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* Nitin D. Parekh

DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare

Good day, ladies and gentlemen, and a very warm welcome to the Cadila Healthcare Limited Q2 FY '19 Post Results Conference Call. (Operator Instructions) Please note that this conference is being recorded.

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

Thank you. Good evening, and welcome to our post result teleconference for the second quarter of FY '19. We have with us Dr. Sharvil Patel, Managing Director; Mr. Nitin Parekh, CFO; Mr. Vishal Gor, Vice President Corporate Finance.

Coming to the key financial numbers during the quarter gone by, on a consolidated basis, our total income from operations was down 8% year-on-year to INR 29.6 billion.

On a quarter-on-quarter basis, the growth was 2%. Earnings before interest, depreciation and tax was down 20% year-on-year to INR 6.88 billion. On our quarter-on-quarter basis, the growth in EBITDA was 7%. Our EBITDA margin for the quarter was 23.2% versus 22.3% reported in the last quarter.

Profit before tax was down 25% year-on-year to INR 5.35 billion and on a quarter-on-quarter basis, excluding the one-off items, the growth in PBT was 6%.

Our net profit was down 17% to INR 4.17 billion and on a quarter-on-quarter basis, excluding the one-off items, the growth in net profit was 2%.

Net profit margin for the quarter was 14.1%.

So let me share some of the highlights of the operations for the quarter. Our business in the U.S. posted sales of INR 13.2 billion, down 20% year-on-year. On a quarter-on-quarter basis, the growth in the business was 7%.

We received approvals for 20 new products for the U.S. market, including 4 tentative approvals during the quarter. We launched 13 new products in the U.S. during the quarter, taking the accumulative number of launches to 22 for the year. New launches include the launch of our own mesalamine 800 milligrams DR tablets, which is Asacol HD. Prior to this launch, we used to sell an authorized generic version of this product.

Recently, on the 12th of October 2018, we launched an authorized generic version of AbbVie's AndroGel, which is testosterone gel. This product had an annual turnover of \$1 billion during the last calendar year. We filed 8 additional ANDAs with the U.S. FDA during this quarter.

Coming to our India formulations business, it posted sales of INR 8.93 billion during the quarter. For the first half of the financial year, the business posted a year-on-year growth of 17%.

We launched 11 new products, including line extensions in India during the quarter, with 2 first in India launches. Our formulations business in the emerging markets of Asia, Africa and Latin America posted sales of INR 2,034 million, up 3% year-on-year. For the first half of the financial year, the business posted a year-on-year growth of 7%. The depreciation

(technical difficulty)

is, during the current financial year impacted the growth of the AMB business. We commenced business in Indonesia with the launch of our biosimilar of trastuzumab during the quarter. We launched 5 new products in different countries of Asia and Africa and 2 new products in Mexico during the quarter.

Zydus Wellness Limited posted sales of INR 1.35 billion, up 13% year-on-year. Net profit was up 14% year-on-year to INR 411 million.

During the quarter, Zydus Wellness Limited entered into a definitive agreement jointly with Cadila Healthcare Limited, to acquire 100% of the equity shares of the Heinz India Private Limited, the subsidiary of Kraft Heinz, which will result into the acquisition of 4 brands in the food, nutrition and skincare categories.

On Animal Health business, posted sales of INR 1.34 billion, up 17% year-on-year.

During the first half of the financial year, the business posted a year-on-year growth of 24%.

On the biologics front, we received regulatory approval for 2 new products in different countries of the emerging markets.

On the new chemical entity research front, we completed Phase II clinical trials in India for Desidustat, a novel H1 FPH inhibitor in chronic kidney disease patients with anemia.

On the manufacturing front, the biologics manufacturing facility located at Zydus Biotech Park in Ahmedabad, successfully completed the U.S. FDA inspection without any observations during the quarter. Our Moraiya formulations facility also successfully completed the inspection by the Brazilian Regulatory Authority, Anvisa, during the quarter.

Thank you, and we will now start the Q&A session. Over to the coordinator of the question and answers.

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Questions and Answers

Operator [1]

(Operator Instructions) The first question is from the line of Sayantan Maji from Crédit Suisse.

Sayantan Maji, Crédit Suisse AG, Research Division - Research Analyst [2]

So I have 2 questions. So first is on the U.S. business and it's on the product Toprol XL, which we have launched in August. So currently, the market share -- volume market share stands at 5%. So do we see that in steady state, we will be able to hit 10% for this product? That is question number 1.

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [3]

Yes. The answer to that question number 1 is yes.

Sayantan Maji, Crédit Suisse AG, Research Division - Research Analyst [4]

Okay. And question number 2 is, we see that inventory days, inventory has increased, it has been increasing like it has -- it stands at 81 right now and it was in the range of 70 to 75. So what is causing the increase in the inventory days?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [5]

Well, that is mainly because of the U.S. new launches plant during this quarter.

Operator [6]

(Operator Instructions) The next question is from the line of Neha Manpuria from JPMorgan.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [7]

Sir, if I look at the constant currency sales for Cadila, it seems that we have seen marginal growth. Is it fair to assume that all of this is associated with new launches versus our existing product gaining market share? And also, could you also comment on what would be the base business erosion that we've seen in the quarter?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [8]

Are you talking about the U.S. or the emerging markets? Or...

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [9]

U.S.

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [10]

For the U.S., the erosion we have had quarter-on-quarter is 2%. And going forward also, we expect that, which would be around 8% to 10% for the year. And going forward also, we expect it in the same range.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [11]

And sir, in that case, on a constant-currency basis, the growth that we have seen, how much of that would be new products versus market share gain in existing portfolio?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [12]

This is a little bit too detailed

(technical difficulty)

with Vishal.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [13]

Okay. I'm just trying to figure out if we have actually benefited from the fact that a lot of large players are existing -- exiting products?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [14]

So what you say is right, there is a lot of supply disruption in the U.S. market, and we do see a lot of queries. But the true -- correct potential of that will be coming up in the coming quarters.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [15]

Okay. So you think that's not fully deflected in the quarters?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [16]

It's not reflected yet. There is some incremental gain, but more gains will come in the coming quarters.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [17]

Sir, what is your sense on given how INR has weakened, do you see customers probably coming back wanting to renegotiate contracts with us historically, there -- I think, you guys have mentioned that there have been instances. Do you fear that scenario playing through over the medium term?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [18]

I do not think so. Let's see. Today the situation in the U.S. is -- has many challenges on supply. So currently, the market is going through a huge disruption, partly, as you said, some players are exiting the market, the whole pressure from China in terms of sourcing and availability of products, more than cost. So today, the whole discussion is on whether one can supply the product rather than one, whether you can give a discount. So the whole discussions in the U.S. have changed to supply surety versus price right now.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [19]

Understood. And I'm not so sure if you want to answer this question here, but on the acquisition that we have announced, what is our plan of turning around the acquired business, particularly given that revenue has been lagging?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [20]

I'll just answer it briefly. The business that we acquired other than Complan, which did face headwinds in the last couple of years, the other 2 brands have -- major brands have grown better than market and have gained share over the period of a few years. Also in the last 6 months, the performance on all the categories is in double-digit growth. So there is a revival that has happened, at least, for the last couple of quarters. And going forward, with what -- with the innovation and other things that we hope to do with the business, we should see momentum going up in the next couple of years.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [21]

Okay. So you don't see a risk to the 20% margin that the business is making right now?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [22]

Currently, no.

Operator [23]

The next question is from the line of Sayantan Maji from Crédit Suisse.

Sayantan Maji, Crédit Suisse AG, Research Division - Research Analyst [24]

So personal -- so other expenses, they have come down sharply if I look at quarter-on-quarter or year-on-year. So typically it happens when we have reduced incentives in India. So is it the case? Or is there some other reason why the other expenses have come down extraordinarily?

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [25]

Other expenses, quarter-on-quarter have not come down very sharply. There are certain cost-saving programs which we are running in the company, both in formulations and APIs, which have contributed to this kind of optimization of the cost.

Operator [26]

The next question is from the line of Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [27]

First question is on Tamiflu. Given that now there's 7 players or so dynamics in this -- for this season, including 3, I think, new approvals in 2018. How does the opportunity look like over next 2 quarters?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [28]

Could you repeat your last part please?

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [29]

Do you think Tamiflu is going to be an attractive opportunity this flu season? Given that now it's a 7 player or so player market at the moment?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [30]

So we have secured our business in terms of market share. So that we are very comfortable with. Obviously, pricing will play the role depending on the competition. On the suspension part of the business, again, there is still very limited competition, so we will still attractive business there. On the oral product, obviously, there is competition, but we have secured market share.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [31]

Okay. And the pricing would be determined as we go along, is that the...

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [32]

Yes, you're right.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [33]

Okay. Sharvil, but would you think that the pricing can fall as much as 80%, 90% because of the 7 player dynamics now?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [34]

So I think better we will know in the coming quarter, but -- so it would be very difficult to say, but there would be competition, but depends how many people are ready with stock and what inventory can they supply. And we have some assured business, so there would be an impact to the 80%, 90% looks too high, but we'll only be able to tell you in the coming quarter whether it was a significant impact or not.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [35]

Okay. And the second question is on Asacol HD. So have you switched your entire share with your product or it's only partly that's been shifted? And how -- and we have not seen the concomitant benefit in the margins, so does it reflect the 2 month, 1 month of switch?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [36]

So first of all, we have switched completely and it -- we switched in...

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [37]

August.

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [38]

August, so it shows -- it's about 1.5 month, 2 month reflection.

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [39]

1 month.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [40]

Okay. And then again on Lialda. What kind of competitive action are you seeing from Teva and has Mylan joined in, both in terms of pricing and volumes?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [41]

Currently, we are not seeing any -- we don't hear anything from the market. We assume there could be a launch in the -- in this coming quarter, but we have not heard anything yet.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [42]

And you're referring to Mylan when you're saying that, Teva is already in the market?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [43]

Yes, Teva is already in the market. I mean, who -- -- one more competitor is in our base case scenario, but currently, you do not hear anything on it.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [44]

So Sharvil, even Teva, if you see their market share, it's very, very low, abysmally low. So are they present in any serious measure? Or...

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [45]

I believe that the product has significant challenges in manufacturing and meeting the tight specifications that are required, and I assume companies are facing those challenges.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [46]

Okay. That's a very good news for you, but I'm just wondering, so when they come in, they take their prices down and then are unable to supply. So you maintain your market share, but have you lost on the pricing on this product?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [47]

I think in pricing, we have been able to -- it has been fair, I would say. The market share loss is very less. So I'm assuming there is supply issue in the market.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [48]

Okay. Fair enough. And one final question from my side. Sharvil, it looks pretty clear that U.S. is going through disruptions, supply, et cetera. But you're really speaking tilt the bargaining power more in favor of manufacturers versus the buyers? But if you see a price erosion, 2% quarter-on-quarter and 8% to 10% for the year, that really doesn't reflect, as so you still have got to a level of bargaining power. I mean because of all these disruptions, could you simply not say no to any price cuts in a way to say?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [49]

Well, see, one has to look at the -- so I would say, on the mature portfolio, we do not see price erosions and there is supply disruption, which is leading to extra opportunities of one-time buys and one-time sale. But if you have launched new products where you had limited competition and if then some more players come in, obviously, so it will depend on which ecosystem or which lifecycle the company is in. So since we have launched a lot of products and from many of the products in the last couple of years, there would be some erosion that you would have see with entry of competition, like potassium nitrate and some others in more competition did enter, or Tamiflu, when more competition has entered. So -- but I would say, it's a modest degrowth that has happened. But you can -- from my interactions that I've seen in the U.S., we hold discussions from price change to supply. So that bodes well for the company that have a good supply chain.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [50]

And when you say 8% to 10% erosion, you are including the price drop in these large concentrated products as well?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [51]

Current, yes. We'll be -- I mean, yes, the currently -- from current business point of view, yes.

Operator [52]

The next question is from the line of Alok Dalal from CLSA.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [53]

One question on U.S. So you have been maintaining that the U.S. sales in FY '19 will be higher than FY '18. Do you still maintain that?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [54]

In the financial year, it could be more flat depending on if the competition enters.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [55]

And this is in dollar terms?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [56]

Yes, dollar terms.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [57]

Okay. Second question is on the acquisition for specialty that you had done about 18 months back, that is Sentynl. Any update you can share? Any progress that you've made with this?

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [58]

It is going well so far. So it is more than the projections we had when we acquired this. That is all I could say at this time.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [59]

And how is the strategy shaping up for this segment?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [60]

So we have, and we said earlier, we are -- had two-pronged strategy: One, is to create an internal pipeline, which we can bring with this team and even expand the team when we are able to bring portfolio. So we continue to work on the areas of pain, supported GI and Onco, so adjacent categories to that and look at some more orphan drugs. So that we can continue to pursue both from a licensing opportunity or acquisition and also our internal development. We were able to launch one of our 505(b)(2) programs with a partner and we have another 2, 3 days, we've finished FDA pre-IND discussion. So we hope that we'll be able to create a basket in the next 3 years, which we can organically build on to this. In the meantime, we continue to keep looking at the opportunities that we see in the market and we do bid for a lot of them, though we have not been successful because our bids have not been that aggressive.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [61]

Okay. And one last question is on biosimilars for Europe. So yesterday, AbbVie mentioned or rather there are news flows that for Humira, there is up to 80% discount from the innovator. Now with this aggressive strategy from the innovator and Cadila being in the second wave of launch in Europe with respect to biosimilars, how do you see yourself playing out in the market with such an aggressive strategy from the innovator side?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [62]

So, yes, I have also heard the similar news about the higher discounts that have been given by the brand. Our current strategy is that we will be building our biologics and, more specifically, the biosimilars business in India in emerging markets. So currently, other than getting FDA and EMA advice on some of our programs, definitely not on Adalimumab, but on Peg G-CSF we have got those advices a couple of monoclonals and cytokines. But we have not put any money behind investments on clinical trials for any of these molecules. We would only do so if we have a potential partner to partner with for the developed market.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [63]

So currently, it will be, yes...

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [64]

(inaudible) It will be given by India in emerging markets and we have a good traction with many approvals and us being able to launch trastuzumab in Indonesia, where we would get probably significant share from the market in the immediate year.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [65]

Okay. And sticking onto India and biosimilar, you've launched quite a few of them now. Is it reflecting well in your revenue numbers?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [66]

It's growing very well. It's currently at about 4% of to -- yes, 4% of our business, growing at about 25%, 30%. This quarter was a difficult quarter for us because, as we mentioned, for the first half, we have grown at 17% for India, but we had almost a 1.5% to 2% GAAP because of nonavailability. And that happened because we had an upgradation of a biologic facilities, which had gone under shutdown and unfortunately, we took a little longer to bring operations back post the shutdown. But the business is doing very well and if you look at the resource data, we have gained significant share in both the therapies of autoimmune and oncology, where in autoimmune, we have the largest number of patients that we are capturing as a therapy now. And obviously, oncology, trastuzumab continues to do significantly well and with the launch of bevacizumab, also we gained good share. This was -- there was a disruption in this quarter, which we hope we will strongly recover in the coming quarter. In spite of that, we had a good growth.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [67]

Okay, sure. And just one last thing, have you clarified Cadila's role in the acquisition that Wellness is making in the sense about the funding?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [68]

So the exact funding is still getting discussed between the board of Zydus Wellness and once they propose something to Cadila Healthcare, we will speak more about this. But broadly, we have said that 1/3 is going to be debt and 2/3 is going to be by equity infusion and with the partner like (inaudible) coming in as well. So we assumed right now that Cadila Healthcare's participation in order for it to maintain its ownership in the structure would be around INR 1,000 crores to INR 1,200 crores of infusion of capital.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [69]

From Cadila's side, yes.

Operator [70]

Next question is from Aditya Khemka from DSP Mutual Fund.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [71]

And I had 3 questions. Firstly on your comment on the base product or the legacy products in the U.S. Did you mention that on the older products or the mature products, you're not really seeing any price erosion because of scarcity of supply and therefore, it is stable in terms of pricing?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [72]

Yes. So far, yes.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [73]

Okay. Which means that if you are saying that you're facing 2% price erosion quarter-over-quarter in the U.S. business at an aggregate level, on the more -- newer products recent launches, complex launches, you're facing higher price erosion, is that the correct influence?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [74]

Yes.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [75]

Okay. My second question is around Lialda. So you said that Teva hasn't really garnered much because of what you're assuming to be supply issues. Therefore, I -- therefore, as a corollary, would it be correct to assess that the pricing of the Lialda generic in the market wouldn't have corrected at all?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [76]

Not significantly.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [77]

Not significantly as in single-digit? Is that..

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [78]

I won't be able to give that information. But there is -- it is not -- there's a share, it's so proportionately small, it's been not a significant erosion.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [79]

Fair enough. And as a corollary to that question, actually, so if I look at your switch from Asacol HD -- AG to Asacol HD own in ANDA, and Lialda not facing much pricing or market share erosion, quarter-over-quarter the EBITDA -- and you're India sales being higher in Q2 versus 1Q, so quarter-over-quarter, your EBITDA margin or the absolute EBITDA actually doesn't show a significant delta to reflect the own sales of NAG or own sales of Asacol or increased India sales? I mean, the delta is only INR 40 crores in EBITDA. So what would explain that?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [80]

For the India business, quarter-on-quarter has not had anything in significant increase, so it's the same. So I don't see the -- so there's no increase from last quarter to this quarter. And even the U.S. business has had a -- not a -- has had a 7%, so not a significant increase.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [81]

No, I meant the profitability of Asacol HD versus profitability of Asacol ANDA. Your own ANDA profitability...

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [82]

There has been a 1% improvement in GC.

Nitin D. Parekh, Cadila Healthcare Limited - CFO [83]

So Aditya, EBITDA margin compared to Q1 has improved in Q2.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [84]

Yes. My point was, it has -- it is probably not as significant as it should have been given that you launched your own ANDA in Asacol, which is a large ticket product, I assume.

Nitin D. Parekh, Cadila Healthcare Limited - CFO [85]

So Aditya, even Asacol HD, the reflection will be for about 1, 1.5 month in this quarter.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [86]

Okay. So coming quarter, we should see that coming through basically as the...

Nitin D. Parekh, Cadila Healthcare Limited - CFO [87]

Yes, a part of. Yes.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [88]

Full quarter impact comes. Okay, fair enough. And the third question is on what the previous participant was asking in terms of financing the Heinz acquisition. So you said about INR 1,000 crores to INR 1,200 crores will go from Cadila Healthcare to Zydus Wellness. This would be -- how would business slip between equity and debt?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [89]

So that exact detail, I said it'll be 1/3 debt, 2/3 equity for Zydus Wellness. There will be a participation by (inaudible) as well. So that's a broader, I mean, more details, once the board is able to finalize the decision and share it with the shareholders, we can give you better clarity. But this is broadly the way we have envisaged it.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [90]

Right. Sorry, one more if I may, on the R&D expenses. So again, there is significant volatility between quarters and I understand, that happens due to drug -- no, clinical trials, et cetera. But could you guide me to an absolute number or a percentage of sales of R&D for the full year FY '19 and FY '20?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [91]

There'll be around 7% to 8% as a share of revenue.

Operator [92]

The next question is from the line of Takesh (inaudible) from Axis Capital.

Unidentified Analyst, [93]

So just to continue with previous participants' question on U.S. guidance. So we recall that in previous call, previous earnings call, we had mentioned about -- we had guided about 50 to 60 launches in FY '19 and the 1H launches in '22, so probably, we need to fill up more 28 to 38 launches. And apart from that, given the guidance of U.S. sales in dollar terms being in FY '18 level, so which was around USD 900 million, and we have done somewhere around USD 372 million in 1H. So can you please guide, like how we will be taking care of the remaining USD 480 billion, USD 530 billion sales and with the pending launches. So are we targeting at some high-value launches or more number of low-ticket sized launches? So how -- can you please reguide on that?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [94]

So we -- for the next half, we will still be launching 30-plus new products, so which will be of a higher run rate than the current run rate, which as there are some important launches in that period as well. Also, we have been able to launch an authorized version of AndroGel, which also will add good value to the revenues.

Unidentified Analyst, [95]

Okay. So you still maintain the guidance in terms of the revenues as well as the launches for the full year?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [96]

Yes. 30-plus launches, yes.

Operator [97]

The next question is from the line of Sayantan Maji from Crédit Suisse.

Sayantan Maji, Crédit Suisse AG, Research Division - Research Analyst [98]

I just had one quick query on the FDC ban impact. But has been the impact on our India sales? Has there been any impact for this quarter?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [99]

So it has not been significant, but we did have about a few molecules that were discontinued, prior to the ban we had already done so. The exact details, I will ask Vishal to share it with you.

Operator [100]

The next question is from the line of Ashish Thavkar from Motilal Oswal Asset Management.
(technical difficulty)

Ashish Thavkar, Motilal Oswal Asset Management Company Limited - Associate VP [101]

Sir, could you help us understand, where are we in terms of monetizing trans business revenue?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [102]

So we expect 1 or 2 launches in the second, I mean, the second half of this year.

Ashish Thavkar, Motilal Oswal Asset Management Company Limited - Associate VP [103]

Okay. The U.S. FDA has come out with a guidance on transdermal. So you feel the pending basket that we have, we should -- that should accelerate now?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [104]

Sorry. The last part, existing basket should what?

Vishal Gor, [105]

Accelerate.

Ashish Thavkar, Motilal Oswal Asset Management Company Limited - Associate VP [106]

But the pending pipeline of transdermal, that should like -- that we should see more approvals coming through now?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [107]

So we -- if the FDA has made a lot of changes to the guidance and so far with all CRLs that we have respond to, we have met up -- met with the current guidelines, which has been the reason for many of the delays.

Ashish Thavkar, Motilal Oswal Asset Management Company Limited - Associate VP [108]

Okay. Fair enough. Now next question is on India. We have had a very good growth in the first half, so would you be guiding anything for the full year?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [109]

Sorry. Can you repeat the first part of your question?

Ashish Thavkar, Motilal Oswal Asset Management Company Limited - Associate VP [110]

Do we guide for the full year India revenues in terms of growth percentage?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [111]

So we are hoping, obviously, we will -- first half has been good and we hope that we'll continue with better-than-market growth.

Ashish Thavkar, Motilal Oswal Asset Management Company Limited - Associate VP [112]

Okay. And market growth as per your understanding would be?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [113]

7%, 7%. Current market growth is 10% to 11%.

Ashish Thavkar, Motilal Oswal Asset Management Company Limited - Associate VP [114]

Okay. 10% to 11%. Okay. Fair enough. Sir, I think last question on Lialda. In the near term, do we see any incremental players entering the space?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [115]

We assume there could be one more player coming, but we don't hear anything right now.

Ashish Thavkar, Motilal Oswal Asset Management Company Limited - Associate VP [116]

Okay. And then you feel so -- even that player would be having the same issues for -- same issues?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [117]

I wouldn't know that. But so far, nobody has entered. So -- but I don't have a view on what would be the issues with different companies.

Operator [118]

The next question is from the line of Jatin Kotian from Emkay Global.

Jatin Kotian, Emkay Global Financial Services Ltd., Research Division - Research Analyst [119]

Just wanted to clarify, you mentioned about launching AndroGel AG, could you just repeat that? Sorry, I missed that in your opening comments.

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [120]

We have launched the authorized generic of AndroGel, which is from AbbVie, which had in the last 12 months a sale of \$1 billion. And for us, it is a good opportunity. In fact, Perrigo has the 180-day exclusivity, so they also launched it on the 12th of October. So between the 2 of us, we should be sharing the generic portion of the opportunity.

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [121]

Speaking about the capability of the U.S. team in terms of gaining market share that we've been able to -- every couple of year and an authorized generic work portfolio as well.

Jatin Kotian, Emkay Global Financial Services Ltd., Research Division - Research Analyst [122]

Okay. And -- sorry, would you have your own filing on this product as well?

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [123]

No.

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [124]

No.

Operator [125]

(Operator Instructions) The next question is from the line of Chirag Dagli from HDFC Asset Management.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [126]

Sir, for the first half, what has been -- what is the adjustment that we need to make to the -- for GST to look at like-on-like growth? Or is the 17% like-on-like?

Nitin D. Parekh, Cadila Healthcare Limited - CFO [127]

So the GST impact was there only in Q1 of last year. So only Q1 of last year was ex-GST.

Unidentified Company Representative, [128]

That's right.

Nitin D. Parekh, Cadila Healthcare Limited - CFO [129]

So it would be for the -- entire half, it would about 1.5% to 2%, or more than that.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [130]

So we have to add 1.5% to look at like-on-like growth?

Nitin D. Parekh, Cadila Healthcare Limited - CFO [131]

You're right.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [132]

Okay. Sir, if I look at your asset base over the last, say 3, 4 years maybe, both working capital as well as the fixed asset base has broadly doubled, while your profits have not increased at that pace and, also importantly, a large part of this profit comes from a few products in the U.S. How should we think about capital efficiency as we get into next few years? How do you intend to improve the utilization of some of these assets? And more importantly, where is it that these investments have been made?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [133]

So to -- so there are a couple of investments that we have made where we still have to commercialize these assets. So our injectables facility, which has come up in Baroda, which is Liva, and our transdermal facility that we have in SEZ, obviously, have still not commercialized any product. So that will come -- start from the coming calendar year in -- so FY '20, you will

see some of these getting commercialized. Then the investments that we have made on the vaccines front, where we have very little revenue right now, but we have 9 approvals that we are now -- started launches, the 2 launches already happened. And with the scale up of rabies vaccines and other things also, we would be launching about 4 to 6 products very soon. So commercializing of that is starting, and we see a significant opportunity in the next 5 years, where both the transdermal, I mean, the biologics and the vaccines business could be \$500 million of business. Which we'll then obviously talk about this. Now you to understand, for all these businesses, the investment happens very upfront from the facility point of view and the clinical aspect point of view. So -- but we are making strong bid on India. On the biologics, we already started strong commercialization in India. We are market share leaders in many of the products that we are selling. We have very good partnerships in emerging markets and we have been able to be the -- in the first wave, for example, trastuzumab in Indonesia, we're in the -- we are the first generic to launch in that market. Similarly, we've been doing so in many of the emerging markets. And we have had a good licensing income coming through for this as well. We hope we will also commercialize the same way our vaccines business. And so put together, these businesses in the next 5 years will become significant for the company and also differentiated from the normal generic.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [134]

Sir, did you say \$500 million potential for biosimilars and vaccines put together?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [135]

\$500 million.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [136]

Dollars? U.S. dollars?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [137]

Dollars, yes.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [138]

Over 3 years, sir?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [139]

5 years.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [140]

Over 5, okay. And sir, your comment on profit dependence on a few products and then you've now embarked on this large capital commitment to the Heinz business. How should we think about.

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [141]

Cadila Healthcare doesn't have any large capital commitment to the Heinz business.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [142]

Okay. So that -- all that -- so there is no incremental capital that we'll commit from the Cadila balance sheet to the -- to Wellness or to -- for this -- for consummation of this?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [143]

Cadila Healthcare will probably invest up around INR 1,000 crores to INR 1,200 crores in form of capital and not more than that, which is not significant from Cadila Healthcare point of view.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [144]

Fair point, sir. And then the last question, sir, you indicated in your earlier comments, transdermal, you expect to launch from this year, second half. How will this change the depreciation charge? Because I understand all this investment is in CWIP, right?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [145]

Yes. So Vishal can give you that. Once we are nearer to launch, we can give you that detail.

Operator [146]

The next question is from the line of Harith Ahamed from Spark Capital.

Harith Ahamed, [147]

So on the acquisition of Heinz business, you mentioned your commitment -- capital commitment will be -- will not be more than INR 1,000 crores to INR 1,200 crores. Is it safe to assume that you will be looking to maintain your current ownership in Wellness opposed the transaction? Is that a right assumption?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [148]

At current -- currently, I won't be able to answer that, but broadly, there would be some dilution. But we will continue to own majority.

Harith Ahamed, [149]

Okay. And then you had mentioned about a preapproval inspection for a biologic drug at your biologic facility. Can you give some color on which product this is?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [150]

So it is -- we are -- FDA audit went through successfully with our biologics facility. We didn't have any observation. So it is for one of the injectables products from that side, which is an (inaudible).

Harith Ahamed, [151]

All right. Okay. And you guided for a couple of transdermal launches in the second half. So we have talked about Exelon Patch in the past. Can you give some more color on which of the approvals that we're guiding for here in the second half?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [152]

So we are 1 Exelon, and we are hope -- thinking we'll get 1 of Estradiols approved.

Harith Ahamed, [153]

Okay. And lastly, on Lipaglyn, we had 2 or 3 Phase II trials going on. Is there any update there? And can you give us some timelines on the next Phase III studies?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [154]

So yes, on Lipaglyn, we continued to put the product through significant amount of clinical trials in India, U.S., Mexico. The trials are progressing well. We're being able to recruit people on time for most of the

(technical difficulty)

Other than orphan indication, where we do find some challenges to recruit. But again, it's going well. We would get rid out of this data in the first quarter of FY '20.

Harith Ahamed, [155]

Okay. All the 3 Phase II studies?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [156]

Majority of the Phase II studies.

Operator [157]

The next question is from the line of Kunal Dhamesha from SBICAP Securities.

Kunal Dhamesha, [158]

So I have just one question. So the INR 500 million, that additional growth that will come from biologics in India and EM. So will it be over and above the 10%, 11% market growth that we see in India? Or will that be a part of that growth?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [159]

It will be additional. There is some business which is in part of the base, but it's definitely putting this business together, the India business will grow up faster than 10%, 11%. And you have to understand, as a strategy, our India business has been separated in to a wholly owned subsidiary, which is known as Zydus Healthcare Limited, whereas the biologics and vaccines business is driven by -- in the parent feature.

Kunal Dhamesha, [160]

Okay. And if I have to look at India -- Indian pharma market, let's say the market is growing at 10%, 11%, how much would you attribute towards a new categories that we are positioning ourself of that 10%, 11%? Are these the major growth drivers that we see going forward?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [161]

So which category are you assuming?

Kunal Dhamesha, [162]

Biosimilars in India.

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [163]

So biosimilars are in the category of autoimmune and oncology majoritively. But also, there are opportunities in gyne and others as well, but largely, driven by oncology and autoimmune. So those are very rapidly growing markets in India and we are gaining share both from the patient point of view and also absolute market share.

Kunal Dhamesha, [164]

Okay. And what would be our current contribution from biologics in India? Indian revenue?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [165]

Around INR 300 crores to INR 350 crores.

Kunal Dhamesha, [166]

INR 300 crores, annualized?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [167]

Annualized.

Kunal Dhamesha, [168]

Okay. And EMs?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [169]

EM has just started. Exact number, I don't have. We have one large contract that we've just got in Indonesia, which will be significant. But more details we can give you in the next couple of quarters once that business becomes sizable.

Operator [170]

The next question is from the line of Tushar Manudhane from Motilal Oswal.

Tushar Manudhane, Motilal Oswal Securities Limited, Research Division - Research Analyst [171]

Sir, just a clarity. This authorized generic version of AndroGel was launched when?

Nitin D. Parekh, Cadila Healthcare Limited - CFO [172]

12th of October.

Tushar Manudhane, Motilal Oswal Securities Limited, Research Division - Research Analyst [173]

Sir, I think there'll be nothing much in the Q2 per se?

Sharvil Pankajbhai Patel, Cadila Healthcare Limited - MD & Director [174]

So it will be in the coming quarter.

Operator [175]

That was the last question. I now hand the conference over to Mr. Ganesh Nayak for closing comments.

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [176]

Thank you very much. And wish all of you a very happy Diwali and a very prosperous New Year, and look forward to again interacting with you in the month of February for the third quarter results. Thank you, and good night.

Operator [177]

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