

Cadila

27 June 2018 05:30

61-77 minutes

Ahmedabad Aug 13, 2018 (Thomson StreetEvents) -- Edited Transcript of Cadila Healthcare Ltd earnings conference call or presentation Monday, August 13, 2018 at 11:30:00am GMT

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PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst

Ladies and gentlemen, good day, and welcome to Q1 FY '19 Post Results Conference Call for Cadila Healthcare Limited. (Operator Instructions) Please note that this 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.

Good evening, and welcome to our post result teleconference for the first quarter of FY '19. We have with us Dr. Sharvil Patel, Managing Director; Mr. Nitin Parekh, CFO; Mr. Tushar Shroff, Senior Vice President, Corporate Finance; and 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 up 30% year-on-year to INR 28.9 billion.

On a like-to-like basis, adjusting for the GST impact, the growth was 31%.

Earnings before interest depreciation and tax were up 133% year-on-year to INR 6.45 billion.

Our EBITDA margin for the quarter was 22.3%.

Profit before tax was up 269% year-on-year to INR 5.7 billion, and our net profit was up 233% to INR 4.61 billion with a net profit margin of 15.9%.

Let me share some of the highlights of the operations for the quarter. Our business in the U.S. posted sales of INR 12.3 billion, up 27%. We received approvals for the U.S. market, including 1 tentative approval during the quarter. We launched 9 new products in the U.S. during the quarter.

Our new launches include ZYPITAMAG, which is pitavastatin magnesium tablets, our first product filed through the 505(b)(2) route.

We filed 3 additional ANDAs with the U.S. FDA during the quarter. Recently, in the month of August, we launched our own generic version of Asacol HD.

Our India formulations business posted sales of INR 8.93 billion, up 40% on a like-to-like basis adjusting for the GST impact, the growth was 44%.

We launched 19 new products, including line extensions India -- in India during the quarter with 4 First-in-India launches.

Our formulations business in the emerging markets of Asia, Africa and Latin America posted sales of INR 1,963 million, up 13%.

We launched 7 new products in different countries of Asia and Africa and 1 new product in Brazil during the quarter.

In Mexico, we filed 1 more product dossier with COFEPRIS and received approvals for 2 more products during the quarter.

Zyklus Wellness Limited posted sales of INR 1.29 billion, up 12% on a like-to-like basis, adjusting for the GST impact, the growth was 25%.

Net profit was up 2% to INR 257 million.

Our Animal Health business posted sales of INR 1.25 billion, up 33% on a like-to-like basis, adjusting for the GST impact, our growth was 37%.

On the biologics front, we received regulatory approvals for 2 products from the regulatory authorities of Indonesia and Myanmar.

On the manufacturing front, formulations manufacturing facility of Alidac Pharmaceuticals Limited, successfully completed the U.S. FDA inspection without any observations.

We acquired 51% stake in the Dehradun-based Windlas Healthcare Private Limited with an objective of expanding our manufacturing base. Windlas has a robust manufacturing infrastructure with a U.S.

FDA-inspected manufacturing facility. It also has a dedicated R&D facility for formulations development and has developed 4 first-to-file ANDAs in the last 2 years.

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

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Questions and Answers

Operator [1]

(Operator Instructions) The first question is from the line of Neha Manpuria from JP Morgan.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [2]

First, on the U.S. business erosion that we have seen quarter-on-quarter. Is it fair to assume that the large part of this erosion is because of Tamiflu, which was there in the quarter and less of because of generic Lialda?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [3]

Yes.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [4]

And if I exclude generic Lialda and Tamiflu, how is the base business in U.S. done for us?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [5]

We are seeing about 2% to 3% price erosion...

Unidentified Company Representative, [6]

Quarter-on-quarter.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [7]

Quarter-on-quarter.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [8]

Okay. And my second question is on the Windlas acquisition that we have done. Now this is a manufacturing facility that we have acquired, are we constrained in terms of oral solids manufacturing that we had to buy this. I mean, what is the idea behind acquiring a manufacturing facility, which is U.S. FDA-approved. I mean, is this to target some business opportunity in the U.S., et cetera?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [9]

Yes. It is. So I'll say, we have -- had 77-plus approvals in the last year, and we continue to believe that we will be getting 50-plus approvals. We have an internal plan of launching between 50 to 60 molecules internally through our network. There are a lot of products which we have -- which have -- are not the very high-price or high-value products, but still have opportunities of becoming those INR 1 million to INR 2 million, INR 3 million products. And there's bandwidth issue that is also there in terms of us being able to manufacture all these products across all network and also commercialize through a marketing team. So we have strategically decided to invest in Windlas, which has the capacity to produce specialty and small value of volume as well as high and large volume products. We map the capacity to the current requirements of the current ANDAs that we have not commercialized to see if we can site-transfer many of these ANDAs to this facility. And we're going to commercialize through this facility. Also this business -- this company has been filing ANDAs also some differentiated first-to-file and other opportunities of ANDAs that they have through their own R&D. So this -- it will double down on some of the ANDAs that we would be able to commercialize through the development that has happened through Windlas. So all in all, first, the money that we have -- gone inside the company for investments in capacity and investments in R&D. And we -- and this will help us to commercialize on 20 to 30 molecules that we have not been able to commercialize through our own efforts.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [10]

Okay, okay. So these are 20 to 30 which you've got approval for but not launched?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [11]

We have more. But we will see, that we'll try and launch between 25 to 30 molecules in the next 2 to 3 years.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [12]

Okay. And how much time would we take, sir, to complete site transfer? This will probably start contributing in FY '20 earliest, depending on the site transfer. Is that correct?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [13]

There'll be some revenue in FY '19 also, but most of it will be for FY '20.

Operator [14]

We have the next question from the line of Prakash Agarwal from Axis Capital.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [15]

Question on Asacol HD, you mentioned, you have done your own generic launch. So just understanding the maths correct, would AG inventory will still be there, and we would take some time to ramp our own market share? Or would it be from August only we would start seeing sales to that extent of the market share we have in the market?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [16]

We will see converted immediately from August.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [17]

Okay, and what happens to the AG product in the market?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [18]

As of now, there will be no AG.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [19]

Okay, so you will pull back the AGs, what I want to understand, okay?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [20]

Yes.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [21]

And could there be AG from the innovator, another AG or something?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [22]

It is always possible but commercially it would not make sense in our view.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [23]

Okay. And any color you could give on the competitive landscape on both Asacol HD and Lialda?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [24]

So current competitive landscape for Asacol we still believe there are no -- nobody is going to be in the market in the next 2 years because there is no active filers in litigation who have moved. So Asacol is still very clean in terms of any competition. For Lialda, we have one generic, which is Teva. We assume maybe there will be one more generic in the end of the year. But it is more likely that in the next calendar year there would be some generic competition. That's what our internal view is.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [25]

Okay, understood. And secondly, the Q-on-Q drop, just Tamiflu -- absence of Tamiflu does not explain, could you help us, give more more color. Is there been a substantial drop in Lialda also, or is there -- I mean, you said just 2% to 3% Q-on-Q price erosion. So maths is just not adding up about 80 -- INR 70 million drop. If you could give more color that would be really helpful.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [26]

2%, 3% is without Lialda and similar as answering for the other person who spoke to me. We have the majority of the value obviously eroded from Tamiflu with sales had come down because of no flu season. And then Lialda also has -- with the entrance of Teva also there is a difference in price. But I would say that both players have behaved well in the market, seems to be still strong for both players.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [27]

So how do we see this run rate moving ahead?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [28]

Steady as of now without any further competition.

Operator [29]

The next question is from the line of Anubhav Aggarwal from Crédit Suisse.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [30]

Sharvil, one question on Lialda. I am little surprised to see on the market share as IMS reports that Cadila is loosing share when Teva has entered. Typically, I don't see that. When AG is there in the market, innovator also has a decent share. I don't see the single generic losing share. It's not that you are owning about 80% share and losing, you'll had 50% and you are losing share there?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [31]

Could you repeat your question, please?

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [32]

Yes, I'm saying that on Lialda, IMS shows that Cadila is losing market share to Teva. Typically, we see this behavior when a generic owns about 70%, 80%, but you have about 50% -- you had about 50% share before Teva came in and innovator still has a decent share with AG. So I am surprised to see Cadila losing share in Lialda to Teva.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [33]

This is not substantial share loss. We have lost about 5% share. (inaudible) would've also lost share.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [34]

But, yes, majority coming from Cadila, that's what I was little surprised with.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [35]

It's not majority, it's 5%.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [36]

Yes, but if you see Teva share, it's less than 10%. So from that perspective, that's what I was meaning by majority.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [37]

Yes, but when a second player comes, generally, the high shares would come down for both, but it's not happened.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [38]

Okay, so is it -- well, see, the import of my question was basically that are you just trying to minimize the price decline when Teva comes in, is it that, that you are just not hung on to your market share? Is that the strategy what you're trying to take?

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

This price discussions we cannot have, just for our governance point of view, we can't discuss this pricing.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [40]

Sure. Okay. I move on to my next question. One is on the Toprol XL, when do you plan to launch that product?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [41]

We have launched.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [42]

When did you launch that product?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [43]

It started commercialization from August.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [44]

From August, okay. And on the transdermal, when can we see first transdermal launch for Cadila, in this financial year or next one?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [45]

This financial year.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [46]

This financial year. And just my last question is on other expenses. Now after 2, 3 quarters, we've seen other expenses going down. I am assuming you would have reduced the discussion expenditure. So is this the new trend now which you're building for other expenses for rest of the year? Or they could go up as a marketing spend?

Unidentified Company Representative, [47]

We have built some cost efficiencies in our spends in adjacent marketing and also R&D. Also, in this particular quarter, when you look at on Q-on-Q basis, freight and distribution costs are lower in this quarter due to reduction in sales in U.S. [as well] added Tamiflu and other products.

Operator [48]

We have the next question from the line of Surya Patra from PhillipCapital.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [49]

Sir, just wanted to know whether after the Asacol HD launch whether there is any price gap between the Lialda and Asacol HD, it seems that prices for both the product has appreciated sequentially in last couple of months. Is that right, sir?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [50]

That will be the brand-related work, so we don't see any -- price is stable.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [51]

Okay. There is no sequential improvement as such?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [52]

To which product?

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [53]

So some trend says that both Asacol HD and Lialda prices are similar only now it has become? And there is a sequential improvement?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [54]

That would be the branded price, not the generic price. Branded could have...

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [55]

I think this is the generic price trend I'm talking about, sir.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [56]

No, we are not aware of.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [57]

Okay. But -- okay, that is fine. On the -- now Asacol is different. So sure, whether the likelihood of ramp-up would you be -- or what would be the likelihood of market, so that we would be gaining or losing after this, and how long this can persist?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [58]

We were hoping to gain market share. And the conversions should be immediate.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [59]

Okay. And second question on the domestic business front. So we have delivered a decent growth number, and also launched around double-digit new products for this quarter. So going ahead, what is the kind of trend that one would see considering the high base of the subsequent quarters of last year? And how sustainable is the number of new launches the way that you have reported this quarter?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [60]

So the new products, we have a plan and we launch depending on the therapeutic area. So we're on track in terms of launching new products. These number of products will vary depending on the quarters. The market has -- this was an exceptional quarter because of the low base last year. So there would, next quarter, you would not see very high growth because, again, because of last year, the July to September base was very high. But end of the year, the business would stabilize and we expect a low double-digit growth going forward.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [61]

Okay. And can you comment anything on the possibility of FDC ban. What there is a -- the movement -- motion on?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [62]

We have -- we don't get affected much by the FDC ban.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [63]

Okay. But whether that will restrict the new launches and hence the growth for the entire industry?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [64]

I won't able to comment on that.

Operator [65]

(Operator Instructions) We have the next question from the line of Nitin Agarwal from IDFC Securities.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [66]

Sir, on Asacol HD, because you mentioned that there is conversion from AG to the product is going to be pretty quick. I mean, didn't in the previous quarter, did we slow down on a primary -- was there a lesser amount of sales that we've done on Asacol to sort of minimize inventory in the channel?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [67]

No, it was steady state.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [68]

Okay. Secondly on what's your initial feedback on ZYPITAMAG sales, anything that you can tell us in terms of how you guys seeing the product scaling up as we...

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [69]

Yes, it's -- (inaudible) last month that we've launched this product and the going is good. It is as per our expectations.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [70]

What kind of a peak sales are you -- can we estimate on this, I mean, you sense on peak sales for this product?

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [71]

We are expecting sales of between \$25 million to \$30 million.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [72]

That's a peak number?

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [73]

Yes.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [74]

And lastly, on the last con call, you mentioned that you're pretty comfortable with the fact that U.S. sales will continue to grow even in FY '19 on the high base of FY '18. After Q1 numbers, I mean, does that -- you still hold to that guidance of a growth in U.S. sales for this year?

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [75]

Yes, for the whole year, yes. Because if you look on quarter-on-quarter, the previous quarter, that is not part of the FY '19, and that is because of the base which we have just discussed, but otherwise, for the whole year FY '19, we expect a growth over FY'18.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [76]

Yes, we are expecting to launch 50-plus molecules. And when you launch products, firstly, they are all staggered towards the late part of the year. And you don't gain market share from day 1, so you build your market share gradually. So the momentum will get build up in the third and fourth quarter.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [77]

And then the second question is the last one. On the manufacturing that you mentioned in terms of the site that you've got so many approvals and with significant launch -- new launches that you've planned. In terms of the manufacturing, sir, do you need to materially scale up your manufacturing capacities over the next couple of years to cope up with the requirements of new launches or how should you see -- how do we see manufacturing -- this whole -- the capacity part of it going forward?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [78]

For the oral solid, we have already built capacities for the critical launches that we have planned for in the next 2 years. For all the new filings, some of the filings are going to happen through Windlas also. But more importantly, the products that we have not been able to commercialize will get commercialize through this partnership. So we don't see any significant investment on oral solid and we have just

build our injectables facilities, which will be due for audit soon. So I think we have build the scale on that as well. So I would say it's incremental CapEx and not large CapEx.

Operator [79]

The next question is from the line of Prakash Agarwal from Axis Capital.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [80]

You mentioned only 9 launches versus 50 launch for the year -- planned launches for the year. You also mentioned you plan to grow from the base that of last year of around INR 900 million. Just trying to understand, I mean, wouldn't the launches would be more front-ended so that it gain some momentum, or what are the missing I mean, what are the next few triggers which would help in growth. Just not able to add up.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [81]

See, the next few triggers are only be the launches that are starting to happen. The large part of the ER portfolio is just getting launched from July, August onwards. So a lot of them will take time to get scaled up in the next 2 quarters. So more of our portfolio on those (inaudible) the metoprolol's and the many products like that to come are all getting now launched too, which will get scaled up. And whichever products we'll launch in the end of the calendar year, last year, they will also be adding up in the coming quarters.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [82]

So from [INR 180 million base to go into INR 250 million], you think there is enough -- I mean these are enough to cover that gap?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [83]

Yes.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [84]

Okay. And lastly on just understanding the maths of the own launch of Asacol, correct me if my understanding is wrong or right, that it's like typically 20% and our own would be, say, 80% to 90%, so it's 4x sales and 4x margins, would that be right way to think?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [85]

Sale is not something that you assume, right? There will be a improvement in margin significantly.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [86]

Okay. Similar sales and may be 3x, 4x the profits?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [87]

Yes, similar sales.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [88]

Okay. Okay. So that will not add up to the U.S. sales, the run rate? It would be the newer product launches and approvals that would add up?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [89]

Yes, Asacol would add mostly on margins.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [90]

Understand, okay, okay. And lastly, the -- acquiring 51% stake, I mean company like your size could have just bought the whole 100%. So what's the thought process acquiring 51%? And we'll be doing our own ANDA approvals, and we'll be launching from that site. So we'll be sharing that profit.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [91]

See, the business is going to be run on an independent basis. By -- and there is a promoter in that business who's (inaudible) up to now. So it'll be run on independent basis. And we want to build that flexibility in that business so that we can scale up with different business models, partly businesses that CHL will manufacture there. But also with the business there to be able to scale up by different kinds of portfolio that we have or we'll be able to license. So it's a mix of both. And we would have liked to have the -- that acting partner to also actively work on (inaudible) business in a lean and efficient manner.

Operator [92]

The next question is from the line of Purvi Shah from Sher Khan.

Purvi Shah, Sharekhan Limited, Research Division - Pharma Equity Analyst [93]

Yes, my question is related to the 4 FDF that you mentioned that the Windlas acquisition -- preferably the investment has, so if you could just highlight what kind of liquidity areas? And what is the size of these FDFs?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [94]

I can ask Vishal to talk later, but we have not disclosed anything right now on that.

Purvi Shah, Sharekhan Limited, Research Division - Pharma Equity Analyst [95]

Okay. And sir, the other thing that you've mentioned was that you plan to transfer couple of products which you have the approval but you were not able to launch maybe because of the scale, which you would like to transfer to Windlas. So wouldn't that take a little bit of time, so is it that you started -- like, since there are no sales and strategically, moving them to that facility makes sense. And so you say that FY '20 onwards what -- is what you expect contribution from those products also, which you have approval, but will -- are not launched?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [96]

Right. We'll need some time, as you said, because we have to site-transfer and then file the product for a change of (inaudible) spending. So most of the commercial value will be created in FY '20. But it has a steady business currently that it runs.

Purvi Shah, Sharekhan Limited, Research Division - Pharma Equity Analyst [97]

Right. So do we add anything from that in this quarter? Have we added anything from the acquisition in this quarter or it will reflect from second quarter?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [98]

No nothing has been added.

Operator [99]

We have the next question from the line of Alok Dalal from CLSA.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [100]

Question on Windlas only. Sir, well, how many times the plant has been inspected by FDA? And any outstanding 483s that they have?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [101]

So they have been -- they were recently -- they have been inspected between, I want to say, 3 times or may be between 2 to 3 times. And as recently as this year, they have been inspected. When they have had a 3 minor -- 3 observations, which are not critical.

Unidentified Company Representative, [102]

I think, today they've got the EIR.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [103]

And they got the EIR today also.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [104]

Okay. So my question is why acquire, why not have a contract manufacturing deal with them? Like you also do contract manufacturing for your partners. So why can't you have a deal like a CRAMS deal with them?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [105]

Because I think long term we would like to own the entity and scale it up from there. So we don't want to be only a contract manufacturer, because you don't get the low-cost position if you're just going to be merely a contract manufacturer. You will not be able to commercialize unless you have capabilities to manufacturing efficiently. Contract manufacturers will not be able to give you the kind of suitability.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [106]

So before looking at Windlas, were their facilities in U.S. and Europe also available? From what we hear in media, larger companies are looking to divest facilities, so were -- was that an option as well?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [107]

No, because the cost position of these facilities will not make it viable.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [108]

Okay. For the products that you want to do?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [109]

See, all of these facilities have very high conversion costs. So it's -- on an ongoing basis it'll be very difficult to be competitive on low-value products with those kind of facilities.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [110]

And most of these products that you want to have, let's say, high volume, low value, you will have your own API backup for you to be even more cost-competitive?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [111]

Not for all, but for some, yes. Which will have a overall, yes, but for not all. They would've been filed with outsource the API also.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [112]

Okay. Second question was related to the guidance only that you will grow in the U.S., despite the \$900 million base. So if we remove Tamiflu and Lialda, which are substantial numbers, they will be still number their numbers will this client substantially, so you need to fill up a big gap for these 2 products, even if you want to maintain \$900 million. So are you confident that you'll be able to achieve that with the high-volume, low-value kind of products that you are targeting?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [113]

So going forward, the product even are not all low-value products. We have good-value products that we are launching. Obviously, not to the size and scale of these 2 products. But with them -- important 30 to 35 products that we have -- which have good value, you would see as a good scale up in the last 2 quarters.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [114]

Okay, and lastly, Nitin bhai, if you can just share the gross debt and net debt number, please.

Nitin D. Parekh, Cadila Healthcare Limited - CFO [115]

INR 5,106 crores.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [116]

INR 5,106 crores?

Nitin D. Parekh, Cadila Healthcare Limited - CFO [117]

And net is INR 3,052 crores.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [118]

INR 3,052 cores?

Nitin D. Parekh, Cadila Healthcare Limited - CFO [119]

Yes.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [120]

INR 5,106 crores and INR 3,052 crores?

Nitin D. Parekh, Cadila Healthcare Limited - CFO [121]

Correct.

Operator [122]

We have the next question from the line of Ashi Anand from (inaudible).

Ashi Anand, [123]

Can you just provide some kind of an update on vaccine strategy, and we were looking for WHO prequalification, I think the target was for FY '20. So if you can just give an update on that?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [124]

So we continue to get approvals on vaccines and file new vaccines for further development, both, some first-in-class as well. We are now scaling up on the commercialization side as specific to first the Indian market, we have launched the influenza vaccine as well as the typhoid conjugate vaccine is already in India. We are following it up with at least being able to launch 2 to 3 more vaccines in the next 6 months in the domestic market. And with our ongoing plans, we have, we will go for WHO prequalification next year for the critical vaccines like -- which are important in the humanization program. We are unique and some vaccines like the varicella and the typhoid conjugate vaccine, so we are one of the very few manufacturers of some of these vaccines. So that we will be going ahead in terms of prequalifications, and you will see some of it starting from FY '20. We've already met with the WHO prequalification official for some of the products that they are very keen to start sourcing. But it will take about 1 to 2 years to get there.

Ashi Anand, [125]

Okay, excellent. And just secondly, if we're looking at biosimilars and vaccines in both India and emerging markets, would it be possible to quantify what kind of revenues we'd be getting from these segments today and, say potentially over 3- to 5-year perspective, how much this could scale up there?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [126]

Today, the biosimilars is about INR 250 crores business, largely driven out of India. Going forward in the next 3 to 4 years, we should see \$200 million business getting billed for the biosimilars and similarly for the vaccine as well.

Ashi Anand, [127]

Okay. So across both of these we could read in \$500 million plus over 3 to 4 your perspective?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [128]

Yes.

Operator [129]

We have the next question from the line of Tushar Manudhane from Motilal Oswal.

Tushar Manudhane, Motilal Oswal Securities Limited, Research Division - Research Analyst [130]

Sir, just on this Windlas Healthcare again, are these FDFs -- have they -- if you can just help us in terms of whether they are already tied up in terms of distribution for these product postapproval as in Windlas has tied up with somebody else.

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [131]

Their current business that they're doing is tied up with partner. The future development will be an opportunity to commercialize by Zydus.

Tushar Manudhane, Motilal Oswal Securities Limited, Research Division - Research Analyst [132]

And these are largely and Windlas Healthcare, this facility has got oral solids only, or in the other...

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [133]

Only orals. Oral solids and it has -- is able to do all simple as well as complicated product.

Operator [134]

(Operator Instructions) We have the next question from the line of Surya Patra from PhillipCapital.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [135]

Just one clarification on the 505(b)(2), what you launched, possible that would have launched under your specialty product portfolio in the U.S. And I think you were talking about building a portfolio for specialty products for U.S., so any progress there and also about the field force word that you have created there? And whether that is boosting the employ cost number for this quarter? And how -- what is the kind of trend that one should anticipate on the employee expenses front going ahead?

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [136]

Two things. One is we have centralized, where we have specialized the products portfolio, which is being sold. ZYPITAMAG is not sold by us, it is outsourced to a marketing agency. So there's no manpower cost which gets added to us, for ZYPITAMAG (inaudible).

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [137]

Okay. But this [FORTEO] sequential 7%, 8% kind of rise on the employ expenses spent what we are seeing, this is normal? And this is normal and this is the kind of a base one should see?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [138]

It is due to increment,

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [139]

Okay, okay. And anything that we have already built, sir, the field force for the specialty business, or we have...

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [140]

We already have field forces. We are not -- we don't need to build it from scratch.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [141]

Okay, okay. Any progress on the specialty product front, specialty product portfolio front?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [142]

Yes. We have plans we have 4 projects that we are working on actively right now and we have finished our FDA discussions on some of them. Some wer are already getting some -- soon to get some approvals so the plan is on to develop specialty product.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [143]

Okay. Most probably this is for the next -- the filings would be happening over the next few quarter time. Is that right?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [144]

Some have -- 1 or 2 have happened. And Yes, some of them will happen in the last 2 quarters, more importantly, next year.

Operator [145]

We have the next question from the line of Damayanti Kerai from HSBC.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [146]

My question is related to this supply disruption from China. Has that leading to any kind of pressure on your material cost?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [147]

Yes. There has been a steady rise in intermediates and certain costs. So we have also had a 5% increase as of now.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [148]

5% increase on back of China disruption, okay. And going ahead, how do you see this situation to evolve?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [149]

It's still forming up, so we could see another 5% increase from the current base on our resourcing.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [150]

Okay. So another 5% increase from current quarter level. That's what you're saying?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [151]

Yes.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [152]

Okay, okay. And when do you see anything like normalizing on that front, or you are looking for any alternative sources?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [153]

Yes, we have multiple -- so part of the increase will -- or a lot of it will be offset by as operational efficiencies that we are driving on the manufacturing side. Also, many savings on the indirect side. We are also working and going to be shifting a lot of APIs in-house, which are volume-driven, and we already started acting on it since the last 8 months. So we have mitigations planes for this. Temporarily, they would be in the next -- there is forming up of prices that has happened. On the APIs business, we have been able to pass on most of the price increases and then by backward integration we should be able to minimize the impact going forward in the latter part of next year.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [154]

Okay. But situation won't to normalize in this fiscal and it'll go on for quite some time, right? That's your assessment?

Sharvil P. Patel, Cadila Healthcare Limited - Joint MD & Director [155]

Yes. How much time is very difficult to predict. With the current sourcing, there is price increases that have happened, which we are mitigating by saving on other cost.

Operator [156]

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

Ganesh Narayan Nayak, Cadila Healthcare Limited - COO & Executive Director [157]

Thank you very much, and look forward to interacting with you during our next Investor/Analyst conference. Thank you, and good night.

Operator [158]

Thank you very much. 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.