we run. One is something on our manufacturing which is both on the supply side as well as on the manufacturing side where we run a program known as PRISM and SLIM. This year, we had run a program for zero-based budgeting for our whole India end-to-end business and we have seen significant savings created out of that. We are also running productivity based initiatives across the organization and two more programs on different quality parameter, so putting all of that together, we have been consistently delivering anywhere between 150 to 200 crores of saving, so that continues because the programs get extended and new programs are getting added.

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

Anubhav Aggarwal: Sir, clarity on these vaccine sir Shilpa, the drug manufacturing, is that being used for the supplying 10 million vaccinations to the government or that is separate?

Sharvil Patel: No, that has still not started. Shilpa is going to take their commercial batches this month, go through that audit and clear that audit, so their doses are still not available.

Anubhav Aggarwal: And you mentioned that this 10 million effectively have been supplied between the current quarter and the next quarter, so all 10 million will be done across these two quarters?

Sharvil Patel: Yes.

Anubhav Aggarwal: And where is bulk of these vaccines used by the government? Are they being getting used off?

Sharvil Patel: Government has given us allocated center and as and when the supply start and we are making sure that we have enough as a person is vaccinated we are protecting their second and third dose, so looking at all of that there is a whole supply chain planning done with the government and the centers designated, so one by one we are rolling out in all of these centers. These are all across India.

Anubhav Aggarwal: But this is for the adult vaccination, there is still not being used of 15 to 18 years ago, adolescence?

Sharvil Patel: My current best estimate on this is that adult obviously has cleared; we have an approval from DCI for children. Our meeting has finished for the 12 to 18 also and I believe that once we start the supplies, we would be seeing a launch in that age group as well very soon.

Anubhav Aggarwal: And do you want to talk about your status of two dose vaccine, is that trial over for that?

Sharvil Patel: So the two dose vaccine, enrollment is completed; day 56 has also been completed, so we believe by end of this month we will have all the data to file with the regulators.

Anubhav Aggarwal: And this is the phase 3 trial which will be done for this?

Sharvil Patel: Yes, phase 3 trial done from ages of 12 and above.

Anubhav Aggarwal: And just last question on the vaccine front is on this South Korean partner, let us say all goes well and they start supplying as well, so would you get a royalty on the sales which is like typically which they charge about

Sharvil Patel: Yes, we do have a profit share arrangement that has been made with them.

Anubhav Aggarwal: And will that be a standard like what we have seen normally about high single digit or there about, is that a standard number?

Sharvil Patel: I can't divulge overall, but I think it is a good profitable business model that has been agreed upon between the two partners. It will all depend on pricing and depending on the pricing you get to know that, right, so it is very difficult to answer that right now.

Anubhav Aggarwal: Just one clarity on the number, so personnel costs, if I see it ex the wellness numbers, the personnel cost decline 50 crores quarter-on-quarter, that is for a substantial drop, so do we have lesser number of people here or the provisioning was such that it resulted in one-off decline?

Sharvil Patel: So in the last one year plus, we have been working on multiple initiatives on productivity improvement whether it was India business starting with zero-based budgeting, then our manufacturing side, we are running a program called WISE which is again improving productivity. We have also rationalized our footprint in terms of manufacturing asset and all of that is leading to reduction in people and reduction in cost as well. Beyond that I think if Nitin bhai or somebody would like to add anything.

Nitin Parekh: Sir, also because our facilities of Nesher and Hercon which are now not in operation, so that manpower cost is also reduction because of that.

Anubhav Aggarwal: And that resulted in no hit to the revenues, you could transfer everything and that resulted in all cost saving?

Nitin Parekh: So there are very few people now, other people have been retrenched. Obviously, there are no revenues also from those sites and attendant cost are also not there.

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

Ranvir Singh: Sir, on Zycov-D vaccine, just wanted the clarity on pricing, so we have a pricing per government, for private hospital or private supplies can you indicate any pricing you have in your mind?

Sharvil Patel: Currently, I don't think we can give that. I think once we are able to get clearance to launch in the private market, we will immediately appraise of the pricing, but suffice it to say that the pricing in the private market will definitely be higher than the current government pricing, but we still believe we will be more competitive than the current players.

Ranvir Singh: And sir, initially, supply would be from your own manufacturing site or Shilpa would also be contributing from next quarter?

Sharvil Patel: It will be our own manufacturing site and the other site is Shilpa which will also start contributing.

Ranvir Singh: And for a global market, getting it registered in different country's responsibility of your partner or you need to get approval?

Sharvil Patel: Majority of the places where we are partnering the responsibilities are of the partner. We will obviously supply the clinical data and also the reviewed journal's data which is that we already in the final stages of publishing in Lancet also this data. So if everything goes well, that data also will be supported.

Ranvir Singh: And just a last one, on Desidustat, what is the progress, so we have submitted with the DCGI, any timeline when we can see it coming to the market in India?

Sharvil Patel: We are estimating a launch in April this year, so it is very eminent, we expect everything is on track, so we should see a launch in April and this will definitely be one of the, I would say one of the best launches in Zydus in the current year, I would say.

Ranvir Singh: So apart from this, any other meaningful product launches in India from biosimilar side, particularly?

Sharvil Patel: Yes, last year we had launched the Ujvira. You would be happy to know that we have, I would say this quarter, we have crossed the number of descriptions even by the nearest competitor which is the brand and it has been one of the very good launches. I think the next would be scaling up, it is not a new product, but with the enhanced indication for Saroglitazar, Lipaglyn and Bilypsa should see significant momentum in the current year and then Desidustat definitely will be potentially large launch for this year. We also have some products where we are seeing patents of products going off patent, so we will be meeting the day one launches. We are also looking an important launch in the iron area, also one critical vaccine which is Varicella. So there are some important launches planned during the year and those are some of the ones which I mentioned to you also.

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

Sameer Baisiwala: Sharvil bhai, what is the visibility of Zycov-D Vaccine order from the government beyond 1 crore?

Sharvil Patel: Our last discussion was, the government wanted us to initiate the supply once we meet a steady base of supply, they did speak to us about further opportunities to add to the vaccine. We believe that this vaccine, there are still significantly large population of people who in the 12 to 18 years who are not vaccinated, so that definitely is the one opportunity and the second is people are looking, we are already seeing booster doses and other indications beyond the single two doses that people may have taken, so those would be a potential opportunity, so currently those are the three opportunities that we are seeing. The government has spoken that once we comfortably

resume our supplies, then we will talk about further discussions on further business, but currently our order is limited to 1 crore.

Sameer Baisiwala: And the fact that government has reduced the vaccine budget by 1/7th for next year from 35,000 crores to 5000 if I am not wrong, does that mean that the opportunity size are shrinking significantly as you go into next fiscal?

Sharvil Patel: I think to some extent, definitely there is uncertainty on what would be the opportunity size and definitely it would be much lower than the earlier years because majority of the population at least in the other side is vaccinated. Having said so, as the capacities that we are talking about which is about producing close to 1 crore doses a month, I think there is still sufficient opportunity to at least do, we believe on the worst case scenario of 3 to 5 crores do this business and that itself is still a significant amount of value and revenue for us. So assuming even a small 3 to 5 crores doses business is still very significant.

Sameer Baisiwala: And Sharvil bhai, the order that you are supplying now, 1 crore, is it from your new scaled up facility or the smaller one?

Sharvil Patel: The smaller is very little and the scaled up facility has just started.

Sameer Baisiwala: So that is commissioned, your supply?

Sharvil Patel: Yes, commissioned.

Sameer Baisiwala: And Sharvil bhai, question on the US business, what is your thought on Asacol HD competitor, when do you think, what is your best case, how the market can unfold over next 3 or 4 quarters?

Sharvil Patel: Did you ask about Asacol?

Sameer Baisiwala: Yes.

Sharvil Patel: So our best estimate is conservative estimate is that we see competition may be in July quarter onwards. There are two possibilities, one is we see an early preponement to April which it seems unlikely, but is always possible and there is also a scenario that we believe could happen where we would see nobody till end of the current calendar year.

Sameer Baisiwala: And for Lialda, Sharvil bhai how much more room is there, what is causing this pressure, is it incumbents competing for market share, I don't think there was no new entrant there?

Sharvil Patel: Yes, it is one incumbent who was competing for market share and they crashed the prices, so obviously we have to match.

Sameer Baisiwala: One final on the US business, so keeping Asacol out, what is your outlook for fiscal 23?

Sharvil Patel: Fiscal 23 I think our best estimate right now is assuming, we believe we will be probably at par growth, so may be just 1 or 2% or may be less than 5% growth for the FY23. That is the current estimate. This is assuming that we don't see any one-time or big opportunities or onetime buys and all and we have assumed 6% to 7% price erosion to the base business and assuming some competition in later part of the year on Asacol.

Sameer Baisiwala: And you have also included Revlimid upside on this?

Sharvil Patel: Partial because Revlimid, we are still not sure what way the pricing go, depending on that, once we launch it, we can give better flavor on that.

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

Prakash Agarwal: My question is on gross margins, so how do we see this gross margin shaping up for the next 12-24 months, you have said that near term US is all flattish, India we are on a high base of some of the COVID products, so how do we see the next 12 months and in the past you have said that end of fiscal 23, early fiscal 24, you expect complex injectables, etc., so if you could just help us understand the next 12-24 months it would be great in terms of gross margins and EBITDA margin trajectory?

Sharvil Patel: So I think on the gross margin side, we would continue to see some pressure in the US on price erosion, which we believe will get compensated by a better geographical mix driven out of India business and consumer wellness. As I said the India business delivered a 17% growth in the last quarter which is one of the highest and we are still seeing a very strong double digit growth in this current financial year, coming financial year also irrespective of Remdesivir. I think that will definitely improve. We have also seen margin improvement on our India formulations business, so that will further aid to the GC, so I think in the GC, we will be able to I think from this quarter 3 onwards protect this and we will be in the similar range of around 62-63% gross contribution. Going forward, in FY24, we believe our estimates right now talk about a very big upscaling in the US generic business for us because of some high value launches that are planned for that. Our aspiration is that we cross the billion dollars in revenue in the next financial year in US which is possible if everything goes well and so that is what we are planning and working towards which will then significantly see an improvement on the margins also in the FY24.

Prakash Agarwal: And secondly, on the R&D side, how should one think about it, your run rate was much higher in the past, it seems to have come down a bit on an absolute basis, so how do you expect given that lot of trials happening in US, then you have biosimilar trials which is kicked off, so various projects are ongoing, how do we see our R&D, either in percentage of sales and absolute if you could guide for the next 2 years?

Sharvil Patel: So with our estimates, we still believe that our current guideline of around 8% of revenue will be our R&D expenses what we are still committing to. That is because many of these expenses that you see we have already been incurring them, so we did a full phase 2 for two indications in the US in the current spends, get on trials on biosimilars and we continue to add more biosimilars, so I think we are looking at around an 8% average R&D spend to sales over the next 3 years.

Prakash Agarwal: And lastly on the CAPEX side, so what are our new CAPEX plans, so we did fairly well in terms of diversification post Moraiya, we had SEZ and couple of others, so do they require expanding or you are looking at new sites, what is the CAPEX plan for the next 2 years?

Sharvil Patel: For the next two years, we have two areas that we are investing behind when it comes to CAPEX. One is, we are expanding our MR vaccine for WHO prequalification to supply to the WHO market in 23-24 which will be a very large volume opportunity. We are also potentially expanding for our flu vaccine. We are the only Indian company and one of the three or four in the world, so we are looking to see the expansion there. We will be having a new SEZ, new site for US formulation which we are benchmarking to have currently the lowest benchmark cost that we are planning for across all our sites, so that will definitely come up over the next 2 to 2-1/2 years and potentially one more additionally debottlenecking for our SEZ site, so those are the current plans for the capital investment.

Moderator: Thank you. The next question is from the line of Keshav Mishra, a Retailer Investor. Please go ahead.

Keshav Mishra: Sir, my question is for the Desidustat, now that we are getting ready for launch, if you can give a flavor of the market size will be competing in India?

Sharvil Patel: I don't have the exact market size, but in terms of patient we are almost targeting a 30-35% conversion of new patients than existing patients not on dialysis and dialysis, which is a substantial conversion that we are building towards. We believe that this molecule has the potential to be a 250 crore plus franchise for the company over the next 3 years. So it is a significantly large opportunity.

Keshav Mishra: And sir, a similar molecule in US, I think got some observations from FDA, so are we looking to do some kind of partnership and launch in some years may be in US market as well, I understand we have a partnership in China, are we looking for similar partnership there?

Sharvil Patel: On Desidustat, our current thinking is that we have seen China and India definitely are one of the two largest markets, so that is definitely one of the potential than obviously which will allude to lot of South Asian countries being covered. The second, in the US we are looking at one or two new indications for this molecule which are again unmet needs and orphan also. As said, our strategy has always been to look at rare and orphan diseases where we can build something,

so that is something that is in current evaluation in US in terms of clinical programs we have already spoken about phase 1 for patients who are on chemotherapy and are anemic and this drug is potentially a good effect there and we have started clinical trial on that in the US, so there are going to be, this is molecule something that we are evaluating for the US. More details, whether we can see an active program in more than one indication also, I can only talk about it, may be in two quarters from now, but definitely we are looking at the developed markets also for Desidustat.

Keshav Mishra: And sir, one last question on Moraiya plant, now that we have physical inspection started, any timelines for reevaluation by the FDA for audit, are they…..

Sharvil Patel: One point just to correct, foreign inspections have not started, FDA has communicated publicly that they are not starting for inspections until February unless when they will give the latest update. So one is, they have not started, if once they start we believe that we could see an inspection happen for Moraiya and originally we were expecting a Jan, Feb, March inspection. We still believe it is possible to happen in Feb or March, but again it is still little too early to say, but we are prepared for it and we are awaiting and FDA has acknowledged that they will plan for an audit once the opening happens. When that would happen is still unknown and we cannot predict that.

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

Anubhav Aggarwal: One question on the gross margin, this quarter I exclude the wellness contribution because wellness gross margins have been weak, but excluding Zydus Wellness, the gross margins seems to have declined 180 basis points quarter-on-quarter, just trying to understand is that weakness largely coming from any particular geographies for this largely driven by raw material mix overall for the dominant factor because it is a very sharp decline?

Sharvil Patel: I think Vishal can answer, my immediate answer would be it is because of US.

Vishal Gor: It is largely because of US business.

Sharvil Patel: And that is because of Mesalamine, Lialda reduction.

Vishal Gor: Some cost inflation, but largely because of US business price erosion.

Anubhav Aggarwal: But just trying to understand our sales are flattish, Lialda is not that profitable for us anymore, it is not like we are running margins equal to Asacol over there, so it is a very steep decline, almost 180 basis points from the total business?

Sharvil Patel: One point I would like to correct before they add, one is, Lialda is definitely not as profitable as Asacol, but definitely very profitable, so I think while the second point of what you say is right,

that is not as profitable as Asacol, but it is still very profitable, so that is when you see an impact on that, that is one of the impact and overall there have been pricing challenges in the US and commodity inflation that has happened. So that led to the gross margin fall. If I have missed anything, may be Vishal or Nitin Parekh can add something.

Vishal Gor: No, that's all.

Anubhav Aggarwal: Second question is from the vaccine front, what are you thinking about the export market, if you want to export at certain point time, you need an approval from WHO or do you need approval from some central agency to export or whenever you feel that you have crashed is now fully ramped up and common India allows I think there is no more controls on exports now, when can we Zycov-d starting to export out?

Sharvil Patel: Still there is control on export, you have to take permission from the government to export, what quantities and how much and when. The second part is, currently the scale that we produce at which we are hoping to achieve is 1 crore per month over the period of next 3-4 months. I don't think that would be sufficient enough that we will be able to export a lot. They will be enough, sufficient only for India right now. Having said, so if we have the opportunity to export today we have already requested from many countries where they would not require WHO prequalification and Indian approval would be enough, but we are obviously not going to export till we complete our obligations in India and potentially the private market of India.

Nitin Parekh: And Anubhav, just one point of clarification, excluding Zydus Wellness number, on Q-on-Q basis, the reduction in gross margin is only 0.5% excluding.

Anubhav Aggarwal: Nitin bhai, I exclude the other operating income, so I was excluding other operating income and then talking about gross margins?

Management: Yes, we do that.

Nitin Parekh: So we have those data, we can furnish the data to you, so it was 64.2% in September quarter and now it is 63.7% in December, there is 0.5% reduction after we exclude Zydus Wellness numbers.

Management: And we also don't include other operating income.

Anubhav Aggarwal: Yes, I will get in touch, somehow second quarter shows 65.5%, so I will get in touch with you.

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

Vishal Manchanda: Could you share an update on biosimilar filings and approvals in emerging market?

Sharvil Patel: On the biosimilar side, we are looking forward as if it we did get approvals in Russia for PEG GCSF and we have started supplies for that. Our critical big approval, we are expecting very soon is in Latin America for at least one and may be two molecules in this next 3 months. So once that happens we can participate in large Latin American market, government contract as well as institutional contract and that would be significant in terms of our expansion in the emerging markets. Besides that we have partnership in South Asia for one or two biosimilars of us. We are also seeing that post approval in one of the LATAM Columbia will activate and we can see approvals coming through in Columbia which would again add to the business that we are trying to build for. So those are the immediate plans on the emerging markets front where we can see at least four biosimilars coming for approval in different markets. In India, we are still on a good track record. We believe now that we are the largest company by revenue on biologics in India specific to biosimilar and I think that traction will continue with more filings and more launches coming up.

Vishal Manchanda: How many biosimilars would we have in India as of now?

Sharvil Patel: We have 12.

Vishal Manchanda: And do we have enough capacities to execute launches in emerging market?

Sharvil Patel: Yes, currently for the next two years, may be up to three we have enough capacity. As we see scaleup happening, we may need to add more capacity in next for FY25 and beyond.

Vishal Manchanda: And can we see acceleration in emerging market growth on approval of these biosimilar?

Sharvil Patel: Definitely, our current business plan for export relies on some of these approvals which we have started to see and once we see that we can definitely immediately starting from a very low base to starting a $30-40 million revenue business.

Vishal Manchanda: And just one final one on vaccine, so WHO prequalification, can you give some color on what it takes to get back WHO prequalification?

Sharvil Patel: From our perspective, I think the phase 3 trial once this is reported and published at one part of the exercise which will be done and we said we have published with a large number of populations. The second is on new facility, we will need to go through some capacity in production and continuous production and show some history of number of batches made and all of that both in drug substance and drug products. Once we are comfortable in doing so, then we will go ahead for WHO prequalification.

Vishal Manchanda: This entire process can take 2 to 3 years?

Sharvil Patel: No, at least in the vaccine side, we believe it is possible to do it in 6 months.

Vishal Manchanda: The phase 3 trials completed or already done?

Sharvil Patel: Yes, we have already been submitted for publication in Lancet.

Moderator: Thank you. The next question is a followup from Ranvir Singh from Sunidhi Securities. Please go ahead.

Ranvir Singh: Just on biosimilar, the 12 biosimilars currently we have in India, so what would be the contribution of biosimilars in Indian business?

Sharvil Patel: Currently, I think annualize is about 600 crores if I am not wrong.

Vishal Gor: So annualize will be roughly all put together about 350 crores.

Sharvil Patel: I think I got disconnected, I assume you had asked for what is the revenue on biosimilars in India, it is about 600 crores right now, annualized.

Ranvir Singh: And what would be the export revenue of biosimilar?

Sharvil Patel: I don't have that, but it is not very substantial right now, because we have just started in a few countries, but I don't have it off hand with me, but it is not substantial.

Ranvir Singh: And secondly on malarial products, so we had Orphan Drug Designation, so what process remains to get it rolled out and when we can expect?

Sharvil Patel: It is a very good opportunity, it is a single dose, one pill and we have seen very good data currently in phase 1. So if you go through the phase 2, phase 3 trial now, if we see equally good data in phase 2, then this program will definitely move into the phase 3 and move forward and because we believe this targets be resistant strains of malaria, Falciparum and Vivax and others, I think it will be a tremendously good opportunity, so I think all we can say right now is it looks very promising, but as we get more clinical data completed which the trials would be very fast because they are only single dose trials. So once we have that data, we can share more in terms of the progress of the molecule.

Ranvir Singh: Being an orphan drug, can we expect it to get trials to complete it in next 2 years?

Sharvil Patel: Yes and I think it is an opportunity for a tropical disease voucher also in the US, so we are evaluating all options.

Moderator: Thank you. We have next question from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: Sir, few questions of Saroglitazar, so if you can just elaborate on what kind of traction you are seeing in India, I think you mentioned 250 crores or so as the kind of expectations you have, but with now expanded indication, what kind of expectation you have on that product and also on the export market, any thoughts there?

Sharvil Patel: You are talking about Saroglitazar?

Saion Mukherjee: Yes.

Sharvil Patel: Let me give you an overall perspective on Saro. Saro, we have launched in India under two indications, one for dyslipidemia and one for NAFLD and NASH. The molecules are tracking very well right now and as I said the opportunity is very big. It is a new market where diagnosis and other things are important. We have started a very large venture on FibroScan usage across all centers we will be able to diagnose this effectively. So we believe that this is definitely will be in the top 5 molecules of the organization, this and Desidustat and both of this combined definitely have the potential to be upwards of 500 plus 600 crores in revenue over the next 3 to 4 years, so significant opportunity is there. With respect to the developed market, I think from our current estimate, we believe for PBC we would file by calendar year 24 and potentially see a launch in early 25. That is what we are building towards. We are also interestingly working to make sure that our label claim is very good. So beyond the current label claims that are available or people are looking at which is obviously improvement in PBC parameters. We are also looking to see how do we improve for people who have gone through organ transplant and see how it is affecting them, people who have been cirrhotic and it is affecting them in sub population and if we see all of that data and if we get that good quality, this is potentially achievement that could be best in class in PBC, so that is what we are aiming for and as such the trials have started which is an adaptive phase 2b/3 trial. On NASH, the trials have also started on phase 2b and again we will be looking at fibrosis score improvement which is our important market beyond just NASH score improvement. So those are the physical areas that have been looked at for Saro. Saro has also got an orphan designation in Europe also now, so I think potentially we are building towards the launch for calendar year 25 for Saro in US, in PBC and 27 launch for NASH potentially in the US.

Saion Mukherjee: And sir, actually I was also looking for other markets, other emerging market, any potential there you see for this molecule?

Sharvil Patel: There is a lot of potential, but I think we are going to focus currently on US and post that Europe and then we will look at other countries.

Saion Mukherjee: And sir, it is extra additional label that you had mentioned about a better label on PBC, how much of an advantage it gives you over other drugs, I mean in terms of timeline, I understand there are couple of drugs under development, how are you in terms of pipeline, when do you expect this particular molecule to come vis-a-vis the other competing one?

Sharvil Patel: Currently, there is not treatment, we believe we could potentially be on a conservative side, the third to come to market or potentially the second, so between the second and third in the market for this indication. The indication and the label, everything depends on that. If we see an enhanced label, from our current estimate we can almost double our estimate, so it is a question of the potential and opportunity size to get the differentiated label with a higher barrier to overcome if we are successful. The potential is that it would become one of the key molecules to drive the PBC program, so that is what it is, but until we have that data or can confirm that it is still very early to say that.

Saion Mukherjee: And sir, just on Desidustat on China, what is the timeline there?

Sharvil Patel: So the trials have started in China, so that is a good part and I think we believe that the trial can also be ramped up in the next 15 months.

Saion Mukherjee: So an approval in next 2 years is possible you think?

Sharvil Patel: Yes.

Saion Mukherjee: And sir, final one question, just clarification, you mentioned about $30 to $40 million biosimilar business, this is based on the approvals in Latin America and other markets that you will get, so this you are expecting for next fiscal or is it over a period of time you are indicating?

Sharvil Patel: I think to be on the safe side, we think this can be in FY24.

Moderator: Thank you. The next question is a followup from Tushar Manudhane from Motilal Oswal. Please go ahead.

Tushar Manudhane: Just one clarification on this Revlimid, when this tentative to be converted to final or what is the key milestone there?

Sharvil Patel: We are expecting this launch in this calendar year, but exact date we cannot give, but it will come up very soon.

Tushar Manudhane: Basically, there is nothing from the Cadila then pending to….

Sharvil Patel: No, it has not been held up for any other reason, it is just the date at launch.

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

Kunal Dhamesha: First one on the clarification that you mentioned the growth for us for the next year could be less than 5%, so is it for the US market or for overall level?

Sharvil Patel: For US and in others, we are expecting a double-digit growth.

Kunal Dhamesha: And that would be excluding the COVID related product base or?

Sharvil Patel: No, including the COVID, not including the vaccine, but including the COVID. Actually the growth will more if we exclude COVID because COVID has a higher base in this.

Kunal Dhamesha: We are not quantifying the COVID contribution in the first 9 months in India business?

Sharvil Patel: I think we have almost, the COVID portfolio was definitely significant in the last calendar year and as the best estimate we can definitely give you that with COVID high base also for the coming financial year, we can see a strong double-digit growth.

Kunal Dhamesha: And in US, we are aspiring to achieve 1 billion topline by FY24 from high value products, so can you name a few, one I would believe would be Revlimid, but apart from that if you can provide some color on what are the other high launches?

Sharvil Patel: We believe that in this year, we would be able to overcome, clear the Moraiya site also and we have two high potential launches in the US in the coming year, so if both of those things all go well, we are talking about launching of the last ANDAs in the coming year and then we can definitely see that we can aim for achieving 1 billion revenue milestone for the US. Exact product, I can't give you for competitive reason.

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

Sameer Baisiwala: Sharvil bhai, it is just on products like Nelarabine, just wanted to hear your thoughts and how should we think about it, it is a small product, are the rebates high in this and how does the pricing go down, so just if you can share your thoughts on this one, it is an exclusive product, therefore, I am asking?

Sharvil Patel: Yes, I think the good part is it is an exclusive product with very limited competition, so it is not a very large opportunity in terms of market size, but in terms of where we are, definitely double digit 10 plus million dollar opportunity for us which we will continue till the exclusivity and then obviously as competition comes it will fall off. So that is I would say to do with Nelarabine.

Sameer Baisiwala: So such products also will get competition beyond 180 you think or?

Sharvil Patel: Yes, we are assuming, for us to assume would be right thing, if you rather assume there is no competition, but I am assuming that there is competition, obviously with small volume, these products do fall off.

Sameer Baisiwala: And Sharvil one more, on Revlimid, let me try, I must not disclose that what could be your volume share to begin with, just general qualitatively, is it like low single, mid single or high single digit if you can just give any color would be very helpful?

Sharvil Patel: I think after launch I will give you all what we can, but currently it is not possible to do. You know the competitive landscape and also there are multiple factors related to it, so I think after launch it will become much clearer.

Moderator: Thank you. The next question is from Anubhav Sahu from MC Research. Please go ahead.

Anubhav Sahu: I heard that on the biosimilar side, you mentioned that currently the revenue annualized the size of around 600 for India, two quarter back, 350 so in that context it looks like we have scaled up really quickly, wanted to understand from you like what is the revenue size you are looking in the biosimilar portfolio in the coming or may be coming two years, both for India and other geographies?

Sharvil Patel: This year has been very good. Majority of the products have done exceedingly well and gained number one rank. The launch of Ujvira has been also significant almost crossing 50 crores mark in the first year and still scaling up significantly, so we are seeing here molecules which are becoming 80 to 100 crores very fast, so that is the first part of it and we continue to hold a good strong market share there. Our overall biosimilar general growth plans are, on a CAGR basis, we can still see, 40 to 50% growth continuing and more importantly I think in 2022, we may not have big launches now, because we already have, we have couple of programs in clinic, but in again 23 and 24, we would see very big launches in the oncology space which would significantly add to the revenue, so that is the current plan. So this business will definitely scale up and be one of the large 1000 plus crores businesses for us. Exactly, when will it happen, I think its best would be that if you give us a 3-year window we would see this business doubling for sure.

Anubhav Sahu: And secondly, you mentioned for US milestone you are looking at just $1 billion that is for coming fiscal, right FY23?

Sharvil Patel: FY24.

Anubhav Sahu: And which are those two high potential molecules, sorry I missed that part?

Sharvil Patel: High potential molecules, but we can't name those molecules. I think if everything falls in order, we get through a good audit with Moraiya and clearance, we have all transdermal franchise launch, we have one critical launch if everything goes well and we are able to do that. If everything works and well we are closer to that billion and stretching for that.

Anubhav Sahu: And lastly, if you can share some views on your biosimilar launch on this antibody-drug conjugate called Trastuzumab?

Sharvil Patel: Trastuzumab Emtansine or Ujvira is our brand has done extremely well in the first year of launch. By this quarter, Jan, Feb, March, we believe we would have crossed the number of patient. Majority of the number of patients who are diagnosed will be on treatment on Ujvira now, so we have even crossed the brand in our view, so this is potentially one of the very good launches where in the first year only we have crossed in terms of market share, in terms of number of patients ahead of the brand.

Anubhav Sahu: And correctly this is for India only, right?

Sharvil Patel: This is only for India right now, this program has also been nominated for global development and we do believe that in the next 3 months, we would have a face to face with the FDA, if we see a good clinical development plan and agreeable with FDA and EMA, then this program will immediately move into clinics for US.

Moderator: Thank you very much. As there are no further questions, I now hand the conference over to Mr. Ganesh Nayak for closing comments. Over to you, sir.

Ganesh Nayak: Thank you very much and look forward to interacting with you again in the month of May for the last quarter and the annual results. Thank you very much. Good night and have a nice weekend.

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