16th May, 2025

(1) BSE Ltd
Listing Department
Phiroze Jeejeebhoy Towers
Dalal Street
Mumbai - 400 001
Scrip Code: 500087

(2) National Stock Exchange of India Ltd
Listing Department
Exchange Plaza, 5th floor
Plot no. C/1, G Block
Bandra Kurla Complex
Bandra (East), Mumbai - 400 051
Scrip Code: CIPLA

(3) SOCIETE DE LA BOURSE DE LUXEMBOURG
Societe Anonyme
35A Boulevard Joseph II
L-1840 Luxembourg

Sub: Q4 FY25 - Earnings Call Transcript

Dear Sir/Madam,

We are enclosing herewith copy of the transcript of the Company's Q4 FY25 earnings conference call dated 13th May, 2025. The transcript is also available on the Company's website i.e. https://www.cipla.com/sites/default/files/CiplaLtd-Earnings-May13-2025.pdf

Kindly take the above information on record.

Thanking you,

Yours faithfully,
For **Cipla Limited**
RAJENDRA KUMAR CHOPRA
Digitally signed by RAJENDRA KUMAR CHOPRA
Date: 2025.05.16 16:33:37 +05'30'
Rajendra Chopra
Company Secretary

Encl: as above

Prepared by: Chirag Hotchandani

“Cipla Limited

Q4 FY '25 Earnings Conference Call”

May 13, 2025

MANAGEMENT: **MR. UMANG VOHRA – MANAGING DIRECTOR AND GLOBAL CHIEF EXECUTIVE OFFICER – CIPLA LIMITED**
MR. ASHISH ADUKIA – GLOBAL CHIEF FINANCIAL OFFICER – CIPLA LIMITED
MS. DIKSHA MAHESHWARI – HEAD, INVESTOR RELATIONS – CIPLA LIMITED

Moderator: Ladies and gentlemen, good day, and welcome to the Cipla Limited Q4 FY '25 Earnings Conference Call. 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 call, please signal an operator by pressing star then zero on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Ms. Diksha Maheshwari, Lead Investor Relations from Cipla Limited. Thank you, and over to you, ma'am.

Diksha Maheshwari: Thank you, Rutuja. Good afternoon, and a very warm welcome to Cipla's Q4 FY '25 Earnings Call. I'm Diksha Maheshwari from the Investor Relations team at Cipla. 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 confirmations, future events or otherwise. I hope you have received the investor presentation that we have posted on our website.

I would like to request Umang to take over.

Umang Vohra: Thank you, Diksha. Good afternoon, everyone, and thank you for joining us on our fourth quarter's earnings call for financial year 2025. FY '25 marks a year of high milestones across our flagship businesses of One India, North America, One Africa and EMEU. Our One India business surpassed the landmark of INR11,000 crores revenues, reflecting our strength in the domestic market.

North America saw remarkable progress with 3 key new drug approvals, further solidifying our foothold in the region. Meanwhile, our One Africa and EMEU businesses maintained strong growth momentum throughout all the 4 quarters, highlighting our commitment to sustainable expansion.

Coming to our business performance. Our One India business posted a healthy growth of 8% year-on-year this quarter with a full year growth of 7% year-on-year, driven by substantial progress across the branded prescription, trade generics and consumer health business. This growth was realized despite seasonal challenges, particularly in the acute category, demonstrating the resilience and derisked business mix in a dynamic market landscape.

In our branded business, our key chronic therapies of respiratory, cardiac and urology continued to outpace market growth. Our overall chronic mix further improved to 61.5% as per IQVIA MAT '25. Foracort, our leading inhalation brand became the first brand in the history of IPM to cross INR900 crores, reaffirming its position as a market leader. This year, we expanded our presence

in the IPM by adding 4 brands with revenues exceeding INR100 crores, bringing our total to 26. Additionally, we have increased our footprint to the top 300 ranks where we have 23 brands in the top 300 ranks.

During the year, Cipla took strategic strides in expanding its portfolio through key partnerships with global players. We collaborated with Orchid Pharma for cefepime-enmetazobactam. In India, we joined forces with Takeda to bring vonoprazan, and we signed a multiregional licensing deal with Formosa for clobetasol suspension. To elevate our offerings, we will be launching innovative products like inhaled insulin and plazomicin backed by -- and are backed by a good pipeline of high potential assets in various stages of development.

Our trade generics business continued its upward trajectory during the quarter on the back of vigorous execution and distribution, new launches and technological advancements. Expanding our portfolio remains a key pillar of our growth with 19 new introductions this year, further elevating our market presence.

Our Consumer Health business delivered strong double-digit growth for the quarter as well as FY '25. Our anchor brands of Nicotex, Omnigel and Cipladine maintained leadership positions in their respective segments, securing the number 1 position in the market again.

North America business achieved a quarterly revenue of $221 million with an all-time high annual revenue of $934 million, propelled by strong traction in the differentiated portfolio and consistent demand for our base business. Our albuterol market share remained steady at 18%. The quarter, we have begun to see supply normalization for Lanreotide, and we remain optimistic about reaching the previous levels from the earlier quarters.

Additionally, apart from receiving a number of smaller approvals, we obtained 2 significant drug approvals this quarter, nano paclitaxel ANDA and the Nilotinib NDA approval. We have already launched and started selling nano paclitaxel in a couple of EMEU geographies and are hoping to do the same in the U.S. soon.

Our One Africa business grew at an impressive 15% year-on-year during the quarter with a full year growth of 12% year-on-year in USD terms. In the private market, our secondary growth outpaced market growth at 6.7% versus 4.9%, enhancing our competitive edge. North Africa also recorded robust growth during the quarter, fortifying our presence across the region. In our EMEU business, a strategic focus on deep market penetration has established a solid foundation, delivering a quarterly revenue growth of 16% year-on-year and an annual revenue growth of 15% year-on-year.

After 4 years of stable performance, our EMEU business is now entering a phase of growth. This performance was led by expansion across both DTM and B2B categories alongside consistent margin, stability and internal pipeline assets.

I'd like to update you about our U.S. pipeline. We remain committed to our organic investments with a strong focus on R&D for the U.S. market. In respiratory, we have filed 6 assets, including

Symbicort and Qvar, the generic versions of both, with launches expected in line with the review process.

Four more respiratory assets will be filed in the next 12 to 18 months. We are now closer to commercializing generic Advair and are pleased by the promulgation signed with the administration for approving launches from U.S. facilities faster.

In peptides and complex generics, 9 assets are already filed and some launches projected -- with some launches projected between FY '26 and '28. We aim to file 10 more peptides and complex generic assets in the next 12 to 24 months. We remain committed to launching 2 to 3 peptide assets in FY '26.

Coming to the regulatory front. As you're aware that during the year, the U.S. FDA audited 5 of our manufacturing facilities based in India at Patalganga, Kurkumbh, Goa, Virgonagar and Medispray and all of these inspections have been classified as VAI. This accomplishment reflects our dedication to quality, compliance and operational excellence.

I would now like to invite Mr. Adukia to present the financial and operational performance.

Ashish Adukia: Thank you. Thank you, Mr. Vohra, and good afternoon to all. I'd like to present the key financial highlights for the quarter and the financial year 2025. And as highlighted earlier in other quarters as well, this is adjusted for QCIL numbers.

In early part of the year, we had issued a range of performance, which we are happy to inform that we have now executed as per plan. We are pleased to report a quarterly revenue of INR 6,730 crores with a healthy Y-o-Y growth of 9%, driven by our focused markets. As a result, we ended the year at INR 27,548 crores with revenues growing 8% Y-o-Y.

The EBITDA margin stood at 22.8% for the quarter, higher by 150 basis points Y-o-Y and 25.9% for the year, marginally exceeding our guidance which was higher by 139 basis points Y-o-Y. As per practice, this EBITDA margin does not include the other income.

Gross margin after material costs stood at 67.5% for the quarter, which is 74 basis points above last year's figure. The gross margin for the year stood at 67.6%, which is higher by 150 basis points -- 157 basis points Y-o-Y. Expansion and profitability is largely due to favorable mix, calibrated price actions across branded and generic portfolios and impact of easing cost escalations.

Total expenses for the quarter include people costs and other expenses, which stood at INR3,003 crores, higher by about 7.4% on Y-o-Y basis. Annually, the expenses were INR11,491 crores, higher by 8.7% Y-o-Y. The R&D investments for the quarter are at INR426 crores, which is about 6.3% of revenue, driven by product filing cost, developmental efforts. Overall, for the year, the R&D investments stood at INR1,524 crores, which is at 5.5% of the revenue.

For the quarter, PAT stands at INR1,222 crores, representing 18.2% of sales, with the effective tax rate of 18.6%. On a full year basis, PAT amounts to INR5,273 crores, accounting for 19.1% of sales, and the effective tax rate for the year is 22.4%. The slightly lower ETR in FY '25 is due to

reversals of previously recognized tax provisions and certain other adjustments. And even after adjusting for this impact, PAT continues to grow strong double-digit growth for the year, reinforcing the company's solid financial performance.

ROIC continued to be strong at 30% plus for the year. Our free cash generation and operating efficiency endures to drive healthy cash net position. As of the year-end, debt on our balance sheet, including the lease liabilities stood at INR438 crores with net cash equivalent balance after adjusting for debt at INR10,369 crores.

Looking forward, our key focus areas for FY '26 will continue to be priority for One-India, would be to continue the growth momentum to be ahead of the market in both branded prescription and trade generics. We'll further work on cementing growth levers for wellness portfolio, including ramping up our new launches.

In North America, our focus would be maximizing the commercial execution and expediting our new launches. In South Africa, as was the year before, our focus will be a margin expansion. EMEU, our top priority is to maximize top line with focus on deepening our penetration in identified core markets, while sustaining our strong margin trajectory.

In terms of our FY '26 guidance, our business model and product pipeline remains resilient, leading to our revenue trajectory continuing in the growth path, and this is despite the generic Revlimid losing its exclusivity during the year. Our outlook for projected EBITDA margin is in the range of about 23.5% to 24.5%.

That's it from my side. Thank you for your attention, and now I'll request the moderator to please take the questions.

Moderator: The first question is from the line of Dr. Kunal Dhamesha from Macquarie.

Kunal Dhamesha: The first question on the nano paclitaxel launch that we are anticipating in U.S. in the near term. Umang, how are we looking at this market, given there are other players with a 505 (b)(2) kind of product. And then with our product, how are we positioned to gain market share? And is there any technicalities regarding a channel -- a particular channel of selling? If you could highlight those aspects would be great.

Umang Vohra: Sorry, we were on mute. Bulk of the market is -- I think there are -- what we know there is 1 NDA player, and there are 2 generics. And I think one of the generics is, it will continue to -- it will expand for ANDA generics, because they are substitutable. And actually, from a reimbursement perspective, it is our belief that all -- that everybody is reimbursed like a generic. But we feel that the market is large enough for us to take meaningful share.

Kunal Dhamesha: What would be your estimate of the total addressable market now?

Umang Vohra: No. At least -- the market was $800 million, $900 million pre generic. I think the IMS would still show it at that level, but there would be a gross to nets to bring the market down which typically is not very high on the institutional side of the business, unlike the retail, where the gross to nets

are really high. But here, the gross to net is going to be very significant -- I mean it's going to be closer to the overall IMS reported number. Our belief is that we should play for fair market share on this product category. So I wouldn't be too surprised if our share reflects that.

Kunal Dhamesha: Sure. That's great. And secondly, I think I missed any commentary on Advair, and then overall on the respiratory pipeline that we suggested. Could you please...?

Umang Vohra: So Advair, as we mentioned, will be commercialized from our site in the U.S. And the product, obviously, we've taken our batches and we've gone through the regulatory process. I think the -- depending on how the U.S. prioritizes domestic site filings, we definitely see it as an FY '26 launch. The question is depending on the priority of the filings, we will probably either be launching it in the early part of the year or the later part of the year.

Kunal Dhamesha: Sure. So we have filed an amendment to ANDA, right, and not the CBE-30?

Umang Vohra: No, no, it can't be a CBE-30 because it's from a new site. So that filing has already gone where it is filing from a new site. So it can't be a CBE-30. I think there was a recent promulgation from the U.S., which said that when you make filings from domestic facilities, right, then your files may be prioritized. So we are -- we yet to see what happens basis that at this filing.

Kunal Dhamesha: With your permission, if I may, one more on the potential pharma tariff. Is there any update, I mean, on your side in the U.S. market, if you are getting something from your partners or distributors? Any color would be helpful there.

Umang Vohra: Actually Ashish is closer to those discussions. So maybe Ashish, you can give a view on that.

Ashish Adukia: Yes. So we -- see we have not, in any way, got impacted by any -- and this is an evolving situation. We have to yet to see on what gets decided finally. But in our portfolio, we've not got impacted. And I think the most recent announcement doesn't really impact the generic players. In fact, it may just benefit. So we're yet to see this evolving situation.

Moderator: Sorry to interrupt, may we request Dr. Kunal Dhamesha to please rejoin the queue. We have other participants waiting for their turn. The next question is from the line of Damayanti Kerai from HSBC.

Damayanti Kerai: My first question is on Lanreotide. So Umang, you mentioned you have started supplies to few markets. But if you can talk -- sorry, for Lanreotide, how should we look at the normalcy or -- normalcy coming back in the supplies for the U.S. market?

Umang Vohra: Yes. Damayanti, I think my comment in the script was more about nano paclitaxel. Yes, nano paclitaxel, we've already supplied to a couple of markets and we are ready to supply to the U.S. as well. I think on Lanreotide, as I mentioned, this quarter is -- the quarter that went by, quarter 4, was significantly higher than quarter 3 and -- in terms of volume. And also this quarter, we are coming back to normalcy. I think the -- our mix of products is something that we are managing, but the product is quite significantly back into the channel.

Damayanti Kerai: Okay. So in first half itself, should we assume it will go back to the level where you left?

Umang Vohra: Well, yes. I mean, remember that, that level was built as a common strategy between the NDA product and the ANDA product. And for some time, the ANDA product took over, and that was -- and now we're coming back into both the NDA and ANDA. So eventually, we will reach that level, if that answer your question.

Damayanti Kerai: Sure. And just a related thing, which product will prefer, like the NDA 1 like the 505(b)(2) or NDA in terms of gaining market share quickly in the market?

Umang Vohra: No, I think the ANDA always gain share faster because it's just -- it's like the brand product. So -- but we are selling both right now.

Damayanti Kerai: Okay. And my second and last question is, if you can comment on your R&D outlook. So fourth quarter, in general, I guess, is more than what we saw in the previous quarters. It could be lumpy. But in terms of spend in, say, '26-'27, how should we look at the R&D cost? And then which are the focus segments in near term?

Umang Vohra: So I think we're generally in the range. And see, we are usually guiding to not being ever higher than 6, 6.5, right? And that's for a full year basis. Some quarters may be slightly higher than that, some may be lower, right? But overall, we never do R&D more than that because that's what our business model allows us.

And quite honestly, we don't need spending more than that basis our pipeline and our portfolio. Focus areas will continue to be respiratory, will continue to be injectables, will continue to be products in the -- products which are for India, including the GLP-1s that are going to go off patent.

Moderator: The next question is from the line of Surya Narayan Patra from PhillipCapital India Private Limited.

Surya Narayan Patra: So first question is on the margin guidance what we have given. It looks like slightly lower than last year number. So is it because the Revlimid number is likely to be lower? Or is it because Revlimid has started seeing any kind of price correction in the last 12-month period of the given block?

Ashish Adukia: Yes, sure. So I can take that question. So it's not the impact of like we mentioned the revenue will continue to be in the growth trajectory. It's basically a mix that is likely to change. And one of the key reasons is generic Revlimid, which will go out of exclusivity towards the last quarter. So that will certainly have an impact on overall margin. And that's why we are guiding towards the margin number that we've given.

Umang Vohra: Maybe if I can just add to what Ashish said, I think in the current year, just to be in all transparency, we have possibly exceeded what we gave as a guidance range. And if you -- Ashish's commentary was about 150 basis points from where we guided is where EBITDA is higher, right? So if you were to just take the 150 basis points out, we're broadly in the same range that we had communicated as a possible guidance range for the last year.

Surya Narayan Patra: Okay. Sir, second question is about the capex for FY '26. What is our thought process there? And for the peptide as well as in the GLP opportunity, how prepared we are? And also a last question, if I just -- since it is the final year -- I mean fourth quarter results that we are discussing, what would be the overall respiratory revenue that we would be making out of the consolidated revenue? If you can give that number, please?

Ashish Adukia: Okay. So I think there are probably 3 questions in that one question. So let me start with the first one on capex. I think -- so see, if you see in the last couple of years, we've actually increased our investments on the capex side. And these are all very strategic calls that we are taking to actually -- and to increase our capacities in respiratory capacities. And so most of the capex that you see are actually -- growth capex that you see are actually oriented to increase the respiratory capacity in MDI, DPI and rescues.

Other than that, we also have our capex oriented towards derisking to the outside India facilities. So we have the China facility that got capitalized recently and the product supply has started from there. And then we have both facilities in the U.S. getting ready to start supplying MDI and DPI from there. And then you have a large maintenance capex as well, which is ongoing. So that's been our capex strategies, all oriented towards our strategic plan that we have in the future.

On your second question, which was on GLP-1, okay? So I think Umang has covered in the past that we'll be ready whenever there is a first wave of launch that will come through. And we are looking at both in-house as well as third-party partnerships out there to make sure that we are in the first wave of launch. And your third question...

Surya Narayan Patra: Was about the respiratory revenue share?

Ashish Adukia: Yes. So it's about -- see, respiratory is one of our top strategic -- continue to be our top strategic pillar. So we continue to be 30% kind of a revenue overall that comes from the respiratory on a global level. So that's what we track very closely.

Surya Narayan Patra: Okay. Sir, did you share any number for the capex for the next year? No?

Ashish Adukia: So about 4% roughly of your -- 5% of your revenue, yes, somewhere around that would be the figure for the capex, 5% of revenue you could take.

Moderator: The next question is from the line of Neha Manpuria from Bank of America.

Neha Manpuria: Umang, on the India market, now that the trade generic restructuring that we were doing is behind, if I look at this year, obviously, that was impacted by seasonality. How should I think about growth? While we have mentioned higher than IPM growth, what's your overall sense on what the market growth can be, therefore, what the trade generic and branded generic growth for Cipla could be?

Umang Vohra: So I think I was just mentioning this a little earlier to someone else, the market -- overall market growth rate range of 10 to 12 has now moved to 8 to 10. And the reasons for that is that we've gone through pretty superlative new introduction movement in the market because you had everything

coming off patents, dapagliflozin, empagliflozin, right? You had sacubitril/valsartan. A lot of products went off patent and therefore, NI growth actually went up. And so therefore, you lost right -- compared to that and now you will see -- possibly 1%, 1.5% lower future growth due to the fact that the NI season, as you may call it, of expiries is gone.

The second aspect is inflation used to be higher. So companies were given pricing adjustments, which was at inflation then. Inflation numbers are now lower, so you lose another 1% to 1.5% there. So what was a 10% to 12% range is now somewhere in the 8% to 10% range going forward for the industry. And Cipla will do better than that overall in India.

Neha Manpuria: Understood. And in trade generics, we have regained all the -- whatever lower volume that we have, so it's fully back to normal?

Umang Vohra: It is fully back to normal, and the whole distribution channel now is completely internalized to Cipla.

Neha Manpuria: Understood. My second question is on capital allocation. Given the cash that we are sitting on, I know you've indicated in the past. But as you just refreshed through what your priorities are, has there been any changes in terms of where you'd look at opportunities inorganically to deploy that cash?

Umang Vohra: Ashish?

Ashish Adukia: Yes. So I think, again, we see India as our growth market. And I think it always gives you a good return on capital as you invest capital in India. We've invested on people. We've been investing on capex that I talked about. And we'll also continue to look at small to large M&A opportunities out there, which can come in the form of not just companies, but product portfolio, etcetera, that we may acquire out there.

I think the second opportunity that we see is always adding to the portfolio in the U.S. So we keep looking at partnerships where complex -- where we can acquire complex generic ANDAs or NDAs, which requires you to pay some sort of milestone upfront, but then the asset is yours and you start to commercialize those assets. I think other than that, EMEU, we look at opportunistically acquisitions out there as well.

It won't be large in size, but more midsized kind of an opportunity that we'll invest in. So we have many avenues to look at from a capital allocation point of view. And you would have seen that we have also accordingly maintained the dividend that we had increased in the last 2 years.

Moderator: The next question is from the line of Shashank Krishnakumar from Emkay Global.

Shashank Krishnakumar: My first one was on the partnered inhalation asset, which we had filed a few quarters back. Just wanted to check if we are on track to commercialize this asset sometime next year. And also just wanted to check which facility is this asset now filed sir?

Umang Vohra: Yes. The asset is on track for commercialization. And also the asset was originally filed from Goa. It will be commercialized from Goa. We're also creating a new filing for -- we are also

supplementing the file if -- where needed by also having the option of doing this from our U.S. facility.

Shashank Krishnakumar: Got it. My second question was on the domestic business. I think we mentioned in the opening remarks that the Consumer Health business saw double-digit growth this quarter. Would it be fair to assume that the trade generic business also grew in double digits this quarter?

Umang Vohra: No, I don't think so. I think the trade generic business did not grow as much as the Consumer Health business. It did not grow double digit.

Ashish Adukia: Yes. So trade generic business, if you see Y-o-Y basis, okay, so the model change that happened impacted quarter 1 of FY '25. So quarter 4 was broadly a normalized quarter of FY '24. So therefore, the Y-o-Y growth out there in trade generic is a normal growth that you would see.

Moderator: The next question is from the line of Sidharth Negandhi from Chanakya Wealth Creation.

Sidharth Negandhi: This was again on the domestic business. How are you thinking of the schedule extension that was given up to 31st December for MSMEs in context of whether that can be a tailwind for further growth on the trade generics business as well as the branded generics business? Do you see that a tailwind coming in should that implementation happen? And how are you thinking whether that is likely to happen?

Umang Vohra: No, I don't think we see that as a big driver for our growth. In fact, I think not having the ability to create more uncertainty in the market. So not -- I don't think we see that as a big headwind -- as a big tailwind for us this year.

Sidharth Negandhi: And the second question was on what you mentioned about the recent most U.S. regulations, right? Now while it is an advantage for generics as far as the MSME is concerned, given certain parts of the portfolio at supplies, also specialty, does that most favored nation policy create any impact on that specialty part of the portfolio?

Umang Vohra: We don't have too much share of new drug spec. I think the focus of the legislation is on new drug spec as against simple 505 (b)(2)s, which are either with different salt forms or with different delivery systems, because most of those 505 (b)(2)s are reimbursement -- that's reimbursed at the same manner in which the ANDAs are reimbursed. So I think the focus of the legislation is on new drug NCs and we don't -- a new drug products, and we don't have those.

Moderator: The next question is from the line of Devang Shah from Asit C Mehta Investment Limited.

Devang Shah: Just I want to know that the way you have mentioned as far as your EBITDA guidance the -- as far as overall revenue for next FY '26, can we expect that your top line is going to go in the range of 7% to 9% kind of thing. The way you already mentioned that you are going to continue the same growth trajectory. So I'm just talking about the overall growth, will be in the same range as far as top line revenue is concerned?

Ashish Adukia: Yes. So Devang, we don't give revenue guidance. And then we usually every year give EBITDA margin guidance, because our focus is on profitability to ensure that we maintain that. So that's why we continue to give the profit margin.

Devang Shah: Okay. And my second question, the way, sir, the U.S. in which the situation somewhere right now evolving related to pharma-related aspects, can you throw some light that it is going to affect the -- our U.S. business or we do not have any kind of challenges due to that?

Umang Vohra: No. I think there are 2 things that are happening in the U.S. One is the tariffs for which right now, there are no tariffs on generic products from India, by and large, and from -- actually a lot of countries other than perhaps one odd country. So I don't think we're impacted by tariffs as yet. And we don't see the markets as being very different in the future on that.

The second one is the recent executive order on pricing reductions that companies are to voluntarily take. I think that is -- generics, quite honestly, is a beneficiary of that order because it creates a market where generic drugs would be preferred. We're not seeing this in -- we're not seeing that impacting our business at all.

Moderator: The next question is from the line of Bino Pathiparampil from Elara Capital.

Bino Pathiparampil: Umang, are we still expecting to launch Symbicort in FY '27?

Umang Vohra: '27, yes. We should be hopefully there.

Bino Pathiparampil: Okay. And sir, there is this product Teduglutide in which you and your partner have filed a -- filed for a declaratory judgment. Could you give some details about when do you expect to launch this?

Umang Vohra: Actually, Bino, I would rather not provide, since the product is competitive. I think it's -- but if you follow the court and what the summary judgment is being -- or the details being asked for, I think, you might be able to figure it out. So yes...

Bino Pathiparampil: Understood. Understood. Okay. And if I can put it this way, I believe the product has an orphan drug exclusivity to May 2026. So is it slightly before that or after that?

Umang Vohra: Yes. I think you're on the right track, Bino. You're on the right track. I'm not -- yes, I think you're on the right track, and it might be a little bit longer than that also -- after that also.

Bino Pathiparampil: Got it. And finally, with Lanreotide coming back, are we looking back to getting to our peak U.S. run rate of $250 million a quarter starting next quarter or something like that?

Umang Vohra: Well, if lenalidomide stayed at where it was now, yes, we would have got there and crossed it. But you also have to see the next 2 or 3 quarters is when we will see a compression in lena. And that will be offset by these new products that are coming up. So our current guidance range is different for the overall U.S. market. We don't comment specifically by product. But as of now, we are looking at something like $220 million for the U.S. going forward in the next quarter or so.

Bino Pathiparampil: Sorry, you said $220 million around?

Umang Vohra: That's right. For the next quarter, considering what we know is going to happen to lena, etcetera.

Moderator: Next question is from the line of Dr. Kunal Dhamesha from Macquarie.

Kunal Dhamesha: Just one clarification on Lanreotide. We said that by quarter 1 or the current quarter, we have enough product in the channel to reach the previous market share. Is that correct understanding?

Umang Vohra: No, I don't think we said enough product in the channel. I think we said we have resumed our supplies back. The channel, quite honestly, is quite -- does not have too much product of Cipla because we are getting back into the business. So right now, we have -- we are projecting enough supply to be able to start building towards that range.

Kunal Dhamesha: Okay. So basically our revenue ramp up would be more or less in line with our market share ramp-up? Is that the correct way to understand?

Umang Vohra: So let me -- yes, so let me probably say that we are right now at a stage where we are beginning to produce to roughly the same levels that we used to produce when we had the market share that you have in mind. And from that -- to go through that market share, because we have to keep a little bit of stock spare as well as fill the pipeline and fill the channel, it will take a little bit of time. But production is roughly coming back to the level that we used to have when you saw the market share you have in mind.

Kunal Dhamesha: Great. Another clarification on Advair. When did we file the amendment to the U.S. FDA?

Umang Vohra: It was -- I don't think we are giving that level of guidance specifically because, again, the product -- the launch time lines can be calculated from that perspective. But I can just tell you that it's already into the FDA, and it's been filed.

Kunal Dhamesha: Sure. And lastly, the 3 peptide assets that we expect to launch in FY '26, any indication as to how should we think about the size of these products with respect to the currently launched peptide products?

Umang Vohra: Ashish, you may have better color on this.

Ashish Adukia: Yes. Sorry, you...

Umang Vohra: 3 peptide.

Ashish Adukia: Yes, yes. so I think it's -- we're not giving guidance of size, but these -- one of them is likely to be a large asset for us. And the other 2 would be smaller assets.

Moderator: The next question is from the line of Anubhav from UBS.

Anubhav Agarwal: One question on Nilotinib. I'm just trying to understand this as an opportunity. Is it a $10 million, $20 million opportunity revenue size or...?

Moderator: Sorry to interrupt you, Mr. Anubhav. Can you speak a bit louder? We are unable to hear you clearly.

Anubhav Agarwal: Yes, sure. Sure. I repeat my question. So first, is this okay? Am I audible now?

Moderator: Yes, you are.

Anubhav Agarwal: Okay. So first question is on Nilotinib, just trying to understand how big is this kind of opportunity? Is it like on revenue, roughly about $10 million, $20 million opportunity annually or this can be a $20 million, $50 million scale opportunity? Just trying to understand this.

Umang Vohra: Anubhav, we are not giving product level guidance or specifically on this, but there are multiple factors that can play out on this. And I think they are related to how soon an ANDA enters versus how soon a B2 product can exist.

Anubhav Agarwal: And you will be launching this product when?

Umang Vohra: It's imminent. It's imminent.

Anubhav Agarwal: And just on the U.S. sales, last year, we did $934 million. When do you expect to reach this level in, let's say, FY '27, '28, '29? When would you again reach that level, roughly?

Umang Vohra: Well, the hope will be to obviously reach at -- to reach the same level. But depending on the challenges in the market, we don't think that there's enough definitive and predictive analytic to suggest where we'll reach because there's -- lena is fairly significant, and it depends on how the lena trajectory unfolds in the U.S. But we've given you a range for next quarter. I think if you use that and add some of our new launches and take an estimate of where lena goes, you might be able to come to a conclusion.

Anubhav Agarwal: Just one last question on the semaglutide in India market. So when you launch it, would you be pursuing both the target and the injectable versions there or only one of them?

Umang Vohra: We will be in whatever variant forms for the market. And I think it will likely to be the injectable first. And I think we'll definitely be in that. And also in -- as and when the market opens for the oral, we'll also be there in that.

Moderator: The next question is from the line of Sanjay Kohli from Gold Stone Capital.

Sanjay Kohli: So this executive order, when does it get implemented? And it's very interesting that you said that generics will actually benefit out of it because the innovator prices are -- if it's going to really target the innovator pricing then just give some -- can you give some color on this...?

Moderator: Mr. Kohli, sorry to interrupt you. Your voice is sounding very muffled, sir.

Sanjay Kohli: Muffled? Okay. Better now?

Moderator: So what is happening there is echo also, which we are getting from your line, sir.

Sanjay Kohli: Just a second, let me come near the window to have a better signal. My question -- am I audible now?

Moderator: Yes, please go ahead, sir.

Sanjay Kohli: So the question is directed about the executive order, which is proposed. How quickly do you expect this to get sort of implemented? And on a voluntary basis, could you give some color on this and how it affects pricing on generics?

Umang Vohra: Well, right now, we don't think it affects pricing on generics. We think that the executive order is probably more towards branded drugs as against generic medicines. And we believe that in the long run, generics will be a beneficiary to this.

Sanjay Kohli: How?

Umang Vohra: Well, look at it this way that if you -- if your overall prices are promulgated to reduce, why would branded companies be interested in spending massive amounts of promotion, etcetera, into it. And therefore, the newer -- the categories of drugs that cannot be -- they may actually move over to those drugs which are already generic but -- yes, go ahead.

Sanjay Kohli: So would it mean that the system is recognizing a certain inefficiency innovator and that is also likely to -- they're likely to -- something to be happening there also for lowering the cost.

Umang Vohra: I don't know. I mean look, I think right now, it's been 1 day since the orders come. They're also digesting it. Maybe we'll be in a better position to speak about it over the period of the next month. It's too recent. I wish them to review it after earnings call today. This has got a lot of questions on it, but we really don't know much about it. Sorry.

Sanjay Kohli: So can I get -- slip in another question, please, on the proportion of your U.S. sales, how much of it do you manufacture in the U.S. close to $1 billion?

Ashish Adukia: Yes. So about 25% comes from U.S. Right now, it's mainly orals, and we'll be adding, like I said, MDI and DPI as well. And about -- roughly about 33% -- 1/3 of roughly comes from India currently. The balance we have CMOs, etcetera.

Sanjay Kohli: And my question was of the 29% of North American sales, what percentage of that is supplied by your facilities over there?

Ashish Adukia: Yes, that's what I'm saying. So if you -- so 25% to 30%, like I said, it's 1/3, 1/3, 1/3 of U.S. sales.

Sanjay Kohli: Right.

Umang Vohra: So 1/3 of U.S. sales. So for the 29%, let's say, 10% will be made in U.S., right, and 10% in India and 10% is the rest of the world.

Moderator: The next question is from the line of Krishnendu Saha from Quantum Mutual Fund.

Krishnendu Saha: Quickly on the India piece, the 7% Y-o-Y growth, is it largely attributable to volume growth?

Umang Vohra: No, actually, it's a mix of all 3. If your question is whether the volume growth is majority in India, no, I think pricing is also there and so is new introduction. So no, I don't think it's all volume.

Krishnendu Saha: Okay. Just one more thing on China, the plant you said it started supplying. What does it exactly supply, to which region? Any color on that?

Umang Vohra: It's a respiratory plant. So it supplies respiratory medication and is built with the intention of supplying the China market and other markets that require that product, including the U.S., if required.

Krishnendu Saha: And this will include the future filings also, which you target for the U.S.?

Umang Vohra: Not really. This is only for the current filings. The future filings are going out of our sites in the U.S. and India. Yes, the China market itself is also quite big for the type of products that we will be managing.

Krishnendu Saha: I see. And just a double check on the Revlimid have we filed for -- sorry, not Revlimid, I mean, sema, have we filed for Canada or some Brazil market?

Umang Vohra: No, we have not.

Krishnendu Saha: And on the Revlimid, do you get any volume increase this year?

Umang Vohra: Yes, I think the -- if your question is, has there been a volume increase as per this, I think for us, very marginally compared to some of the other players who've had huge amounts of -- who have commented on larger volume share. For us, it's very marginal as per the agreement that we've signed with them.

Moderator: The next question is from the line of Nitin Agarwal from DAM Capital.

Nitin Agarwal: On the Europe and emerging market business as well as South Africa, we've had a pretty strong recovering growth this year. How should we look at these markets from here on? These are the -- has something really changed in these businesses?

Ashish Adukia: See, I think South Africa, there are a couple of portfolios that helped us to grow at those numbers. So 3 levers actually -- let me put 3 levers out there. So one is the Actor acquisition that we had made that helped us to grow out there on the OTC side primarily. Second is some opportunistic tenders that we did out there, which also helped us to grow out there. And the third is new launches that we've been doing.

So our new launches share has been higher than our competition. So that has actually also helped us grow. But overall, if you look at the market, it's a 4%, 5% market -- growth market. So I think on a normalized basis, we should take 4% to 5% kind of a growth for South Africa and not necessarily the beating growth that we have done because our focus will also be on the profitability there.

EMEU is a multitude of many markets. So therefore, it is difficult to give a number because there will be different growth rates in different markets. But I think we -- last year, we focused a lot on execution, which has helped us to achieve a 15% growth on USD terms. And like we've said that it has entered the growth phase. So next year also our target is to actually grow that in that market.

Nitin Agarwal: And secondly on the U.S. with the guidance that you put out about $220 million thereabout for Q1. Do you see a lot of the impact of lena actually getting factored probably in that number? So with some of our bigger launches coming through the year, do we see this number picking up as we go along? Or this is a number which potentially can down further depending on how lena plays out?

Ashish Adukia: I think Umang has covered that question. I think we are not giving guidance right now beyond quarter 1. for U.S.

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

Tushar Manudhane: So just on the peptide assets, if you could elaborate in terms of the investment done till date as far as R&D or manufacturing is concerned? And what kind of investment sort of we are targeting over the next 2 to 3 years?

Umang Vohra: Ashish bhai?

Ashish Adukia: So peptide is -- a lot of our peptide portfolio, we go outside to the CMOs. We -- like we said that we don't have injectables facility. So therefore, a lot of our investment is on the development side on peptides. And -- so there are 3, 4 broad categories of R&D expenditure that we have. Peptides is one of them, respiratory, bio is there. And then there are other complex and long-acting injectables, etcetera, that we have. So it's part of the R&D expenditure that we incur.

Tushar Manudhane: Got it. And one last -- in the earlier comments, you referred to some large assets probably we can be there for FY '26. So this approval, what is the -- if you could share the expected time line for the approval for this product?

Umang Vohra: No, I think there are -- we have 2, 3 products which are peptides, which we are expecting this year. Then we've got -- we've just recently been given the approval of nano paclitaxel, and there are a few others that we have in our pipeline. So we are hoping that these approvals can come in the second half of the year. And -- I mean, they will come when -- as they are approved in the first half and second half. But some of the -- you will see the full impact of a lot of these products in our second half of the year numbers.

Moderator: Ladies and gentlemen, this will be the last question for today, which is from the line of Vishal from Systematix.

Vishal: So basically, my question is on the inhaled insulin...

Moderator: I'm sorry to interrupt you, Vishal. We are unable to hear you. Can you speak a bit louder?

Vishal: So on the inhaled insulin that you got approval for in the last quarter, just wanted to get the sense on the opportunity size. How are you going to price it versus the other injectable insulin? And largely because the asset has not done well globally so anything that you can kind of make it work in India?

Umang Vohra: Well, I think the -- obviously, on pricing, etcetera, we have an idea of where the market needs to be. I think we are working towards that. I think the launch is somewhere around -- should hopefully follow in 3 to 4 months, and we have a market plan for this. The idea of inhaled insulin is never to replace the way insulin is served in the market in India. So we don't -- by its very nature, the asset is a niche asset for people who cannot take injectable drugs or people who are hesitant to take injectable drugs.

So that is the reason and the niche where it will be positioned. It's not a mass product. So I don't think the product needs to do hugely well in any market because it's not intended to do that. It's intended to serve a section of population and an unmet need for that population.

Vishal Manchanda: Okay. All right. So kind of any number as to like, can it be a low single-digit market share product in terms of volumes?

Umang Vohra: The overall insulin market, yes, probably that's where it will end up. It's not going to be a huge market share product. But the insulin category is huge. And our research says that there is a list of people who have injectable phobia and who might actually benefit from inhaled insulin.

Vishal Manchanda: Right. And just a follow-up on GLP-1. Have we initiated the clinical trials on the -- for the India market?

Umang Vohra: Well, as I mentioned between -- we will be on the day of the market creation. We are not giving specific detail on the product per se right now.

Moderator: Ladies and gentlemen, that was the last question for today. I would now like to hand the conference over to Ms. Diksha Maheshwari for closing comments.

Diksha Maheshwari: Thank you, everyone, for joining in. If you have any further questions, please write it to investor.relations@cipla.com.

Umang Vohra: Thank you.

Moderator: On behalf of Cipla Limited, that concludes this conference. Thank you for joining us, and you may now disconnect your lines.