“Cipla Limited

Q4 FY '23 Earnings Conference Call”

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Moderator: Ladies and gentlemen, good day, and welcome to the Cipla Limited Q4 FY '23 Earnings Conference Call. We've been joined by: Mr. Umang Vohra, MD and Global CEO, Cipla Limited; Mr. Ashish Adukia, Global CFO, Cipla Limited; Mr. Naveen Bansal, Head, Investor Relations, Cipla Limited; Mr. Ajinkya Pandharkar, Investor Relations team, Cipla 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 star then zero on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Mr. Ajinkya Pandharkar from Cipla Limited. Thank you, and over to you, sir.

Ajinkya Pandharkar: Thank you, Dorwin. Good evening, and a very warm welcome to Cipla's Q4 FY '23 earnings call. I'm Ajinkya Pandharkar 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 our future events. These estimates reflect the 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 Umang to take over.

Umang Vohra: Thank you, Ajinkya. Good evening to all of you and I appreciate your joining us today for our fourth quarter earnings call for financial year '23. I hope you have received the investor presentation that we've posted on our website. I'm pleased to share that we continue to make significant progress across our strategic priorities. In fiscal year '23, we recorded the highest ever revenue and EBITDA, including several major milestones in our One India and U.S. businesses, pivoting our business on an accelerated growth and a strong margin trajectory.

We also continue to invest capital across multiple growth initiatives, including investments in the complex pipeline in new science into our big brands and expanding our consumer portfolio among others. I would like to cover some key themes that have played out in our financial performance for the last year. One of the key themes is delivering market-beating growth in our focus markets of India, South Africa, United States and some of the large emerging markets. Our India branded prescription business delivered sustained momentum across all our therapies, achieving 13% excluding COVID year-on-year growth while the IPM growth was 8% as per IQVIA at March '23.

Importantly, our overall share of chronic therapies expanded year-on-year by 300 basis points to 59% of the total portfolio, an 80 basis points increase in the market share from -- in the market

share for the chronic therapies from 7.5% to 8.3%. We do not expect the NLEM pricing impact to influence our growth significantly as it will be balanced via allowed price increases and continued volume growth. This business has consistently posted market beating growth for 2 consecutive years as per IQVIA.

In South Africa, Cipla grew at a 3-year CAGR of 8.9% faster than the market, which is growing at 4.4%. Our focus continues on driving market-leading growth and increasing our share in the market of South Africa. I will cover the U.S. market subsequently. Within India, the other focus area for us has been growing our big brands across all our businesses. In India branded generic, we now have 21 brands featuring in the top 300 brands and which are over INR100 crores of sales as per MAT March '23. In our trade generics business, we have 8 brands that are above INR50 crores of sales and are much larger in volume terms catering to the length and breadth of the country.

Cipla Health has successfully transitioned and consumerized some of the existing brands into megabrands with sales of over INR100 crores. This has been achieved through leveraging brand strength to its maximum deepening market penetration, significantly higher consumer-oriented packaging and positioning. Our India consumer franchise is already tracking at INR1,000 crores plus on an annual basis, and we expect the EBITDA margin to move closer to mid-teens in FY '24 and grow sustainably from there on.

I'd now like to talk a little bit about our U.S. market. One of our core themes has been to broaden our pipeline in this market. We are pleased to share that our U.S. business has crossed $200 million for the first time in this quarter. The full year for this business stood at $733 million, growing over 23% from last year. This has been achieved through our pipeline and execution.

We had announced a peptide pipeline earlier in FY '23, and this has added a new muscle of institutional capability and portfolio, which we aim to further enhance. Our lead asset of lanreotide now has 17% share in this market.

While launches are a focus area for all markets, noteworthy of the 50-plus launches in India, trade generics market and the 32 brands launched across multiple therapies in South Africa. This new leg of revenue in South Africa is likely to offset the reduction in the tender business and the margin pressures we have seen recently.

We continue to invest in growth franchisees. In line with our strategy to continue our focus on expanding our One India franchise towards the higher share of chronic therapies, we recently signed a perpetual license agreement with Novartis for Galvus and its combination brands, which, as per MAT March '23 IQVIA had reported sales of nearly INR270 crores. This will be a strong strategic fit to strengthen our IBDs portfolio.

We also entered into a strategic partnership to market and distribute Scapho, a human IgG1 monoclonal antibody used for the treatment of psoriasis. In Cipla Health, we acquired Endura MASS, a renowned nutritional supplement, which has a niche positioning in this market. While we continue to invest in brands, we also focused investments in enhancing people capabilities

in the field force. In -- over the last 2 years, our field force in India has grown by over 800 people.

Our R&D investment continues to increase. In terms of pipeline, we've made significant progress on initiation of trials across some of our complex products. On the pipeline front, we have 3 differentiated products undergoing clinical trials with filings targeted in FY '24.

Our last but most clinical theme has been to derisk our U.S. portfolio. Our U.S. supply continues to be well diversified across all our sites and partner sites in -- and partner sites from our partners. On our compliance front, at Fall River, Massachusetts, we recently completed the CGMP audit, which resulted in 0483 observations. We have approval to produce our respiratory assets in this facility. Respiratory assets are being derisked to this in-house facility.

For Indore, we expect classification by mid-May. However, we do not see any risk to commercialize product portfolio. Generic Advair is already being derisked to another in-house facility. Remediation efforts are ongoing for our Goa facility, and we expect a CAPA completion by end of Q1. Reinspection is required for plant clearance, which is being targeted for quarter 3. Our generic Advair file is now solely dependent on the facility approval, having cleared all other questions from the agency. We have already commenced the derisking process for this product, as I mentioned earlier, to our other in-house facility. The value stays intact as no new generic is expected before we launch.

Nanopaclitaxel is being used, as I mentioned earlier, to a partner CMO site, and exhibit batches are being taken. We expect to be able to supply from 2 sites by fiscal year '25. We don't see any change to the value of this product as well as there are clearly no generic launches till date.

With this, I would now like to invite Ashish to present the financial and operational performance.

Ashish Adukia: Thank you, Umang. This quarter, we witnessed strong performance across all our core businesses with overall expansion and profitability. The quarter reflects our consistent performance in One India with better than market growth and our performance in our differentiated product launches in U.S., which was done earlier this year.

Coming to the key financial highlights for the quarter. Overall, we are pleased to report a quarterly revenue of INR5,739 crores, with full year revenue closing at INR22,753 crores. The overall revenue growth for the quarter was at 9% Y-o-Y on a reported basis and on ex-COVID basis, a strong 14% growth. And for the full year, the same number on a Y-o-Y growth stands at 5% on reported and 11% on ex-COVID basis.

Our One India franchise further expanded its market share in a traditionally weak seasonal quarter by growing at healthy 16% on an ex-COVID basis on back of extended countrywide flu season. The North America business reported a highest ever revenue driven by traction in the differentiated portfolio with revenue of $733 million, growing at 23% Y-o-Y.

Our free cash flow generation and operating efficiency continue to drive our healthy net cash position. Our reported ROIC for the trailing 12 months stood at about 24%, which is over our long-term range of 17% to 20% that we've talked about earlier. In line with our expectation,

EBITDA margins stood at 20% plus for the quarter on a reported basis, whereas we ended full year at robust 22%. This EBITDA margin is not including other income. Our EBITDA margins for the year subsumes the impact of lower-than-anticipated SAGA performance, a high inflationary market and a higher R&D spend and certain COVID provisioning. Adjusted for COVID, the margin for the full year stood at 23%.

Higher R&D investments driven by ongoing clinical trials on differentiated assets, as well as other developmental efforts, including contribution to biosimilar JV was higher in the quarter by 15% versus last year and is part of our profitability model. Our reported gross margin after materials costs stood at 64% for the quarter, which is 480 basis points above last year's figures, driven by contribution from new launches and overall mix change. As you may recall, last year, we had onetime COVID charge of inventory provision in quarter 4, which had impacted the reported gross margins.

Total expenses for the quarter, including employee costs and other expenses, which stood at INR4,565 crores, up by 3.7% on a sequential basis. The other expenses, which includes R&D, regulatory, quality, manufacturing and sales promotions are at INR1,537 crores, increased by 6.1% sequentially, driven by judicious promotional and growth link investment. Total R&D investment for the quarter are at INR371 crores, about 6.5% of revenue and were 15% higher, like I said, on a Y-o-Y basis. R&D expense for the full year stood at INR1,344 crores, which includes material cost, depreciation, etcetera, etcetera.

Profit after tax for the quarter is at INR526 crores or 9.2% of sales, adjusting for onetime impairment charge on account of divestment of certain noncore assets in Africa and Middle East, adjusted PAT stood at INR708 crores, which is 12.3% of sales. The adjusted growth rate over last year is 436 basis points and adjusted ETR, effective tax rate, is at 24%.

Full year PAT is at INR2,802 crores while adjusted PAT is INR2,984 crores to 13.1% of sales. As of March '23, our debt primarily constitutes ZAR 720 million in South Africa. We have repaid our working capital loans of about $50 million in the U.S. given the interest cost environment.

Turning now to our outlook. We established strong threshold for revenue growth and operating profitability with core margins trending in the 22% range.

To close, we saw robust momentum across portfolio and geographies for FY '23. The growth levers in the subsequent quarters will include continued market beating growth across One India, prescription, trade generics and consumer health. Full year operating profit in line with our guidance of about 22%, which includes continued investment in R&D programs.

Robust traction in our North America franchise across complex portfolio and continued contribution from respiratory and peptide products, creating a more resilient business through de-risk portfolio and supply. And lastly, incubate and drive growth in stable geographies in international market.

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

Moderator: The first question is from the line of Tushar Manudhane from Motilal Oswal Financial Services.

Tushar Manudhane: Sir, first one, while this is derisk to another in-house site, will that require reinspection?

Umang Vohra: Yes. It will probably require an inspection at that site since this will be PPI product from that site.

Tushar Manudhane: Sir, secondly, while this might take some time, even nanopaclitaxel, adding this to FY '25. And at least as per the presentation, we have seen maybe just 2 to 3 final approvals in FY '23. So how should one think about FY '24 growth prospects for North America business?

Umang Vohra: Yes, I think we are signaling fairly -- signaling a fairly significant growth even this year as compared to the rest of the reporting universe.

Tushar Manudhane: That is on the back of Q4 sales run rate primarily?

Umang Vohra: I'm talking about all of last year, and I think that is on the back of continued traction in lanreotide continued traction in some of our existing product families and where the market itself may be expanding. As well as the -- so I think those 2 factors should result in continued profits in the U.S. portfolio.

Tushar Manudhane: And just on this depreciation quarter-on-quarter, from INR270 crores to INR346 crores. So if you could clarify this?

Ashish Adukia: Yes. So I think the depreciation figure that you're talking about, some increase that you're seeing out there is on account of some of the impairments in the intangible assets that is taken. Every year...

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

Kunal Dhamesha: So first one on the domestic consumer health business. It seems like 9-month run rate was around INR975 crores plus. And full year, we have done INR1,022 crores. So there is, I think, significant Q-o-Q deceleration because H1 was INR675 crores. So from INR300 crores a quarter, we have gone down to INR47 crores. Is it seasonal? Or there is more to it?

Umang Vohra: It's seasonal, we have a portfolio which is fairly large for the summer months in terms of things like ORS. And I think that's the reason why you see a fair amount of sale in quarter 1 and quarter 2.

Kunal Dhamesha: So it's expected to recover, right?

Umang Vohra: Yes, yes, yes.

Kunal Dhamesha: And as far as generic Advair is concerned, I was under impression that it requires a specific production line, right? Now we are transferring it to another site. So would it mean that we would be putting another line for it? Or how does it work?

Umang Vohra: Yes. There will be another line that will be put up, a different line that will be put up in the new facility.

Kunal Dhamesha: And would you be sharing what would be the expense related to that, capex.

Umang Vohra: Not much, not significant in the scheme of things for the product or for our overall franchise of GPI because now our strategy is to try and file every product that we are doing on the respiratory side from 2 sites and not 1.

Kunal Dhamesha: And last one from my side. U.S., we have reported $200 million plus. Do we believe that this is expected to be sustainable in the coming quarters? Or there will be some variation here and there?

Umang Vohra: I think we had guided last time that till the range of $190 million to $195 million, we expect that should -- that's a good trajectory for the base business.

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

Prakash Agarwal: Just trying to understand this better. So we mentioned about nanopaclitaxel in '25. So where is there a time line guidance that we are giving? Or we're just saying that, okay, we are derisking and we have another facility and probably in the next 12 months, we'll see something? Or just in terms of some time line would be useful.

Umang Vohra: I think from now, Prakash, a time line of about 12 months or so for most products is something which is probably a good average to take.

So if we are faster than this, it will be -- if the facilities get here, where they are filed from right now, then the launches are imminent. If the facilities do not get cleared for whatever reason, then this derisking operation will result in a product in the next 12 months.

Prakash Agarwal: Specifically Advair, so unlikely to be within 12 months?

Umang Vohra: Yes. Advair would be slightly longer than 12 months, but nanopacli has a good chance within this. And there's a third product also that is being derisked.

Prakash Agarwal: Yes. So that was my second question. In terms of -- in the last couple of quarterly calls, you had shared presentation, which had some color on the pipe on respi and peptide products. So how are we on the remaining products?

Umang Vohra: No, I think for every product that we are going to be filing for which the trials may have started or what we will be filing from 2 sites now. So I think that is a decision we have taken. Which are the big products will all be filed and will have derisking within the filing. But the 3 products that we had guided to earlier, there's a large share of our product pipeline that comes from outside, including -- which includes most peptides in our pipeline.

And then in these 2 specific things, rather than keep waiting for the outcome of the inspection, etcetera, we are now moving to a strategy of derisking them at the fastest pace that we can.

Prakash Agarwal: And that would be what $2 billion, $3 billion kind of additional costs or it's a higher cost to the bid?

Umang Vohra: No, I don't think there's a cost -- there's no clinical trial on this; on any of these products that we think is required.

Prakash Agarwal: Okay. And just to tie that up, so R&D, the new -- or the increased efforts, which is a Y-o-Y increase, etcetera. So while the respi and peptide pipeline you showcased, so what is the new or the existing areas we are investing in for the next 3 year growth?

Umang Vohra: I think it is largely respiratory. Respiratory peptides, I think between these, there's a fair number of assets that we have.

Ashish Adukia: Yes. Just to further clarify, see one is, what stages these assets are in? So some of these assets are in clinical stages, so that's why the expenses are higher. And then there is biosimilar as well the development cost that is included in that. So biosimilar is beyond these respiratory and peptide.

Prakash Agarwal: If you allow, I'll ask one more question. So Q3 around December -- November, December, we had the [inaudible 0:24:30] impact on a few of the products, inhalation products also. And price has come down. So how has been the response in the Jan to March quarter for those kind of products? Have you seen material change? And obviously, in April, you would have taken price hike, you mentioned that you don't expect the volume to come down. So if you could just give more color on these 2 aspects would be great.

Umang Vohra: Yes, I don't think we're seeing any significant change in the market because of either the impact on pricing either way. Let me put it that way. I think the volume growth continues to be strong, irrespective of the action, and the price decreases are already in the numbers.

Prakash Agarwal: Yes. Already within the numbers, but price hike will take time to -- or it would start coming in from the current quarter itself?

Umang Vohra: That's right. So the price hike impact will start coming in from quarter 1. It will start coming, but it builds up depending on when the price hikes were taken for the product in the previous year. So the real impact of price hikes will start showing up in quarter 2 and quarter 3.

Prakash Agarwal: And finally, any read on the volume decline seen in April month? I mean while respiratory anti-infective did fairly well. But on the market level, volume was surprisingly low.

Umang Vohra: Actually, our category is on volume, they seemed okay even beyond respiratory and anti-infective. We haven't seen much of a concern. Actually, our volumes are higher than the market based on what we know.

Moderator: The next question is from the line of Damayanti Kerai from HSBC.

Damayanti Kerai: Coming back to Advair, Umang, can you clarify, like I missed your initial comments. So you mentioned Indore FDA status will be known in mid-May, and this plant will be likely audited in third quarter. Did you mention that?

Umang Vohra: No. What I mentioned was that right now -- so there are 3 things I said on Advair. I'll just recap them forward again. First is that the file has cleared the entire -- everything else from the FDA other than facility? So there are no other pending questions from the FDA on the file, from what we have received so far.

The second thing is, if in dollar cleared, then there is an imminent launch for it; Advair. Having said that, we are also derisking the asset because it's always good to have 2 sites of manufacturing for an asset of the type of Advair or nanopaclitaxel. And so therefore, this asset is being transferred to another in-house site, which is -- which will take perhaps another 12-odd months. And that's what we are doing. So the asset will get transferred and there'll be new batches, and then we will file. So the time line for Advair shifts by a year if the Indore outcome is unfavorable.

Damayanti Kerai: When is Indore plant audit, do you think you -- you have any date.

Umang Vohra: No, no. The Indore plant audit has happened. I think we will hear the final -- the FDA classification of it, hopefully, sometime in May.

Damayanti Kerai: And like you have derisked it to another plant. So there also, you need fresh FDA audit or since that plant is clear, it's not required or it's required.

Umang Vohra: Probably. Probably, there will be an audit needed at the new site as well. Because this will be the first PPI from that new side.

Damayanti Kerai: Is it from Invagen unit, like where you are --

Umang Vohra: We're not actually giving that level of detail, but yes, it will be a site, not in India.

Damayanti Kerai: My second question is, what is the rationale for Galvus deal because we understood like there are multiple competitors, all the brand is big, but nonetheless, it's a very competitive space. So what is the rationale for going into this perpetual deal?

Umang Vohra: These chronic therapy brands never die, they keep increasing in scale and size. And the second -- so that's number one. Number two, this is a relatively large brand in the diabetes segment and Cipla historically always been a big respiratory player but not that big in the diabetes area. That's to 3, the market actually for Galvus was found almost 2 years back or 3 years back. So we are not buying at a time when the market is just about the general size, right? It's a relatively stable market. And four, we believe that with our reach and our penetration, we will be able to impact and increase the sales of Galvus year-on-year.

Damayanti Kerai: My last question is, you mentioned you have added 800 MRs in last 2 years and your presentation mentioned that you will be adding another 1,000-plus people between '23 and '24. Is that correct? And what kind of, I would say, cost build up we should set for these kind of sales force expansion?

Naveen Bansal: Yes. Damayanti, just a quick clarification for what Umang mentioned of 800 plus. So that is basically FY '22 and '23. And the number that you see on the presentation is 1,000, which is FY '23 and '24. So there's obviously an overlapping year between the 2 statements of FY '23. So it's

only the incremental which will be added in FY '24. And in terms of the focus area, as you have mentioned, the idea here is not to add field force across the board. We are basically investing behind therapies and largely chronic, as Umang mentioned, which includes respi, diabetes, etcetera.

Damayanti Kerai: So between FY22 and FY24, what is the total increase in head count, if you can specify that?

Naveen Bansal: Damayanti, maybe we can come back on that 1,000 - over 1,000, yes.

Moderator: The next question comes from the line of Rohan Vora from Purnartha Investment Advisers Private Limited.

Rohan Vora: So just one question. So I just wanted to understand how you look at transferring the asset to some other sites versus transferring it to -- so you said that you are transferring it to an in-house side. So do you consider options of any other CMO probably in getting it manufactured from there? And have you considered it for your existing products?

Umang Vohra: Yes, we have considered this. And yes, I mean, nanopaclitaxel is going to a partner site. It's not going to our own site. So yes, we do consider options of others as well.

Rohan Vora: And Advair is going to your own site?

Umang Vohra: Yes.

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

Surya Patra: Sir, just the first question is on the U.S. business as well as the India business. So based on the prescription trend, what we have witnessed for, let's say, Revlimid in the U.S. and as per the data, I am sure in India. So the growth number for both U.S. as well as India looks relatively lower. How should we read this because, let's say, for Revlimid, if I talk then for a specific set of prescription amount of your competitors would have reported a much higher number, and we have booked relatively much lesser. So whether there is a timing gap in terms of booking and prescription trend for U.S. And in India, whether the numbers we have reported single-digit growth in the domestic market, it is compared to the prescription trend, what is given not matching.

Umang Vohra: I'm not sure what your sources for prescription trend is, but our numbers seem to suggest on India that both the prescription trends as well as the IQVI, whatever numbers that we are getting, both are actually moving in the same direction. So I'm not sure -- you can send us the details, and we'll take a look at it and try and come back to you with a more informed answer.

Surya Patra: About Revlimid?

Umang Vohra: Yes. On Revlimid, I see, it is all dependent on the arrangements the companies have with the branded player. So some others may have arrangements, which allows them more volume than potentially what allows us. So that's the reason you will see higher sales and contribution for some others versus us.

Surya Patra: And the volume on both, just a clarification, sir, the volume number and the prescription count to both are significantly different to really consider or they should move parallelly?

Umang Vohra: And this is for which market, the U.S.

Surya Patra: US.

Umang Vohra: Yes, the volume number because this is a -- there can be a lead lag here. I think the reason is that the volume number may lag the prescription number because of the fact that these are through specialty pharmacies as well.

Surya Patra: So my second question is on the profitability of the consumer health division. So obviously, we are seeing a kind of a consistent progress and so it's a full year presentation and discussion. So if you can give some sense what is the kind of a profitable progress of that? And how is that you are seeing going ahead, let's say, next 1 or 2 years, contributing to your overall margins?

Umang Vohra: So our objective is for this business to get into the higher range of the mid-teen to double-digit profit growth, double-digit EBITDA level in the next -- in this year. So we are hoping that that's where the profitability ends up for the consumer franchise. And once that level is hit, then I think it will slowly, over a period of the next 2, 3 years, graduate towards the company average.

Surya Patra: Just last question, sir, on the U.S. business again. So how big a concern for your growth in the U.S. in FY '24 due to Albuterol, whether Albuterol, you say concern for you the kind of competition what we are witnessing and how big are opportunity that you are factoring the Revlimid for your FY '24 growth?

Umang Vohra: I think Revlimid is in the numbers. And it's all as per the agreements that people have signed, as I said earlier. So it's already in our numbers. I think on the other question that you raised on Albuterol as you told, the market is constantly growing. There is one category which is constantly growing in the U.S., and we hope to participate in the growth there.

Moderator: We have the next question from the line of Neha Manpuria from Bank of America.

Neha Manpuria: Umang on lanreotide, if I were to look at the latest data, we are close to about 18% market share. I know we've guided to about 15% exits doing much better than that now. How should we look at market -- sort of the volume share that we can get in this product, given there's not too much -- there's no competition at the moment? Or is -- are we -- is incremental market share for this limited by capacity?

Umang Vohra: Neha, not completely by capacity, but it will be limited by how the market accepts the product. So I think it will be a gradual rise, which is what we had guided even earlier. It's not going to be -- because it's a B2 product. So I think it will be a gradual rise. I think we're slightly better than what we thought we'd do. And our objective is to keep it -- so I don't think it will be -- we're not suddenly going to increase share in this category, but over a -- a share increase will be there gradually over the next couple of quarters.

Neha Manpuria: So nothing -- if the product continues to be accepted by the market -- okay, we'll be able to grow the share for that?

Umang Vohra: Yes.

Neha Manpuria: And second, on the India market. As I look at FY '24 and given the competitive intensity in the market appears adding sales force, etcetera. What's your view on how much Cipla can grow, keeping in mind the industry growth and the NLEM changes. There's also talk about change -- regulating the multiple brands in the same molecule, etcetera.

Umang Vohra: I think the India market, there, we see the growth -- I think there is no competition. There's no doubt about it. But what we are also seeing, we are seeing 2 aspects Neha. The first is we are seeing a pretty strong Tier 2 to 6 growth, and that is feeding some of our products that are in the areas of respiratory and anti-infectives because those are the type of products that will deepen in India. We're also seeing a very strong growth on our generics business in this side of the market.

And I think on the Tier 1 markets, we are seeing a trend where therapies are getting upscaled, which means that if somebody is taking, for example, a diabetes drug, which was an oral they're now migrating to perhaps take obesity drugs and better diabetes drugs that could be injected, right, which are slightly more costlier. So we're seeing this migration constantly in Tier 1 towns, where people are moving up the therapy ladder. And in Tier 2 to 6 towns, we are seeing pretty -- a deepening of health care. So a lot of our expansion is in Tier 2 to 6 and in the areas of respiratory and anti-infective.

Neha Manpuria: And this should allow us to continue the market meeting growth that we've seen in the last 2 years?

Umang Vohra: Yes. That is -- we are hoping for that. Yes.

Neha Manpuria: And last, if I may, Ashish, what would be the R&D guidance for FY?

Ashish Adukia: Yes. So we continue to be in the same range of about 6% -- 6.5% as -- because for the reasons that we've talked about, the derisking strategy, etcetera.

Neha Manpuria: In which case, given that we'll see growth in India, U.S., given amongst commentary U.S. growing. Any reason for keeping the margin guidance at the 22%?

Ashish Adukia: So there are other investments as well. So our R&D is there and we are investing in people cost as well, which goes into the P&L and not necessarily as an investment. So given all those things and plus, if you look at the material cost because of further inflation that we've seen in the last year, we have, of course, taken a lot of steps to control that cost increase but that also seems to be more at a stable rate rather than reducing. So given all those things, I think we continue to be -- to maintain about 22% range.

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

Bino Pathiparampil: Umang this nanopaclitaxel, has a patent, which expires in October 2024. Do you think that is a relevant data point from the perspective of competitive intensity in the market?

Umang Vohra: I'm not sure that, that's the -- that's what's holding the market formation at this stage.

Bino Pathiparampil: Is there any update on the generic filing for Dulera from your side?

Umang Vohra: Bino, we're not going to comment on that. I think as and when we have more clarity, we will certainly come and give you more clarity on that. But we're not commenting on it. I'm not sure that at this stage -- I do know I can tell you that Dulera is there for the U.S. but not for the -- for Europe, but not -- I don't want to comment on the U.S. specifically.

Moderator: The next question is from the line of Nithya from Bernstein.

Nithya: Umang, can you give us an update on the partner respiratory asset. I think a couple of quarters ago, you had mentioned that it's now in the 9-month revenue cycle.

Umang Vohra: Yes. Nithya, that's the third asset we spoke about in the derisking and that asset, I think that asset is -- currently batches are being taken for it in our facility in the U.S.

Nithya: So that was from Indore and therefore, you're now adding another facility.

Umang Vohra: That was from Goa actually, not Indore.

Nithya: Umang, can you also talk about 2 other respiratory assets. Q1, which we know there is a litigation out there, so we know you are kind of Symbicort, where you have registered a clinical trial. If you can talk to us about what is the current state of these 2 assets?

Umang Vohra: Nithya, I'm not sure we can give too much detail on QR considering the proceedings in the IP court. So it's very much part of the pipeline, and there is progress on the product, but it's currently in sub judice. So we can't comment on it.

Nithya: Symbicort, what is your anticipated time line on the filing?

Umang Vohra: Symbicort, I believe we should file by quarter 4 of this year.

Moderator: The next question is from the line of Punit from Helios Capital.

Punit: So sir, we had earlier indicated that for generic Advair, we have localized the supply chain. Now that the product is being transferred to a facility that is located outside of India, how the cost structure and the unit economics change for Advair assuming that the product is launched from outside India facility that's my first question.

Umang Vohra: Yes. So I think what we have localized is the components that go into Advair. We have not localized -- and the production of Advair at that point in time more than in broad. So the localized aspect of whatever goes into Advair stays in India, that doesn't have an issue. The issue is the final site if Indore does not -- it Indore meets an adverse outcome, then that particular

manufacturing will happen elsewhere. But if Indore has an outcome, which is fine, then we are ready to commercialize completely from India.

Punit: My follow-up question to that is, if the components are sourced domestically and assuming the product is manufactured outside India facility, then slight cost should we will be incurring a higher cost, right?

Umang Vohra: Well, you could say production costs may be slightly higher in the U.S. Is that your question?

Punit: So if we source the components locally, then there will be some cost of transferring these components to the say, outside of India facility. That was my question.

Umang Vohra: Yes. So I think the only thing I would say is that in any case, if we had made this product in Indore, we would have had to ship it to the U.S. too, right?

Punit: My second question is, does the localized supply chain include also the HFO propellant because if that is the case, so does it include HFO propellant? That would be my second question.

Umang Vohra: No. The propellant actually as an industry is pretty global. I don't think there's any -- it's a commodity across. So it will also be -- it's the same price available pretty much in the U.S. as it is in India. I don't think there's any change there.

Moderator: We have the next question from the line of Tarang Agrawal from Old Bridge Capital.

Tarang Agrawal: A couple of questions from my side. One, how much is respiratory revenue for the U.S. for FY '23?

Ashish Adukia: Yes, the respiratory portion we'll just come back to you -- it's likely to be in the $150 million to $200 million range.

Tarang Agrawal: The second question is in terms of the segment reporting, what all does new ventures capture in the segment reporting?

Ashish Adukia: So it's basically your new, like we have CDHL, right? So digital health. These are our new initiatives that are captured out there. Some of the investments that we've done in the new ideas.

Tarang Agrawal: The consumer health business doesn't get captured there?

Naveen Bansal: It is. Sorry, Tarang just a quick clarification in our segmental reporting, yes. Our CSH business does get captured and also the U.S. specialty business, although it does not add significantly to the top line, but the cost structure of that business also is captured under that segmental reporting.

Tarang Agrawal: And the third, again, bookkeeping. Saw quite a significant rise in the other income line item for FY '23 versus '22, if you could comment?

Naveen Bansal: Tarang if your question is related to other income or other operating income, if you can clarify that.

Tarang Agrawal: Other income.

Ashish Adukia: So see, it's -- I can give you a directional answer out there. It could be interest income that is coming on account of your larger facility that we have.

Umang Vohra: We don't consider that as part of our EBITDA calculation in any case.

Tarang Agrawal: And the respiratory figure for FY '23?

Umang Vohra: $160 million.

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

Kunal Dhamesha: So the first on the CAPA planning, is there any remediation cost which is being built into our numbers in this quarter because other expenses ex-R&D are up about INR70 crores.

Umang Vohra: Yes. Our remediation costs are part of our numbers. They are being spent and our quarter 4 numbers and our quarter 3 numbers had them.

Kunal Dhamesha: Okay. So -- and do you expect...

Umang Vohra: No, we don't expect a spike from these levels. So this includes both your -- there may be some capex, there may be some opex, also consultant costs, etcetera. These would be the broad categories. So that's all been included in Q3, Q4.

Kunal Dhamesha: And that is -- that should the reinspection happens in quarter 3 FY '24, it should go down from there.

Umang Vohra: Yes, that is right. That is correct. We don't see a spike in the remediation costs from what is already.

Kunal Dhamesha: And what was stopping us from, let's say, derisking these key products earlier? Was it cost? And how does U.S. FDA view it? Because from U.S. FDA's perspective, it's an incremental administrative burden to visit 2 sites for the same product from same company, right? So how likely are they to reinspect our new facility from wherever we are derisking?

Umang Vohra: No, I think if it's a first generic or a limited generic there is a chance that the FDA will visit, especially if that allows the market to form for a generic product. That's one. I think to your other question, yes, it could very well have been something that we could have thought of earlier. But generally, what happens is when your file is under active review, and scientific-based questions are not closed, that is not the time that you introduce a new facility because it creates more complications and delays your file review process. So in our case, frankly, if we have the ability to launch from Indore and Goa and if the site is clear that we will launch from these sites, while we continue the derisking in any case.

Kunal Dhamesha: And lastly on -- I think you alluded earlier in terms of production costs could increase a little bit if we produce it from outside India site. But will there be material change to our cost

competitiveness on that part because at one point, we were quite confident that we would be the cost leader in generic and win. So does that change if we produce it from outside India site?

Umang Vohra: Not sure because I think a large chunk of the production cost is also the localization of components in India. So we won't I think we will still be very competitive.

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

Prakash Agarwal: Just 2 quick follow-ups. One is on the MRs. What is the number for fiscal '23?

Umang Vohra: You're referring to number of MRs?

Prakash Agarwal: That's correct.

Umang Vohra: It's about 10,000.

Prakash Agarwal: This includes the supervisors and everything? Or this is just the field force?

Umang Vohra: Yes. So maybe you can take Prakash for -- I understand your question. So maybe you can split that between 7,000 and 3,000 roughly in terms of MR and the others.

Prakash Agarwal: And second clarification, on the US, you mentioned that despite these 2 assets delaying, you would still expect a growth given the peptide products are still ramping up. Is that correct understanding?

Umang Vohra: Yes. That is versus last year. So this year, we -- let's say, we've done $733 million as the full year revenues for US We expect growth over that.

Prakash Agarwal: And was the comment on SAGA markets also?

Umang Vohra: Yes. South Africa, we will see growth this year, yes. And a lot of focus will be on the margins in the South Africa market.

Prakash Agarwal: So last commentary was that the private market is still doing okay, and the tender market base, the volatility and the idea is to increase the private and reduce the tender market. So that attempt to improve margins and improve the mix is there?

Ashish Adukia: Yes. That's going to be the focus. And I think the focus will be on new launches in the private market to compensate for the reducing tender market.

Prakash Agarwal: So overall basis, growth on that base as well as improvement in margins?

Ashish Adukia: Yes, absolutely.

Prakash Agarwal: So just some participant asked on the margin outlook. So SAGA had a drag down maybe this year, '23 last year, US fairly okay, India, I think, ex-COVID growth. So I mean the profitability could have been better because your cost initiatives are also there for the next 2, 3 years, you have called out. So what are you buffering in here, lack of large launches? Or how should we think about that?

Umang Vohra: No, I think the way to look at it is, look, we will want to also invest in new areas and new opportunities, overall. So while we expand people in India, the lead lag impact is almost 6, 9 months. So we put people from the time they start becoming productive, it's a 6-, 9-month story, right? So that's one area of investment.

The second investment will be happening in our consumer plans business, right? That also takes from the time you invest till the time you begin to see higher growth, it is -- there is a lead lag effect. Then also, R&D is constantly investing. We've got 3 clinical trials going on. We've got 2 respiratory products that is fairly significant as a clinical outlay for the products to get to market. That's number three.

And number four, are some of the initiatives on our biosimilars, etcetera. So I think all across we are not wanting the business to get impacted by the lack of investment. And the other thing, like we mentioned on an earlier call, we would much rather invest for a higher top line growth if we are at the 22%, 23% margin level as against push margin to 24% and compromise top line growth.

Prakash Agarwal: And R&D you mean 7% or 7% to 8%?

Ashish Adukia: About 6%, 6.5% is somewhere in that kind of range. It will continue to be there. And I think R&D expense has to be also looked at from a U.S. revenue point of view rather than from overall revenue point of view because of a substantial part of it goes to U.S.

Moderator: The first from the line of Kunal Randeria from Nuvama.

Kunal Randeria: Umang, a few years back, there was some attempts to expand the U.S. business through some specialty acquisitions like IV Tramadol and Pulmazole. It doesn't seem to have worked out as you would have liked. So just wondering what your thought process is now considering that you have a much more sizable balance; cash balance?

Umang Vohra: So Kunal, you're right. I think we had our strategy to expand this on the basis of an in-licensed asset, which unfortunately did not meet a clinical outcome. So I think we went back at that point in time, and we reconfigured our strategy to say that even if we acquire an asset, which is in late clinics, we must have our own pipeline to add to it.

And the time distance between -- I mean, the time difference between when our pipeline comes to market and when we add an in-licensed assets should not be more than 2 years. Because otherwise, it's very difficult to have to make the business productive. So what we've been doing over the last 2 years, ever since we've had that negative news on IV Tramadol is actually being investing in creating our own internal pipeline. These are not products that are going to be $100 million or $200 million in sales, but we may have 2, 3 products that could well be $20 million to $50 million in sales.

So let's say, we invest in this for another year. And if we have a sizable pipeline of 2, 3 products with the revenue profile of $30 million to $40 million, that's the time where this business can then begin to build out for the future. So it's still about a year away from that vantage point, but we've gone back, retooled strategy and are investing in developing our own internal pipeline.

Kunal Randeria: But now with almost $700 million in the bank, I mean, that gives you a bit more freedom to go inorganically? Or are you saving money for some one big acquisition. I just want to understand what you're going to do with the cash now going forward?

Umang Vohra: So I think if you look at our overall capital allocation priority, I think India continues to be our priority. So the whole -- the disproportionate part of capital, we would look to invest in India for the growth that is available out here. If you look at the overall share that we have, there's still scope to increase the therapies and geographically as well. So -- from use of cash point of view, that would be the top most priority for us. And then there are more bolt-on acquisitions that we may look at in other geographies, could be Africa could be U.S., could be Europe as well for facility asset or any other products.

Kunal Randeria: And just one more from my side on the India piece. I think you have on a INR580 crores of revenue from in-license specialty products. I would assume the margins here would be maybe lower than your normal India margins. So what would be the sweet spot where you would say enough of in-licensing and you would rather build brands organically now?

Umang Vohra: I think if the brands are relatively smaller, then it doesn't make sense to pay a lower margin on it. So you really want big brand franchisees that you can create which is when we turn our thinking into trying to improve the margins by doing the brands ourselves. So it's a mix of both. If we are getting a brand that is relatively smaller then the interest to create because then the interest to take the low margin doesn't make sense. But if you have a relatively higher sized brand, which you can -- which eventually you can grow much faster, that's the time when your costs get amortized a lot better.

Kunal Randeria: And just one more, if I can squeeze in. Of the 43 pending ANDAs under Cipla Limited, how many would be from Indore and Goa?

Umang Vohra: We can provide that data. But if your question is whether both Indore and Goa had huge sensitivity to the launch calendar of the U.S. in the next 2 to 3 years, the answer to that is no.

Moderator: We will take the last question from the line of Ankush Mahajan from Axis Securities.

Ankush Mahajan: Sir, any outlook on consolidated EBITDA margins for the FY '24? Any guidance, sir?

Ashish Adukia: Yes. So for FY '24, like I had said, I think the 22% or thereabout is what we are targeting for next year.

Ankush Mahajan: Sir, I missed the initial remarks. So what kind of number of molecules that we are launching in the next year, '24 in the US market?

Ashish Adukia: So like Umang talked about, we are looking at 3 filings in the coming year, mainly in the respiratory side, and there could be some in the peptide, which is more third-party partner products rather.

Moderator: I would now like to hand the conference over to Mr. Ajinkya Pandharkar for closing comments. Over to you, sir.

Ajinkya Pandharkar: Thank you for joining us, everyone. In case you have any further questions, please feel free to reach out to us at investor.relations@cipla.com. And wishing everyone a good evening ahead. Thank you.

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