

29th January, 2024

- | | |
|---|---|
| <p>(1) BSE Ltd
Listing Department
Phiroze Jeejeebhoy Towers
Dalal Street
Mumbai - 400 001
Scrip Code: 500087</p> | <p>(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</p> |
| <p>(3) SOCIETE DE LA BOURSE DE LUXEMBOURG
Societe Anonyme
35A Boulevard Joseph II
L-1840 Luxembourg</p> | |

Sub: Q3 FY24 - Earnings Call Transcript

Dear Sir/Madam,

We are enclosing herewith copy of the transcript of the Company's Q3 FY24 earnings conference call dated 25th January 2024. The transcript is also available on the Company's website i.e., <https://www.cipla.com/sites/default/files/Earnings-Call-Transcript-Q3-FY24.pdf>.

Kindly take the above information on record.

Thanking you,

Yours faithfully,
For **Cipla Limited**

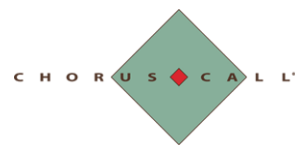
Rajendra Chopra
Company Secretary

Encl: as above

Prepared by: Chirag Hotchandani



“Cipla Limited
Q3 FY '24 Earnings Conference Call”
January 25, 2024



MANAGEMENT: MR. ASHISH ADUKIA – GLOBAL CHIEF FINANCIAL OFFICER – CIPLA LIMITED
MR. UMANG VOHRA – MANAGING DIRECTOR AND GLOBAL CHIEF EXECUTIVE OFFICER – CIPLA LIMITED
MR. AJINKYA PANDHARKAR – HEAD, INVESTOR RELATIONS – CIPLA LIMITED

Moderator: Ladies and gentlemen, good day and welcome to Cipla Limited Q3 FY '24 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 question 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 Mr. Ajinkya Pandharkar, Head Investor Relations from Cipla Limited. Thank you, and over to you, sir.

Ajinkya Pandharkar: Thank you, Yusuf. Good evening, and a very warm welcome to Cipla's Q3 FY '24 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 future events.

These estimates reflect management's current expectation 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 statements, 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, Ajinkya, and good evening to all of you. I thank you for joining us today for earnings call for quarter 3 fiscal year '24. Let me address the issue of the results released at the outset. On Saturday, it came to our attention that there was a potential leak of parts of our standalone results on the social media. We took prompt action to inform the stock exchange and took a decision to advance our results in order to avoid investors trading on the basis of unapproved results. We're investigating the matter and would like to highlight that the leak was not attributable to internal employees or systems of Cipla.

Coming to the results of this quarter, we continued our growth trajectory across the flagship businesses of India, North America and South Africa and improved our operating margins. So, this was our seasonally strong quarter across all our markets.

I would like to cover themes which played out into our financial performance for this quarter. These themes include continuing market-leading growth in our core markets, focus on growing our large brands, investing in our future pipeline organically and inorganically, and regulatory resolution at our facilities. In-line with our theme on delivering growth across key markets, our One-India business posted a healthy growth of 12%, backed by traction across branded prescription, trade generics and our consumer health business. In our branded prescriptions business, we grew ahead of the market with our Chronic portfolio outpacing the market with a growth of 13% against the IPM growth of 11% as per IQVIA MAT December '23. Respiratory, cardiac and urology were key drivers of the growth for the quarter. Share of chronic therapies and portfolio has improved by 115 basis points year-on-year to 60.3%. Our trade generics business further consolidated its leadership position in the market by posting consistent year-on-year

growth. This performance was supported by execution of our order book, traction and new introductions and deepening distribution network and technology to improve reach. Business will further execute these work streams to expand their offerings and reach.

Consumer health franchise posted year-on-year growth supported by traction in leading brands and stronger reported brand equity, albeit in a slower market. The operating profitability continues to be sustainable. In North America, we reported an all-time high quarterly revenue of \$230 million, which represents an 18% growth over last year. This was the 15th consecutive quarter of year-on-year growth for the business. Positive volume traction due to seasonality in our products and demand and base business, which is usual for this quarter every year, propelled this consistent growth.

In Lanreotide, we have set a -- we now have a 20% market share. In SAGA, we completed our sale of QCIL during the quarter. Excluding QCIL, SAGA recorded 35% year-on-year growth in USD terms backed by growth in South Africa as well as Cipla Global Access. In our South Africa prescription business, our growth in secondary market was at a healthy 7% versus the market growth of 2% as per IQVIA MAT November '23. We are inching closer to the market leader. Our tender and OTC business has also witnessed positive traction during this period. In Cipla Global Access, our tender business for rest of Africa posted a year-on-year growth supported by execution of the order book.

Our next theme is growing our big brands bigger. Big brands continue to be at the forefront of our India story. In branded prescription, we have 20 brands with revenues over INR100 crores as per IQVIA MAT December '23. Foracort, our leading inhaler brand, is now the biggest brand in IPM as per IQVIA Q3 FY '24, gaining 3 ranks year-on-year to reach the top spot. Cipla now has the highest number of brands in the IPM top 10, top 50 and the top 100 as per December '23 IQVIA report.

Our trade generics business now has over -- has 8 brands over INR50 crores. Whereas Cipla Health derives its growth from 5 anchor brands, which are well over INR100 crores in trailing 12 months. In South Africa, big brands have been the key reason for growth in our OTC business. Cipla Actin, Coryx and Broncol are now tracking in the range of ZAR 100 million in the trailing 12 months. Acquisition of Actor Pharma has recently received the approval of the competition commission, and integration is expected to be completed in quarter 4 of FY '24. Actor's portfolio includes products with great potential of becoming the next set of big brands.

Investments -- the third theme is the investments in the pipeline -- in the future pipeline, and this remains one of our key themes.

R&D investment is focused on funding developmental efforts and filing new products. In this quarter, we were successful in filing 2 products to complement our respiratory portfolio in the U.S. We have completed filing of generic Symbicort and 1 other generic inhalation asset for which we should provide details in our next call.

In line with our strategy of lung leadership, we have continuously focused on investing in the pipeline over the years with number of assets in high single digits. Some of these assets are already

filed. On our peptide portfolio, we are ready with one peptide asset and waiting for its approval to launch, while there are 4 launches planned in FY '25. We are also working on several other peptide 505(b)2 opportunities and complex products, which are currently under development and will be key to the future portfolio.

Our focus continues on regulatory efforts in Goa and Indore. Earlier in this quarter, we have updated you of the warning letter we had received for the Indore facility, which was audited in February '23. We have duly responded to queries from USFDA and are now focusing on remediation. In Goa -- at Goa, we have submitted all the pending acquisitions.

Derisking our top launches remains our top priority.

Derisking of Advair has been progressing as per expectation. We expect to file this asset in mid FY '25. For generic Abraxane, we are more likely to launch this fastest from the Goa facility. Given the complexity of the product, third-party transfer has been time consuming and will take longer compared to a launch from our Goa facility.

I would now like to invite Mr. Ashish Adukia, our CFO.

Ashish Adukia:

Thank you, Mr. Umang Vohra. This quarter, we progressed further with exceptional performance across core businesses with expansion in profitability. Coming to the key financial highlights for the quarter, the numbers are adjusted for QCIL disinvestment, which was completed in this quarter. We are pleased to report a quarterly revenue of INR 6,544 crores, with a healthy growth of 14% driven by flagship businesses of India, North America and South Africa.

EBITDA margin stood at impressive 26.3% for the quarter. As per practice, this EBITDA margin does not include other income. Expansion and operating profitability is largely due to favourable mix, calibrated price action across branded and generic portfolio, and impact of easing cost inflation.

Gross margin after material cost stood at 66.3% for the quarter, which is 90 basis points above last year's figures, driven by overall mix change, again, contribution from new launches as well as lower procurement cost of key APIs.

The total expenses for the quarter include employee costs and other expenses, which stood at INR2,621 crores, which was flat on a sequential basis. R&D investments for the quarter are at INR400 crores, which is 6.1% of the revenue, driven by product filings, development efforts and is higher by 10% on quarter -- Y-o-Y basis. Extraordinary expenses mainly include impairment of intangible asset and winding down provision of Pulmazole, which was one of our products that we were developing with Pulmatrix, Inc. for the U.S. market. While we've impaired the entire asset, we may look at continuing to develop and launch this asset in India and other markets.

Profit after tax for the quarter is at INR1,049 crores or 16% of sales, and the ETR is constant at 27.5%. Free cash generation and operating efficiency strives a healthy cash -- net cash position. We've repaid all our long-term loans, including the term debt that we had in South Africa of ZAR 720 million. With this, as of 31 December '23, the gross debt on the balance sheet is only about

INR449 crores, which constitutes lease liabilities and working capital facilities. Cash equivalent balance as on the date stands at INR7,591 crores.

The key focus areas and growth levers in the subsequent quarters will include priorities for One-India, would be to grow in Rx led by chronic portfolio, sustained leadership in GX, while working on further strengthening growth levers for wellness portfolio.

In North America, our focus would be on commercial execution of existing portfolio and resolution of USFDA observations. Product launches through delisting strategy and as well as inorganic partnerships and acquisitions will remain one of our key priorities for the U.S. market.

Build on performance in South Africa, aided by growth in private and select tender business with greater emphasis on margin expansion. In emerging markets and Europe, top priority is to improve top line while margins are maintained at sustainable levels. As per the yearly trend, quarter 4 will have an impact of weaker seasonality in India and North America.

EBITDA margin for the full year is trending at a higher end of what we had guided earlier, which was a range of 23% to 24%. The RoIC continues to be very healthy at about 29% for the trailing 12 months.

I would like to thank you for your attention and request the moderator to now take the questions.

- Moderator:** First question is from the line of Tushar Manudhane from Motilal Oswal Financial Services.
- Tushar Manudhane:** Just clarity on Abraxane, if you could just highlight any particular reason for delay -- rechange in the plan as far as filing for the alternate site is concerned? And secondly, if it is so, then it would be again subject to the reinspection of Goa facilities. So accordingly, is there a change in timeline as far as the approval is concerned for Abraxane?
- Umang Vohra:** Yes. I think, Tushar, that what you're saying is correct. I think the fastest route that we are guiding is the fastest route is in approval from Goa because of the fact that we might have to do clinical studies if we transfer the product to another site, etcetera. The process of getting a reapproval is significant. Having said that, our activities are ongoing for transition.
- Tushar Manudhane:** And -- but now then the reinspection of Goa and then subsequently the approval so likewise, any change in the timeline for approval for Abraxane?
- Umang Vohra:** No. I think the timeline -- see, if Goa -- our thinking is that Goa should be due any time for inspection from starting with quarter 1 of the year because it was inspected in August of 2022. So, on a 2-year clock -- sorry, it should be ready for reinspection starting from a quarter 1 of fiscal year -- of the next fiscal. So therefore, actually, that is -- if that inspection clears, then actually nanopaclitaxel will be ahead of market -- ahead of our estimate if that inspection clears.
- However, if there is no inspection or that inspection does not clear, then nanopaclitaxel will be further delayed because there will be additional requirements of regulatory to do the trials on that product, etcetera.

- Tushar Manudhane:** All right, sir. And the market price for this -- the product, which is expected to be launched in which quarter, the potential launch? [Will be there a competition of the week]?
- Umang Vohra:** Are you talking about the peptide asset, Tushar?
- Tushar Manudhane:** Yes, sir. Yes, sir.
- Umang Vohra:** Yes. That asset should hopefully launch, I think, when the quarter 1 -- will definitely be launched, we think, in the quarter 1 of fiscal year '25 -- quarter 1 of next year, which means basically the next quarter.
- Tushar Manudhane:** Just if you could share the market size for the product? And if there are any existing number of players for that product in the market?
- Umang Vohra:** Well, as of now, Tushar, we feel we are the first -- we will be the first generic, if they have given approval for it. The market size is fairly significant..
- Tushar Manudhane:** At least \$100-plus sort of million?
- Umang Vohra:** Tushar, I cannot guide to that. It's not because I don't want to, but because it's -- there will be different market dynamics that will play out.
- Moderator:** Next question is from the line of Amey Chalke from JM Financial.
- Amey Chalke:** First question on Lanreotide. There is an orphan drug exclusivity expiry somewhere in September 2024. So, what is our strategy here? Are we going to launch generic as well instead of promoting 505(b)2? Or we will wait for other generic players to enter this plan?
- Umang Vohra:** Actually, Amey, I'm not so sure that the orphan drug -- I mean, I think the orphan drug expiry is with reference to certain indications. I think -- so I'm not sure that, that holds up the generic for other indications that are already -- that the patents have already expired.
- Amey Chalke:** Okay. So, you may see that the products which we have launched it doesn't have any binding on the orphan drug exclusivity if any other generic wants to launch...
- Umang Vohra:** So, I cannot comment on that because the -- right now what is allowed for launch the product that we are selling is allowed for one set of indications. It is not allowed for all indications. And I think when you say orphan drug exclusivity, you mean to say that other indications may also be allowed for the same product as and when they expire. And I don't think that -- I don't think we have to introduce a new product for that. I'm not sure about that.
- Amey Chalke:** Sure. So, you mean to say the filing of 505(b)2, can we convert it to generic products without launching it to it?
- Umang Vohra:** No, no, no. The 505(b)2 and generic products are 2 different products. We are currently selling a 505 (b)2 product. Because the orphan drug exclusivity protects a certain indication, whether you are a 505 (b)2 product or any NDA product, you cannot sell -- your product cannot be used in that

indication. So, when the orphan drug exclusivity expires for that indication, we believe at that point in time, the product could be used to sell in that place.

Amey Chalke: And then second question is related to Symbicort. How easy or difficult it is to get an approval for Symbicort vis-a-vis Advair, if you can give some colour on the same.

Umang Vohra: They're similar. The clinical trial requirements and the clinical trials that have been done for both products are very similar. I'm saying the sizes of the product population. So, we have done it once before with Advair where, of course, the issue more with facility. We believe that the file has cleared all the other -- taken all the other reviews but for facilities. So, I think we are fairly confident. But it will take the time that the FDA needs to review it.

Moderator: Next question is from the line of Damayanti Kerai from HSBC Securities and Capital Markets India Private Limited.

Damayanti Kerai: Umang, can you clarify your comment on the Advair opportunity? So, you're saying you're looking to file it by mid of FY '25 from alternate site? And also want to understand the way for Abraxane, if you transfer it to a CMO site, you might require to do some clinical trials, etcetera. For Advair, is there any such requirement for additional studies, if you transfer to a different site?

Umang Vohra: No, we don't think so. I don't think any additional studies are required for Advair. And your -- what you've picked up on the timing is correct.

Damayanti Kerai: Okay. And say like you filed within the stipulated timeline, mid '25. And then it will again go through the entire review cycle by the FDA? Or how should we think about the...

Umang Vohra: Unlikely that this will go through a review cycle. I think we will be submitting data from the new site versus data from the old site. And then the FDA should take a 6-month, 9-month period to review it. Our sense is it could be closer to the 6 months.

Damayanti Kerai: So very broadly, we can assume, if everything goes well, we don't run into any other queries by the FDA, this approval could come by end of next fiscal, right -- towards the end of next fiscal?

Umang Vohra: Towards the end of next fiscal is correct. Yes..

Damayanti Kerai: Okay. My second question is on Lanreotide 505(b)2. So, you are at now at 20% market share, I guess, which is very similar to what we saw at the end of second quarter. So, do we see further headroom for growing market share? And what kind of visibility you have to improve on -- from this level?.

Umang Vohra: Yes. We have guided earlier that the market share will be going up incrementally, and we will not see big takes of market share every quarter. So marginal increases from this are still on the cards for Lanreotide 505(b)2.

Damayanti Kerai: Okay. My last question is on leuprolide. So last quarter, you said you have resolved some supply bottlenecks, etcetera, but we are yet to see any pickup in the market share. So how are things moving there for that particular product?

- Umang Vohra:** I think we are seeing higher offtake on leuprolide. And hopefully, in the next -- in this quarter or the next quarter, we will begin to scale up. But in this quarter, we have seen higher offtake compared to the last quarter.
- Damayanti Kerai:** Okay. So, all supply issues were resolved and market share and prescription trend, etcetera, should pick up from here on?
- Umang Vohra:** Yes, yes.
- Moderator:** Next question is from the line of Neha Manpuria from Bank of America.
- Neha Manpuria:** Umang, On the Indore warning letter, the FDA has brought out the Advair customer complaints - the recurring complaints, and the fact that we didn't recall it despite the recall in March, which was -- I know you mentioned it was unrelated.
- Do you think there's a risk to the albuterol market share that we have now because of the warning letter? Is that something that we should be concerned about? And have you addressed the -- or do you think the FDA expects you to recall Abraxane given the way they've mentioned it in the warning letter?
- Umang Vohra:** Okay. So, Neha, just -- the warning letter in Indore site is albuterol.
- Neha Manpuria:** Yes, sorry, albuterol. My bad. Apologies.
- Umang Vohra:** Yes. So, on albuterol, Neha, I think we have submitted revised data to the FDA. And of course, the FDA has to make its determination post our response of the warning letter. And the company submitted even during the earlier recall analysis of the recall specifically, and of the factors that impact the product. At this point, we are -- we can safely say that all parts of the product are safe and efficacious and that we believe that there is a natural phenomenon of these products.
- At times, they get clogged like the product information leaflet say so for any inhaler, right? So, we are waiting for the FDA to review the application in total. And company believes that we do not have an issue with the product.
- Neha Manpuria:** Understood. And post the recall of albuterol in March, we did see market share obviously go down as expected, that seems to have improved. Do we think we can go back market share that supply had in the product before the recall issue? Or is there any constraint to that?
- Umang Vohra:** So, I don't think -- I think there was a period where there was one customer that may have derisked their supply. But at this point in time, we have actually recovered a little bit of share between the last quarter and this quarter. So, we think it's stabilized. And yes, I think my guidance to the team is clearly to try and see how to improve the share, but we are in no hurry to do so..
- Neha Manpuria:** Got it. And my second question is on the U.S. base, in the current 225, 230, I know there was some benefit from seasonality this quarter. But if I were to look at next year, given the peptide launches that we have, we'll have probably 5 peptide launches next year based on your guidance and probably a couple of more launches -- bread and butter launches, do you think that helps us push

the U.S. sales above the \$1 billion mark in the next few quarters? Is that a fair assumption? Or do you think it will be a little longer than that?

Umang Vohra: Well, I think, Neha, difficult question to answer, more probably appropriate to answer this at the end of this quarter when we give our guidance. We'll have a good idea of where we think the U.S. market can be for us. We will see some attrition on a few products as is typical of the U.S. And I think we will form a view on this possibly closer to when we come back in the next analyst call.

Moderator: Next question is from the line of Surya Patra from PhillipCapital.

Surya Patra: Sir, my first question is on -- let's say, on Advair. So given the recent SAR price cut -- list price cut by the innovator, so whether this is a kind of a risk to the kind of a potential opportunity, what we have been targeting in case of Advair.

Umang Vohra: Surya. I think the issue with the generic market, Surya, is that the innovators price cut matters, but in the end, it is the net price that a customer is buying it. And so, rebating on this product, at least the way we've understood it is significant already and discount in the marketplace is also significant. So, our estimate of where the Advair price is somewhere right now at around \$30 per inhaler mark as a net price...

Surya Patra: This is the net price?

Umang Vohra: Yes. So, I think it offers some opportunity for us as well, depending on the share you take.

Surya Patra: Okay. In fact, my understanding was that in the current financial year or current calendar year, even the net prices have seen a kind of some meaningful impact so that's why my question...

Umang Vohra: Correct. Yes, yes. And that's why I'm saying it's roughly around \$30 depending on the mix of the customer. But -- I mean, if you're seeing -- if there is something that is more recent that you have seen, then I may not be fully aware of it.

Surya Patra: Yes. Okay. Secondly, sir, in fact, the Symbicort filing that you have done, well, which sites that you are linking this product to? Is it Indore or...

Umang Vohra: I think it's a 2-site filing. And we have also done it from -- we are also going to -- or sorry, let me correct myself. It is a single site filing as of now, and the second site transfer has also happened, and it will be added to the file once we receive the queries.

Surya Patra: Okay. Okay. And just last one...

Umang Vohra: By the time we are approved -- so just to clarify, assuming that this will take 2 years plus to approval, by the time we are approved, we will have 2 sites in the file.

Surya Patra: Okay. Okay. And just last bit on the domestic formulation business. See, we have seen very strong growth in the -- during last 2 years period, during the COVID time, in terms of volume. And this year, while the industry is facing volume challenge, because of the respiratory mainly, we have still maintained a kind of positive growth in terms of volumes.

So, going ahead, what is the kind of momentum that we should see for our overall domestic business? Is it possible to sustain double-digit growth, let's say, if we exclude the fourth quarter, which is generally the soft quarter?

Umang Vohra: I'll request Mr. Ashish Adukia to answer this, please.

Ashish Adukia: Sure. I think in your -- Indian market is very attractive. So, if you take a little bit of a longer-term view, okay, then you will get the price as well as volume growth in the market, right? And we are also going and expanding into Tier 2 to Tier 6 to realize that potential of volume growth. Coming to a more near-term next year horizon, we'll have to see because we'll have to see where WPI lines up and assuming that's flat so on the portfolio that constitutes a WPI portion.

We may not be able to take the increase in price, but we'll try to push volume out there. And for the balanced portfolio, we'll take a combination of volume and price. So, we are still -- will target higher than the market growth next year for ourselves.

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

Bino Pathiparampil: Umang, just a clarification on Symbicort. Did you say that it is as of now file from Indore?

Umang Vohra: Bino, yes. The asset originally is an Indore filing, and it will be -- we're already taken batches at the -- our site in the U.S. and that will be added. As and when required, we will alter the strategy for the product. Either it will be 2-site file product or it will be a single site depending on which one we keep and which one we withdraw.

Bino Joseph P: Got it. Second, an accounting question. I can see that your total depreciation and amortization expense has come down for the quarter as well as for the 9 months for year-over-year. What is leading to this decline?

Umang Vohra: I'll request Mr. Ashish Adukia to answer that.

Ashish Adukia: Thank you. Thank you, Mr. Umang. We had some impairment last year Bino which has led to the higher depreciation that you see in the previous year. But generally, it's a flat to declining trend of depreciation.

Bino Pathiparampil: Okay. So that impairment is gone. So, on this year's base then, as we do more CapEx, we should see this moving up as we go along, right?

Ashish Adukia: Absolutely. Our CapEx typically is in the range of INR1,000 to INR1,500 crores type of a range, is what we should estimate and that...

Bino Pathiparampil: Understood. And finally...

Ashish Adukia: As well as the maintenance.

Bino Pathiparampil: Got it. And finally, from your note, I can see there is some INR18 crores-odd loss from sale of an asset, which we have recorded, which line item does that fall into?

- Ashish Adukia:** Yes, yes. So that's the sale of QCIL that we completed. We sold that entity to our partner. That sale is being booked, and the loss of that is sitting in other income.
- Bino Pathiparampil:** Sorry, other income?
- Ashish Adukia:** Yes, that's right. That loss is sitting in other income.
- Moderator:** Next question is from the line of Kunal Dhamesha from Macquarie.
- Kunal Dhamesha:** The first one on the other expenses, excluding R&D. If I look at the first 9-month runway, we are almost close to 50 basis point savings in terms of other expenses as a percentage of revenue. So, is this more driven by some of the external moving parts like logistic, power, fuel cost? Or would you say a lot of this is coming from synergies of One-India business? How should we look at the sustainability of this number?
- Ashish Adukia:** I think more specifically -- we'll have to unpack numbers to give you more specific answers where it has come down. Overall, there has been cost control, R&D. Probably few quarters, we had the clinical studies cost, which has come down when you compare it to the percentage of revenue growth.
- There's some operating leverage benefit also that you're seeing out there because the revenue has grown significantly and cost has not as much, which you'll see in some of the other line items as well. So that line item that you're referring to other expenses has many items sitting out there. So, without being specific, I'm just giving you a general trend.
- Moderator:** It seems that we have lost the line for Mr. Dhamesha. Next question is from the line of S. Mukherjee from Nomura.
- S. Mukherjee:** Umang, this peptide assets that you talked about, are they 505(b)2 or substitutable generics?
- Umang Vohra:** There is a mix, Saion.
- S. Mukherjee:** Okay. And the opportunity that we are expecting in quarter 1 FY '25, will that be a 505(b)2?
- Umang Vohra:** No, that is an ANDA.
- S. Mukherjee:** Okay. My second question is on the R&D expense at INR400 crores a quarter. How should we think about from the next 2, 3 perspective? Are you thinking about any major investments, new areas, if you can guide on R&D expense in absolute terms, how should we think about it?
- Umang Vohra:** I'll request Mr. Ashish Adukia please to answer the question.
- Ashish Adukia:** Sure, sure. See, we try to stay in the zip code of 6% of our revenue. And more importantly, try to also see how U.S. revenue is doing when we look at the R&D because R&D is primarily allocated to our U.S. revenue. So, we stay around 6% range.

And then, of course, we have some flexibility. If we're getting a good growth, we can actually toggle it up because it's actually an investment into future. So that's how we look at it, but you should maintain 6% because U.S. market has been growing as fast or faster than the company. So likewise, R&D would also follow.

S. Mukherjee: Yes. But Ashish, R&D spend I would assume would depend on your aspiration of the products you are trying to build and you have to invest for it from a longer-term perspective because U.S. revenues can go up and down depending on whether you get approval or you get market share, etcetera, but R&D spend has to be sort of decided, right? So, this -- as a percentage of sales, it's not very clear to me.

Ashish Adukia: See, that flexibility is with us. But at the same time -- see, your -- our R&D is mainly focused on fewer products but with higher potential, right? And of course, we keep watchful eye on launches that you're having so that there is no erosion or reduction in the revenue that you have on the U.S. to balance both R&D costs that you're incurring and -- as well as maintaining the U.S. revenue overall and maintaining a growth rate out there. I think for the next couple of years, at least, we see this trend continuing..

S. Mukherjee: Okay. And my final question would be on the cash balance. So, what are your thoughts around that? How are you going to use this or pay out dividend, if you can give some colour?

Ashish Adukia: See, I think we still to kind of -- by end of the year, we'll take a call on -- board will take a call on distribution of cash. However, the -- our growth aspirations in India, some of the inorganic launches that we talked about in U.S., some of the markets in international as well where we may look at opportunities plus CapEx, etcetera, we'll factor all that in when we are taking a call on distribution.

Moderator: Next question is from the line of Aejas Lakhani from Unifi Capital.

Aejas Lakhani: Umang, I just want to get a sense of the U.S. and the pricing pressures in the U.S. And if you could double into a little more about how the regulators thinking there? How are the buyer groups thinking? Is the pressure easing? Or is it the same like you suggested last quarter?

Umang Vohra: Well, there's not too much difference quarter-on-quarter. All I can say is that in the U.S., we typically see in quarter 1 of every year, which is when the new budgets come out for every buying group that there is always more number of price challenges compared to the rest of the year. But as of now, we have not seen anything onto it.

Aejas Lakhani: Got it. And the environment, is it even a little -- has it changed a little for the last, say, 2, 3 years? Or is it the same that you feel?

Umang Vohra: No, I think it's a little -- so it's like this. It's a little calmer, but I don't think that this will -- between 0 -- we always see this -- the price compression in the range of 0 to 10 every year. Years are extreme bad pricing environment, which means where we see more compression, is 8 to 10. Years, which are normal compression, are about 4 to 6. So that's how I would put it.

- Aejas Lakhani:** And we are today in the 4 to 6 band?
- Umang Vohra:** That is correct. We are today in the 4 to 6 band. And this is a commodity cycle. It starts shifting quickly to the -- over a period of time to the 6 to 8 band, and then the 8 to 10 band.
- Aejas Lakhani:** Got it. And if I would just to ask you to hazard a guess of how this band may play out, given the data around ANDA filings and how the competitive intensity is as you see it today. Do you think it can continue to be in the 4% to 6% range? Or can it inch up towards 6% to...
- Umang Vohra:** It'll never be -- it'll never constantly be in the 4% to 6% range, that I'm clear about. I think the general trend is that every 3 or 4 years, there's a full up cycle or a down cycle. I think we are almost an year -- I would say, year 1 plus or year 2 of this down cycle. And my guess is within a year, things will be very different.
- Moderator:** Next question is from the line of Nitin Agarwal from DAM Capital.
- Nitin Agarwal:** Umang, when we look through the 9 months of the year, we've had 2 very exceptional quarters from a profitability perspective. I mean, overall, when you look back at the start of the year versus the way the year has panned out, I mean, in your assessment, what has really gone much better than what you really expected at the start of the year?
- Umang Vohra:** I think the -- actually, from a -- to be honest, from a budget perspective, we are largely on track with our budget. I don't think we are -- our assumptions are marginally different. I think our assumptions, where they are different, I'll tell you, they are around, let's say, the launch of Advair. That's an assumption that is different because of issue for us.
- And that frankly got compensated with potentially some launches that we were able to launch through our partners in the U.S. and possibly a better pricing environment. I think what's also better for us is the volume -- is our India growth and if it's in much better. And India is a huge business for us. Every 1% over delivery creates a fair amount of length on top line as well as on the model.
- Nitin Agarwal:** And if I would just probably push that point, Umang, we've seen a reasonable expansion in our gross margins over the last couple of quarters. Is there anything which is not sustainable, you want to call out in terms of the gross margin, especially for this quarter, 66%, almost -- we are almost - - it's amongst the highest we've done in a while.
- Umang Vohra:** Ashish?
- Ashish Adukia:** Yes. No, I think it's a combination of pricing. So, growth that you see out there is driven a lot by pricing, which flows through to your gross margin. And there is a better mix of the business in both quarter 2 and quarter 3. We got a better mix of Chronic. So that has also helped us. So -- and of course, we talked about reversing seasonality in quarter 4. So, these are the things that have helped us, and it's likely to sustain the gross margin levels that you talked about, that's the whole idea. We are pushing for sustainment or even better gross margin..

- Nitin Agarwal:** Ashish, the way the business mix is, in your assessment, evolving as you go forward, do you see opportunities for meaning expansion of gross margins on an annualized basis from where we are in FY '24?
- Ashish Adukia:** No, no, you're not seeing meaningful expansion of gross margin. Like I said, right, in next year, we'll not have pricing advantage as we did -- as we got from -- through WPI this year. So, it will be more, hopefully, volume-driven growth apart from some pricing advantage.
- Nitin Agarwal:** This is going to be the last one. Umang, on the U.S., there is a fair bit of peptide launches, you've talked about, over the next few quarters. Whereas the salience in the business along with respiratory, then -- I mean how large does peptide start to become as big a component of respiratory for us when you go forward from here-on?
- Umang Vohra:** I -- let me ask -- well -- no, I think, respiratory will still be much larger for us as a category because we've got other flow on assets that are -- follow-through assets that are also coming in respiratory, which are fairly significant. So, peptide will be a meaningful category for us, but the largest category will always be respiratory and so to margin-wise -- so to margin-wise. Because we own a large portion of the chain in the respiratory side. We own some part of the chain on the peptides.
- Moderator:** The next question is from the line of Nithya from Bernstein.
- Nithya:** Congratulations on a strong print this quarter. On U.S. specialty, Umang, I think we saw that Tramadol didn't work out. And more recently Pulmazole also you are backtracked in terms of what you're thinking about it for the U.S. So broadly, stepping back, how are you thinking about U.S. specialty? Is it still part of your long-term growth strategy? What has changed, if anything?
- Umang Vohra:** I think what's changed, Garrett, is that we'll have to build our own -- sorry, what's changed, Nithya -- my apologies. Garrett is our team member in specialty. But what's changed, Nithya, is really the ability to actually to get our own assets into the market. And actually, we've got 3 now.
- None of them are going to be -- our strategy was to pick winners and bigger value assets. I don't think that's played out for us. Maybe our understanding of this therapy is not -- of therapies is not strong enough to do diligence on these assets.
- So, I think it's better that we focus our attention on generating these assets from within and be content with the fact that no one asset will be higher than 50 million or so and try to build a portfolio. And when we have critical size, then pick up something that we feel more comfortable about. If we had to pick up an asset today in spec, it would have to be an asset that is already approved. I don't think we want to take any more approval risk for any of the assets we decided to pick up.
- Ashish Adukia:** And to go up the value chain, we are anyway focusing on complex 505(b)2s, which gives us that advantage of market share, right?

Nithya: See, this new strategy of growing it or developing it in-house, obviously, has a much longer gestation cycle, do you believe then that you have enough PEGs for growth before that strategy starts to kick in for you?

Umang Vohra: For the rest of the business, Nithya, yes, because look '26, '27, '28, you'll see the other range of inhalers coming. Before that, hopefully, Symbicort around that time. So, then you have the -- so you have those assets. And I think we have the other peptide portfolio. So, I think around the '27, '28 period, yes, I'd like to think that if we can get 1 or 2 assets in the market, it will be a validation of what we can create in this space.

That may be a good time to perhaps go and acquire some in-market assets at that point in time. Right now, I'm not clear if we're fully understanding this market the way it should be understood. So, we're shy of investing anything more which has a development risk attached to it.

Nithya: Got it. Umang, I know you've been asked this before and I'm going to ask it again. Are the promoters still looking to sell their stakes in Cipla? And should we be reading anything more into -- Samina is stepping down as -- from her executive vice-chair role?

Umang Vohra: No, I don't think so. I think Samina's decision -- so firstly, there's no sale. There is no -- as of this moment, there is no sale, and there hasn't been any discussion or any information or any dialogue over the last at least 2 to 3 months that we are aware of. Samina's decision -- Samina is still continuing as a nonexecutive director. I think she has switched roles from being an executive to a nonexecutive and that is driven more with the overall promoter family plan to create an institution for Cipla that survives various promoter transitions.

And as much as they are planning for it, I have to also plan for the management continuity of this company through -- so that the company stays professional and as an ever growing and everlasting phenomena to it.

Moderator: Ladies and gentlemen, we will take last 2 questions for the day. The next question is from the line of Kunal Dhamesha from Macquarie.

Kunal Dhamesha: Sir, just continuing on my last question about the other expenses. I mean, we had expected that other expenses might move up in the second half of FY '24. At least in quarter 3, we have not seen other expenses, excluding R&D, right? So, is it more, you can say, this quarter phenomena or we continue to run cost efficiency programs, which is now starting to kick in?

Umang Vohra: Mr. Ashish Adukia will address your question.

Ashish Adukia: So, we can see -- like I said, this is a sustainable number, okay? And more specifically, we can unpack the numbers and discuss.

Kunal Dhamesha: Sure. And...

Umang Vohra: Sorry -- just one minute. I think his question is, you have reached a sustainable level of expenditure on other expenses. So is there a need for you to relook at these expenses from a perspective of

creating some productivity. That's the question I think he's raising, which frankly is -- I mean -- yes, I mean we should -- yes. Yes. No.

Ashish Adukia: No, sure. I think there is an opportunity for us out there. And as we get into the next year's numbers, we'll be able to give you a better idea.

Kunal Dhamesha: Sure. And one more on the peptide assets that are being launched -- that have been planned for launch next year. This year, we are just waiting for approval. But for those other 4 assets, which are the pending tests for us to commercialize those assets? Is it just the approval? Is it IP-related issues? How should we think about it?

Umang Vohra: So, I think most of the IP-related issues for the assets that we have selected will resolve in the '24, '25 time frame. And the -- there are some where there are no IP issues. Those are clearly linked to approvals.

Kunal Dhamesha: Would you quantify between the 4, how many are just approval related?

Umang Vohra: We are not giving that quantification, but obviously, the assets that we are hoping to launch recently is completely linked to approval, not to IP. The other assets that we'll drive -- there are 2 assets that probably are not linked to IP anymore because we believe the patents would expire for those. And the assets after that are clearly linked to IP.

Kunal Dhamesha: Sure. And just the last...

Umang Vohra; I'm sorry, but it's close to 50-50.

Kunal Dhamesha; Okay. Sure. Sure. And just the last one on the cash we have, I think the other participant also asked in terms of what would you decide. But let's say in terms of inorganic, if we have to think would it be more bolt-on acquisition, which we have done in the past or now the thinking has specifically on some of the branded market that we can deploy more capital there? What's the current thinking?

Umang Vohra: See, our discipline towards approaching some of these opportunities will not change just because we have excess cash, just not that we will compromise on our IRRs. We follow the same approach, and it will be bolt-on in some of the markets where our capital allocation is limited, but some BU like in India, there, we are quite confident of the growth that it offers, and therefore, we can go aggressive in India in terms of the size.

But of course, the value creation, etcetera, is an important element when we are looking at any acquisition opportunity. And yes, one more like the CHL is again -- and we see that -- Cipla Health that as we see that as a growth of the share, continuously looking at brands out there to acquire as we speak. Again, more bolt-on and addition of brands, not very large platform out there. But that's one area where we see a good potential.

Kunal Dhamesha: Sure. Since we just touch up on Cipla Health, I think last year quarter 4 for Cipla Health was quite weak, right? Would you say that trends are better this time around versus last year, quarter 4?

- Ashish Adukia:** See, this business is in a growth trajectory. In fact, this year, we saw a bit of a slow start of the year because of the overall beverages market was slower and we had some inventory rebalancing also that took place because of the transfer that happened from generic business to Cipla Health. But after that has gone back to its path of growth with their top products, that is all about INR100 crores.
- Kunal Dhamesha:** My sense is completely different on this. Probably I will touch base on the numbers once again. But my view is, the first quarter was exceptionally strong in terms of growth, and then quarter 2, quarter 3 has seen some more moderate growth for the CHL business for India, not including South America, just consumer business in India.
- Ashish Adukia:** Okay. You're talking about country as a whole, okay. No, that's fair enough. I think that...
- Kunal Dhamesha:** No, just the consumer business in India, I'm talking about CHL in India.
- Ashish Adukia:** Yes. So CHL in India, I think quarter 1 -- we'll give you set of our numbers Kunal offline. I think CHL business probably services India by and large. There's no other market.
- Moderator:** Ladies and gentlemen, we'll take a last question from the line of Smit. from RDA.
- Smit.:** My question is on U.S. generics. How was the pricing environment in Q3 for inhalation products?
- Umang Vohra:** I think it's more or less -- well, when you say pricing environment, it's going through its regular price compression. No, nothing accelerated or accentuated at this stage.
- Moderator:** Ladies and gentlemen, that was the last question for the day. I now hand the conference over to Mr. Ajinkya Pandharkar for closing comments.
- Ajinkya Pandharkar:** Thanks, everyone, for joining. If you have any further queries, you may reach out to investor.relations@cipla.com. Have a great evening ahead and Happy Republic Day to everyone.
- Umang Vohra:** Thank you, Mr. Ajinkya.
- Moderator:** Thank you. On behalf of Cipla Limited, that concludes this conference. Thank you all for joining us, and you may now disconnect your lines.