

## Management Discussion & Analysis for the Second Quarter of FY 2024-25

### Revenue Figures for Glenmark Pharmaceuticals Ltd.

*(In Rs. Million)*

	For the second quarter ended September 30			For the six months ended September 30		
	FY 2024-25	FY 2023-24	Growth (%)	FY 2024-25	FY 2023-24	Growth (%)
<b>India</b>	12,817	11,252	13.9%	24,778	21,945	12.9%
<b>North America</b>	7,405	7,498	-1.2%	15,213	15,681	-3.0%
<b>Europe</b>	6,874	5,997	14.6%	13,831	11,729	17.9%
<b>Rest of the World<sup>1</sup></b>	7,041	7,339	-4.1%	12,749	12,867	-0.9%
<b>Total</b>	<b>34,137</b>	<b>32,086</b>	<b>6.4%</b>	<b>66,572</b>	<b>62,222</b>	<b>7.0%</b>
<b>Other Revenue</b>	201	-12	--	208	212	-2.2%
<b>Consolidated Revenue</b>	<b>34,338</b>	<b>32,074</b>	<b>7.1%</b>	<b>66,780</b>	<b>62,434</b>	<b>7.0%</b>

1. Russia + CIS (RCIS), Latin America (LATAM), Middle East and Africa (MEA), Asia-Pacific (APAC)

Average conversion rate in 6M FY 2024-25 considered as INR 83.59 / USD 1.00

Average conversion rate in 6M FY 2023-24 considered as INR 82.42 / USD 1.00

USD figures are only indicative

**Review of Operations for the Quarter ended September 30, 2024**

For the second quarter of FY25, Glenmark’s consolidated revenue from operations was at Rs. 34,338 Mn (USD 410 Mn) as against Rs. 32,074 Mn (USD 387.9 Mn) in the corresponding quarter last year, recording overall year-on-year (YoY) growth of 7.1%.

For the six months ended September 30, 2024, Glenmark’s consolidated revenue was at Rs. 66,780 Mn (USD 798.9 Mn) as against Rs. 62,434 Mn (USD 757.5 Mn), recording an increase of 7%.

**FORMULATION BUSINESS**

Glenmark’s global formulation business is spread across Branded, Generics, and OTC segments in the therapy areas of Dermatology, Respiratory and Oncology, along with strong regional/country-specific presence in other therapeutic areas like Cardiac, Diabetes and Oral Contraceptives.

**INDIA**

Sales from the formulation business in India for the second quarter of FY25 was at Rs. 12,817 Mn (USD 153 Mn) as against Rs. 11,252 Mn (USD 136.1 Mn) in the corresponding quarter last year, recording a growth of 13.9%. The India business contribution was at 37.3% in Q2 FY25.

The Indian pharmaceutical market (IPM) continued to witness a slow-down in the overall market, however Glenmark continues to significantly outperform the IPM in terms of YoY growth. Accordingly, as per IQVIA, Glenmark’s India formulation business recorded a growth of 12.7% in Q2 FY25 and 13.1% as per MAT September 2024, compared to the overall market growth of 7.6% in both Q2 FY25 and MAT September 2024. In Q2 FY25, acute respiratory market continued to witness a slow-down due to the seasonality factor; as a result, both the overall respiratory market and Glenmark’s respiratory business recorded single-digit growth. Glenmark continued to outperform the overall market in both Dermatology and Cardiac therapeutic areas.

	IPM	GLENMARK	IPM	GLENMARK
SUPERGROUP	VALUE GROWTH (JUL'24 - SEP'24)	VALUE GROWTH (JUL'24 - SEP'24)	VALUE GROWTH (MAT SEP'24)	VALUE GROWTH (MAT SEP'24)
CARDIAC	11.9	15.3	12.0	23.9
DERMATOLOGY	9.3	19.5	7.8	13.7
RESPIRATORY	2.3	3.7	2.0	3.6
DIABETES	9.4	-2.2	8.2	-8.5

Glenmark’s India business is now ranked 13<sup>th</sup> with a market share of 2.22% (IQVIA MAT September 2024).

The Company continues to have 9 brands in the IPM Top 300 Brands in the country on the basis of IQVIA MAT September 2024. In terms of key therapeutic areas, Glenmark is ranked 2<sup>nd</sup> in Dermatology, 3<sup>rd</sup> in Respiratory and 5<sup>th</sup> in the Cardiac segment as per IQVIA MAT September 2024.

In spite of the challenging market environment, Glenmark has improved its market share in the key therapy areas as per IQVIA MAT September 2024 data.

	GLENMARK	
SUPERGROUP	MARKET SHARE (%) MAT SEP'23	MARKET SHARE (%) MAT SEP'24
CARDIAC	5.3	5.9
DERMATOLOGY	7.5	7.9
RESPIRATORY	5.7	5.8
DIABETES	1.5	1.3

**LIRAFIT™**

- The Company was the first to launch the biosimilar of Liraglutide under the brand name LIRAFIT™ in India. It continues to be the only biosimilar in the market. LIRAFIT™ has seen strong traction in the GLP-1 market in India post launch.
- The Company also plans to launch other GLP-1 agonists in the near future.

**JABRYUS® (PARTNERED WITH PFIZER)**

- In January 2024, Glenmark launched JABRYUS® (Abrocitinib), a first of its kind oral advanced systemic treatment for the treatment of moderate-to-severe atopic dermatitis (AD) in India in partnership with Pfizer.
- The Company has initiated promotional activities, and JABRYUS® has been well received by dermatologists as a novel treatment for moderate-to-severe AD, with improved efficacy and oral convenience to patients.

**TISLELIZUMAB AND ZANUBRUTINIB (PARTNERED WITH BEIGENE)**

- Glenmark and BeiGene entered into an agreement for marketing and distribution of Tislelizumab and Zanubrutinib in India in May 2024.
- 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.
- These two products will be launched in the next 6-9 months post the receipt of the required regulatory approvals.

## **INDIA – GLENMARK CONSUMER CARE (GCC)**

Primary sales for GCC in Q2 FY25 was Rs. 733 Mn with a YoY growth of 15%. The Company's flagship brand Candid Powder™ delivered revenue growth YoY of 13% for Q2 FY25. The brand continued to gain market share, and recorded 57.4% share for the month of September 2024. In Q2 FY25, the Scalpe™ portfolio delivered a robust revenue growth of 40% YoY. The key variant, Scalpe Plus grew by 13% in Q2, while Scalpe PRO doubled its business and registered a 131% growth. D'Acne™ Portfolio switch was initiated in the second quarter and the brand has grown by 22% in Q2 FY25.

## **NORTH AMERICA**

The North America business recorded revenues from the sale of finished dosage formulations of Rs. 7,405 Mn (USD 88.4 Mn) for the second quarter of FY25 as against revenue of Rs. 7,498 Mn (USD 90.7 Mn) for the second quarter of FY24. This translates in to a YoY decline of 1.2%. For the second quarter of FY25, the North America business contribution was at 21.6%.

In the second quarter of fiscal year 2024-25, Glenmark received approval for and launched Topiramate Capsules USP (Sprinkle), 15 mg and 25 mg. In addition, Glenmark launched 3 new over-the-counter products: Adapalene Gel USP, 0.1% [Paraben Free Formulation], Cetirizine Hydrochloride Tablets USP, and Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%. Glenmark also acquired the previously approved ANDA for Acetylcysteine Injection, 6 g/30 mL (200 mg/mL) in Q2 FY25; this will be Glenmark's 8<sup>th</sup> commercial product in the injectable portfolio for the US market. Glenmark has also leveraged its strong development capabilities in the Respiratory therapeutic area to build a portfolio for the US market. The Company has filed two ANDAs for generic nasal sprays and is awaiting approval for the same. In addition, the Company has filed the ANDA for gFlovent® 44mcg pMDI in May 2024.

One ANDA was filed during the second quarter. Glenmark plans to file two ANDAs in the upcoming quarter, and the Company plans to launch 3-4 products in the upcoming quarter. Glenmark's marketing portfolio through September 30, 2024 consists of 198 generic products authorized for distribution in the U.S. market. The Company currently has 50 applications pending in various stages of the approval process with the US FDA, of which 21 are Paragraph IV applications.

Note: All brand names and trademarks are the property of their respective owners. IQVIA National Sales Perspectives: Retail and Non-Retail, August 2024

## **EUROPE**

Glenmark Europe operations' revenue for the second quarter of FY25 was at Rs. 6,874 Mn (USD 82.1 Mn) as against Rs. 5,997 Mn (USD 72.5 Mn) recording a growth of 14.6%. Europe business contributed 20% of the total revenues in Q2 FY25.

Glenmark's European operations continued their strong trajectory, driven by a robust uptick of the branded business and sustained growth across all key markets in the region. Glenmark continued to outperform the overall pharmaceutical market in the key Central and Eastern European (CEE) countries such as the Czech, Poland and Slovakia. Growth in the CEE region was also aided by 3 new product launches. The Western European business clocked double-digit growth for Q2; the branded Respiratory portfolio continues its strong trajectory. Glenmark is now ranked 14<sup>th</sup> in the generic market of Germany as per IQVIA MAT August 2024 data. Key Respiratory brands such as RYALTRIS<sup>®</sup> and Salmex<sup>®</sup> / Asthmex<sup>®</sup> continue to sustain their market share, both, in terms of volume as well as value, across the region. The Company continues to focus on sustaining the increasing contribution from the branded markets / portfolio in Europe. It is awaiting approval of four respiratory products which were filed in Q4 FY23. The Company is also planning to launch WINLEVI<sup>®</sup> in select markets of Europe in FY26.

## **ROW REGION (RCIS, LATAM, MEA & APAC)**

For the second quarter of FY25, revenue from the ROW region was Rs. 7,041 Mn (USD 84.1 Mn) as against Rs. 7,339 Mn (USD 88.8 Mn) for the corresponding quarter last year, recording a decline of 4.1%. For the second quarter of FY25, the ROW business contribution was at 20.5%. In spite of the lack of growth in the first two quarters of FY25, Glenmark anticipates to finish the year FY25 with a high single-digit YoY growth in ROW on a constant currency basis.

As per IQVIA Q2 FY25 and MAT September 2024 data, Glenmark's Russia business recorded secondary sales growth of 16% and 19% in value, respectively. RYALTRIS<sup>®</sup> sustained its momentum and gained further market share during the quarter. Amongst the Dermatology companies in Russia, Glenmark ranks 9<sup>th</sup> as per MAT September 2024. Amongst the companies present in the Expectorants market in Russia, Glenmark continues to maintain a strong position, ranking 2<sup>nd</sup> as per MAT September 2024.

The Respiratory portfolio continued to be the key growth driver for Glenmark in the LATAM region. Glenmark launched the first generic Salmeterol + Fluticasone MDI in the Brazilian market in Q1 FY25 and the product has done well post launch. RYALTRIS<sup>®</sup> was launched in the Mexican market in Q2, and is expected to be launched in another 1-2 markets in the region over the next 6 months, along with multiple other device-based respiratory products.

In the Middle East and Africa region, the Company continued to achieve secondary sales growth in key markets. Glenmark is now ranked 2<sup>nd</sup> in the overall pharmaceutical market in Kenya. RYALTRIS<sup>®</sup> continues to be the leading nasal spray for Allergic Rhinitis in South Africa, and has seen strong pick-up post launch in key markets in the region.

In the Asia region, some markets witnessed slowdown due to the ongoing political and economic

challenges. New product launches in Dermatology and Respiratory are expected to contribute to growth in the upcoming quarters. RYALTRIS® continues to significantly outperform the overall market in the region.

## **CREATING GLOBAL BRANDS**

### **RYALTRIS®**

- As of September 2024, marketing applications for RYALTRIS® have been submitted in more than 90 countries across the world and the product has been commercialized in 41 markets. Further, it has received approval and will be launched in 10-11 additional markets over the next few quarters
- As per IQVIA June 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 Australia, the Czech Republic, South Africa, Italy, Poland and other European markets. Further, RYALTRIS® continues to witness strong uptake in markets where the product was recently launched across Europe and ROW regions.
- Glenmark's commercial partner in the USA, Hikma, recorded consistently better performance on a YoY basis in the second quarter, backed by strong demand and stable supply.
- Menarini, Glenmark's partner in the EU, has witnessed steady increase in market share across all its licensed markets.
- Glenmark's partner in Mainland China, Grand Pharmaceutical (China) Co. Ltd., has received acceptance of the NDA in February 2024. The Company expects approval to be received in FY26.

\*Market share: Top 10 products within "R1A1 – Nasal Corticosteroids without Anti Infectionives" category as per IQVIA + RYALTRIS® as of June 2024

### **ENVAFOLIMAB**

- In January 2024, Glenmark announced the signing of a license agreement with Jiangsu Alphamab Biopharmaceuticals Co., Ltd (Jiangsu Alphamab) and 3D Medicines (Beijing) Co., Ltd. (3DMed) for Envafohimab for India, Asia Pacific, Middle East and Africa, Russia, CIS, and Latin America.
- Envafohimab, under the brand name ENWEIDA®, has been approved in China by the National Medical Products Administration (Chinese NMPA) in November 2021 as the global-first subcutaneous injection PD-L1 inhibitor for the treatment of adult patients with previously treated microsatellite instability-high (MSI-H) or deficient Mismatch repair (dMMR) advanced solid tumor.
- In China, Envafohimab has been officially included in the "List of Breakthrough Therapies" by the NMPA in December 2023. Up until November 2023, Envafohimab was recommended by 12 clinical guidelines in China and the US including 3 Chinese versions of the National Comprehensive Cancer Network (NCCN) guidelines for the treatment of multiple malignancies. Envafohimab has the potential to provide an effective treatment for such population across India and Emerging Markets.

- Glenmark plans to file Envafohimab in more than 20 markets in FY25 and the first market launch is expected in FY26.

## **WINLEVI®**

- In Q2 FY24, Cosmo Pharmaceuticals N.V. (“Cosmo”) and Glenmark, announced the signing of distribution and license agreements for WINLEVI® (clascoterone cream 1%) in 15 European countries as well as the UK and South Africa.
- The Company is awaiting approval in its licensed markets and plans to launch WINLEVI® in FY26.

## **ICHNOS GLENMARK INNOVATION (IGI)**

IGI features a robust pipeline of three innovative oncology molecules targeting multiple myeloma, acute myeloid leukemia and solid tumors currently undergoing clinical trials. Two of these molecules have received orphan drug designation from the U.S. FDA. Additionally, IGI has two autoimmune disease assets that have been out licensed to leading companies.

## **MULTIPLE MYELOMA OVERVIEW**

- Multiple myeloma (MM) remains a devastating and often fatal disease, with no current cure available. Despite advancements in treatment, many patients continue to face poor outcomes, especially those with relapsed or refractory (r/r) disease.
- The market for multiple myeloma therapies is projected to grow from \$23.5 billion in 2023 to approximately \$33 billion by 2030. This growth is driven by an aging population and increasing incidence of MM, highlighting the urgent need for effective treatments.

## **ISB 2001 TREAT™ TRISPECIFIC ANTIBODY**

- ISB 2001 represents a groundbreaking approach in the fight against multiple myeloma. It is a trispecific T cell engager (TCE) that targets BCMA and CD38 on multiple myeloma (MM) cells while engaging CD3 on T cells to harness the body’s immune system against the cancer. This dual targeting mechanism enhances tumor cell destruction and offers a new pathway to address the challenges faced in treating relapsed/refractory multiple myeloma.
- ISB 2001 is amongst the first trispecific antibodies developed for use in multiple myeloma. In July 2023, ISB 2001 received Orphan Drug Designation from the FDA for the treatment of MM.
- The Phase 1 first-in-human study of ISB 2001 for the treatment of r/r MM is divided into a dose escalation part and a dose expansion part. First patient was dosed in November 2023 and the trial is now active in the US, Australia and India. Dose escalation is currently still underway,

with expansion scheduled to initiate in H1 CY2025.

## **ISB 2001 DATA PRESENTATION AT ASH2024**

- IGI recently announced that it will present first-time data from its Phase 1 study of ISB 2001 in an oral presentation at the 66th American Society of Hematology (ASH) Annual Meeting in San Diego, CA. The oral presentation will detail results from the dose-escalation portion of the study. The abstract features data as of July 2024, including:
  - An overall response rate (ORR) of 75% (9/12) in efficacy-evaluable patients, including one (1) MRD negative stringent complete response (sCR)
  - A favorable safety and tolerability profile that showed no dose-limiting toxicities (DLTs), only one adverse event of special interest (AE) above Grade 2, and no treatment discontinuation
  - The most updated data presentation will be available at ASH2024
- IGI aims to initiate partnering discussions post ASH2024

For further updates on IGI, including the pipeline assets, please log on to <https://www.iginnovate.com/>

## **KEY OBJECTIVES FOR FY25**

- **Consolidated Revenue: INR 1,35,000 – 1,40,000 million**
- **R&D Investment: 7-7.25% of total sales**
- **EBITDA Margin: ~19%**
- **Consolidated CAPEX: INR 7,000 million**
- **Target double-digit PAT margin**

### **Disclaimer:**

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