



“Cipla Limited Q3 FY20 Earnings Conference Call”

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MODERATOR: **MR. CHIRAG TALATI – ANALYST, KOTAK SECURITIES LIMITED**

Moderator: Ladies and gentlemen, good day, and welcome to Cipla Limited Q3 FY20 Earnings Conference call hosted by Kotak Securities Limited. As a reminder, all participant 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, 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. Chirag Talati from Kotak Securities Limited. Thank you, and over to you, sir.

Chirag Talati: Good evening, everyone. This is Chirag from Kotak Institutional Equities. I thank the Cipla management team for giving us the opportunity to host this call today. From Cipla, we have with us today, Mr. Umang Vohra - MD and Global CEO, Mr. Kedar Upadhye - Global CFO and Naveen Bansal from the Investor Relations team. Over to you, sir.

Naveen Bansal: Thank you, Chirag. Good evening, and a very warm welcome to Cipla's Quarter 3 FY '20 Earnings Call. I'm Naveen from the Investor Relations team.

Let me draw your attention to the fact that on this call, our discussion will include certain forward-looking statements, which are predictions, projections or other estimates about future events. These estimates reflect management's current expectations of the future performance of the company. Please note that these estimates involve several risks and uncertainties that could cause our actual results to differ materially from what is expressed or implied. Cipla does not undertake any obligation to publicly update any forward-looking statement, whether as a result of new confirmation, future events or otherwise. I would like to request Kedar to take over.

Kedar Upadhye: Thank you, Naveen, and good evening to all of you. Welcome to our earnings call for the third quarter of fiscal year 2020. I hope you have received the investor presentation that we have posted on our website. Before sharing commentary on the numbers for the quarter, I would like to talk about certain key themes and capital allocation choices we are making.

Over the last few quarters, we've consciously made relatively higher allocation towards the India prescription business in terms of investments. As an example, we are investing towards expanding our portfolio offerings in the market. Recently, as you know, we've acquired the Vysov brand from Novartis. We've in-licensed patented product called Elores from Venus Remedies, many other investments that we have made through in-licensing. Similarly, the second edition of our flagship inhalation awareness campaign named as Berok Zindagi 2 is seeing very good progress. In the coming period, you will notice similar many more focused growth-enhancing initiatives.

Secondly, we are coming off a peak in terms of R&D spends as generic Advair clinical trial, approximately \$25 million of spend in the current financial year, comes to an end. We also see opportunities to rationalize the overall pipeline of the products under development. And you'll notice a sharp focused approach for the generics pipeline in the coming days. Going forward, we will have on the specialty spends, which are primarily focused on only respiratory molecule

instead of the total 3, which we had, including 2 in CNS that we have contracted for. Similarly, no major incremental spends will be made on the IV Tramadol until we have a definitive view on the categorization of the molecule from the agency.

Finally, over the last few years, we have made focused efforts to drive improvement in the return-on-capital employed profile of the business. It used to be around 10-11% in FY18. The trailing 12 months of December 2019, we are around 13.9%, and we will continue this focus on improving the return on capital employed and invest aggressively towards return-accretive businesses.

Coming to the quarter now:

In line with our expectations and after a healthy quarter 2, we had yet another good quarter with strong performance across our businesses. This quarter has seen strong double-digit growth in the prescription business in India, with seasonal triggers driving growth in Respiratory and Acute segment. In line with our commentary in the last quarter, the trade generics business delivered year-on-year growth, highlighting healthy recovery post the model change. On the branded market franchise in South Africa, continued to deliver growth significantly above the market.

In the U.S. generics business, despite multiple competitive entries across product categories, we retained a healthy share, delivering 133 million of sales during the quarter. Contribution from Cinacalcet is now largely normalized.

The gross margin line this quarter is impacted by a couple of items. One is the shelf stock adjustment, which we have taken on the Cinacalcet post the drop in prices. Secondly, 120 basis point charge accounting adjustment towards the overhead due to the reduction in the finished goods inventory. And while the U.S. business topline on a quarter-on-quarter basis did not change materially, the mix is a bit different now with the erosion of Cinacalcet in the reported numbers versus last quarter.

With that, let me come to the financials. For the quarter, overall income stands at Rs. 4,371 crores, recording a healthy 9% Y-o-Y growth. Gross margin after material cost is about 62% for the quarter on a reported basis. As highlighted earlier, this was impacted by nearly 200 basis points on account of Cinacalcet shelf stock adjustment, revenue mix in South Africa and overheads on the inventory.

Total expenses, which include employee costs and other expenses, stood at Rs. 1,968 crores, declining 3% on a sequential basis. Employee costs for this quarter stood at Rs. 746 crores, declining 2% on a sequential basis. The other expense for this quarter, which included R&D, regulatory, quality, manufacturing and sales promotion expense, stood at 1,222, again declined by 3% on a sequential basis. Total R&D investments for this quarter stood at 7% of revenues or Rs. 308 crores. This includes charges for the ongoing respiratory trials. As mentioned earlier,

R&D expenses are coming off the peak now and we will be more focused going forward. Adjusted EBITDA for the quarter stood at 18.5% to sales and grew 13% over last year.

Tax charge for the quarter is 153 crores. We are looking at a full year ETR of 29% to 30%. Profit after tax is at 351 crore or 8% of sales.

Finally, our long-term debt now stands at US \$440 million, which was mainly used to fund our U.S. acquisition, and South African ZAR 100 million for the Mirren acquisition. We also have working capital loans of \$24 million, and South African ZAR 416 million, which act as natural hedges towards our receivables.

Total net debt-to-equity ratio is very healthy at 0.04. You would have seen healthy cash generation initiatives over the last several quarters. Outstanding forward contracts as a hedge for receivables as of 31st December are US \$222 million and South African rand 627 million. During the quarter, we also hedged a certain portion of our forecasted export revenues. And outstanding cash flow hedges as of 31st December are US \$109 million and South African rand 212 million.

With this, I would like to invite Umang to present the business and operational performance.

Umang Vohra:

Thank you, Kedar. We are pleased to report another strong quarter driven by strong performance across our businesses. Overall revenues for the quarter grew 9% on a year-on-year basis. Let me start with some key highlights for the quarter.

India Prescription:

The prescription business has its second straight quarter of 13-plus percent growth. The quarter saw robust performance across all key therapies, which outpaced the market significantly. The fundamentals of the business, including field force productivity, attrition rates, new product launches and our product ranks are extremely healthy and reflective of the quality of our revenue growth.

India Trade Generics:

As we had mentioned in the last quarter, our trade generics business normalized in the last quarter and reported a strong revival in the quarter, growing 7% on a year-on-year basis.

In South Africa, our business delivered strong performance, growing 9% year-on-year in ZAR terms. The private market business delivered strong numbers, growing 20% in local currency terms during the quarter. In U.S. generics, the business delivered 13% growth on a year-on-year basis to close the quarter at 133 million. Overall with revenues growing 9% year-on-year, we saw adjusted EBITDA growing 13% on a year-on-year basis and reported at close to 18.5%.

With that, let me move to the business-wise performance.

The Prescription business grew 14% year-on-year basis, driven by performance across both chronic and acute therapies. We will continue our focus on driving growth in our priority products portfolio and building stronger brands in the market. On the secondary side, Cipla continued to perform well across key therapeutic areas. Chronic therapies continue to drive a significant share of growth for us and grew 13% as per IQVIA MAT December '19 versus the 11% reported for the market. Amongst our key therapies, in Respiratory, Cipla grew by 13% versus market growth of 11%. In Cardiology, Cipla grew 14% versus a market growth of 11%. We continue to maintain our leadership position across Respiratory and Urology. In Diabetes, where we are a challenger with a strong portfolio, Cipla grew 17% versus the market growth of 12%.

For the North America business, despite multiple competitors entering the markets in various product categories, we retained good share. In addition, on an overall basis, launches such as Pregabalin have facilitated relatively strong growth of 13% on a year-on-year basis to 133 million. Increasing contribution from the new launches has been driving gross margin expansion for the business. During quarter 3, the gross margin expanded by over 350 basis points versus the same quarter last year. On a YTD basis, the gross margin expansion is 750 basis points. We are progressing well on our trials for Advair, and our limited competition engine should resume launches very soon.

In the SAGA region, which includes South Africa, Sub-Saharan and Cipla Global Access business, all 3 businesses delivered strongly during the quarter. Our overall South Africa business grew strongly at 9% in local currency. The private market business delivered, as we mentioned before, 20%. In secondary terms, private market continued the momentum, growing at over 2x the market at 6.5% per IQVIA MAT December '19. Cipla ranked number 3 in the South African private market in both volume and value. We retained our position as one of the fastest-growing companies in pharma. Outside of South Africa, the Sub-Saharan African business grew 12% year-on-year basis, and the CGA business also delivered a growth of 7%.

The Emerging Markets business declined 17% in the quarter due to order shipments getting pushed to quarter 4. We are expecting a healthy recovery in the next quarter. The quarter also saw the commercialization in this business of products in the market for our partnership with Novartis in Australia and in Sri Lanka. We are on track for all our biosimilar filings, including those for Australia. In Europe, our market share in FPSM now stands at over 15%.

On the Institutional Specialty business in the U.S., in line with the commentary on the last call, we have submitted the IV Tramadol NDA via Avenue Therapeutics in December.

On the regulatory front, we continue to work with the USFDA to comprehensively address the observations at Goa. We were recently inspected at our API facility in Bangalore as well and which ended in 4 observations, which are procedural in nature. Over the last year, we had a total of 6 of 8 USFDA inspections covering most of our facilities. We have already received the EIR for 6 of these, with Goa and Bangalore is pending as they were recently concluded. We remain

extremely focused on maintaining the highest standards of quality across our manufacturing network, and we will work with the agency to comprehensively address the observations received in Goa.

On a long-term note, we recently concluded a strategic review with our Board. As an outcome of the same, we would like to highlight our strategic priorities and key capital allocation choices as we build our business for sustainable growth in the future. We've covered some of these in the Slide 3 of the investor presentation, and I will try and cover some of them on this call as well.

The first refers to our continued investment in performance in India, we call it the One India initiative. Over years, Cipla has built a formidable prescription business and trade generics franchise in India. We have incubated our wellness business under Cipla Health, which now markets some of the most progressive brands in their categories. Going forward, we will integrate all the 3 businesses, prescription, trade generic and Cipla Health, under a single capital allocation framework. We believe there are strong synergies across portfolio distribution and consumer-focused initiatives amongst these 3 businesses, which will help the business deliver market-leading growth in the future.

Under the One India initiative, we recently launched the TV campaign for OMNIGEL, India's #1 pain relief gel. We will share more details in our future interactions.

Our South Africa franchise remains strong and is on a strong footing. We will further strengthen our portfolio, including deepening the OTC space in the market. South Africa remains a key priority market for us.

On the U.S. Generics business, we will be recalibrating our investments in R&D significantly and focus on large value-accretive assets. We will share further details on the same in our year-end call in May. On the buildup in the U.S. Specialty business, we will sharpen our focus on setting up an institutional business and Lung Leadership initiative through differentiated assets. As a result of this, we will be focused and out-license our CNS assets in the near term. We are already in discussions with potential partners for the same.

In the coming year, FY '21, our P&L spend on U.S. Specialty on total U.S. specialty will be limited to 1% of sales and less than 5% of our total EBITDA, which is roughly similar to the numbers absorbed in the P&L on a YTD basis in our current numbers. In our Emerging Markets business, we will look forward to further consolidate our presence in priority markets and execute in fewer, bigger markets. We will continue to remain focused on establishing our businesses in China, other than the markets of Australia, New Zealand, Algeria, Morocco and some parts of Southeast Asia.

In terms of overall capital allocation, going forward, we will continue to invest aggressively in our established branded market franchisees of India and continue our focused investments in

South Africa, while calibrating our investments in U.S. Generics and in the Specialty business. This will help us drive improvement in the overall ROCE of our business, which, Kedar has already mentioned, has improved significantly in the last 3 years.

Finally, in terms of our outlook for the next quarter. As you are aware, quarter 4 will behave in line with historic seasonality and may see sequential moderation in the overall numbers. But on a year-on-year basis, we're expecting the momentum to continue in quarter 4 and report yet another healthy quarter for the business.

I would like to thank you for your attention and will request the moderator to open the session for Q&A.

Moderator: Thank you very much. We will now begin the question and answer session. The first question is from the line of Nitin Gosar from Invesco Mutual Fund. Please go ahead.

Nitin Gosar: My first question is related to One India campaign, the change in strategy, where in all 3 divisions are put together to drive synergies. But in past, it has been seen, a lot of companies have clearly said generics, Gx, Rx, OTC are all different model and promotion strategy approach to consumer are totally different. They need different mindset. Your thoughts on why putting them together?

Umang Vohra: So I can talk about a few areas. We see distribution converging as the markets deepen beyond Tier-1 cities, right? So we see distribution chains converging. We see a huge initiative between the brands in the Generic business and the Rx business and the consumer. There are lots of brands that can switch to become consumer categories, and that switching can happen under the One India initiative. We are also seeing significant synergies in terms of information data that can be unlocked by the 3 businesses going forward. And finally, amongst the Prescription business, there is a fair amount of focus on trying to create focused investments behind the top brands. And therefore, there are some other brands, which possibly could leverage the distribution reach and the focus that the other 2 businesses could provide in the Rx Prescription business. So we see a lot of synergies. I have to tell you that the teams in the 3, they are still led by independent people, but there is one person who heads all the 3 businesses to create commonality. So by approach, the businesses are operating as strategic clusters, but they are basically all aggregated at the top by a single person who is looking at trying to extrapolate synergies across the 3 businesses. A great example is the OMNIGEL campaign. OMNIGEL was a generic product and now is switching to the consumer side by virtue of our programs that we are doing in terms of advertising etc. So the product is still being sold by generic, but the consumer arm has been able to add a very significant positioning argument for this product.

Nitin Gosar: And when we say distribution channel are converging, are we limiting our definition of distribution channel to dealers or distributors? Or are we expanding it towards retail, too?

- Umang Vohra:** No. We are looking at all distribution. We are looking at how Cipla can be a significant share of an e-pharmacy, how Cipla can be a significant share of the aggregators in the market, how the distribution in Tier-2 and below cities can incorporate not just generic products, but possibly even our branded products. So it's covering all aspects of the distribution chain in India.
- Nitin Gosar:** And my second question is, I think you called out what's the cost on trials for generic Advair. I think I missed that number.
- Kedar Upadhye:** That's about 25 million, that's booked in the current financial year. There's some spend in the previous years as well on capital and trials. Current year has about \$25 million.
- Moderator:** Thank you very much. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** On the strategic review that you spoke about on relooking at the R&D initiative and the number that you just spoke about. So what kind of number you are really looking at for next year for the R&D? And why just focus on large value-accretive assets? What about the base business? How do you look at that business?
- Kedar Upadhye:** Prakash, currently, we are spending about 7%. And Umang spoke about incremental investments for the Specialty, including IV Tramadol within 1% of the full company revenue. We are comfortable, Prakash, to build the portfolio within this overall ambit. In our view, that adds a lot of focus, that adds emphasis on commercial value and allows us to focus all our efforts in regulatory, quality development towards a very focused pipeline.
- Prakash Agarwal:** So in terms of R&D as a percentage to sales, would that be similar given the focus of large assets also? Or would it come down going forward?
- Kedar Upadhye:** That would come down because we are coming off the peak. Like, what we mentioned, we are coming off the peak now. And it's very unlikely that any one product having such a meaningful spend would come into the pipeline. So I think there will be a downward bias for the R&D spend going forward.
- Prakash Agarwal:** Yes. Any number we are looking at, like 5%, 6% or?
- Kedar Upadhye:** Not, at this stage. But directionally, I think this is very clear.
- Prakash Agarwal:** Okay, perfect. And secondly, on the outlook that we shared last quarter on one limited competition product from 4Q and respiratory trials, Advair filing by end of fiscal '20 and launch of Albuterol by first half '21. So are we on track on all these 3 accounts?
- Kedar Upadhye:** Yes. Towards the end of this year onwards, we are on track. So I mean, the definition of a limited competition could vary company to company. But towards the end of this fiscal year onwards, first quarter onwards, I think we'll be on track as far as...

- Umang Vohra:** Prakash, the Advair trial, the readout of results is in March. And if the readout picks off the way we hope it will, then we will have a filing shortly after that.
- Prakash Agarwal:** And on this one, Albuterol, if you could finish that we are on track for the launch and...
- Umang Vohra:** So we are on track, but I think we're still in discussions with the FDA. We continue to receive their responses for queries that they have. And I think, while we think it's pushing out from what we thought earlier, the second half of the year, it seems it's going to be towards the latter half of the second half of the year. But there is active review of the file, and we're answering all the queries that the FDA is raising.
- Moderator:** Thank you. Next question is from the line of Tushar Manudhane from Motilal Oswal. Please go ahead.
- Tushar Manudhane:** Just with respect to this One India strategy, switching of brands, maybe from trade generics to OTC, will that help in getting them out of the trade cap margins if as and when that proposal comes through from the government side?
- Umang Vohra:** So I'm not sure it will help us get us out of trade margin cap because I think the trade margin cap will apply equally to Rx to Gx, possibly even to some products in the consumer space as well, right But I think what it helps us do is to create enough demand for some of these products to become more consumer like, right, where the categories permit this. And I think that results in your demand not getting hijacked because of the margin issue that the trade may face. So I think that is the first thing that we are trying to do. And separately, look, we've evaluated the margin risk to us. And I think at where we are today, I think we are quite confident that this can be managed relatively well. There is a risk, but the way we are looking at it, it's not a huge risk to our business today.
- Tushar Manudhane:** So if you can just elaborate how can that be managed?
- Umang Vohra:** For example, we have an absolute amount that we think that the risk for this will play out. The second aspect is the whole One India initiative also allows us, in some way, to position different products in different pockets to drive more demand for it. So I don't think we have an option to change anything from a value perspective to trade at this stage. But I think what we have is a way to try and offset some of the value through a more robust volume growth.
- Tushar Manudhane:** Secondly, just on this allocation of investment towards India business. Just a cumulative number, if you can just help in terms of in-licensing Vysov, Elores brand, overall?
- Umang Vohra:** It will be fair to say that we have funded almost over the last 2 years, we've been funding almost 150 to 200 basis in our India business, whether it's for in-licensing assets, whether it's for more focused marketing investments. On a year-on-year basis, we funded almost 150 over and above

our trajectory. And I think we are beginning to see the results of that coming out through the growth we are showing on the topline.

Tushar Manudhane: And just lastly, how many ANDAs would have been commercialized out of 170, maybe like in this quarter or maybe 9 months FY '20?

Naveen Bansal: Tushar, maybe we can take that up offline. I'll come back to you.

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

Anubhav Aggarwal: Umang, a question on the India business. I very well understand that's a good initiative, you switching some of the trade generic brands to OTC. But just can you elaborate on how does the Rx business benefit? One, you mentioned that, just to check, are you saying that because the trade generic distribution was very strong and beyond Tier-1, so your Rx business would benefit by overlapping up this distribution? That's one question. And second question on the same is that I have not understood how does the Rx business benefit from the One India initiative beyond the distribution thing?

Umang Vohra: Yes. So let me start where you're right. I think when we mentioned distribution, it was exactly that, that the Rx will be able to also penetrate deeper into the India market because of this. The second is the overall value proposition. See, today's trade is very different. We are dealing with people who are aggregators, e-pharmacies. They look at portfolio approaches, right? And earlier in our business, we could have been having 2 or 3 different approaches to the same set of customers. It allows us to combine this. So that will help Rx as well, along with the distribution initiative that we are doing. But look, there's another angle also. There are some Rx products also, which have a consumer-like appeal and which are permissible to be consumer-like as a category. So this will allow either the shifting of some products or the brand-building campaigns of those products across the 3 businesses.

Anubhav Aggarwal: Sure. I take that. And what are you, in particular, doing for growing the Rx business? So these are like integrating the 3 business and helping the Rx business. But when you take Rx business as one basket, so last 2 quarters have been pretty good, when you look at this business, what do you think, let's say, 1, 2 years down the line, assuming the market grows at about 9%, 10%, how much Cipla Rx business can grow over the next 1, 2 years, let's say?

Umang Vohra: So our attempt is we've refocused this business now to grow at higher than market growth rates. And this is what we are trying to demonstrate in 2 quarters and hopefully, in the future as well in the next 2 or 3 quarters, so that we have a good MAT view of India over a 4-, 5-quarter basis, and we are quite confident of getting there. And I think the big thing here is that what we are doing in the Rx business is quite interesting. I think, a) it's a focused brand strategy. Second, it's a strategy also focused on how number of products can improve for prescription. So it's about allocating our capital, allocating our effort behind product categories, which can create more

productivity in the marketplace and not go after every product line etc. So that's one. The second is we are beginning to grow categories. So for example, for us, Respiratory is 1/3 of our business. And the problem with the growth in that business really is that we have to educate people that asthma is curable, that inhalers are absolutely safe. And it's not about a Cipla product or otherwise. And that's exactly what we've been doing for the past 2 years through the Berok Zindagi campaign. So it's really about creating more patient awareness, more patient centricity, doctor centricity and improving more products per prescription from every doctor. So it's about the SFE engine, the sales force effectiveness engine. So it's stuff like that, that we're trying to do for the Prescription business.

Anubhav Aggarwal: Just can I have one clarity. What's your ROCE target in next 3 years? Let's say, all goes well for us, 14% what you highlighted pretax, where can we end up?

Kedar Upadhye: Well, firstly, Anubhav, this 14% has a little bit of our Cinacalcet benefit. But directionally, Anubhav, obviously, the focus is to improve across all the categories. In the fixed assets, the utilization of the plants in the working capital, better structures of inventory holdings and credit periods in receivables, those are going to be the levers and drivers to continue to improve the ROCE.

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

Saion Mukherjee: Just one clarification on the specialty strategy, Umang. So are we saying that we are not looking at expanding or investing in terms of M&A in that space? And what is your thought process there? You mentioned the spend to be limited to 1% of sales, which is similar to this year number, right? So there's no incremental investment. I'm just wondering what is your end game there? Let's say, tramadol, if it doesn't work out the way you think, you'd exit Specialty completely? How are you thinking about it?

Umang Vohra: Yes. I mean, if the tramadol strategy doesn't work out well, then obviously, we will try and see if there's another product we could go after. But that is not going to be at the expense of our P&L, that is, a.; b) I think we're very clear that the amount we can spend as a percent. So we are exploring multiple partnering options right now with various partners in terms of what we can do with this business. So I don't think the business is necessarily a business that will be completely 100% owned by Cipla. There could be a partnering option where we could invite some participation from another partner or merge with a significant player, right, in the Specialty business already. So we will do everything to make sure that our metrics and allocation and the fund available to us can defend the creation of this business, along with growing our core business metrics.

Saion Mukherjee: And just, Umang, on the U.S. market, the revenues have stabilized. So if you can share what's your top 3 products like in terms of contribution today? And also, any comment you have on the pricing environment and opportunities that you are seeing?

Umang Vohra: So I think just, while we get the numbers out, on the U.S., we are looking at our base business or our regular tracking business somewhere in the range of 120 to 130. Some quarters, it will be close to 120. Some quarters, it could be slightly higher than 130, like in this quarter we've shown. So that's the rough range that our business operates in. And I think the top 3, if you want to say roughly, so our top 3 products are about 25-odd percent.

Saion Mukherjee: In case, if I can, just one question, Kedar. Your other operating income is running at a high level. Is that sustainable? Anything you want to call out there?

Kedar Upadhye: There is not much one-off Saion in that. All the items are routine in nature. It is little bit of export incentives, a couple of other service income and things like that. So there is no any significant one-off in this quarter.

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

Damayanti Kerai: Sir, you spoke about having more sharp focus for U.S. market where the focus will be on select equity assets. So you just mentioned our base run rate is stabilized somewhere in 120 and 130 range. So given now like you will be focusing more on selective products, how should we see U.S. ramping up from here? Though, like in your opening remarks, you mentioned that we have seen significant improvement in gross margin. But in terms of topline, how should we see the trajectory going ahead?

Umang Vohra: I think the topline will respond to product launches. So the moment the product launches, we've had a little bit of a hiatus in terms of product launches for the past 6 months. So as the product launches start coming in, it will grow. But we are looking at our business, which is in the range of 120 to 130, depending on how customer buying happens in a quarter. So I think, for us, that's the range. And when the launches come, they will begin to add on that as and when they arrive.

Damayanti Kerai: Sure. And sir, what's the reason, like, why we are seeing a bit slow launches in this particular like, say, last 2 or 3 quarters?

Umang Vohra: We're not getting approvals. I think it's probably some of it is linked to product, some of it is linked to the type of products we are after; for example, Albuterol is a type of a product where there is no approval. But all the 4 products that we call limited competition, there has not been a generic approval so far.

Damayanti Kerai: Sure. Sir, my second question is regarding this corona virus issue, which we have been hearing about. So what kind of dependency we have on China for raw materials? And also like if the situation prolongs, what kind of impact we will be expecting on the raw materials side?

Umang Vohra: See, a lot of our pharma value chain is linked to China. Well, not just for Cipla, it is linked for the entire pharmaceutical industry. I think a lot of us in the pharmaceutical industry have some stock cover available. But I think if this corona virus thing continues for more than a month or

45 days, that will begin to create a huge amount of issue for the pharma sector, for those supplies which are dependent on China. Not everything is dependent on China, but China has a significant value chain linkage for all pharma companies.

Damayanti Kerai: So for a month or 1.5 months, it should be okay. Beyond that, it will be problematic for the entire industry, right?

Umang Vohra: Right.

Moderator: Thank you. Next question is from the line of Chirag Dagli from HDFC. Please go ahead.

Chirag Dagli: Sir, in your initial comment, you mentioned about 120 basis points impact. And then somewhere, you also mentioned about 200 basis point impact. So what is it exactly? And if you can just split between shelf stock adjustment and overhead.

Kedar Upadhye: Chirag, 120 basis point was specifically on the overhead, that's the accounting adjustment you have taken after the reduction of the finished goods inventory. The 200 basis point impact, it's a little higher, that includes a couple of other things as well, including the shelf stock adjustment and a couple of others.

Chirag Dagli: So shelf stock is 80 bps and the other pieces, 120 bps. That's how we should think about it?

Kedar Upadhye: Well, I'm not specifically calling out. What I'm saying is about 200 basis point is this 2, 3 items taken together.

Chirag Dagli: Okay, fair point. And how many products can we move to this, like what we've done for OMNIGEL. On our current portfolio, how many more can we sort of move to the OTC or that sort of a bucket?

Kedar Upadhye: In fact, 3, 4 products have been already moved across various types of therapies. And we do have a portfolio ready. But we'll do it in a staggered manner depending upon the ability to consumerize, and we will pick up the timings appropriately. At this stage, OMNIGEL is still with the Generics business, but...

Chirag Dagli: Sir, is there a limit on spend that we have in mind that this is our budget?

Kedar Upadhye: So there is no limit on spending. It depends upon the scale, the capabilities, and we have to stagger it. We will look at it appropriately.

Chirag Dagli: Can some of these products also move to ethical marketing structure, back to promotion kind of a structure?

Kedar Upadhye: Unlikely, very few. Because I think the geographies in which this gets sold, the kind of therapies in which they are and the price point, they could be a little bit difference compared to what we sell in Prescription business.

Moderator: Thank you. Next question is from the line of Neha Manpuria from JPMorgan. Please go ahead.

Neha Manpuria: Sir, on the first question, U.S., given we indicated that our R&D strategy will be focused towards larger products, wouldn't that increase the risk of potential delays impacting, leading to no growth in the U.S., essentially like what's happened with Albuterol? Shouldn't the investment in a base portfolio help us right through periods where we potentially see delays in approval?

Umang Vohra: Neha, even today, we have a mix. The same mix percentage is going to be there. So it's not going to be that, for example, today, if you file 25 products, there is a certain mix we operate in between this and limited competition products. And I think the same mix will continue. It's not going to mean that now if we make 15 filings, for example, that all 15 filings will be complex and difficult to do it. That won't be the case. So the mix will continue to operate.

Neha Manpuria: So the rationalization in R&D spend is essentially reducing the number of filings, the products that we are looking at.

Umang Vohra: That is one. And then disproportionate amounts to a single product would also be reduced.

Neha Manpuria: And beyond Advair, sir, how do we look at the Respiratory pipeline?

Umang Vohra: So we have a product that we have partnered, and that is also at fairly advanced stage and then we're going to look at the other 2 inhaler products that are also in the '23-'24 time period. So we're not disclosing names right now, but the pipeline is building up fast.

Neha Manpuria: And the product, which is in advanced stage, should we expect filing for this next year? Or this would be more again, 24 type of...

Umang Vohra: No, it's a large product. I think we can't disclose too much of it. It's a fairly large product, and we are hoping that we will be able to finish the work required and resubmit at possibly in end of this year.

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

Sameer Baisiwala: Umang, just taking it from the previous person. So the second product you said end of this year, your referring fiscal '20?

Umang Vohra: Yes, that's right. Well, not fiscal '20, I'm sorry. I meant calendar year. Calendar year fiscal '21, calendar year '20.

- Sameer Baisiwala:** Okay. And this partnered product, is it a DPI or MDI?
- Umang Vohra:** Sameer, we are not giving that detail. It's a fairly significant product.
- Sameer Baisiwala:** And just on Advair, Umang. Where do you go from here? I mean as in all goes well and you do the filing in Q1. And what's the approval time, market launch time that you are looking at?
- Umang Vohra:** I think, Sameer, my sense is this is at least a 2-year review product, right? We are hoping that it comes in 2 years, but it's a 2 - 2.5-year review product. That's how we look at it right now. Considering the fact that there's only one generic in the market, we could be granted a more priority review. But it's basically, if all checks out well with our clinical trial, and we are hoping that we can see the readout in March, then it's probably a 2-year-from-now type of an approval status.
- Sameer Baisiwala:** And just, specifically to U.S. business, Umang, 2 questions. When you say you'll be focusing on large value assets, any color you can share, which therapeutic areas, which kind of formulations you are looking at?
- Umang Vohra:** So Respiratory will be big for us and relatively big for us in this mix. I think that would be one. The second would be assets in the peptide space, more injectable, more peptide. That would be a second category that we'd build out. And then the third would be the mix of the other assets that we have in terms of oral solid dosages etc.
- Sameer Baisiwala:** And, Umang, to your point on U.S. business, the growth is dependent on new launches. Assuming this, I'm saying hypothetically, if there were no new launches, I'm making it up, for next year, what happens to your base business? What kind of erosion, what kind of pressure are you seeing?
- Umang Vohra:** No, I think if we look at our base business, we look at our base business as, in this year, it's somewhere around the 120 to 130. So if there's no launch, Sameer, then the 120 will also erode. So minus any new launch, the 120 could become 110 per quarter because that's the usual erosion in the U.S. market.
- Sameer Baisiwala:** One last question with your permission, if I may. For domestic business, Umang, how many in-licensed products are you having in your portfolio? And what is the revenue share all of these put together?
- Kedar Upadhye:** I think our in-license portfolio, so annualized sales today is around 250 crores, Sameer. So the multiple deals, which have been entered, and we've seen launches in the last 3 years almost. Cumulatively, we are running at a rate of almost 250 crores now.
- Sameer Baisiwala:** 250 crores, yes?

- Umang Vohra:** Yes. So that's 250, Sameer. Of that, one of them, which is a sizable product, has just been bought by us and becomes our own now, right? Vysov, I mean. So Vysov now becomes a product that we sell, our own product kind of a thing.
- Sameer Baisiwala:** And this is your share of the revenue or the total including...
- Kedar Upadhye:** This is what we book, Sameer. This is our share of the revenue.
- Sameer Baisiwala:** And how strategic is this for your future growth to keep doing these licenses?
- Umang Vohra:** It's largely strategic, Sameer, for 2 therapeutic areas. The first is Diabetes because we had absolutely no portfolio, and there was no point taking a metformin and glimepiride to a doctor. So we needed some new assets. So a large portion of our in-licensing is in the Diabetes and a little bit in the Cardio space. So that's where it's strategic for our business. Respiratory, we have none. Acute, we buy products, like we are trying to buy Elores and other type of products, that's where we'll buy them. So it's there. And on the biosimilar side, which goes direct to the hospital channel, that's the other area that we are trying to do business with. There, the models of EBITDA are quite accretive from a perspective of not needing too much of spend. So here, it is only strategic in some way for Cardio and for Diabetes, more Diabetes than Cardio.
- Moderator:** Thank you. Next question is from the line of Hari Belawat from Techfin Consultants. Please go ahead.
- Hari Belawat:** This is regarding distribution channel. You said e-pharmacy could be one of the distribution channel. Sir, the guidelines for e-pharmacy is not yet decided by government of India, one. Second thing is there are several court cases and different rulings are there for this. Do you think this e-pharmacy will be streamlined in a shorter period?
- Kedar Upadhye:** Hari, what we meant is as the third largest company, we have to find a way of engaging with this. Given that the volumes, which are being sourced to e-pharmacies and their adoption is going up in metro and Tier-1, Tier-2 towns of India, it will be imperative for us to see how is the best manner in which we engage with this. So that's what you mean when we say that we'll deal with that.
- Hari Belawat:** Some news was there that you are acquiring Medlife e-pharmacy company. Is there any progress on that?
- Kedar Upadhye:** Hari, all that was speculative in nature. We would not like to comment on that at this stage. But what is important, whether we hold equity or not, I think we have to find the best possible way in which we engage with them.
- Hari Belawat:** Understood, sir. One more, just a query, are you planning any big acquisition because there was a news, some acquisition of the select business of a big company? Is there any plan for that

acquisition? Even name was also there, Wockhardt name was there. Is there any planning for that?

Kedar Upadhye: Hari, we keep looking at strategic targets for acquisitions. At this stage, any specific name, we wouldn't like to comment. We will announce when any definitive agreement gets signed.

Moderator: Thank you. Next question is from the line of Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: Sir, just wanted to have a sense that in the overall business restructuring plan, where are you placing this biosimilar opportunity? And what are the kind of a way forward that you are looking for the biosimilars in emerging as well as domestic market?

Kedar Upadhye: Surya, if you remember, a couple of years back, we have exited from the organic development and manufacturing efforts for biosimilars. Over the last 2, 3 years now, either for India or for emerging markets or for some countries in Europe etc., we are more working on an in-licensing business. So that effort will continue. And we are happy with the kind of deals which we have signed. You could see a significant contribution from these deals starting from fiscal '22.

Surya Patra: Okay. And secondly, on the Lung Leadership across market. See, anyway, in the Respiratory business front, we have been delivering. I think we are growing much faster than the industry growth. And because of this, what is the kind of initiative that we are taking on this front? And do you see that, okay, led by this, the overall growth of your Rx business in India as well as in the other part of the world will be accelerated because of this initiative?

Umang Vohra: Yes, you're right. I think if you look at our Lung Leadership initiatives, one is around the area of asthma and COPD. So the Berok Zindagi campaign, for example, is a big Lung Leadership initiative from our side, that's one. And if you look at it, the total market for Respiratory, we're driving that market up to almost 14% growth from where it used to be at 10%. And the second is we are delivering through the lung, various antibiotics now. We are working on trying to repurpose. And this is largely happening more for the emerging markets. And we have one program for the U.S. that we are also working on in terms of delivering an inhaled antifungal. You are also aware that we have filed with a partner with Mannkind Pharma of the U.S., we have filed a product for inhaled insulin also. So we call classified for India. So we classify all of this as Lung Leadership in India, which is not only curing ailments of the lung, but delivering and making more efficacious medicines through the lung route.

Surya Patra: So any update on that front, inhaled insulin front? If you can update...

Umang Vohra: So we have filed with the government. And I think at this stage, we are in discussions with them on how this product can be approved for India.

Moderator: Thank you. Next question is from the line of Krishna Prasad from Franklin Templeton. Please go ahead.

Krishna Prasad: Maybe I didn't understand your U.S. specialty strategy pretty well. I mean so are you now going to focus only on the anti-infective and the Respiratory business? Is that what you said?

Umang Vohra: We are looking at the hospital sector. And if that overlaps with the anti-infective, it's good. If it overlaps with inhaled delivery of medicine, it's good. So the channel is going to be largely the hospital sector. And that is our strategy. And within that, we want to be clear that we will not be spending more than 1% of our sales by ourselves, right? And if there is a partner, then obviously, the rest of the spending will be done by the partner.

Krishna Prasad: Understood. At this point in your portfolio, the hospital product would only be the tramadol, that you have filed.

Umang Vohra: We have an anti-infective, which is called plazomicin, which is there.

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

Nitin Agarwal: Umang, starting Q4, we start to run into a high base accredited by Sensipar from a profitability perspective. So I mean, how should we look at the next 2 or 3 quarters from an overall profitability trend perspective from here on?

Umang Vohra: See, I think we'll have to guide you on what was the mix of Sensipar roughly when we report our numbers for quarter 4. We are looking for base business growth. Sensipar was fairly significant in quarter 4 of this year, quarter 1 and actually even in quarter 2. Quarter 2 less so, but the large portion of Sensipar was quarter 4 and quarter 1. So when we report our results, we'll try and show you a split of Sensipar and base business profit adding to the total. And we want to show base business growth.

Nitin Agarwal: Perfect. That will be helpful. Secondly, Kedar, this seems like a reasonably normal quarter from a recurring business perspective. So this gross margins of 61.5%, you average it, you add back another 200 basis points to it. So 63%, 63.5% is where the base margin for the business is on a recurring basis, the gross margin?

Kedar Upadhye: That's right, Nitin. I would probably use that number more as a floor. We shouldn't go below that. We should be ideally growing higher than that, subject to improved business mix and product mix.

Nitin Agarwal: So 63%, 63.5% should be a base number on the gross margins?

Kedar Upadhye: That's right, Nitin.

Nitin Agarwal: And lastly, Umang, in this whole ROW business. So we've clearly spelt out our target geographies, focused geographies being South Africa, U.S. and along with India. I mean how do you look at the ROW piece in the overall scheme of things? Is it something which is at some stage going to be meaningful as a business for us? Or that there are challenges in these

businesses, which sort of constrain their ability to contribute in any meaningful way to the businesses in general out of India?

Kedar Upadhye: Nitin, actually, if you are aware already, I think there are many countries in this portfolio of international business which we call, where we are #1, #2, #3. I mean in top 5 of these respective countries. And many of these are respi products. Many of these are HIV-based products. So there's a lot of synergy with the portfolio that we have in India and U.S. and other businesses. Many of them leverage based on the U.S. pipeline as well. So this is very core and very strategic. And in our view, we have done well selectively across multiple countries. You could see Australia growing very fast. You could see Sri Lanka, for example, coming back to #1. And likewise, there are multiple countries. In LATAM, in Middle East, in Asia, which we are doing well. As we have always communicated, this is the business which has the highest profitability percentage within Cipla's business portfolio. So that remains core to us. Once a while, subject to currencies or liquidity issues or geopolitical matters, I think there's a volatility. So that's the only aspect for this business. Otherwise, fundamentals of the business are intact in this part of the portfolio.

Moderator: Thank you. Next question is from the line of Aditya Khemka from DSP Mutual Fund. Please go ahead.

Aditya Khemka: Umang, this 200 basis point of one-off in the raw material cost, that amounts to about 87 - 87.5 crores. Is that the right number I'm looking at? I'm slightly confused by the numbers people are throwing on the call.

Kedar Upadhye: No. So there is 120 basis point adjustment, Aditya, on the overhead charge. So that's about 52 crores or so. And the balance is because of couple of other factors, which we said these are one-off for the quarter.

Aditya Khemka: But these are all in the material cost that you reported?

Kedar Upadhye: That's true.

Aditya Khemka: So a total of about 87 - 88 crores, right? 200 basis point of the revenue this quarter is about 87 - 88 crores?

Kedar Upadhye: Correct.

Aditya Khemka: And secondly, you have 170-odd ANDAs approved in the U.S. How many do you market today, including the PEPFAR ANDAs that you market?

Kedar Upadhye: I can come back to you, but it's going to be slightly higher than 100-odd, between the acquired and ordinary...

Umang Vohra: But he is saying including PEPFAR. So PEPFAR is marketed outside of the... We'll have to get back to you.

Aditya Khemka: One last question from my side. When you spoke of the strategic review and your priorities in terms of capital allocation. Just slightly confused on the strategy between India and the U.S. Both are very different sort of strategies. India is where you go to the masses, the Tier-2, the Tier-3, requires a lot of legwork, requires a lot of promotion and advertising expense. And then you have the U.S. which is incrementally very R&D extensive, and you have a lot of machinery going behind that. And when you rationalize your R&D spend, as you mentioned, would you be laying off people? Would you be reducing the number of projects that you are looking at? Any numbers on that side would be really helpful.

Umang Vohra: I don't think we're at the stage where we're going to lay off people. I think we are building a business for China. We are building a business for Australia. I think our people will be reeducating their time and effort to other geographies as well. I think the project expenditures will come down, because the U.S. development is fundamentally costlier than our development in other parts of the world. So there is no layoff or anything being contemplated at all by us. We are redeploying our business, our people and their time.

Aditya Khemka: And just one clarification. But going by your commentary you've given so far on the call, fair to say that within the Indian business, you are looking for more depth rather than width in terms of the therapy areas that you are present in?

Kedar Upadhye: Yes, you could say that. We are actually present in quite a few therapy areas, but we're going to become deeper in these with more focused effort on the top products.

Moderator: Thank you. Next question is from the line of Shyam from Goldman Sachs. Please go ahead.

Shyam: Just on the regulatory side, you announced that you've got an OAI for Goa. So just want to understand, from a regulatory perspective, what is missing? And what is the regulator asking you to do? And what are the timelines on the Goa plant?

Umang Vohra: So we were essentially given 3 sets of observations. I think most of you are aware of them because it's in the public domain. I think the first concern, cleaning processes in some of our equipment. The second and third were more around sterile practices. And I think where we are today is that we have committed to the FDA that there were certain actions we'd put in place by mid-March to March end. After which, we will provide them an update of what happened through all the actions that we have done. So we are working already. We've been working with inside the company, and we also got consultants advising us. And all of that is happening within the organization right now. So mid-March to end March is when we reply back to the FDA with all the actions that we were asked to do. We'll reply back with our assessment and our completion of them, and then we will hear back from the FDA.

Shyam: So just trying to see the next step. So does an OAI mean it's a warning letter already? Or that's not how the FDA will now work? They basically will look for response from you and then go as those responses go. How does it work from their end at this point of time?

Umang Vohra: So in the way that the FDA works, I think they pretty much want to make a determination of whether a site is an OAI or not an OAI, pretty much within 90 days to 120 days after an inspection. I think there are some exceptions to this. But usually, the FDA makes a determination at that point in time. It is our understanding that if your site activities that were committed by you are not completed and are significant to the FDA determination of the status that if you have not completed that within the time the FDA makes a determination of an OAI or otherwise, you will be under the OAI category. From here, there are 2 routes that it can take. A, the FDA does not get satisfied with what we do in March etc., the FDA could then begin to think of issuing a letter to us and give us further queries. On the other hand, if the activities we have done are completed and the FDA is satisfied with them, then the status of the plant changes, and it reverts back to how it was before.

Shyam: Got it. And until then, all the pending files, I think you have called out it's high single digit ANDA applications from Goa, right?

Umang Vohra: That's right.

Shyam: That would be kind of pending at this time?

Umang Vohra: That is right.

Shyam: Got it. And my second question is just on IV Tramadol. I think you mentioned earlier on that you have filed. So can you just refresh us the updates on the timelines, again, on IV Tramadol?

Umang Vohra: I think they have an NDA date for November end or December of this year. And usually, now we have seen that most of these new drug applications have one round where the FDA sends back queries. So more or less, every product that is filed is usually taking about 1.5 years on the NDA side as well to be approved. So realistically, if the categorization of this product is as per what we want, then an approval could be anywhere in the time period of December to maybe March, April, May, June time period.

Shyam: Next year, you mean, right? March, April next year.

Umang Vohra: That's right.

Shyam: And the potential commercialization would be when?

Umang Vohra: After approval. Based on what we are planning etc.; we are limiting the amount that we would spend pre-approval. And maybe the most of the spending would happen post-approval.

Moderator: Thank you. Ladies and gentlemen, due to time constraint, that was the last question for today. I will now hand the conference over to the management for closing comments.

Naveen Bansal: Thank you, everyone, for joining us on the call today. In case you have any follow-on questions, please feel free to reach out to me. So once again, thank you so much. Have a very good evening. Thank you.

Moderator: Thank you very much. On behalf of Kotak Securities Limited, that concludes this conference. Thank you for joining us. You may now disconnect your lines.