“Glenmark Pharmaceuticals Limited

Q1 FY ‘25 Earnings Conference Call”

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Moderator: Ladies and gentlemen, good morning, and welcome to the Q1 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 an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing star, then zero on your touch-tone phone. Please note that this conference is being recorded.

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

Utkarsh Gandhi: Thank you, Lizanne. Good morning, everyone. Welcome to the Q1 FY '25 Results Conference Call of Glenmark Pharmaceuticals Limited. Before we start the Q&A, we'll review the performance of the company for the first quarter of FY '25. For Q1 FY '25, Glenmark's consolidated revenue from operations was at INR32,442 million as against INR30,361 million in the corresponding quarter last year, recording a Y-o-Y growth of 6.9%.

In terms of our overall performance across regions, starting with India. So for India, our formulation business recorded revenue of INR11,962 million as against INR10,693 million in the corresponding quarter last year, recording a growth of 11.9%. India business contributed 36.9% of the consolidated revenue for Q1.

In terms of secondary sales, Glenmark's India business continued to outperform the industry. As per the IQVIA June 2024 data, Glenmark's India formulation business recorded growth of 16.9% in the first quarter and 11.3% as of MAT June 2024. In comparison, the IPM grew at 8.7% in the first quarter and 7.5% as of MAT June. Glenmark continues to outperform the market in terms of the key therapeutic areas of cardiac, dermatology and respiratory. Our growth is almost doubled, especially in cardiac and dermatology compared to the market.

Glenmark India business continues to be ranked 14th with a market share of 2.19% as of IQVIA MAT June 2024. The company continues to have nine brands in the IPM Top 300 on the basis of IQVIA MAT June 2024. Glenmark has also improved its market share across key therapeutic areas.

In May 2024, Glenmark and BeiGene entered into an agreement for marketing and distribution of Tislelizumab and Zanubrutinib in India. Under this strategic collaboration, Glenmark will be responsible for locally required development, registration and distribution, providing access to BeiGene's innovative oncology medicines for cancer patients across India. This is Glenmark's second differentiated product in the oncology segment after Akynzeo IV. Glenmark has also successfully launched differentiated products in other key therapeutic areas over the last six months and has seen good market traction for these launches.

In terms of our consumer care business in India, primary sales in Q1 was around INR870 million with a growth of 11.3%. The company's flagship brand, Candid Powder delivered revenue growth of 22% for Q1 and recorded its highest monthly market share of 58.8%. La Shield portfolio delivered Y-o-Y secondary sales growth of 12.1% while Scalpe portfolio witnessed a strong uptake for one of its variants, Scalpe PRO.

Moving on to North America. The North America business registered revenue of INR7,808 million for the first quarter of FY '25 as against INR7,557 million for the fourth quarter, which translates onto Q-o-Q growth of 3.3%. North America region contributed 24.1% of the consolidated revenues in Q1.

In the first quarter of FY '25, Glenmark received approval for and launched Acetaminophen and Ibuprofen Tablets and Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution. In addition, the company added a couple of pack sizes to its existing products.

Glenmark filed one ANDA in Q1 FY '25 and plans to file two ANDAs in the upcoming quarter. Glenmark has also leveraged its strong development capabilities in respiratory to build the portfolio. We have mentioned this in the past. The company has already filed two ANDAs for generic nasal sprays and is awaiting approval for the same. In addition, the company has also filed the ANDA for generic Flovent 44 mcg. This is a pMDI. This was filed in May 2024. Glenmark is also working on the ANDA filings for the other two strengths.

As of June 30, 2024, Glenmark's marketing portfolio in the U.S. consists of 196 generic products authorized for distribution. The company currently has 50 applications pending at various stages in the approval process, of which 21 are for Paragraph IV applications.

Moving on to Europe. Glenmark Europe operations' revenue for the first quarter of FY '25 was INR6,957 million, as against INR5,732 million in Q1 FY '24. This translates into a Y-o-Y growth of 21.4%. Contribution from the Europe region to the consolidated revenue was 21.4% for Q1.

Glenmark's Europe operations continues to remain strong in terms of overall business performance. All the key markets for Glenmark in the EU region recorded healthy growth in the first quarter. In CEE markets like Czech and Poland recorded high double-digit growth, aided by strong performance across key segments. Branded respiratory portfolio, including Ryaltris continues to do very well in the CEE region. Growth was also aided by new product launches during the quarter.

Western European market also performed well. The generic/tender business returned to growth during the first quarter. The company continues to focus on sustaining the increasing contribution from branded markets and branded products in Europe. It is awaiting approval of 4 additional respiratory products, which were filed in the fourth quarter of FY '23. And the company is also planning to launch Winlevi in select markets in FY '26.

Moving on to ROW region, which consists of Russia, CIS, Latin America, Middle East, Africa and Asia Pacific. For the first quarter of FY '25, revenues from the ROW region was INR5,708 million as against INR5,528 million for the corresponding quarter last year, recording a Y-o-Y growth of 3.3%. The ROW region contributed 17.6% of the consolidated revenues in Q1.

Moving on to market regional data. So as for Russia, as per IQVIA data, Glenmark's Russia business recorded growth of 15% to 16% in Q1 as well as MAT June 2024. In terms of key therapeutic areas, Glenmark recorded very strong growth in the Dermatology segment, especially versus the market. Glenmark continues to be ranked 9th amongst Dermatology

companies in Russia and continues to be ranked second in the Respiratory expectorants market in Russia as per IQVIA MAT June data.

Latin America region also witnessed strong growth in Q1 with the respiratory portfolio being the key contributor. Glenmark maintains its strong position amongst the top companies in the covered market of the chronic respiratory segment in Brazil. Glenmark also launched the first generic for Salmeterol + Fluticasone MDI in the Brazilian market. And secondary sales growth is also very strong in the other key market in Latin America, which is Mexico. Ryaltris has also been approved in Mexico and will be launched soon along with other respiratory products.

In Middle East Africa, the company continued to achieve secondary sales growth in key markets such as Kenya, South Africa. Glenmark continues to be ranked third in the overall pharma market in Kenya. Ryaltris continues to be the leading nasal spray for Allergic Rhinitis in South Africa, and the product was also launched in other key markets, such as Kenya and Saudi Arabia in the last couple of quarters.

The Asia Pacific region for Glenmark recorded slightly subdued growth in terms of secondary sales across key markets, such as Malaysia, Philippines, Sri Lanka. Glenmark received approvals for multiple new products during the quarter, mainly in the respiratory and dermatology segment. And Ryaltris continues to do quite well in Asia region.

Moving on to the -- some of our key global brands, starting with Ryaltris. As of June 2024, marketing applications for Ryaltris have been submitted in more than 90 countries across the world. Product has been commercialized in 40 markets. It has received approval and will be launched in 10 to 11 additional markets over the next 1 year.

Glenmark's commercial partner in the U.S., Hikma, recorded better performance on a Y-o-Y basis, backed by strong demand and increasing coverage across pharmacy chains and online platforms as well as other awareness events. Menarini, Glenmark partners in the EU has witnessed steady increase in market share across all its licensed markets. Glenmark's partner in Mainland China, Grand Pharma, has received acceptance of the NDA in Feb 2024. The company expects approval to be received sometime in FY '26.

As per IQVIA March 2024 data across markets, Ryaltris has seen robust performance in terms of both value and unit market shares. The product has achieved high double-digit market share in markets like Australia, Czech Republic, South Africa, Italy, Poland. Further, Ryaltris continues to witness strong uptake in markets where the product was recently launched across Europe as well as ROW regions.

Moving on to Envafolimab. So as mentioned in Jan 2024, Glenmark announced the signing of a licensing agreement with Jiangsu Alphamab and 3D Med for Envafolimab for India, Asia Pacific, Middle East, Africa, Russia, CIS and Latin America. This product has been approved under the brand name ENWEIDA in China. It is the global-first subcutaneous injection PD-L1 inhibitor for the treatment of adult patients with previously treated MSI-H or deficient Mismatch Repair or dMMR advanced solid tumors.

More than 30,000 patients have already benefited from this treatment in China. It has been listed as a -- officially included in the List of Breakthrough Therapies. And Glenmark plans to file Envafolimab in more than 20 markets in FY '25 and the first market launch is expected in FY '26.

Lastly, WINLEVI, in second quarter FY '24 as we had announced that we had signed a distribution licensing agreement for WINLEVI, which is clascoterone cream 1%, in 15 European markets as well as the U.K. and South Africa. The company is currently awaiting approval in these license markets and plans to launch WINLEVI in FY '26.

Ichnos Glenmark Innovation, as we announced before, all our innovation efforts are being channeled through IGI. And as of June 2024, we have two biologic assets in Phase 1 clinical development and one small molecule in pre-clinic, all in oncology. The clinical assets are progressing well. We have an update, an August update for IGI, which includes some more details on the clinical assets. You can go through the web -- you can go through the same on the IGI website.

Some notes to the results before we open the call for Q&A. ForEx loss in the first quarter was INR22 crores, which was recorded in other expenses. Adjusted for this, the EBITDA margin was 18.8%. R&D expenditure in Q1 FY '25 was around INR241 crores, of which USD 13.8 million was spent for IGI.

Consolidated total asset addition to the block in the quarter -- in the first quarter was INR115 crores, of which tangible asset addition is around INR88 crores, and intangible asset addition is INR27 crores.

Net cash for the period ended June 30, 2024, was at INR359 crores. And in terms of working capital at the end of June 2024, inventory was at INR2,756 crores. Receivables was at INR2,059 crores and payables was at INR2,534 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, Lizanne.

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

Damayanti Kerai: My first question is like you have seen a good pickup in India. So that, I guess, very comforting. But looking at U.S., I guess, still remains a bit soft. So what are your expectations on U.S. sales recovery? And how do you see -- like do you have any visibility on FDA regulation for Monroe plant?

Glenn Saldanha: Sure. So the U.S. business continues to remain challenging. But I think the second half of this year, right, once we get our respiratory products approved, right, I think that's when you'll really see the recovery, right? As you know, we have a number of respiratory products, which are filed

and we are waiting for approval. So as and when that happens, you will see a significant recovery for the U.S. business. As regards to the Monroe facility, the FDA has given us a meeting in September. So we are hoping that it will bear onwards, the facility will restart.

Damayanti Kerai: Okay. So better U.S. we should be assuming starting second half. So even if, say, Monroe takes some time, you mentioned you have a couple of respiratory products. If those come, those should be -- may contribute meaningfully and then see better U.S. sales?

Glenn Saldanha: That's correct.

Damayanti Kerai: Okay. And then a question on margins. So this quarter, obviously, you have delivered healthy margins. But moving from, say, close to 18% margin in 1Q, you have given guidance of 19% for the full year, which will be the key contributors, if you can just update us on those?

V. S. Mani: So thanks for the question, Damayanti. So obviously, we had in this quarter also adjusted for ForEx, we were almost 18.8%. We have guided to about 19%. Obviously, the key contributors will be -- obviously, India continues to do well. India is a high-margin market. Besides that, our product, Ryaltris, continues to do well. Last year, we have guided to almost $80 million of sales this year. And as earlier we alluded, we already filed it in a number of markets and some key filings are also coming up across various geographies.

So I think -- and also a number of Respiratory products that we are hoping to get approved and launched in Europe as well. So I think all in all, all this put together, that gives us the confidence to come very close. Besides, as you see -- you can see on our R&D expenses are lower compared to last year as well. So all this should help us to reach close to 19%.

Utkarsh Gandhi: Sorry, just to add. So typically, our second half is a little better because of the respiratory products getting further uptick. So margin profile also will accordingly be slightly better than H2.

Damayanti Kerai: Okay. Just a question on your R&D spend for Innovation IG. So is this the label like, which will sustain? Or do you have further room to reduce it?

Glenn Saldanha: I think for this year, we will be around the same level, so around 55 million full year. Next year, if you look at our investor presentation, right, we're clearly guiding towards -- I mean, I think if we do a partnership, automatically, these numbers will further reduce substantially in FY '26.

This year, our goal with IGI is to get to PoC, and we are seeing some very good data on 2001, which we'll present at ASH. And next year, you should see some partnership activity, right? I mean that's the road map for IGI.

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

Tushar Manudhane: So just extending on this U.S. FDA thing, if you could also highlight what's happening with respect to Goa and Baddi side?

Glenn Saldanha: So we've completed the remediation for Goa and we will be lobbying with the FDA to come and inspect us, right? I mean that's kind of where we stand with Goa. Regarding Baddi, for the time

being, our focus for the U.S. market from the Baddi side is reduced. So it's not that significant for us.

Basically, the 4 major sites for the U.S. market for Glenmark are Goa, Indore, Aurangabad and now Monroe, right? These are the 4 sites which we supply the U.S. market. Also, keep in mind now U.S. market is 24% of total sales, right, for Glenmark, right?

And given the European performance, right, we are thinking that the European business could be as big as -- almost as big as the U.S. business by the end of this year. So there is a big shift in the overall revenues for the company if you look at the overall picture.

Tushar Manudhane: Understood, sir. So -- and further this, the gross margin, even on a quarter-on-quarter basis where our India, Europe sales has been higher, still the gross margin is sort of lower. If I think about it on a quarter-on-quarter basis, whereas even the raw material cost has been relatively subdued or soft at least as far as the industry-wide phenomenon goes. So if you could explain that.

V. S. Mani: Yes, so I mean, compared to quarter-to-quarter, it was almost 67% in the last quarter. I also guided at that time. It can always be plus/minus 1%, depending on product mix, yield, etcetera. On an overall basis, we would like to guide that will always be close to 65% to 67%, give and take a percentage here or there. That's how we look at it.

Tushar Manudhane: Understood, sir. And if you could also call out how much has been the Ryaltris sales overall for the quarter?

V. S. Mani: It's closer to $20 million in this quarter.

Tushar Manudhane: And how big this potential can be for China market?

Glenn Saldanha: So I think, look, Ryaltris for a full year, right, we anticipate close to $80 million of sales, right? We are pretty much on track to achieving that, right? I think China, some of the new markets, we are still not guiding towards but the launch is still a year or 2 away. So we have 3, 4 markets, which are still to be launched starting next year, which is mainly China, Brazil and a couple of other major markets, which will start contributing.

Tushar Manudhane: Understood. And sir, just lastly on WINLEVI, the launch still in FY '26. So anything -- any major milestones to be achieved before we go ahead with the launch? Given that it's taking almost 3, 4 quarters.

Glenn Saldanha: I mean it's just we're waiting for the approval from the European agencies, then we have price approval to be taken. That takes its own time. So it's all the pre-launch activities that we are working on. There's nothing beyond that to look at. And in some markets, we could launch end of this year. But conservatively, we are seeing F '26.

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

Kunal Randeria: So first, on the India business, you launched liraglutide in January. I just want to understand how the launch has been progressing?

Glenn Saldanha: So I think the liraglutide is a great opportunity. We are still challenged with some supply issues as and when we have sought that, it should be a good product to have in the portfolio. Currently, the initial offtake is very good for the product.

Kunal Randeria: But then, what's the market size, I mean pre-generic market size?

Utkarsh Gandhi: So Kunal, the whole GLP-1 market is -- it is about, I think, INR1,000-odd crores as per IQVIA. But I mean that's not a good reference point because it's still very much under-penetrated and...

Glenn Saldanha: And also, I mean, keep in mind, liraglutide is a daily injection, whereas sema and some of the others are weekly injections and beyond. So it's a great product to have in the portfolio. It will do well. However, with semaglutide and some of the other GLP-1s, eventually, the focus will shift to the other GLP-1s over time.

Kunal Randeria: Sure. Sure. So then if I understand correctly, generics could increase the volume, but then it will be offset by some of the existing patients moving to sema and others. So there -- I mean not really much from a revenue perspective to increase the market price.

Glenn Saldanha: No, there is scope, and that's something you will see in the second half of this year. We will continue to gain market share on liraglutide in the second half, right? But I think keep in mind that semaglutide goes on patent in '26. So there will be some shift, which will happen between lira, sema and some of the other anti-diabetic treatments, right, post '26.

Kunal Randeria: Yes. Got it. Okay. Second, again on India. So while 12% growth is quite strong. IQVIA showed somewhere around 15% to 16% over the last few months. So I just want to understand what there -- is there a discrepancy?

Glenn Saldanha: It's hard to -- I mean, look, our India growth is strong. The takeaway message is that we are outperforming the market consistently. And that will sustain, I think, going forward. So we're seeing strong growth in all our therapeutic segments that we operate in. And except for acute respiratory and diabetes, these are the 2 segments where there was a slight struggle in Q1, which we think will change over the course of the year.

India growth, all in all, is strong, right? But I think overall, you should peg us at 10% to 15%, right, 10% to somewhere thereabouts, right, on a full year basis.

Kunal Randeria: Sure. Sure. And just one for Mani sir, the depreciation and the tax was quite low in the quarter. So if you can just run us through what happened and what the expectations now for the rest of the year and next year, too?

V. S. Mani: So just to give you our guidance broadly, the depreciation and tax as well as interest, all this will be pretty consistent throughout the year what we see in Q1. And as far as depreciation goes, as you know, last year, we did have some of the write-downs, etcetera. So all that helped us to bring down the depreciation.

Plus, obviously, you can see in the Q1 also, there has not been too much addition to the block. So I think we'll see how the year progresses, but broadly, this is where it should be. As far as the

tax, even last quarter, last year, I kind of indicated and guided that will be between 25% and 27%. That's where we will be. Yes.

Kunal Randeria: So what is driving lower tax? I mean U.S. would still be making losses, right? Perhaps Ichnos losses have come down, but what's driving this?

V. S. Mani: Yes. But some of the other -- like Ryaltris, etcetera, are doing well, some of them are based out of Europe, etcetera. So some of those places the tax rate are little lower now. So that helps us a lot. Yes.

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

Nitin Agarwal: Glenn, on the Ichnos, what should we look forward to in Ichnos over the next 12 to 18 months? I mean any milestones? And by when you should expect them to play out?

Glenn Saldanha: So Nitin, as I mentioned, right, 2001 is doing really well for us, and we will do a presentation at the ASH conference, right, in December, right? At that conference, we will put out our clinical data, which should generate quite a lot of excitement in the community. So that's the near-term thing. And then after that, of course, the goal is to do a partnership sometime next year around 2001.

Nitin Agarwal: And when is the readout for the other molecule expected, Glenn?

Glenn Saldanha: So currently, there are two, which are in active clinical trial, right? It's 2001 and 1442. 1442 is taking a little longer to get to PoC, but 2001 is ahead right now. So that will be the first followed by 1442. These are the two in clinical development. 1342, we are not doing any more clinical work, but we are actively looking for partnerships around 1342.

Nitin Agarwal: And are there any other assets which are any preclinical assets that you're looking to build out the sort of to grow through as we go along?

Glenn Saldanha: Near term, it's just these three that we are talking about, Nitin.

Nitin Agarwal: Okay. And secondly, Glenn, on the U.S. Now, obviously, you talked about the fact that it's become like a less than half quarter of the business now. Again, strategically, how do you look at U.S. now? What kind of investment in the generic part that you're looking to make? And where do you see opportunities, if any, in the U.S. business there?

Glenn Saldanha: I mean, clearly, on the U.S. business, the near term, the next 2, 3 years will be driven by our respiratory launches and the injectables coming out of Monroe. These are the 2 drivers, right, that we have for the U.S. business. Following that, we have some sole FTFs like Gabapentin Enacarbil, Beta, Calci foam. So these are some of them.

We have a unique position on Axitinib. So I think these 2, 3, there are some very select products, but I think post H2 of this year, the U.S. business should start showing some good traction, right, in the second half of this year and beyond, right, mainly coming out of some of these unique launches, right, that we have for the U.S. business.

Nitin Agarwal: And, Glenn, what are timelines of some of these launches that you mentioned?

Glenn Saldanha: So H2 is broadly what I can give you, Nitin. I can't be more specific than that.

Nitin Agarwal: Okay. And lastly, Mani sir, on the cash flow, what is the outlook for the working capital last year? Where do we see ending the year end at?

V. S. Mani: So Nitin, as you recollect, even during the Q4 call, we had guided that we would be closer to 70 to 75 days. So as of now also, we are at about 62 days. So I believe that there could be some uptick because as you can see, the business is also growing, and we may have some little more increase in the working capital side, especially on the receivable side. Yes.

Nitin Agarwal: So all in all, we should 70, 75 days is what we should work through on a sustained...

V. S. Mani: Yes. 70 to 75 days would be ideal that you should work through. Yes. That's correct.

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

Utkarsh Gandhi: Okay. Thanks, Lizanne. So before we end the call, we'd just like to state that the discussion materials provided during today's call, including information, statements and analysis made describing company's or its affiliate's objectives, projections and estimates are forward-looking statements. These are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause our actual outcomes to differ.

No representation of warranty, either expressed or implied, is provided in relation to these discussions, and this should not be treated by the recipients as a substitute for the exercise of their own judgment. The company also does not undertake any obligation to update or revise any forward-looking statements.

With that, we can close today's call. Thanks a lot for your participation.

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.