“Glenmark Pharmaceuticals Limited

Q3 FY '25 Earnings Conference Call”

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Moderator: Good morning, ladies and gentlemen. Welcome to the Q3 FY '25 Earnings Conference Call of Glenmark Pharmaceuticals Limited. As a reminder, all participant lines will be in the listen-only mode, and there will be no opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing star, then zero on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Mr. Utkarsh Gandhi, Senior General Manager, Investor Relations for Glenmark Pharmaceuticals. Thank you, and over to you, sir.

Utkarsh Gandhi: Thank you, Lizan. Good morning, everyone. Welcome to the Q3 FY '25 Results Conference Call for Glenmark Pharmaceuticals Limited. Before we start the Q&A, we'll review the overall performance of the company for the third quarter of FY '25.

In Q3 FY '25, Glenmark's consolidated revenue from operations was at INR33,876 million as against INR25,067 million in the corresponding quarter last year, recording an overall Y-o-Y growth of 35.1%. For 9 months of FY '25, Glenmark's consolidated revenue was at INR1,00,655 million as against INR87,501 million, recording a Y-o-Y growth of 15%.

We'll cover the -- each of the regions in a little bit more detail, starting with India. Sales from the formulation business in India for the third quarter of FY '25 were at INR10,637 million as against INR2,658 million in the corresponding quarter last year, recording a growth of about 300%. The India business contribution in this quarter was 31.4% to the overall revenue.

In terms of our overall secondary sales, Glenmark continues to outperform the Indian pharmaceutical market in terms of Y-o-Y growth. As per IQVIA, Glenmark's India formulation business recorded a growth of 9.6% in Q3 of FY '25 and 12.3% as per MAT December 2024 compared to the overall market growth of 7.2% in Q3 and 7.4% in MAT, respectively.

Glenmark continued to perform well in its overall -- in its key therapeutic areas, particularly in dermatology and cardiac. Glenmark's India business is now ranked 13th with a market share of 2.23% as per IQVIA MAT December 2024 data. The company added 1 brand to the IPM Top 300, so we now have 10 brands in the IPM Top 300 brands.

And in terms of our key therapeutic areas, we are ranked second in dermatology, third in respiratory and fifth in the cardiac segment as per the IQVIA MAT December data. So obviously, we have improved our market share in some of these key therapeutic areas as well, some of which has been provided in the MD&A.

We have some key launches in the last few quarters in our key therapeutic areas, products like LIRAFIT, which we launched as the first biosimilar of Liraglutide. It has seen good traction in the market post launch. We are also planning to launch other GLP-1 agonists in the near future.

And in the dermatology segment, we launched JABRYUS, which is Abrocitinib. This is in partnership with Pfizer. It's an oral systemic treatment for moderate-to-severe atopic dermatitis. And again, this product has also been received well by dermatologists.

We also have two oncology products, which we had partnered with BeiGene: Tislelizumab and Zanubrutinib. We will be responsible for locally required development, registration and distribution of these products in India. And Glenmark plans to launch these products over the next 3 to 4 months once we receive the required regulatory approvals.

In terms of our Consumer Care business in India, primary sales for the GCC business in Q3 was INR566 million with a Y-o-Y growth of 13%. The company's flagship brand, Candid Powder, gained market share as per IQVIA data, and our brand market share now is at 55%. In the third quarter, the Scalpe portfolio also delivered robust growth as well as La Shield, which delivered growth of 13.5% as per IQVIA MAT December data.

Moving on to North America. The North America business recorded revenue in Q3 of INR7,813 million for the third quarter as against INR7,705 million for the third quarter of FY '24, which translates into a Y-o-Y growth of 1.4%. For the third quarter of FY '25, North America business contribution was at 23.1%.

Glenmark U.S. business continued to remain challenging due to lack of meaningful launches during the quarter. However, the company expects an uptick in the business, particularly from FY '26 onwards on the back of potential launches in the respiratory and injectable segments. Glenmark expects to launch some of its respiratory ANDAs from H1 FY '26 onwards. And the company continues to augment its commercial portfolio in the meantime through partnered product launches to help the business growth in the near term.

In the third quarter of FY '25, Glenmark launched Travoprost Ophthalmic Solution and Lacosamide Oral Solution. We filed one ANDA during the quarter and plan to file one more ANDA in the upcoming quarter. We have eight commercial products in the -- 8 commercial injectable products in the U.S. market.

We have also leveraged our strong development skills in the respiratory area. Glenmark has filed two ANDAs for generic nasal spray and is awaiting approval for the same, as well as we mentioned earlier that we have filed the ANDA for generic Flovent 44mcg MDI in May 2024. Glenmark is also working on filing the other -- ANDAs for the other two strengths of Flovent as well as other respiratory products which are currently in the pipeline.

Glenmark's marketing portfolio through December 31, 2024, consists of 201 generic products authorized for distribution in the U.S. The company has 51 applications pending at various stages in the approval process along -- of which, 22 are Paragraph IV applications.

Moving on to Europe. Glenmark's Europe operations revenue for the third quarter of FY '25 was at INR7,297 million as against INR6,357 million, recording a Y-o-Y growth of 14.8%. Europe business contributed 21.5% to the total revenues in the third quarter of FY '25. The branded business in Europe – in Glenmark's European operations continued its trajectory, driven by sustained growth across all key markets.

Overall, CEE region did face some challenges due to seasonality, however, RYALTRIS particularly has done very well. It continues to gain market share across the countries where the product has been launched. And branded respiratory portfolio in the Western European business also has sustained its growth momentum with key brands like RYALTRIS, Salmex continuing to sustain and gain the market share in terms of value and volume.

Glenmark is now ranked 13th in the generic market of Germany as per the IQVIA data. Going forward, we continue to focus on sustaining the increased contribution from branded products and branded markets in Europe. Glenmark is awaiting approval of four respiratory products, which were filed in Q4 FY '23. And recently, the company announced that it has received approval from the MHRA to market WINLEVI in the U.K. The company is planning to launch WINLEVI in the U.K. as well as other select markets of Europe in FY '26.

Moving on to the ROW region, which consists of Russia, CIS, Latin America, MEA region and the Asia Pacific countries. For the third quarter of FY '25, revenue from the ROW region was INR7,491 million as against INR7,271 million for the corresponding quarter last year, recording a Y-o-Y growth of 3%. For the third quarter of FY '25, the ROW business contributed 22.1% to the overall sales. The reported growth for the ROW region during the quarter was impacted due to the adverse currency movements in some of the key markets.

As per IQVIA MAT December data, Glenmark's Russia business recorded secondary sales growth of 16.6%. RYALTRIS sustained its momentum and gained further share during the quarter in the Russian market. In dermatology, Glenmark demonstrated strong growth of 20-plus percent in value versus overall retail market growth of around 16%, as per the IQVIA data. Glenmark continues to be ranked ninth amongst the dermatology companies in Russia as well as second amongst the companies present in the respiratory expectorant market in the Russian country.

For Latin America, the respiratory portfolio continued to be a key growth driver. Glenmark launched the first Salmeterol + Fluticasone MDI in the Brazilian market in Q1. The product has done well post launch. The company also received approval for Salmeterol + Fluticasone DPI in Mexico, and RYALTRIS was also launched in Mexican market in Q2 and since has gained share in that country.

In the Middle East, Africa region, the company continues to achieve good secondary sales growth in key markets. Glenmark continues to be ranked second in Kenya. And RYALTRIS, which is a major product in the South African market, continues to be the leading nasal spray for allergic rhinitis there.

In the Asia region, key markets like Malaysia and Sri Lanka recorded double-digit growth. RYALTRIS continued to drive the, again, the significant outperformance in the Australian market. And we have some new product launches in dermatology and respiratory, which will contribute to growth in the upcoming quarters.

Quickly covering some of our key global brands. So we talked about RYALTRIS. As of December '24, marketing applications for RYALTRIS have been submitted in more than 90

countries, and the product has been commercialized in 43 markets. Further, we expect to launch in another 12 to 15 additional markets over the next few quarters.

As per the IQVIA data, we have -- RYALTRIS has seen robust performance in terms of value and unit market shares, particularly in some of the markets we covered during the earlier part of the commentary. Glenmark's commercial partner in the U.S., Hikma, recorded decent performance on a Y-o-Y basis in the third quarter.

Menarini, Glenmark's partner in the European region, has also witnessed steady increase in market share across its licensed markets. The product also does well in the South Korean market where Yuhan Corporation, our partner, is marketing on our behalf. And Glenmark's partner in Mainland China, Grand Pharmaceutical, expects to receive the product approval sometime in FY '26.

So moving on to Envafolimab. We had announced earlier in Jan 2024 the signing of a licensing agreement with Jiangsu Alphamab and 3D Meds for Envafolimab for India and the ROW regions. Envafolimab is already marketed in China. It has already been included in the list of breakthrough therapies by the Chinese regulatory agency.

And Envafolimab is -- along with its key indication of being a PD-L1 for treatment of adult patients with previously treated MSI-high biomarker, Envafolimab is also being investigated in clinical trials for additional oncology indications like non-small cell lung cancer. Glenmark plans to file Envafolimab in more than 20 markets in the current year, and the first market launch is expected in FY '26.

WINLEVI. In Q2, we announced the licensing of WINLEVI with Cosmo. As mentioned earlier, the company recently announced the approval from MHRA in the U.K., and we are planning to launch WINLEVI in FY '26 in some of our licensed markets.

Lastly, covering IGI. IGI, Ichnos Glenmark Innovation, features a robust pipeline of three innovative oncology molecules targeting multiple myeloma, AML and some solid tumors. Two of the molecules have received orphan drug designation. In addition, IGI also has two autoimmune disease assets that have been out-licensed to companies: ISB 880, which has been out-licensed to Almirall; and ISB 830, which has been out-licensed to Astria Therapeutics.

In terms of ISB 2001, this is a trispecific antibody for oncology and immunology. It is a BCMA CD3 -- CD38 trispecific T cell engager that targets all the three biomarkers to harness the body's immune system against cancer. It is amongst the first trispecific antibodies developed for use in multiple myeloma, and it received orphan drug designation in July 2023 from the U.S. FDA.

The Phase 1 trial, first-in-human trial for relapsed/refractory multiple myeloma was initiated in November '23. That's when the first patient was dosed. The trial is now active across centers in the U.S., Australia and India. Dose escalation is currently underway.

And in December '24, we announced the first-time data presentation at the American Society of Hematology Conference in San Diego. The oral presentation was circulated to the investors as well, and it detailed out the dose escalation part of the study. ISB 2001 has shown a very

favorable safety profile with a very strong efficacy, overall response rate of 83%, along with 22% complete response or better and 50% very good partial response.

The overall response rate was 75% in patients pretreated with CAR-T or bispecific T cell engagers. And 80% of our patients remain on the treatment at the time of the data cutoff. IGI has initiated partnering discussions post the ASH conference, and the company aims to conclude a partnership in calendar year 2025. Further data from the Phase 1 dose escalation study will also be presented at the American Society of Clinical Oncology, ASCO, Conference in June 2025.

Before we start the Q&A, just a quick update on the notes to the results. Forex gain in this quarter was INR23 crores, which was recorded in other income. R&D expenditure in Q3 was around INR225 crores, roughly 6.6% of sales for Q3. Investment in IGI was USD13.8 million. The total asset addition to the block during the quarter was INR143 crores, of which tangible asset addition was around INR72 crores and intangible asset addition was around INR71 crores.

In terms of working capital, at the end of December '24, inventory was at INR3,090 crores, receivables was at INR2,914 crores and payables was at INR2,212 crores. Net debt for the period ended December '24 was at INR109 crores.

We have the management of Glenmark Pharmaceuticals on the call today Mr. Glenn Saldanha, Chairman and Managing Director; Mr. V.S. Mani, Executive Director and Global Chief Financial Officer; and Mr. Ashish Mukkirwar, Group Vice President and Head of Corporate Strategy.

With that, we can open the call for Q&A. Over to you, Lizan.

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

Damayanti Kerai: My first question was India business. So in some of the key therapies, you have definitely grown much better than the market. But just want to check your diabetes profile, it seems -- the growth profile for diabetes seems weaker than the market. So can you explain what is happening there? And how should we look at this?

Glenn Saldanha: Sure. So let me just talk about the entire India business. And then I'll come specifically to your question on diabetes. So if I look at our India business, we started the year by guiding to around INR1,100 crores per quarter, which is about a 9%, 10% growth. If I look at the first half, we did exceedingly well. We outperformed those numbers. And Q3, we've seen some slowdown in the respiratory space. But I think on a full year basis, we are pretty confident that we'll be able to meet our guidance, for the India business.

If I look at specifically each of the segments, cardiovascular, dermatology continue to do exceedingly well. Respiratory, acute respiratory, we've seen some slowdown, although we are growing faster in the chronic area. And diabetes, we've had some challenges in terms of stock levels for LIRAFIT. But every month, we're getting better in terms of the supply of LIRAFIT. So I think LIRAFIT, once we come into full supply, which should be in the month of -- in this month or next month, in this quarter, then you'll see the diabetes growth coming back.

The other thing to keep a watch out for is, obviously, once the GLP-1s -- this is the first GLP-1, but once the subsequent assets come to market, that will further enhance our diabetes sales. So across the four therapeutic areas that we operate in India, and of course, oncology, we are looking at a good FY '26 primarily because of the BeiGene products, Tislelizumab and Zanubrutinib, which should contribute pretty significantly to the oncology business in India, so these five segments will continue to do well for the company going forward.

Damayanti Kerai: But the stock level problem which you mentioned for LIRAFIT, is it specific to that particular product? And in other part of the portfolio, how is the performance? Because market has grown, but you seem to be in...

Glenn Saldanha: So in diabetes, we've traditionally had two molecules, remogliflozin, with the new -- remogliflozin and teneligliptin. With the new DPP-4s and SGLTs that have come into play, we've lost some share on both these molecules. But some of it has been offset with the launch of LIRAFIT, and LIRAFIT continues to do well. So I think across the board, the segment continues to do well and will continue to grow every year from here on.

Damayanti Kerai: Okay. Got it. My second question is on your U.S. business. So again, if you can share the status of Monroe plant because I guess we have been waiting for like quarter after quarter, but if you can share the latest status, that would be helpful?

Glenn Saldanha: So let me start with just giving a broad overview on the U.S. business, before I go to Monroe. So if I look at the U.S. business, I mean every quarter, things are getting better. I mean I think Q4, we have some interest from some good launches, which will ensure that we have Q-on-Q growth in the fourth quarter.

If I look out to FY '26, we have 2 major launches in the first half of FY '26. One is, of course, fluticasone 44 MDI, Flonase, where we believe we have an exclusive position. We also have fluticasone nasal spray, getting launched in first half of FY '26. Both these are very big products, so should contribute pretty significantly to the growth.

In addition, we have the other strengths of fluticasone MDI getting filed in FY '26 and one other respiratory MDI product getting filed in FY '26. I mean all this put together, in FY '27, if you see the market potential of this entire franchise, the filings and the launches we are doing this year, you're looking at almost $600 million, $700 million of franchise coming to market in FY '27.

In addition, we have 3 sole 180-day exclusivities/180-day first-to-file/exclusivities coming up in FY '27 and '28, which is another $800 million market. So I mean, the next 2, 3 years, FY '26, '27 and '28 should be strong years for the U.S. business.

Now with that backdrop, Monroe, we are still waiting for the FDA to come in and inspect us at Monroe, but we continue to take batches, and we continue to file some of our products out of Monroe. So -- and these are mostly injectables, complex injectables. So I think longer term, given the geopolitical situation, I mean we think Monroe should have a significant benefit, as we go forward. So it's only a matter of time. We think Monroe should pay back and start playing out as we go forward.

Damayanti Kerai: Sure. And when did you have your last communication with the FDA regarding Monroe plant?

Glenn Saldanha: So we did a meeting with them, I think it was a couple of months ago. And since then, we give -- we send in constant updates to them on the status of our remediation.

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

Nitin Agarwal: Glenn, on ISB 2001, is there any more update post the ASH data that you presented? And how should we look at this asset now going forward?

Glenn Saldanha: So clearly, ISB 2001 is a super-exciting product, and has the ability to be a transformational asset for Glenmark and probably the entire multiple myeloma space, given the data we put out at ASH. And subsequent to that, we've opened partnering discussions. So we were at JPM. We did a number of meetings with a lot of companies, and there is tremendous amount of excitement about the potential of this asset.

So we are clearly on course to finding a partner to drive ISB 2001. So I mean, we've given ourselves till the end of this year, but it could be earlier. But there is a tremendous amount of interest in the asset from a partnering perspective.

And the trial continues. I mean we continue dosing patients. We are hoping to start the dose expansion cohort in the next 3 to 6 months. So I think that process continues. So we'll have a significant number of patients before the end of this year. We'll have an update at ASCO on ISB 2001. So the rest of the process continues.

Nitin Agarwal: And from a partnering perspective, again, are there any specific data points which are make-or-break data points that incrementally that you are waiting? Or how should...

Glenn Saldanha: No, go ahead, Nitin.

Nitin Agarwal: I'm saying, so is there any trigger or anything, any milestone that will probably enable or accelerate the whole licensing part? I mean, what will take licensing to go through or not go through from here?

Glenn Saldanha: So we don't think that we are waiting on anything as of now, Nitin. So it's only -- I think it's all procedural from here. So we've just opened discussions in Jan. So it's going through the process.

Nitin Agarwal: I mean the point I was trying to ask is the data that you've got so far is enough for us to conclude the deal?

Glenn Saldanha: Yes, it is.

Nitin Agarwal: Okay. So how should one think about now depending upon when the licensing happens on the innovation R&D spend for us going forward?

Glenn Saldanha: Our view is FY '26 will be the last year where Glenmark will have to put capital into IGI. I mean, IGI, given the partnering interest that we are seeing and the excitement around the asset, we are pretty confident that we'll be able to close a deal, which will fund IGI going forward. And then,

of course, the long-term goal for IGI is then to IPO the company in the U.S. So that's the journey for IGI. So we believe F '26 will be the last year of investment into IGI from Glenmark.

Nitin Agarwal: Right. And secondly, on the balance sheet, there has been this buildup of net working capital again. I think we are a little away from what we guided to at the start of the year for F '25. So any thoughts on that? Where should we end the year at? And what is driving this increase right now?

V. S. Mani Yes, sure. So Nitin, we are already -- I mean, in the beginning of the year, we did sort of guide that the working capital will go up. And some of the working capital items are pretty much close to what the industry levels are. In this quarter, obviously, there is some increase in the inventory based on the -- we already read out the numbers.

So we had to buy some -- as you know, we had also earlier discussed about some critical launches coming up in the next couple of quarters. So we had to build up some inventory for that. So Nitin, I expect it to sort of normalize in the coming quarter and the first quarter. So I think broadly, that will help us to sort of improve our working capital.

Nitin Agarwal: And sir, if you could remind us what working capital days should we work with on a sustainable number?

V. S. Mani: So we are -- so maybe last quarter, we were at about 90 plus. So I think those are the levels at which I would expect to be there, yes.

Nitin Agarwal: Okay. And then lastly on -- you mentioned about Fluticasone MDI. What -- when are we looking at an approval? What's your assessment on when the -- what is sort of -- when does the approval come through for that for the first time?

Glenn Saldanha: So we've given ourselves till H1, Nitin. It could be earlier in the -- right? But H1 is when we anticipate first half of next year, 44 -- Fluticasone 44 will get approved.

Nitin Agarwal: Okay. And last one on the -- Glenn, for the guidance for the year, we'll keep tracking a little below on the EBITDA number -- EBITDA percentage number that we had earlier...

V. S. Mani: I'll take that, Nitin. So obviously, we are almost at about 18% for the 9 months so far. And as we had already sort of given during our commentary that we had some currency hits during the third quarter, especially. If we adjust for that, we would be close to 19%. So we almost had about INR71 crores coming out of some of the emerging markets in LATAM and also in South Africa, etcetera, and Russia as well.

So I think if we were to take for that, we should be close to what we guided in the beginning of the year. Also, our turnover is also at about INR10,000-plus crores. So Q4 is generally a good quarter. So we should close to be about INR3,500 crores. So I think broadly, we would be able to meet the numbers that we gave you and barring for this adjusting for some of the currency.

Glenn Saldanha: So on the full year, Nitin, we will hit both our top line as well as EBITDA guidance, adjusted for currency.

Nitin Agarwal: And this is going to be my last one, on the overhead, staff costs, other expenses, there has been a reasonable control which has come through in the first 9 months in terms of Y-o-Y growth. I mean, do we expect -- I mean, these are now more sort of sustainable trends on these overhead increases?

V. S. Mani: Yes, absolutely. So as I told you, even in the last quarter, slightly, the other expense picked up. But I did tell you that full year would be about 27%. And broadly, we are there only. We are not going to exceed that. And obviously, the expenses don't happen, and sometimes a little bit comes here and there in terms of how we want to do sales and marketing, but I pretty much see where it is.

Moderator: The next question is from the line of Ashish from JM Mutual Funds.

Ashish: Sir, any update on respi and injectable segments for the U.S. market? Especially you guys are there on the ground, any update regarding the tariff discussions possibly in the U.S. market?

Glenn Saldanha: So respiratory, I have pretty much given you the road map. Between the three fluticasones, fluticasone 44, 110 and 220 put together is almost 500 million. In addition, you have fluticasone nasal spray, which can be a substantial product, and we have one more respiratory MDI filing this year, which is another $200 million product. So I think we are on a good track to get these 5 or 6 key respiratory launches, over the next few years.

On the injectable side, Monroe, we are continuing to file products. We're continuing to take batches, and we have some exciting filings going out this year and next year out of Monroe. We are just waiting for the FDA to come in and audit us in the interim. So these 2 segments, we continue to move forward nicely as a company.

We also -- in the near term, especially in Q4, you should see some good in-licensing products coming to market. We have some good launches coming up in Feb and in March, which should help this quarter partially, but help the next quarter in a significant manner. So I think all in all, it looks pretty good.

As far as the tariffs go, it's extremely hard to predict for anyone. What we've heard is that some of these are getting postponed, but it's extremely hard to predict how this will all play out in the long run.

Ashish: Fair enough. And any update on the entire GLP-1 category? You did mention about one of the biosimilar launches. But going forward, from a 2- to 3-years perspective, as and when the GLP market in India opens up, how are we positioned? And yes, any update on this will be very helpful.

Glenn Saldanha: So in the GLP-1 Liraglutide, LIRAFIT, Glenmark was the first to launch the GLP-1 in India, injectable GLP-1. And we are well positioned to also launch semaglutide injectable and eventually oral also. So I think -- although I think it will be a crowded market, I think we are well positioned to launch the products in India.

Ashish: And how about -- in terms of integration, obviously, we might be sourcing the drug substance and other products, other fill/finish opportunities from the other parties. But in terms of the MRs, the field force, our front end, would we have to deploy incremental capital or resources?

Glenn Saldanha: We already -- at Glenmark, we already have a strong diabetes franchise. So we won't need any additional resources. So we have all the necessary capabilities to commercialize these products.

Ashish: Fair enough. Sir, lastly, obviously, adjusted for currency, you did mention that 18%, 19% EBITDA margin run rate that we are already clocking. But going into FY '26, with India coming back, U.S. also a lot many launches coming into picture, any guidance on EBITDA margins you would like to give?

V. S. Mani: Yes. So if you recollect, even during our investor presentation, we had said that year-on-year, we expect a 1% to 1.5% improvement. So I think if things go well, we should definitely -- with these critical launches that we expect to come through, we expect to be improving by 1 percentage and 1.5 percentage.

Moderator: The next question is from the line of Kunal Randeria from Axis Capital.

Kunal Randeria: Glenn, I heard your commentary on domestic business, but I'm afraid I'm not fully...

Moderator: Sorry to interrupt, Kunal, can you speak a bit louder? We're not able to hear you.

Kunal Randeria: Yes, sure. I hope this is better. Glenn, yes, I heard your commentary on the domestic business, but I'm not completely sure I fully understand this. See, the IQVIA growth was around 9.5% for Q3, while your reported growth -- I mean, reported would be on a decline, I guess, on a year-on-year basis. So why such a big delta? And even after I were to assume that primary sales were higher in H1, that still does not explain such a big delta. So if you can just...

Glenn Saldanha: Yes. So Kunal, as I said, look, we had guided to INR1,100 crores in the beginning of the year, which is a 9%, 10% growth. If you see the 9 months, we are at 6.3% growth, okay? Yes, Q3 was a soft quarter for us. And we discussed it's primarily because of acute respiratory, which is a big part of Glenmark's portfolio, okay. And we had a very good H1. So I think we will meet our guidance, of 9% to 10% and the INR1,100 crores per quarter on an average, that we've guided towards.

Kunal Randeria: But then how would 4Q pan out? Because if I were to assume you'd be around INR4,400 crores for the last -- for the full year, last quarter would be, what, around INR900 crores, I guess, which would be, what, flat to slight declining?

Glenn Saldanha: It could be better than that. Look, this is what we guided at the beginning of the year, Kunal. That's the way to think about it. We could definitely be better than that. We will be better than that.

Kunal Randeria: Sure, sure. Okay. Got it. Secondly, on Indore plant, just can you talk a bit more about the observations and how critical this plant is in terms of revenue contribution and outstanding filings?

Glenn Saldanha: Sure. So I think the Indore plant got audited after 6 years. That's -- it's been a long time since we got audited. We had a very thorough inspection from the agency. There were no DI observations, and we're pretty confident we'll be able to address the observations. So I think from a revenue perspective, it's probably around 25% -- or 25% to 30% of total U.S. revenues comes from there, from that facility.

Kunal Randeria: Sure. And in terms of outstanding filings?

Glenn Saldanha: We have probably about four or five outstanding filings, but none of the products I mentioned are coming from Indore.

Utkarsh Gandhi: So it's more of our base OSD portfolio that's essentially filed from Indore. So we have some four, five-odd pending filings from there in the more near term. But none of the respiratory products or the injectable ones are coming out of Indore.

Kunal Randeria: So the injectable one would be from Nagpur.

Utkarsh Gandhi: Injectable is from Monroe.

Glenn Saldanha: Monroe.

Moderator: The next question is from the line of Anil Shah from Insightful Investments.

Anil Shah: No, most of my questions have been answered. Thank you so much.

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

Tushar Manudhane: Sir, just with respect to generic Flovent, just want to understand if you have additional queries here.

Glenn Saldanha: No, we've responded to all the deficiencies from the agency, and we are waiting for them to respond.

Tushar Manudhane: So I mean, has this happened recently and that's the reason why the approval is sort of indicated in first half FY '26?

Glenn Saldanha: I can't give more visibility than that. We've responded to everything. We're just waiting on the agency to -- for the approval.

Tushar Manudhane: Okay. Sir, secondly, on these three products which you highlighted about FTF 180-day exclusivity, where are we in terms of sort of filing approval cycle for these products?

Glenn Saldanha: So to the best of my knowledge, all the three are tentatively approved and are ready to get launched.

Tushar Manudhane: Okay. So more of -- so there's no litigation angle to these products?

Glenn Saldanha: No, they've all been settled.

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

Bino Pathiparampil: Glenn, just a follow-up from the previous question. There is this product Axitinib or Inlyta brand name in which you have a tentative approval, and I believe you are one of the first to file. Are you the first to file? And is that a launch we can expect in the next 1 or 2 years?

Glenn Saldanha: Bino, I cannot comment on the status of Axitinib. But clearly, we will -- you will see us launching this product as we go forward.

Bino Pathiparampil: In the next 12 to 24 months or beyond that?

Glenn Saldanha: I can't give you any visibility around that.

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

Nitin Agarwal: Glenn, on the respiratory business, barring the set of filings you've talked about for this year, both on the -- I mean, can you give us more color on how is the -- is there anything more from a pipeline perspective in respi for the U.S.?

Glenn Saldanha: Nitin, we are constantly working on respiratory being a focus area for us. I think our current focus is even if we can get these products approved, Nitin, I mean you can imagine the kind of sales potential, between the three strengths of Flovent, $500 million market, the one extra MDI we are filing this year, another 200 million, and the nasal sprays put together.

So you're looking at a very large market potential. So I think even if we are able to get all these approved, the next 3 years should look very strong on the respiratory side for us.

Nitin Agarwal: Which I entirely get, Glenn. I'm just curious, is there more beyond this because...

Glenn Saldanha: Of course, we are working, Nitin, on the next set of products. But I mean now, we can't give any visibility.

Utkarsh Gandhi: More near-term opportunities, obviously, we have outlined here.

Nitin Agarwal: And secondly, if you can just give us a little more color on how RYALTRIS is faring? Any sense on the size it has got to? I mean, what size are you extending for the year on this?

Glenn Saldanha: So RYALTRIS, this year, we will be close to about $80 million, second year of launch. We're already tracking last quarter's almost $19 million, $20 million of sales. So almost $80 million product for us. And we still -- next year, we still have some major markets to launch next year and the year after that, like Brazil, China and many more smaller markets where we are still waiting to launch the product. So I think RYALTRIS, over time, we are pretty much on track to achieving $200 million, $300 million of sales -- peak sales over time.

Nitin Agarwal: And from an accounting perspective because I presume a lot of -- is there a large proportion of the $80 million which is coming in form of your royalties or profit share? How should one think about that number?

V. S. Mani: Sorry, come again?

Nitin Agarwal: Is there $80 million on royalty that you're booking? Is it a large chunk of it coming in from a profit share, which has a lot of more flow-through to the EBITDA?

V. S. Mani: No, no, no, that's not the case. It's quite stable. I don't think there is any royalty only. There's no major royalty in that. It's all sale of -- I mean we have what we have sold to partners or what we are selling directly. In a lot of markets, as you know, we have put our own field force. We have almost launched it now in 43 countries, Nitin. So it's not a question. So there's no major -- any royalty or anything in this.

Nitin Agarwal: Sir, what I really meant is, is there a much higher-margin business overall for us in the -- as a product than...

V. S. Mani: Yes, yes, it is a better-margin product, Nitin. It's because in a lot of geographies, we have launched it ourselves. So that's how it works.

Moderator: As there are no further questions, I now hand the conference over to Mr. Utkarsh Gandhi for his closing comments.

Utkarsh Gandhi: Thanks, Lizan. Before we end the call, we would just like to state that the discussion materials provided during today's call, including the information, statements and analysis made by the company or its affiliates, objectives, projections and estimates are forward-looking statements.

These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, and actual outcomes could differ materially from these statements depending on the economic conditions, government policies and other factors.

No representation of warranty either expressed or implied is provided in relation to the discussion and the documents, and it should not be used as -- by recipients as a substitute for the exercise of their own judgment. The company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

With that, we can end today's earnings call. Thank you for joining us.

Moderator: Thank you, members of the management team. Ladies and gentlemen, on behalf of Glenmark Pharmaceuticals Limited, that concludes this conference call. We thank you for joining us, and you may now disconnect your lines. Thank you.