“Cadila Healthcare Limited Q3 FY20 Post Results Conference Call”

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Moderator: Ladies and gentlemen, good day and welcome to the Q3 FY20 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 that this conference is being recorded. I now hand the conference over to Mr. Ganesh Nayak – COO & Executive Director of Cadila Healthcare Limited. Thank you and over to you, Mr. Nayak.

Ganesh Nayak: Welcome to the first earnings call of 2020 and I wish you all a very prosperous year ahead. We have with us Dr. Sharvil Patel – Managing Director; Mr. Nitin Parekh – Chief Financial Officer; Mr. Harish Sadana - Chief Strategy Officer & Vishal Gor – Senior Vice President-Corporate Finance.

During the third quarter of FY '20, we posted a consolidated revenue of Rs. 36.4 billion, up by 8%, adding Rs. 2.7 billion over Rs. 33.7 billion reported in the previous quarter. On the back of this increase, consolidated EBITDA grew to Rs. 6.93 billion, up 11% on a sequential basis, adding a delta of Rs. 676 million over the previous quarter. Overall, we expanded our EBITDA margins by 50 basis points to 19.1% against 18.6% registered in Q2 FY '20. The resultant consolidated PAT for the quarter was Rs. 3.74 billion, up 18% on a sequential basis. Our India geography comprising of human health, consumer wellness and Animal Health has grown by 24% on a year-on-year basis, registering a revenue of Rs. 13.7 billion.

On a comparable basis, our business in India in the Indian geography grew by 7% during the quarter. The U.S. geography comprising of generics and specialty, registered a revenue of Rs. 16.8 billion, up 16% on a sequential basis. Our rest of the world business, comprising of multiple emerging markets grew at 18% year-on-year during the quarter. On a sequential basis, the business grew by 21%.

Now let me take you through the operating highlights for each of our business lines. Starting with our human health business in India geography. Our strategy of restructuring our India formulations business between mass and specialty has started showing signs of some early successes. Further, the execution focus started by revamping our sales operating system has also shown good progress. As a result of these initiatives, our branded human health business grew by 9.6% on a year-on-year basis during the quarter.

As per the AWACS data, the business grew by 12.1% during the quarter, outperforming the overall Indian pharmaceutical market growth of 9.5%. In terms of therapeutic performance, our gynecological, gastrointestinal and pain management portfolio grew better than the market. Getting into specifics, our gynaec portfolio grew by 10.1% versus the market growth of 7%. Our gastrointestinal portfolio registered a growth of 9.5% vis-a-vis the market growth of 8.1%.

While the growth in the pain management portfolio was 15.2% as against the market growth of 9.7%. Our cardiac portfolio grew at 10%, which was in line with the market.

On the brands front, our pillar brands having annual sales in excess of Rs. 500 million each continued to grow in double digits with 11% growth during the quarter. Mid-sized brands having annual sales between Rs. 250 million and Rs. 500 million also grew in double digits, with 14% growth during the quarter. Overall, our human health business is showing good promise, and we intend to maintain this momentum in the coming quarters.

On the consumer wellness front, Zydus Wellness business posted sales of Rs. 3.24 billion during the quarter, up 129% on a year-on-year basis. The focus during this quarter primarily was on scaling our go-to-market model to double our direct reach, integration of supply chain operations, including CFA consolidation, and also the upgradation of our ERP system with implementation of SAP and the S/4HANA in line with the requirements of increased scale and complexity.

We are happy to report that we could finish these initiatives in time to ensure that we are ready for the upcoming season across the value chain. Our Animal Health Business bounced back during the quarter as the business grew by 9.1% year-on-year to Rs. 1.4 billion during the quarter, after going through a couple of quarters of muted performance.

Now let me take you through the performance of our U.S. formulations business. As mentioned earlier, the overall business grew by 16% on a sequential basis. The growth was driven by market share gain in some of the key products, increase in the sales of Oseltamivir on account of the flu season and launch of new products during the quarter.

Excluding the specialty portfolio of Sentynl, the business grew by 17% on a quarter-on-quarter basis. According to the latest IMS, we are now the fourth largest generics company in the U.S. in terms of prescriptions. We launched 9 new products including Day-1 launch in the U.S. during the quarter. We filed 14 additional ANDAs with the US-FDA, taking our cumulative number of filings to 386 and received final approvals for 6 new products and tentative approvals for 2 new products from the US-FDA during this quarter.

Coming to our emerging markets business, we launched 3 new products in Brazil and one new product in South Africa. Major brands of all the key markets grew in double digits, which contributed to the overall growth. Our biologics portfolio continued its momentum and recorded a sale of Rs. 737 million during the quarter.

Now on the operations and compliance front, we continue to take all the remediation measures necessary to address the observations raised by the US-FDA in the warning letter issued to our

Moraiya formulations facility. And we have also sent them the periodic updates to brief them about the actions which have been taken by us against the commitments made to them.

As shared with you earlier, we have already initiated site transfer of all our injectable products from Moraiya to Liva and expect the same to be over by the end of FY '20. We continue to maintain our successful track record of regulatory compliance at our other facilities. During the quarter, our Topical Formulations Manufacturing Facility, and one of the API manufacturing facilities, completed the US-FDA inspections without any observation.

Coming to the inspections done by other regulatory authorities, one of the API manufacturing facilities successfully completed the WHO audit, while the Biologics Finland Finnish facility, completed the audit by the Mexican Authority COFEPRIS for 4 products during the quarter.

Now this concludes the business review, and I would request Dr. Sharvil Patel to take you through the progress and initiatives in our innovation program.

Sharvil Patel: Good evening. In line with our strategy to focus on innovative products and technologies, we continue our thrust on taking our lead NC molecule, Saroglitazar Magnesium to additional indications. In fact, just a day before, we received the approval from the Drug Controller General of India for the use of Saroglitazar Magnesium in the treatment of Type 2 Diabetes Mellitus. In the month of December 2019, we filed a new drug application of this molecule with the DCGI for non-alcoholic steatohepatitis, NASH indication. This is the first NDA filed with any regulatory authority across Asia, and only the second across the globe for NASH indication.

Recently, the committee of the 29th Asian Pacific Association for the Study of Liver has selected the abstract of the study of Saroglitazar in NASH for an oral presentation. In the month of November 2019, we made a presentation of Saroglitazar in NAFLD at the American Association for the Study of Liver Disease, AASLD, Boston, as a molecule, achieved statistically significant improvement compared to placebo in its primary endpoint. The paper was selected as a part of the best of NAFLD and NASH debrief given by the AASLD. For our other novel molecule Desidustat, we have initiated a Phase III clinical trial in India, targeted at the treatment of anemia in dialysis-dependent CKD patients.

Recently, in the month of January 2020, we entered into a licensing agreement with the China Medical Systems Holding Limited, CMS, for the development and commercialization of Desidustat in Greater China for the treatment of anemia and CKD patients who are not undergoing dialysis as well as those who are on dialysis. On the biologics front, we initiated preclinical studies for one biosimilar, and submitted an application to the Department of Biotechnology for conducting preclinical toxicity for one more biosimilar drug during the quarter.

Talking about vaccines, we have submitted the dossier to DCGI for obtaining the marketing authorization for the Pentavalent Vaccine during the quarter. We have also received regulatory permission to conduct Phase I clinical trials for the HEP A vaccine and the Hepatitis E vaccine during the quarter.

Coming to our 505(b)(2) and in-licensing initiatives, we have developed a portfolio of innovation-driven 505(b)(2) molecules and products. The portfolio comprises of novel concepts offering incremental innovation and fulfilling unmet medical needs. Our focus is to address these medical needs, enhancing patient ease and offering better treatment options to physicians.

There are more than 15 products in the different stages of development with a focus on neurology, pain management, dermatology and orphan diseases. We are targeting to submit one NDA every year post-2020. Our first NDA is likely to be ready for submission by December 2020. During the quarter, we have submitted a pre-IND request for one more molecule.

During the quarter, we also entered into two co-development and licensing agreements for one, an oral oncology product, and one injectable product. Subject to approval, we will get exclusive marketing rights for both of these products.

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

Moderator: Thank you very much, sir. Ladies and gentlemen, we will now begin the question-and-answer session.

We have the first question from the line of Hari Belawat from Techfin Consultants. Please go ahead.

Hari Belawat: This is regarding acquisition of Heinz India, this was in January '19. It was acquired at a total cost of something like Rs. 2,575 crores. What is the status of that? Is it fully integrated in the group? One; second thing is, does the consolidated results also include this? And what is the turnover and profitability of this section, this division of Heinz?

Sharvil Patel: So the integration largely is completed. Now the final stages of Salesforce integration is ongoing. The results, obviously, include the consolidated revenues of Zydus Wellness as well. And their sales revenues are in the range of Rs. 300 plus cores.

Hari Belawat: How much good margin is available in this acquisition?

Sharvil Patel: Yes.

Ganesh Nayak: See, actually, we have a separate telecom for Zydus Wellness Limited. And in this conference, we just briefly make a reference to that, but detailed questions, we can take it off-line.

Moderator: Thank you, sir. We have next question from line of Aditya Khemka from DSP Mutual Fund. Please go ahead.

Aditya Khemka: Sir, on the India business side, so once now that you have got the diabetes indication for saroglitazar, what should we expect from the product? I mean, diabetes, molecule wise, is a pretty crowded space, there is gliptin, there is oral antidiabetics, et cetera. So where does saroglitazar fit in the scheme of things? And what is your expectation from the product?

Sharvil Patel: So it is not going to be the first-line treatment for diabetes. So as a second line treatment, it will compete with the whole pioglitazone market and also, to some extent, the DPP-4s.

Aditya Khemka: So do you have like a number as to how big that market is in India, the second-line treatment for diabetes?

Sharvil Patel: I would hazard a guess, but it is in more than Rs. 1,000 crores. But it is significantly larger. I mean I do not have the exact number right now, but it will be at least, I mean, it will be significantly larger. I can ask Vishal to give you that market size.

Aditya Khemka: No problem, sir, I will take it later. On the U.S. business this quarter, so this $30 million incremental revenue we have seen in third quarter versus the second, fair to say all of this is coming from Tamiflu and seasonal products like Tamiflu?

Sharvil Patel: No.

Aditya Khemka: So has there been a growth in our base business because of incremental launches?

Ganesh Nayak: Yes. In fact, in my statement, I did make a mention that this increase has come from volumes, some new products, as well as products like Oseltamivir, where we have sold more.

Aditya Khemka: Yes. So I am just trying to get a sense of, Ganesh sir, as to how much is coming from both these halves. Is it like equally divided? Or is it tilted more towards Tamiflu than the base business and otherwise?

Ganesh Nayak: See these new products have given us 1% growth over the previous quarter, and rest of them are equally distributed between these two. And before somebody asked this question over the previous quarter, the price erosion has been 1.8%.

Aditya Khemka: And one last question on the cost side. So if I see the growth in the other expenses and employee costs, so employee cost is growing at 18% YoY this quarter. And you have 26%

inflation and other expenses also. What is driving such a high amount of expenditure? And I mean, is this like a growth that we normally would sustain?

Management: So other expenditure as well as HR costs include costs related to Heinz acquisition in terms of their HR costs and their other expenditure. Also, we have, during the current year, capitalized commercialized Zydus technology operations, which results are consolidated with our results as 100% subsidiary.

Reason is that our other expenditure, last year same quarter because of lower performance of India business, we had curtailed some of the expenditure, which now because we are in a good growth trajectory, we have spent those marketing-related and other spends.

Sharvil Patel: And on the HR, because Heinz was not there as part of last year, obviously, we would see a growth on HR cost.

Aditya Khemka: Yes. So just one small clarification on that sir, so Heinz is a highly seasonal business where two quarters give you a bulk of your revenue. And I am assuming a sales force of Heinz or the promotional ad spend on Heinz would also be seasonal in nature. Is that not a correct assessment?

Sharvil Patel: There is some seasonality, but for Complan it is throughout the year. And the last two quarters, as a percentage to sale, it looks larger because the revenues are lower, but the cost and the A&P is higher on Complan.

Moderator: Thank you, sir. We have next question from the line of Kunal Dhamesha from SBICAP Securities. Please go ahead.

Kunal Dhamesha: This is related to the China situation. So I would like to know what is our vertical integration in terms of API for our pharmaceutical business, and does it differ between geography to geography in terms of U.S. might have a higher integration versus India business?

Sharvil Patel: So on a broad basis, on the API front, we do not have any significant exposure to China because a lot of our APIs are backward or sourced not from China. So we do not see a major impact on API on account of the disruption that may happen in China.

And for most of the critical businesses like U.S. and India, in terms of size and scale, there should not be an issue because of API, but we are still evaluating on the intermediate sourcing of many of these because they will, in the future, may get affected.

Kunal Dhamesha: Okay, so even if, let us say, we do not have API issues, we might have intermediate issue if the supply is not there for maybe how much days? Any indication there? How much?

Sharvil Patel: We are okay up to 60 days. We have depending on the molecule, but we have covered for some longer. But at least for the next 60 to 90 days, we have a cover.

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

Surya Patra: Just wanted to know sir, the U.S. business growth. See, I believe last quarter that you had mentioned the volume growth on the base business front was around 22% or something like that. And similarly, you are maintaining that the volume growth momentum even this quarter is remaining strong. So is it possible to share what is the kind of volume growth that you are talking about YTD as well as this quarter?

Sharvil Patel: So I do not have the exact number on the volume, but the volume growth continues for this quarter also. But I do not have the exact volume, I have the value growth, but not the volume growth.

Surya Patra: Sir, just what I was trying to understand from that question is that are we getting, is it the integrated operation hence, the cost advantage which is supporting us in playing a kind of important role in the U.S. market, which is currently cost conscious? And if that is the case, then for that reason, are you maintaining the filing momentum significantly strong compared to your peer group?

Sharvil Patel: We continue to see strong volume growth in the U.S., and our strategy is to continue filing aggressively for the U.S. market. And I think it is an opportunistic market. So we are building both I mean, capabilities in terms of filing and also in terms of risk-mitigating by having multiple clients being able to service demand. So that will continue, and we see volume growth continuing in the U.S.

Surya Patra: Okay, but whether the cost advantage that you are really on the costing front, you are significantly better compared to the competition or something that sort of advantage that you are enjoying or anything on that side? And if that is the case then what is?

Sharvil Patel: We have good volumes in the U.S., which helps us being competitive in terms of cost.

Surya Patra: And sir, can you share something on your level of integration towards API level?

Sharvil Patel: So our effort is that we have at least close to 50% of whatever we sell in the U.S. in terms of value we produced ourselves. So it is an ongoing journey. We are continuously trying to second source many of the products over filing sources using Zydus' products. Our strategy is to have around 50% of value-driven out of products manufactured by us?

Surya Patra: Own APIs?

Sharvil Patel: Yes.

Surya Patra: And do you have any thought process about integrating backward to intermediate levels also? Or are you currently having, at least for few set of products? Or are you currently integrated for any chunk of your APIs to intermediate?

Sharvil Patel: As a strategy, we do have a very good relationship with our KSM suppliers. Sometimes, we have more than one KSM intermediate supplier. And we are creating a network of 10 KSM suppliers who would work in a strategic manner with our company. So that is our current plan.

Surya Patra: Sir, second question on the domestic formulation business. Say in fact, we have, in the recent past has restructured our overall domestic business into the mass segment and the specialty segment, with an intention to really do better or outpace the industry growth. So are we still in that process of restructuring or what because even this quarter, we are seeing a kind of a number which is slightly lower than the industry growth?

Sharvil Patel: So this quarter, we have not grown below industry growth, we have grown faster than industry. If you look at the AWACS data. So I do not know where you get that data from. Also, I think us restructuring is over in terms of our strategy. So now it is only execution, and we have grown better than market.

Ganesh Nayak: In fact, I had mentioned it in my opening talk, that against the market growth of 9.5%, we have grown at 12.5%. So from where did you get this?

Surya Patra: Okay, my mistake then.

Moderator: Thank you, sir. We have next question from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: First, on R&D. We are tracking north of 8% in the last two quarters. This quarter, even given the high base. So how should we look at that? Is the current quarter number more reflective of how much we will spend, given the progress we are making in the innovative pipeline and generic otherwise?

Sharvil Patel: So our year-to-date is currently still below 8%. We are at 7.8%. So we should be in the around 8% level only.

Neha Manpuria: Even for next year, sir?

Sharvil Patel: Yes. So for all our current R&D expectations, we will be around that. I have always said that if we have to do a large Phase III trial for saroglitazar, then we would be looking at how do we plan for that work. But currently, with our current expectations, we should be in around 8%.

Neha Manpuria: And can I have the net debt number for the quarter, sir?

Management: Yes, so net debt for the quarter was Rs. 6,532 crores.

Neha Manpuria: And lastly, on Moraiya, when do we expect to invite the FDA for a reinspection?

Sharvil Patel: So between by May and June, we would complete our remediation in terms of what we have committed to the FDA. And currently, we are on track to do so by May and June. So I think I would say the earliest, it would be the third quarter of the FY '21, where we could expect an FDA audit.

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

Prakash Agarwal: Just on the U.S. API sales as well as emerging market sales, there seems to be a strong traction. How much of these is sustainable?

Sharvil Patel: So both our emerging markets are on track in terms of its growth. And we expect a double-digit growth to continue in the coming year as well. And API also, what are the first business you said?

Prakash Agarwal: U.S. sir. I mean, U.S., Mr. Ganesh said, this is a part of it is Tamiflu also. So I am just trying to understand this run rate of Rs. 235 million, how much of it is sustainable or can we grow from this base also on a Q-on-Q front?

Ganesh Nayak: Yes, Rs. 235 million is sustainable. And if you are talking about the future, we are expecting growth between middle and high single digits.

Prakash Agarwal: On the U.S.?

Ganesh Nayak: Yes, only for the U.S.?

Prakash Agarwal: Yes. And the API also, quite a big jump in API in emerging market. So is there a one off there or these are like a sustainable base of what you have achieved in this quarter?

Ganesh Nayak: In the emerging markets, we were not getting approvals in Brazil, which we have started getting now. So in the last quarter, year-on-year, we have grown at 81%. And even over the preceding quarters, we have grown at 21%. And this is in spite of the fact that our Sudan is still not bearing sales. So answer to your question is, yes, it is sustainable. Why such a high-growth or good growth is because we have got approvals in places like Brazil, which is a large market. And also South Africa has done well.

Prakash Agarwal: Okay. And API, sir?

Management: On API, Prakash, API. You will have to see the year-on-year YTD growth because YTD, the growth is about 2.5%. So there was some timing effect also.

Sharvil Patel: So I think this quarter's API outside growth is not representative of the full year.

Prakash Agarwal: Okay, so we expect a double-digit growth in this segment going forward?

Sharvil Patel: In API?

Prakash Agarwal: Yes sir?

Sharvil Patel: We will be around low I mean, 8% to 10%, not higher on an external API.

Prakash Agarwal: And secondly, on the gross margin side, we have seen good sustainability of 64, 64.5, 65. This is despite U.S. has done well, all the business geographies have done well, but India has come down. So is there a one off there or again, this is sustainable? That would be helpful.

Sharvil Patel: What? I did not get the second part, when you say India has come down.

Prakash Agarwal: So on a Q-on-Q front, if you see, India has actually come down a bit, given the Q2 is normally the highest quarter for us. So from Rs. 977 crores to Rs. 910 crores, which is, I would understand that this is the highest gross margin business. So I am just trying to understand.

Sharvil Patel: So I think a large part of it is driven by the U.S. And obviously, the other businesses like in Animal Health, Emerging Markets, all have also grown well. But I would say still a good amount is driven by the U.S.

Prakash Agarwal: And lastly, on the cost front, you spoke about this saroglitazar for diabetes also. So is the footprint ready and the cost is already baked in, in the past few quarters? Or we are going to ramp up our MR, the separate divisions are being formed? Is it done or is it going to happen in terms of cost scale up?

Sharvil Patel: No. We already have these teams in the market, two teams in the market for the last, one for at least 5 years and one at least for the last 2 years. So we do not have any additional cost to launch this product now.

Prakash Agarwal: Okay, so 19% to 20% is a good margin to look at for next year, is what I am trying to understand?

Sharvil Patel: Yes, our aim is to achieve close to 20% margin.

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

Kunal Mehta: Sir, just continuing on the question one of the earlier participants asked. If I look at the other expenses, I see an increase of at least Rs. 200 crores for each of the last 3 quarters. So I am sure you have explained that some of it is because of the Heinz portfolio. But can you just throw some light on the balance portion because out of Rs. 200 crores, roughly Rs. 60 crores should be for the Heinz portfolio per quarter, and the rest, can you please, give us an understanding of that?

Management: No, it is not Rs. 50 crores per quarter for Heinz, it is substantially higher. I can get more break up for you, in terms of how much it is because of Heinz and how much of it is because of also R&D, the third factor, which obviously, Mr. Nitin Parekh mentioned was about the charging of the operating expenses and R&D expenses of Zydus Technologies, which started from first quarter of this financial year. So there is a final break up is available, I can provide to you offline.

Nitin Parekh: Also, the business mix is responsible because of the higher growth on Q-on-Q basis that you see in the U.S. business. Obviously in U.S. selling and distribution expense, especially freight is much higher than what it happens in India. And therefore, the business mix of this quarter is also responsible.

Kunal Mehta: Sir, the second question is on the India business. If one looks at the portfolio, we have made steady improvements over the last 2, 3 quarters, and that is reflected in the number as well in terms of secondary growth and the primary growth. So sir, how should we look at the EBITDA margin for this business in the next, I would say, 4 to 6 quarters?

Because I am sure at the present, you would have converted EBITDA margin, which you had earlier. But as you gain traction in these set of measures, which you have implemented to improve the productivity of the team, how do you currently look at EBITDA margins of the India business?

Sharvil Patel: Our EBITDA margins for our India business are much better than our overall company margin, which I have always stated before. The other part is that even when we had a phase of low growth, we still had seen an improvement in EBITDA margins. And our endeavor is that in the next 3 years also, we would see a good amount of improvement in EBITDA margins, even after putting in more investments in terms of sales growth as well. So you should see a good trajectory of margin improvement continuing in the India business.

Kunal Mehta: And sir, the last question is on Asacol. Do you foresee any competition in the next few quarters? Or do you expect the competition to come in once the product patent expires?

Sharvil Patel: Currently, no. Currently, from whatever we understand, we do not see any immediate competition.

Moderator: Thank you. We have next question from line of Anubhav Aggarwal from Crédit Suisse. Please go ahead.

Anubhav Aggarwal: One, just clarity on the U.S. So this quarter did have some benefit of Tamiflu. Just asking between quarter 3, basically between the December and the March quarter, which one is stronger because we are already in a good part of February seeing the flu season right now. So would you say that for Tamiflu, quarter 3 would have been stronger or March will be stronger?

Ganesh Nayak: Yes, point #1 is, it is not only because of Tamiflu. Tamiflu is only a small portion of that 16% quarter-on-quarter growth which we had. In fact, the growth on volumes is much higher. It is slightly offset by the 1.8% price erosion, which I said. Since I had to give you a complete picture, I mentioned Oseltamivir also, but it does not form a major part of the contribution to the growth. That is one. Second is, the larger sales for Oseltamivir comes in the months of January, February and March.

Anubhav Aggarwal: So absolutely, I am with you. So you mentioned when you were breaking down the U.S. sales, you mentioned that other than the new product launches, where their incremental growth was 1%, rest of the growth was divided equally between the Tamiflu and volume gains side? Adjusted for the price erosion of 1.8%?

Ganesh Nayak: Just little bit. I said it is more because of the volumes, and I just told you a few seconds ago.

Anubhav Aggarwal: Yes, it is more because of volume. Okay, understood. Second question on the Rivastigmine patch. Now it has been 2, 3 quarters since you launched. Maybe the IQVIA data does not reflect well, it does not show much market share for us. So just wanted to understand, is there a problem with the IQVIA data or is it much more difficult to penetrate the patch market?

Sharvil Patel: So we have a private label business that will start, so you will see the market share being reflected properly in a few quarters.

Anubhav Aggarwal: But as of now, is it a IQVIA problem or is it that we have not got much market share right now?

Sharvil Patel: So we still expect to get better market share, but the current market share reflected is not the current market share we have.

Anubhav Aggarwal: And for the next year FY '21, just the expectation, how many new products you have looked forward to launching?

Ganesh Nayak: In the U.S.?

Anubhav Aggarwal: Yes.

Ganesh Nayak: 30.

Anubhav Aggarwal: But if I just get it right, earlier in the year when we shared our pending ANDAs, we had about 96 ANDAs, out of which almost 1/3 are from Moraiya. And I am assuming those will not come, and we already have launched quite a number this year, right? So from the pipeline, so you are assuming that outside Moraiya, all of the products will come for approval from the other side?

Ganesh Nayak: No. Out of 30, there are 10 which relate to this Moraiya, 20 are outside of that.

Anubhav Aggarwal: The one which you are shifting, that is what you think?

Ganesh Nayak: No, these are from Moraiya.

Management: So Anubhav, the latest number is there are about 110 ANDAs which are pending approval, of which 34 are from Moraiya, remaining all, so more than 2/3 are from other sites, and we expect a good number of product approvals from other sites next year, which will help us launch these many products.

Sharvil Patel: Including partnered in products.

Anubhav Aggarwal: That is where my confusion was that this year, we would have filed almost like 20, 30 products?

Management: More than 30.

Anubhav Aggarwal: More than 30, right? So this will also be part of this 110, right? So that is what I was saying that since we filed this year, this at least will not be the ones which will be available for launch. So when you guide for 30 new launches, other than what we are filing this year and what is pending from Moraiya, then effectively 30 is very similar to what is pending from the other sites?

Sharvil Patel: I will tell you a couple of things. Obviously, we have a backlog of products which are there. Also, in what we have filed, even we will see some, we are getting first cycle approval in 9 months also, so yes, we do expect a few products, not multiples but a couple of important products, which will also go for first cycle approval. And then we have this whole backlog. So we should be without Moraiya between 20 to 25 products approval and launches, but with Moraiya, we will be about 30.

Management: Anubhav, we have about 280 approved products, and we do not have many launches. Now some of them we might not launch in the near future because of their commercial potential not being there, but others, we will be launching in due course.

Anubhav Aggarwal: Just one last clarity on the saroglitazar for NASH indication in the U.S. What is status? Our Phase III readout was good. Have we started Phase III, or we are clear that we will not do Phase III and we will partner it out or sell it out before that?

Sharvil Patel: So our plan is that in quarter 1 of FY '21, we will be going to the FDA with our plans for the next clinical phase of studies for saroglitazar. So we are in the work of preparing for that. So currently, I cannot give you any more further input because after our FDA review post quarter 1, we will be able to give you more clarity.

Moderator: Thank you. We have next question from the line of Nirmal Gopi from IDFC Securities. Please go ahead.

Nitin Agarwal: This is Nitin form IDFC. Sir, on the India business, the big challenge in the portfolio historically has been that we had a fairly large component of mature products. In the restructuring and going forward, how are you planning to get around this issue? I mean, what is the strategy for rejuvenating this portfolio?

Sharvil Patel: So if you would see the data of the market which is coming out, the mature products are also doing very well for many of the companies. So through life cycle management, and also, I think, better segmentation in terms of divisions and business units, we are able to still see growth on mature products. Also, we have a new line of reaching a low-cost model to reach further penetration, which is a new e-business unit of ours, which has a higher penetration in Tier 3, 4 and rural towns which is also helping push through some of the mature brands of ours.

And with the segmentation that we have done in terms of our clusters and the business units, we have room to grow in terms of our critical mandate brands across all the business units. So I think after all of that restructuring, I think we have given enough capacity in the teams for them to focus on between 2 to 4 molecules, each of the business units revisions.

And with the expansion into rural and some of the Tier 3 and 4, we are also seeing additional reach happening. So all put together is helping us in terms of what we are planning to do in terms of reviving growth. Also, we do have life cycle management with some brand extensions that are planned.

Nitin Agarwal: Sir, this deepening of distribution reach that you talked about, is it the trade generic channel or is it different or was in the traditional trade generic business?

Sharvil Patel: No. This is not, these are branded generic driven channel.

Nitin Agarwal: And sir, secondly, on the U.S., sir, what would be a barring Asacol, which would be our, apart from Asacol, are there any large chunky products which are there in the business now, which have a risk of erosion going forward? More than say, $30 million in size?

Sharvil Patel: Sorry?

Nitin Agarwal: I mean, sir, more than $30 million, $35 million?

Sharvil Patel: Yes, So I would say Asacol is obviously the largest, and then it would be Lialda.

Nitin Agarwal: There is no other percentage in risk in the portfolio now with?

Sharvil Patel: No, nothing on that large scale.

Moderator: Thank you, sir. We have next question from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: I was just following up from what Anubhav was saying on saroglitazar. For Phase III, I know they need to meet FDA, but roughly, how many patients would there be for NASH, U.S., Phase III? And what kind of total outlay it would involve?

Sharvil Patel: So our current strategy, we are under the discussion in terms of what strategy we follow in terms of our Phase III. So it will be too early to say because we are also evaluating a strategy in one of the orphan indications by which we could come to market early and then do a NASH ongoing study later. So I would say, in a quarter or so, I can give you more clarity. But at this point in time, it will be very tough to give you any clarity on numbers. Having said so, if it is a full-blown NASH trial, it would mean a large number of patients.

Sameer Baisiwala: Okay. Like a few hundred or few thousand?

Sharvil Patel: No, it will be around I mean, it varies, you will have to see, but it will be between 450 to 600.

Sameer Baisiwala: And Sharvil, the second question is on transdermal patches. If I got my numbers right, I think you filed for 9, and expecting 5 approvals next year? Can you update us on this? And how are they making progress in terms of FDA review?

Sharvil Patel: So transdermals, I have said before, we have been significantly delayed in terms of what we had planned for. So now we have a few contraceptive products, which are still very, very valuable, 3 of them, which are important. So we are looking at approvals for these in the next financial year. And if we are able to successfully do that, we see still a very good business

opportunity for the overall transdermal franchise. We are still filing 2 more products. So that will be currently at the end of cycle in terms of what we need to file in terms of transdermal.

In terms of CRL, we have CRLs, which we are responding by July for two of them, and one of them post July. So most of the CRLs, and we feel we have only an extractable and reachable study which FDA changed the guidelines on EML studies. So that is what we are trying to overcome now. So once we are able to do that, that is the only a rate-limiting step left for the approvals.

Moderator: Thank you, sir. We have next question from the line of Kunal Mehta from Vallum Capital. Please go ahead.

Kunal Mehta: Sir, two questions. Sir, if I look at the top 10 brands, I am sure you gave us a number that the top 10 brands grew by 11% in terms of secondary growth. But there is one brand where we are seeing a constant decrease in revenues and volumes, especially in the last few quarters, which is Skinlite. So can you just through some insight on how we are trying to protect our share in this brand and even trying to revamp it?

Sharvil Patel: So Skinlite, we are moving it to a field force for deeper penetration, into a larger field force team. And so the move of the brand has happened from one business unit to the other. And for that reason, we have seen some fall in prescriptions and fall in sales. So with the new team, we are hoping that in, not next quarter, but by quarter 1 of FY '21, things will come back to normal in terms of growth.

Kunal Mehta: So in the next few quarters, we would see at least positive prescription growth for Skinlite? Is that right? Once this exercise is completed?

Sharvil Patel: Yes, so this value growth by quarter 1.

Kunal Mehta: And sir, the second question is that if I look at the volume growth numbers across large sized companies, and by that defined companies with revenues north of $500 million in the U.S., most of them have reported very good volume growth during this quarter. So can you just give us an understanding of the situation in the market right now in the U.S.? I mean, are we seeing companies of your size experiencing good demand in volumes just because the top 3 players are now vacating a lot of products? And can you just give us an understanding on that front?

Sharvil Patel: Consistently for the last couple of years, we have seen very strong volume growth. And our belief is that we will still continue to see good volume growths for Indian manufacturers.

Moderator: Thank you. We have next question from the line of Nirmal Gopi from IDFC Securities. Please go ahead.

Nirmal Gopi: Sir, on the U.S., just following up on the previous question. Sir, are you seeing given the fact that we have an advantage of a fairly large market portfolio, I mean, are you seeing incremental opportunities to supply into shortages? And I mean, how is that? And are these kind of shortage opportunities increasing more in your experience, through the last few quarters?

Sharvil Patel: Yes. We are seeing more opportunities for share. We are also being able to revive some of the older ANDAs. So I think there is a stabilization phase in the U.S. that we are seeing right now. And I feel it is the breadth of portfolio that a company would have, it would be advantageous in terms of gaining share.

Nirmal Gopi: Sir, how many marketed products would we have in the U.S. right now on an active basis?

Sharvil Patel: Marketed products in the U.S.?

Sharvil Patel: More than 150, but Vishal can give you the exact number. Vishal will give it offline to you the exact number, but it should be more than 150.

Moderator: Thank you. We have next question from the line of Rajesh Upadhyay, individual investor. Please go ahead.

Rajesh Upadhyay: Sir, I want your view on biosimilar product launches?

Sharvil Patel: So biosimilar, currently, our major of our revenues driven out of our India geography where we have commercialized 11 plus biosimilars. We are clocking about Rs. 75 crores of revenue every quarter right now. So it is a good beginning for our biosimilars business. In most of the biosimilars that we have launched, we have a good market share.

Our next phase of growth, which will be driven will be coming out of our out-licensing of our biosimilars in a lot of the emerging markets through our partnership model that we have created, and we should see our regulatory approvals coming through in the financial year FY '21, which would then scale up our biosimilars business.

As a portfolio, we continue to develop a large number of biosimilars and novel biologics. So we have 18 plus products under development. And as I have said in my earlier opening statement that we have moved a few products into clinic and a few other products into early preclinical stages. So that pipeline development continues. And so that is how we hope to scale up our whole biosimilars franchise, and over the next couple of years, build both India and emerging markets business.

Rajesh Upadhyay: Okay. And how much we are spending currently on R&D on biosimilars?

Sharvil Patel: Rs. 50 crores or less. Less than Rs. 50 crores.

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

Ganesh Nayak: Thank you very much and look forward to interacting with you again in the month of May when we declare our last quarter results.

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