“Cadila Healthcare Limited Q1 FY20 Post-Results Conference Call”

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Moderator: Ladies and gentlemen, good day, and welcome to the Q1 FY'20 Post-Results Conference Call of Cadila Healthcare Limited. As a reminder, all participants' lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note conference is being recorded. I now hand the conference over to Mr. Ganesh Nayak -- COO and Executive Director of Cadila Healthcare Limited. Thank you and over to you, sir.

Ganesh Nayak: Welcome, Ladies and Gentlemen. It is my pleasure to take you through the Performance and the Results of the First Quarter of FY'20.

We have with us Dr. Sharvil Patel -- Managing Director; Mr. Nitin Parekh -- CFO; Mr. Harish Sadana -- Chief Strategy Officer; and Mr. Vishal Gor -- Senior Vice President, Corporate Finance.

During the first quarter, on a consolidated basis, our revenues grew by 21% YoY to Rs.34.9 billion. We posted an EBITDA of Rs.6.3 billion. Excluding the impact of certain one-off expenses aggregating to Rs.700 million, our EBITDA for the quarter stood at Rs.7 billion which was 20.1% of our revenues. Profit after tax excluding the impact of such one-off expenses was Rs.3.58 billion for the quarter.

Our India geography, comprising of Human Health, Consumer Wellness and Animal Health has grown by 46% on YoY basis, registering revenue of Rs.16.7 billion. On a comparable basis, our business in the India geography grew by 8% during the quarter. Contribution of the India geography in the overall business was 49%.

The US geography, comprising of Generics and Specialty portfolio registered revenue of Rs.13.7 billion. At 40% of the total business, the US geography posted a growth of 11% YoY. Our rest of the world business, comprising of multiple emerging markets grew at 12% during the quarter.

Now, let me take you through the journal of initiatives and the outcomes for each of our business lines:

Coming to the Human Health business in the India geography, I shared with you during our earlier interactions; we have been working on multiple strategic interventions to bring back growth in the Human Health business. So, far we have worked on the following initiatives: We have revamped 70% of our territories to the new sales operating system wherein the focus is on demand generation by improving the sales planning cycle and also improve the quality of interactions between the field business officers and the business managers. There is an extensive use of data at the back of the newly created digital tools to help improve quality of decision-making and customer engagement strategies.

We have also undertaken a portfolio rationalization exercise and have decided to discontinue 233 SKUs where we were not able to build scale. These SKUs represent 17% of the total SKUs that we sell.

We have also been working on improving our customer engagement model depending on the nature of the therapy to get maximum value for our efforts. On the back of these initiatives, our overall India Human business posted a growth of 6% during the quarter compared to the 2% YoY growth registered in the last quarter. Growth in the Branded portfolio, excluding the generic products, was 7% during the quarter.

As per the AWACS data, our Human Health business grew by 9.5% during the quarter, outperforming the overall Indian pharmaceuticals market growth of 7.9%. Our Gynecological and Hormones portfolio grew faster at 14.5% versus the market growth of 7.7%. Our Derm portfolio also grew 1.5x the market at 9.91% versus the market growth of 6.3%. In the Cardiac portfolio, we are on the recovery path QoQ and our market share has improved from 4.5% to 4.53% during the quarter.

I am happy to share that our pillar brands having annual sales in excess of Rs.500 million each which contribute to over 30% of the India Human Health business, have grown by 11% during the quarter. In fact, some of these brands have registered market-building growth in excess of 15%. Also, the brands having annual sales between Rs.250 million and Rs.500 million which contribute to one-fourth of the India Human Health business have registered a growth of 9% during the quarter which is in line with the market growth. In this bucket, too, some of the brands have posted growth in excess of 15%. Our emphasis will now be to sustain the momentum in the above two buckets and to revive growth of the remaining portfolio. To achieve these objectives, we are in the process of transformative restructuring of the business around Mass and Specialty. In the case of mass cluster, the focus will be to improve penetration by expanding reach, and in the Specialty cluster, the focus will be on intensified engagement efforts with the key opinion leaders. As expected, such a transformative change will require a couple of quarters to stabilize and we expect the current growth momentum to continue. EBITDA margin for our India Human Health business is significantly higher than average margins at a consolidated level which has further improved in this quarter.

On the India Consumer Wellness front, we are happy to report that the integration of the acquired business is growing as per plans. On the back of a good season and focused sales and marketing efforts, Zydus Wellness Limited registered sales of Rs.6 billion during the first quarter, and on a comparable basis, the sales of Zydus Wellness Limited grew by 13% YoY. Now having acquired this business in February and knowing that this quarter contributes to one-third of the annual sales, we are happy that the performance of this quarter has been above our expectations.

On the Brand front, our key brands namely, Sugar Free, Everyuth Scrub, Everyuth Peel-Off, Glucon-D and Nycil have not only maintained their leadership in their respective categories but have also grown better than the market. In Complan, we can see a good opportunity to regain the lost share by investing in the brand by increasing media weightages in the key markets through multiple media efforts.

The quarter gone by has been challenging for our Animal Health business due to a delayed monsoon and drought-like situation in some parts of the country and we expect it to catch up in the coming quarters. This summarizes the components of our businesses in the India geography.

Now, let me talk about the next big geography which is the US:

As mentioned earlier, the overall business grew by 11% YoY on the back of new launches and the consolidation of market shares in the base business. On QoQ basis, as anticipated, the decline in the business is largely attributable to over 90% reduction in the sales of seasonal products like Oseltamivir and the authorized generic of testosterone gel. We also saw over 25% declines in the sales of Levorphanol. Base business excluding these products was able to maintain the same level of sales as registered in the previous quarter.

We received approval for ten new products, including two tentative approvals for the US market during the quarter. We launched eight new products in the US during the quarter, including the Rivastigmine Transdermal Patch, the first transdermal patch launched from our own pipeline. During the quarter, we filed four additional ANDAs with the USFDA.

Overall, for FY'20, we expect our US generic business excluding the one-time AG business to grow in single digits on the back of 25 additional launches planned during the next three quarters, including five to six high value products. This is in spite of the significant reduction in the sales of mesalamine 1.2 gms delayed release tablets and the loss of business to the tune of over $15 million due to the suspension of production of Injectable products and highly-potent Oral Solid products at Moraiya as part of our remedial actions.

Our emerging markets including the core geographies of Brazil, South Africa, Mexico and Sri Lanka grew at 12%. We retained our #1 position in the Sri Lankan private market for seven quarters in a row with the market share of 6.5% with leadership position in the Cardiovascular, Gastrointestinal, Orthopedics and Gynecology Therapy areas. During the quarter, we commenced business in the French West African region.

Our Biologics portfolio which presently gets clubbed in India and other geographies recorded a sale of Rs.2.46 billion in the last 12 months. Sales for the first quarter of FY'20 were Rs.648 million, up 26% YoY.

Our Vaccine business has launched five products in the India private market. We shall give regular updates as we get ready for the WHO pre-qualification for some of our products.

On the Operations and Compliance front:

Recently, the USFDA has classified its inspection conducted at the Moraiya facility from the 22nd to the 3rd of April-May as Official Action Indicated which is the OAI. We believe that this classification will not have any impact on the current supplies or revenues from this facility and the process of remediation is on as per the commitments made to the USFDA. We are continuously updating the USFDA on the progress of remediation. There are 32 ANDAs filed from Moraiya pending approval which are one-third of the total ANDAs pending approval. We have initiated site transfer of all our Injectable products from Moraiya to Liva and expect to complete the site transfer of these injectables by the end of FY'20. While we are working on bringing back Moraiya on the compliance track, our other facilities have maintained their successful track record of sustained compliance.

During the quarter gone by, our Oral Solids Dosage Formulations manufacturing facility located in our Ahmedabad SEZ successfully completed the USFDA inspection. Production in this facility has been significantly ramped up from an average of 130 million pills per month last year to 270 million pills per month.

Our Transdermals manufacturing facility of Hercon in the US and both the Oral Solid Dosage Formulations manufacturing facilities of Nesher Pharma in the US have also successfully completed the USFDA inspections.

In addition, recently in the month of July 2019 last month, our Oral Solid Dosage Formulations manufacturing facility at Baddi, and our API manufacturing facility at Ankleshwar successfully completed the USFDA inspections without any observations.

With this, I conclude the "Business Review" and I would now request Dr. Sharvil Patel -- Managing Director, to take you through the progress and initiatives in our innovation program. Over to Dr. Sharvil Patel.

Dr. Sharvil Patel: Thank you, Dr. Nayak. As a company, we believe that innovation is the only way to have a sustainable pharmaceutical business. This has been evident from our continued investments on different technological platforms as well as capabilities that we have built across these platforms. Behind all of these investments, one thing that has always guided us is to do more with less. As a result of this philosophy, in spite of running multiple programs in diverse areas, we have been able to manage a research spending within the 7-8% of our revenue. I believe we will maintain the same level of investment and achieve targeted milestones across multiple programs.

Let me give you an "Update on the Key Innovation Programs" that are underway at the organization. On the NCE front, for Lipaglyn lead molecule, we completed enrollment of patients with non-alcoholic fatty liver disease which is NAFLD, including NASH, in EVIDENCE IV Phase-II clinical trial across 20 clinical sites in the US. We also completed enrollment of patients in non-alcoholic steatohepatitis in EVIDENCE II and EVIDENCE III and EVIDENCE IV, V Phase III clinical trial across different clinical sites in India and Mexico. Recently, in the month of August, we successfully completed Phase-III clinical trial in India of Lipaglyn in patients with type-2 diabetes. The trial was a multi-centric randomized double-blinded study to evaluate the safety and efficacy of Saroglitazar compared to Pioglitazone in patients with type-2 diabetes. The Phase-III trial enrolled 1,140 subjects, and the study on the patient was over a period of 56-weeks. The trial has demonstrated efficacy and achieved statistically significance for its primary endpoint which is the change in main HbA1c as compared to the baseline. No severe hypoglycemic events were reported. There was also no weight gain or edema observed during this trial of Saroglitazar. For Desidustat, an investigational new drug targeted at treating anemia in non-dialysis-dependent chronic kidney, liver disease patients, we announced the commencement of Phase-III clinical trial in India after completion of a successful Phase-II trial.

On the Biologics front, we initiated Phase-III clinical trial in India for TDM-1 during the quarter. We received regulatory approvals to initiate pre-clinical study for one of our next monoclonal biosimilars Denosumab.

On the international front, RabiMabs, our novel biologic to treat rabies received orphan drug designation from the USFDA for the quarter. We continue to file the dossiers of different biosimilar products with the regulated authorities of different emerging markets. We also continue to have four active novel biological programs running.

Talking about our Vaccines portfolio, we initiated work on the development of hepatitis A, E, hepatitis A and typhoid conjugate combination vaccine and the Tetravalent Human Papillomavirus Vaccine. We completed the dossier for initiating Phase-IIb clinical trial of our inactivated therapeutic tuberculosis vaccine. We have also been selected by WHO as a potential technology receiver of Sabin Injectables, IPV after numerous rounds of due diligence.

Coming to Initiatives on the 505(b)(2) Developments: We have 15-products under different stages of development at present, targeted towards supportive oncology, dermatology and pain management therapeutic areas. Of these, three products are at the pre-IND stage of development, while one product is ready for NDA submission. As mentioned earlier, I would be to manage all these programs and also the generics as well as the specialty pipeline within our resources.

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

Moderator: Thank you. Ladies and gentlemen, we will now begin the question-and-answer session. We will take the first question from the line of Neha Manpuria from JPMorgan. The first question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: Sir, in the opening comments, you mentioned certain one-off. Could you give us some color on what this was related to?

Management: Neha, these were mainly related to the stamp duty which we paid in our Wellness business for merger of the acquired business with the listing entity. Some consultancy fees for integration and on the other projects which we are running in the Human Health business and also some one-time donation. The total amount was about Rs.70 crores.

Neha Manpuria: This does not include any remediation cost for Moraiya or payment to consultant related to Moraiya?

Ganesh Nayak: No.

Neha Manpuria: Could that be significant in this quarter onwards?

Ganesh Nayak: No.

Neha Manpuria: My second question is on Moraiya. What is your expectation in terms of timeline to complete remediation and therefore invite the FDA for reinspection?

Dr. Sharvil Patel: As we have spoken about earlier, there are two areas which were of the observation related to – one was related to the crop-contamination issue. I think largely we have been able to address the concern on the crop-contamination and we have committed that we will be doing 100% analysis of all retain samples and also submitting that data to the FDA and that we should be able to finish in the second quarter here. In regard to facility upgradation on the Injectable side, this is something that we are working on and we feel we should be able to do so by end of third quarter.

Neha Manpuria: So, realistically, we should be able to call the FDA next calendar year?

Dr. Sharvil Patel: There is a new method in terms of how FDA looks at it. So, it is very difficult for me to give that view. What you said would be the base timeline. Yes, that logically they will come in the next year calendar year but there is also a possibility of something happening this year as well.

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

Prakash Agarwal: On the US business, just trying to understand the fall clearly from the big three products going down but on the guidance that you gave, I could not hear it properly, so you said on a generic space, ex-specialty you still expect the single digit growth led by 25 new launches, out of which 5-6 are high value, is that correct?

Dr. Sharvil Patel: Yes, that is right.

Prakash Agarwal: In the past, we have talked about $900 million kind of number. How does that number look for '20?

Dr. Sharvil Patel: So, the $900 million had the sale of five specialty products of Sentynl. It had obviously the AG sales of testosterone gel. So, those two are not the pure generics business that we are doing.

Management: Prakash, just to reiterate what Mr. Ganesh Nayak said in his opening remarks, our US generic business excluding the one-time AG business which we did last year, we expect that business to grow in single digit in the financial year '20 and there are two products – AG business which was one-time and Specialty business.

Prakash Agarwal: So, is there a number we are guiding to versus $900 million which we guided last time?

Management: Generic business last year was $800 million.

Prakash Agarwal: The other two continue to see price erosion, right, the Sentynl has one competition and AG has several competitions now?

Dr. Sharvil Patel: In the quarter gone by, Sentynl has already had the price erosion, so it is already built into this quarter and no AG sale in this quarter. So, both are there in the current base.

Prakash Agarwal: Also, wanted to understand the IndAS 116 impact. What would be the cost which would have gone down below the EBITDA line as the depreciation and…?

Management: It has not been material at all; it is not even worth mentioning, you can see there is no impact.

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

Kunal: My question pertains to R&D expense in terms of what we have guided for FY'20 because R&D expense has increased year-on-year significantly?

Dr. Sharvil Patel: As Mr. Nayak also covered, we expect the R&D expense to be between 7-8% of our revenue.

Kunal: On the India business, could you give the split of branded and generic business maybe for FY'19 and then how those segments moved in Q1 of FY'20 in terms of growth?

Dr. Sharvil Patel: About 8-10% of our branded business is generic-generic, everything else is branded.

Kunal: So, this generic-generic business is growing at slower pace than branded business?

Ganesh Nayak: It is not growing right now. There is a significant disruption to the generic business.

Moderator: Thank you. The next question is from the line of Purvi Shah from Sharekhan. Please go ahead.

Purvi Shah: In the first question when you stated that there was one-off of Rs.170 crores. That was included in other expenses. So, if you remove that, around Rs.850 crores is the other expense. So, is that the run rate that we expect to be going forward as well?

Management: Purvi, the one-off expenses, which are included in the other expenses are not Rs.170 crores, but Rs.70 crores excluding them, the other is Rs.950 crores.

Purvi Shah: So, Rs.950 crores is the number that we should be going for?

Management: Without any one-off.

Purvi Shah: So, that is what I am saying, so Rs.950 crores is the actual number without the one-off which is the run rate that we should be going for?

Ganesh Nayak: Yes.

Dr. Sharvil Patel: Yes.

Purvi Shah: If you could just also help with the debt figure and the tax rate that we are guiding for FY'20?

Ganesh Nayak: So, the gross debt as on 30th June 2019 Rs.7,740 and net debt of Rs.6,515. Tax rate overall at the consolidated level, we are guiding about 20-22%

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

Anubhav Agarwal: One question on Levorphanol. Now, Sharvil, are we thinking about reducing sales force now or have we already cut it?

Dr. Sharvil Patel: We have reduced already the sales force. We are doing one more restructuring in the last quarter. I do not think significant reduction of sales force will happen but reorganization will happen.

Anubhav Agarwal: So, when you say reorganization, do we have any other products that we promote?

Dr. Sharvil Patel: No, because sales force that we will be covering our business into mass and specialty. So, accordingly the sales force is organized. You are talking about India business or…?

Anubhav Agarwal: No, Levorphanol.

Dr. Sharvil Patel: Levorphanol, we have not reduced sales force yet. We continue with the same strength on the sales force as of now. We will take a call depending on further entry of any generic, which we do not see on the immediate front, but we are evaluating the business every month and depending on it we will decide whether to continue the sales force or not.

Anubhav Agarwal: But, IMS shows that the competition has already taken almost 60% market share. IMS could be wrong. But just trying to understand is the product size sufficient enough for us to carry the sales force?

Ganesh Nayak: If we continue the trajectory right now, we can break even and go little better than that profit which we do not feel will fall further, then we should still be able to sustain it because we are looking to add some portfolio for the current field force to promote. So, if we are successful in doing so in the next three to six months, we would not need to take any drastic call.

Anubhav Agarwal: Just a clarification. You mentioned that last year fiscal '19 this Levorphanol plus the Androgel agent put together for the full year was just $100 million?

Ganesh Nayak: $125 million plus.

Anubhav Agarwal: Just clarity. The Mesalamine 1200 basically, Aldagen is sub-$100 million product for us or more than $100 million?

Dr. Sharvil Patel: Yes, it is substantially lower; it is lower than $50 million.

Moderator: Thank you. The next question is from the line of Kunal D from SBI Capital Markets. Please go ahead.

Kunal D: So, profitability in consumer business, does it change drastically quarter-to-quarter? And we have said that revenue is higher in Q1 and Q4 in our press release. So, revenue goes down in Q2, Q3, but then profitability improves significantly in that business?

Ganesh Nayak: Q1 is the highest in terms of revenue and also in terms of profit absolute for the acquired business and Q4 is also good in terms of both sales and profit. Q2 and Q3 for the acquired business are much lower because we build working capital requirements and also inventory for the season and the sale of the product which are more to do with the summer season come

down, that is only for the acquired business. For our Zydus Wellness business, they have a more even trajectory to the quarter.

Moderator: Thank you. The next question is from the line of Yashvi Gopani from Gopani Securities & Investments. Please go ahead.

Yashvi Gopani: Actually I just missed the debt figure number. Can you please repeat it again?

Management: The debt as on 30 June was Rs.7,740 crores, that is gross and net debt was Rs.3,316 crores.

Moderator: Thank you. The next question is from the line of Damayanti Kerai from HSBC. Please go ahead.

Damayanti Kerai: You mentioned some 32 pending ANDAs from Moraiya. So, out of that, how many are for Injectables which we are transferring to Liva?

Dr. Sharvil Patel: So, currently whatever we are transferring to Liva are mostly all the approved products and all the new products are being filed from Liva. I do not believe it is substantially a large number, but I will ask Vishal to give it to you offline but it would be probably one or two and not any significant.

Damayanti Kerai: Moving to India, obviously you mentioned we have around 10% sales coming from the Transdermal business and you mentioned there is some significant disruption to that part of the business. So, can you explain a bit further what is happening there and how do we see outlook for this business?

Dr. Sharvil Patel: So, currently that business is challenged. I think there is a lot of pressure on the availability of credit and the availability of capital in the market with many of these indirect wholesale channels. So, on account of that we are seeing issue in terms of movement of goods for this. So, I think the financial stress that is existing for these types of particular business is affecting the growth of the sector. So, we have to wait and see whether it improves or not and we will know more so in this quarter whether this was just a one-off or whether there is a significant issue to demand.

Damayanti Kerai: On the branded part, I believe some of the secondary data sources like AIOCD after reporting very weak growth on the volume side for last couple of months, this month they have reported double-digit, good growth. So, what is your take on that, how do we see the volume growth in India market -- is it actually slowing or there is some problem in how these data sources capture the reading?

Ganesh Nayak: That is a good question you raised and I am glad that you are so updated because that data came just this morning or late last night. As you would have seen, the market is now showing

13.4% growth or so. I mentioned in my opening talk because that data also shows that Zydus is growing at 18%. So, it is in line with what we have been talking about, trying to grow at 1.5x what the market is growing. So, coming back to your question of whether this data is right or wrong, we have no reason to believe that because we have definitely seen in the last 45-days an increased demand and I have not gone through the data, but they give category wise, respiratory and GI and cardiovascular. So, we have reason to believe that in the coming quarter also this growth of 10-plus should continue.

Dr. Sharvil Patel: If you look at the four months period, there is still decent growth for the overall market and we hope this growth trajectory for the market improves.

Ganesh Nayak: Even if you see the last four months, that is from May to July, the market has grown at 9% and we are growing at some 11.5% or so. So, the market is also showing good growth and it also reflects what our internal progress are which I mentioned in my talk which is against 9% if we are growing at 11.5%, it means the market is growing and we also are getting back on the fast track.

Damayanti Kerai: Any comment on impact of the online pharmacies on our business or in the India pharmacy business in general, anything you are seeing or it is too small to make an impact right now?

Ganesh Nayak: Not as yet.

Damayanti Kerai: But once they scale up, we can see some pricing pressure coming, right?

Ganesh Nayak: Time will tell.

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

Prakash Agarwal: Like you said, Lialda is around sub-$50 million currently. Any color you can throw on the Levorphenol run rate?

Dr. Sharvil Patel: It is about $8-10 million quarterly.

Prakash Agarwal: On the Moraiya, as you said, there is a lot of work going on already but in terms of the cost, a), is there a substantial consulting and remediation cost that we expect and also you mentioned one point on the Injectable business. So, should we factor in some loss of sales on the Injectable front also?

Dr. Sharvil Patel: So, I will answer the last question. On the Injectables front, yes, … in my last call also, I did allude to it that we have suspended selling of Injectables from our Moraiya facility and some of the other products for the last quarter that impacted about $15 million of revenue

annualized. So, that is the impact that we have had. This will resume more so probably in the next financial year once the Liva site transfers are finished and start getting approved. With regards to Moraiya, Moraiya has had a good cost reduction during the year gone by and it would continue to have cost reduction going forward also. We do not believe because due to remediation we would see any significant cost increases.

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

Saion Mukherjee: I have a few questions on the domestic business. You mentioned lot of SKUs have been discontinued. I am wondering, sir what is the amount of revenue that we would have lost on account of discontinuation, just too kind of understand the real growth there?

Dr. Sharvil Patel: So, the revenue loss is on two accounts; one is that it goes away from the base and the second is we get good return because we discontinue some of the selling products. So, it is not significant; it is about 1%-1.5% maximum if you take goods back as well.

Ganesh Nayak: Otherwise on the sales itself per se it is exactly 0.7%. But Sharvil bhai did account all the collateral damage and that is why he mentioned that number.

Saion Mukherjee: You also mentioned about your Mass market and Specialty products. That is the way you are kind of looking at it and strategizing. So, in your branded business revenue mix, how do you fragment between these two segments -- Mass and Specialty?

Dr. Sharvil Patel: Once the whole reorganization over, I will come back to you with that detail because it is still work-in progress, so if you can give me one more quarter, I can come back to you and we will definitely talk about the reorganization.

Saion Mukherjee: To improve reach is one of the things you mentioned I think you have like 6,500-odd field force. Are you planning to add substantially to that, anything that you can share?

Dr. Sharvil Patel: No, we would not be adding any more field force. We are going to reorganize business units which will lead to some deeper penetration. So, the field force numbers will remain constant for the moment.

Saion Mukherjee: On the profitability front, I think you alluded to substantial improvement in profitability with margins being lot higher. So, FY'19 despite all the reorganization, it appears that you had a margin closer to 30%. Do you think that the domestic business, EBITDA margin could even go higher than 30% going forward?

Dr. Sharvil Patel: Yes, I think if our sales trajectory improves to strong double-digit we can see even further margin improvement. Also we have to see we build new facilities last year in Sikkim and all

which are not 100% utilized. So, all of those are also going to help going forward once we are able to fully utilize them and the other facility in Daman. So, all of that will help better utilization of resources.

Saion Mukherjee: Overall, when you look at your EBITDA margin profile, if you have let us say doing 20%, 22% EBITDA margin, domestic is like north of 30%, you have scaled up US business, your R&D is very much on a sight which is not very high, what are the key segments today that is dragging down your profitability?

Dr. Sharvil Patel: So, Europe is one which is dragging our profitability. The second is the emerging markets which is still to be scaled up and we are doing some investments in EMB in terms of facility as well as in terms of R&D. While on the EBITDA side it is good, but it will have some effect immediately on this. Then the whole biologics and vaccines front, we do not break even or make profits on that right now. And our plan on biologics and vaccines in the next four to five years, we are talking about creating $0.5 billion business and we believe that business once it scales up will build good profitability to the business, but currently, these are all loss-making businesses. And finally, we have invested a lot of money on patches but obviously we do not have any returns on it yet.

Saion Mukherjee: Just one clarification. You had mentioned number for biosimilars. So, that will be entirely India, right, sir?

Dr. Sharvil Patel: No, it will be India plus emerging markets, but emerging market is smaller right now, we are just starting.

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

Sameer Baisiwala: Sharvil bhai, just to understand the US trajectory, I think in Q1 you did $195 million and I should back out Liva about $10 million. So, $185 million is your pure generic run rate and this has to be compared with the full year last year $800 million?

Dr. Sharvil Patel: $186 million and $800 million.

Sameer Baisiwala: On $800 million, you are going to grow at a single digit for this year?

Management: Sameer, in the last year, $800 million, there was authorized generics business also which is not going to be repeated this year.

Sameer Baisiwala: The second question is for ePharmacies in India. My understanding is that they sell the branded products if that is correct, so therefore if ePharmacies scale up, it should not impact

really your business because they should then be buying the branded products from the manufacturer which are companies such as you?

Dr. Sharvil Patel: What you said is correct. Currently, they are selling branded prescription medicine which they do discount on their own, but the current model will not affect the branded generics part unless the model changes.

Sameer Baisiwala: I am a bit confused about Lipoglyn. Now, you have successfully completed Phase-III trials in India for type-2 diabetes, but for the US, you are going to start trials for NASH. So, why are you pursuing two different indications and which of the two are more promising?

Dr. Sharvil Patel: Let me give you a perspective. In terms of the molecule and its attributes, it has overall mechanism of action which obviously helps both on the lipid front and on the metabolic disorder related to diabetes. And all of those lead to lower dragging price and lower fatty content which is obviously some of the markers in liver. We believe that this product has the potential for multiple indications. There are two more niche indications which we are also working on which is PBC and Lipodystrophy which are one of them being an orphan indication. So, there are multiple opportunities for this market. In India, we first wanted to demonstrate the results on diabetes. That is why we had indicated this trial for India for Phase-III. For doing a global Phase-III on diabetes is very I would say expensive trial to do which requires large outcome trials. So, that I think we could not immediately prioritize. But we believe that the immediate and the most critical opportunity is that there is a gap in the market where there is no molecule available today for NASH/NAFLD. We have data of Phase-II in India which showed very good data. So, we decided that we would initiate the Phase-II trial in the US for NASH. So, that is the trial we have just completed enrollment on and we are going to publish these results in the third quarter of this year, and if the data is good, then that product will move forward for the global trial for Phase-III. We believe NASH/NAFLD area is a very large opportunity. When we design for opportunity for product, we look at the opportunity in the market and competition. So, on this area, there is no product that is currently approved. There are a few products that have entered Phase-III. So, there is still a lot of opportunity to be able to quickly complete this Phase-2 which we have and in niche and move on to Phase-III. So, that is the opportunity that we have decided to target for the global market including India and we will further add all these new indications also. India is further ahead in terms of the developed clinical pipeline programs, development pipeline which we have. So, India has already finished its diabetes trial as well.

Sameer Baisiwala: So, why did you not do NASH Phase-III in India?

Dr. Sharvil Patel: The NASH Phase III in India is also finished recruitment and Mexico also.

Sameer Baisiwala: Sharvil, in the US of global trials Phase-II, Phase-III, India submission approval my guess is it is at least five years away and if I am not wrong you have been developing this for last 8 years to 10 years. So, why your development cycle has been such a long one?

Dr. Sharvil Patel: Couple of things; this product was never identified for the areas of NASH. We had identified this for the areas of hypertriglyceridemia and diabetes. So, we did get the DG approval. Now you can see globally the DG market is not very large. So, we did not want to try for the DG approval for the global market. The diabetes trial has its own issue. So, that was obviously the concern. NASH is something that we saw good data coming out and that is why the program for NASH has just started just two years ago. So, from that point of view, our speed is pretty good because we just identified the program a couple of years back. And NASH/NAFLD is an area that has just really recently got developed in the last five years. From that molecule point of view, what you say is right. Molecule has been under development for longer period of time, but in terms of which target to go after and which is the mode of action and which area to look after, that is something that has happened recently for us.

Sameer Baisiwala: When you say you would be launching five to six high value products in the US, any ballpark range of the dollar value of these assets?

Dr. Sharvil Patel: So, they are between $5-10 million each.

Sameer Baisiwala: And that is high value?

Dr. Sharvil Patel: Yes, because I do not believe that you will always find very, very large products, there will be some of part, we believe we will continue to launch multiple products and all of that will help in terms of overall building the value and then there will be some much more higher value products that come through, but those will only be handful.

Sameer Baisiwala: Sharvil, you said you have launched 35 or so. So, if I back out this five to six, balance 30 launches would be all under $5 million?

Dr. Sharvil Patel: We have a lot of specialty around complex injectables which will come up in the coming year and then some of the first-to-file which are date-driven. So, those are still a year or two out.

Ganesh Nayak: Sameer, just to reiterate, we said we are planning to launch not 35, 25 new products in the US in the next three quarters, of which about five to six could be between $5-10 million kind of annualized opportunities.

Moderator: Thank you. The next question is from the line of Heer Goklani from Isha Securities. Please go ahead.

Heer Goklani: Wanted to know what has been your focus on therapy areas in the US business and what are our like top revenue contributing products there especially in the generics space?

Dr. Sharvil Patel: US business which you are talking about is a generic business, so there is no therapy focus when it comes to the generics in the US.

Heer Goklani: Like what therapeutic areas like the new launches have been...?

Dr. Sharvil Patel: No, US generics are built on opportunity size and developing portfolio depending on the dosage form, they are not defined by therapy area.

Heer Goklani: What have been like top revenue contributing products or what will be the important products for FY'20 per se?

Dr. Sharvil Patel: We do not give product-by-product details.

Heer Goklani: Like a rough idea which are our main products there?

Dr. Sharvil Patel: The Mesalamine franchise is a large portfolio. The Tamiflu or Oseltamivir franchise have been good for us so far. Then all of the others are sum of parts.

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

Nimish Mehta: On the domestic one, I am just trying to understand the trade generic disruption. You mentioned that there have been some issues with credit availability I guess mostly for the distributors. So, will it not also be impacting the branded generic distributors, I mean, how do we segregate these problems in the industry?

Dr. Sharvil Patel: So, it has not affected the branded. I do not have any firm data points to collaborate any of the details, but we believe that Jan Aushadhi stores that are there and all of the government initiatives which are for low-price generics will impact directly the GX part of the business and then the generic wholesalers work on very different margin profile and, obviously their financial capabilities also would be very different than the formulations stockists. So, I believe far more pain was probably there in the generics distributors versus the branded distributors.

Nimish Mehta: Those set of distributors are different as in for the trade generic and the branded generic?

Dr. Sharvil Patel: Yes, they are different.

Nimish Mehta: One minor question on the discontinuation of products in Moraiya. You mentioned about $10-15 million. Have we kind of seen the impact this quarter or will we be…?

Dr. Sharvil Patel: All of that impact is there in this quarter.

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

Nitin Agarwal: On the Specialty business, now with Levorphanol actually coming down to a reasonably low number, how are we looking at this business going forward in terms of adding incremental products… what is the outlook for the business for us going forward now?

Dr. Sharvil Patel: So, there are two-pronged strategies that have been our way; one is we talked about our own portfolio that we are developing. One of the products we are going to soon be able to file an ANDA on and there are still a few products that are under development which will need next one or two years. So, our core pipeline is going to take at least around two years to fructify in terms of having a good, decent scalable pipeline. Till then we are actively looking at in-licensing products and we have some good ongoing ideas and discussions going on, on that and we are potentially looking for some acquisition also in our area to overcome the next two years gap in portfolio.

Nitin Agarwal: You mentioned that in the fines business is a pretty heavy quarter from a revenue perspective in Q1. Does it have correspondingly high component of other expenses also in this quarter?

Dr. Sharvil Patel: Yes, it does.

Nitin Agarwal: So, ideally, we should see some of that moderation also coming through as the revenue from the business comes off in the coming quarters?

Dr. Sharvil Patel: Yes, you are right because lot of them are sales-linked. So, once the absolute sales come down, some of those costs also come down.

Nitin Agarwal: You said one-third of the business comes in this quarter. How does the other three quarters really play out from a seasonality perspective on this business?

Dr. Sharvil Patel: So, I said, Q4 and Q1 are the large quarters because of Glucon-D and Nycil which are seasonal in nature. The large part of Q2 and Q3 sale of the acquired business comes from mostly Complan and some pretty sales. So, that is how the mix of the business is. For Zydus Wellness current brands, I would say they are more even in terms of their QoQ.

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

Vishal Manchanda: So, this is regarding Mesalamine 800 mg, Asacol HD in the US. I could see that you have launched that product under a brand name called ZALDYON in the US. Any reason to promote it under a brand name?

Dr. Sharvil Patel: First of all, you are getting the names wrong. So, I do not think we have any of that brands. It is Asacol; it is not LEFLU whatever brand you are talking about. But that Asacol HD that is not the brand that you are talking of?

Vishal Manchanda: Asacol HD, but I could see your own brand for that product, this is ZALDYON.

Dr. Sharvil Patel: No.

Moderator: Ladies and gentlemen, that was the last question. I now hand the conference over to Mr. Ganesh Nayak for his closing comments. Sir, would you like to add any closing comments?

Ganesh Nayak: Thank you very much. It was nice interacting with all of you and looks forward to interacting with you again after this quarter's results. Good night and have a nice weekend.

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