

November 10, 2023

To,
Dy. General Manager
Department of Corporate Services,
BSE Ltd.,
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001

To,
The Manager – Listing,
National Stock Exchange of India Ltd.,
Plot No. C/1, G Block,
Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051

Ref: Scrip Code: 532296

Ref: Scrip Name: GLENMARK

Dear Sirs,

Sub: Press Release and Management Discussion & Analysis

Pursuant to regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements), 2015, we are enclosing herewith the Press Release and Management Discussion & Analysis of the Company for the Second Quarter ended September 30, 2023.

You are requested to take the same on record.

Thanking You.

Yours faithfully,
For Glenmark Pharmaceuticals Limited

Harish Kuber
Company Secretary & Compliance Officer
Encl: As above

Glenmark Pharmaceuticals Ltd.

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Press Release

For Immediate Release

Glenmark Pharma reports consolidated revenue growth of 6.3% and adjusted EBITDA growth of 8.3% YoY for Q2 FY 2023-24

Highlights for Q2 FY 2023-24

- Europe Business grew by 58.4% to Rs. 5,997 Mn.
- RoW Business grew by 19% to Rs. 7,324 Mn.
- India Business grew by 2.8% to Rs. 11,217 Mn.
- North America Business declined by 1.9% to Rs. 7,392 Mn.

Mumbai, India, November 10, 2023: Glenmark Pharmaceuticals Ltd. (Glenmark), a research led, global pharmaceutical company, today announced its financial results for the second quarter ended Sept 30, 2023.

Consolidated Figures (Glenmark and Glenmark Life Sciences Ltd. [GLS] combined)

For the second quarter of FY 2023-24, Glenmark's consolidated revenue was at Rs. 35,879 Mn as against Rs. 33,752 Mn recording an increase of 6.3% YoY.

Adjusted EBITDAⁱ was at Rs. 6,732 Mn in the quarter ended Sept 30, 2023 as against Rs. 6,216 Mn in the previous corresponding quarter, registering an increase of 8.3% YoY, and margins of 18.8%.

Reported Figures (Continuing Operations - Glenmark excluding GLS)

For the second quarter of FY 2023-24, Glenmark's revenue was at Rs. 32,074 Mn as against Rs. 30,179 Mn recording an increase of 6.3% YoY.

Adjusted EBITDAⁱ was at Rs. 5,053 Mn in the quarter ended Sept 30, 2023 as against Rs. 4,790 Mn in the previous corresponding quarter, registering an increase of 5.5% YoY, and margins of 15.8%.

Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals Ltd. Said, "We maintained a strong growth momentum during the quarter that was led by Europe and the RoW markets. We continue to take strides and move up the value-chain with the in-licensing of Winlevi® for Europe and South Africa. The recently announced proposed divestment of 75% stake in Glenmark Life Sciences is another step in this direction. Our first global brand, Ryaltris®, has demonstrated robust growth across the 29 markets in which it is already present. Our partner in China successfully completed the Phase 3 clinical trial on Ryaltris®; with the product meeting the primary endpoint. We are expecting to launch it in newer markets over the course of the year."

GLENMARK PHARMACEUTICALS LTD.

India

Sales from the formulation business in India in Q2 FY 2023-24 was at Rs. 11,217 Mn as against Rs. 10,916 Mn in the previous corresponding quarter, recording growth of 2.8% YoY.

North America

North America registered revenue from the sales of finished dosage formulations of Rs. 7,392 Mn for the quarter ended Sept 30, 2023 as against revenue of Rs. 7,533 Mn for the previous corresponding quarter, recording decline of 1.9% YoY.

Asia, MEA, LATAM and RCIS Region (RoW)

For the second quarter of FY 2023-24, revenue from RoW was Rs. 7,324 Mn as against Rs. 6,154 Mn for the previous corresponding quarter, recording growth of 19% YoY.

Europe

Glenmark Europe's operations revenue for the second quarter of FY 2023-24 was at Rs. 5,997 Mn as against Rs. 3,785 Mn, recording growth of 58.4% YoY.

GLENMARK LIFE SCIENCES LTD. (GLS)

External sales for GLS in Q2 FY 2023-24 were at Rs. 3,930 Mn as against Rs. 3,744 Mn in Q2 FY2022-23, recording a growth of 5.0% YoY.

In September 2023, Glenmark announced that it has entered into a definitive agreement with Nirma Limited to divest 75% stake in its subsidiary, Glenmark Life Sciences Limited (GLS) at a price of Rs. 615/- per share for an aggregate consideration of Rs. 56,515 Mn, subject to closing adjustments. Glenmark would own 7.84% in GLS after the divestment. The transaction is subject to customary closing conditions precedent, including receipt of regulatory and shareholder approvals.

For further updates on the organization, please log on to www.glenmarklifesciences.com.

ICHNOS Sciences

Glenmark invested Rs. 1,613 Mn in Ichnos in the second quarter of FY 2023-24 compared to Rs. 1,727 Mn in the corresponding quarter last year. For the first six months of FY 2023-24, Glenmark has invested Rs. 3,030 Mn compared to Rs. 3,363 Mn invested in the corresponding period of the previous financial year.

For further updates on the pipeline and the organization, please log on to www.ichnossciences.com.

About Glenmark Pharmaceuticals Limited

Glenmark Pharmaceuticals Limited (BSE: 532296 | NSE: GLENMARK) is a research-led, global pharmaceutical company, having a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 10 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. In Vivo/Scrip 100 positions Glenmark amongst the Top 100 Companies Ranked by R&D and Pharmaceutical Sales, 2021; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2021. The company has also been Great Place To Work® Certified™ in India. Glenmark's Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), becoming the second Indian Pharmaceuticals company to achieve this approval. The organization has impacted over 2.9 million lives over the last decade through its CSR interventions. For more information, visit www.glenmarkpharma.com. You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram (glenmark_pharma).

For more information, please contact

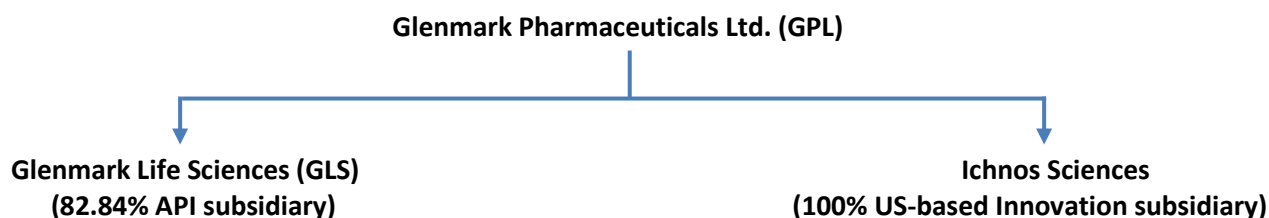
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References

i. Adjusted for Forex loss of Rs. 430 Mn.

Management Discussion & Analysis for the Second Quarter of FY 2023-24

Glenmark operates its businesses through three separate entities



Each of these three entities operate independently with separate Management Teams and Board of Directors.

Revenue Figures for Glenmark Pharmaceuticals Ltd. (Consolidated)

(Rs. In Million)

	For the second quarter ended September 30			For the six months ended September 30		
	FY 2023-24	FY 2022-23	Growth (%)	FY 2023-24	FY 2022-23	Growth (%)
India	11,217	10,916	2.8%	21,860	21,268	2.8%
North America	7,392	7,533	-1.9%	15,477	14,161	9.3%
Europe	5,997	3,785	58.4%	11,729	7,085	65.5%
Rest of the World¹	7,324	6,154	19.0%	12,836	10,380	23.7%
API	3,930	3,744	5.0%	7,699	6,994	10.1%
Total	35,860	32,132	11.6%	69,600	59,889	16.2%
Other Revenue	18	1,620	-98.9%	294	1,636	-82.0%
Consolidated Revenue	35,879	33,752	6.3%	69,895	61,525	13.6%

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

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

Average conversion rate in 6M FY 2022-23 considered as INR 78.30 / USD 1.00

USD figures are only indicative

Review of Operations for the Quarter ended September 30, 2023

For the second quarter of FY24, Glenmark’s consolidated revenue from operations was at Rs. 35,879 Mn (USD 434 Mn) as against Rs. 33,752 Mn (USD 425.0 Mn) in the corresponding quarter last year, recording overall year-on-year (YoY) growth of 6.3%.

For the six months ended September 30, 2023, Glenmark’s consolidated revenue was at Rs. 69,895 Mn (USD 848.0 Mn) as against Rs. 61,525 Mn (USD 785.8 Mn), recording an increase of 13.6%.

GLENMARK PHARMACEUTICALS LTD. (GPL)

GPL is primarily focused on building a global formulation business with Branded, Generics, and OTC segments in the therapy areas of Dermatology, Respiratory and Oncology. It also has strong regional/country-specific presence in other therapeutic areas like Diabetes, Cardiovascular and Oral Contraceptives.

INDIA

Sales from the formulation business in India for the second quarter of FY24 was at Rs. 11,217 Mn (USD 135.7 Mn) as against Rs. 10,916 Mn (USD 137.2 Mn) in the corresponding quarter last year, recording a growth of 2.8%. The lower growth was mainly on account of the impact of divestment of few non-core brands and some impact of the NLEM price revisions, as well overall slow-down in the Respiratory and Dermatology therapy areas in the first six months of FY24. The India business contribution was at 31.3% in Q2 FY24 compared to 32.3% in Q2 FY23.

The Indian pharmaceutical market (IPM) witnessed a slow-down in the acute segment due to a delayed onset of monsoon; volume growth in key therapy areas such as Respiratory and Dermatology was impacted in the first 6 months of FY24. Accordingly, as per IQVIA Q2 FY24 data, Glenmark’s India formulation business recorded a growth of 5.4%, compared to the overall market growth of 6.9%. In Q2 FY24, the Company’s growth remained strong in the Cardiac therapy area, but was impacted in other therapy areas such as Respiratory & Diabetes.

	IPM	GLENMARK
SUPERGROUP	VALUE GROWTH (JUL'23 - SEP'23)	VALUE GROWTH (JUL'23 - SEP'23)
CARDIAC	10.0	20.1
DERMATOLOGY	5.2	8.8
RESPIRATORY	0.2	-1.5
DIABETES	6.0	-22.9

Glenmark’s India business continues to be ranked 14th with a market share of 2.11% (IQVIA MAT September 2023). The Company continues to have 9 brands in the IPM Top 300 Brands in the country on the basis of IQVIA MAT September 2023. In terms of key therapeutic areas, Glenmark is ranked 2nd in both the Respiratory and Dermatology segments. In addition, Glenmark is ranked 5th in the Cardiac segment and 17th in the Diabetes segment.

In spite of the challenging market environment, Glenmark has improved its market share marginally in the key therapy areas as per IQVIA MAT September 2023 data.

	GLENMARK	
SUPERGROUP	MARKET SHARE (%) MAT SEP'22	MARKET SHARE (%) MAT SEP'23
CARDIAC	5.0%	5.3%
DERMATOLOGY	7.3%	7.5%
RESPIRATORY	5.3%	5.6%
DIABETES	2.4%	2.0%

In August 2023, Glenmark joined hands with OMRON Healthcare India, the Indian arm of the Japanese global leader in home blood pressure monitoring and solutions for cardiovascular disease management, to raise awareness on measuring blood pressure at home from the age of 18. Glenmark and OMRON Healthcare India’s collaboration, named as the “Take Charge @18” initiative, comprises of generating effective communication to enhance awareness around the cause via incorporating an inlay card into every OMRON Blood Pressure monitor sold in India.

The Company continues to have a healthy pipeline of differentiated products across the key therapy areas which it plans to launch in the market going forward.

INDIA – GLENMARK CONSUMER CARE (GCC)

Primary sales for GCC in Q2 FY24 were Rs. 634.4 Mn with a growth of 15.3%. Our flagship brand Candid Powder™ delivered revenue growth of 10% for Q2 FY24. La Shield™ portfolio delivered 23% growth in Q2 FY24. Finally, the Scalpe+™ portfolio recorded 29% growth in Q2 FY24. Scalpe Pro recorded 41% growth in “new to brand” orders and 75% growth in repeat orders. Scalpe Pro is the #1 Anti Dandruff Shampoo on large e-commerce channels such as Amazon. Recently, Candid Dusting Powder was recognized with the Economic Times Iconic Brand Awards 2023.

NORTH AMERICA

The North America business registered revenues from the sale of finished dosage formulations of Rs. 7,392 Mn (USD 89.4 Mn) for the second quarter of FY24 as against revenue of Rs. 7,533 Mn (USD 94.8 Mn) for the second quarter of FY23, and Rs. 8,085 Mn (USD 98.4 Mn) for the first quarter of FY24. This translates in to a YoY decline of 1.9% and a quarter-on-quarter (QoQ) decline of 8.6%. For the second quarter of FY24, the North America business contribution was at 20.6% compared to 22.3% in Q2 FY23.

In the second quarter of fiscal year 2023-24, Glenmark launched the previously approved Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules, 1 mg/20 mcg, the generic for Taytulla®. Glenmark received approval and launched Saxagliptin Tablets and Tacrolimus Ointment, 0.03%. Glenmark also launched Varenicline Tablets through a partnership. These launches are expected to contribute to the overall sales growth for the region from Q3 FY24 onwards.

Glenmark filed two ANDA applications during the second quarter of FY24. The Company plans to file 10-12 ANDA applications in FY24. Glenmark's marketing portfolio through September 30, 2023 consists of 185 generic products authorized for distribution in the U.S. market. The Company currently has 51 applications pending in various stages of the approval process with the US FDA, of which 21 are Paragraph IV applications.

In August 2023, Glenmark Pharmaceuticals Inc., USA ("Company") announced that it has entered into an agreement with the U.S. Department of Justice, Antitrust Division (DOJ) to resolve all of its court proceedings with the DOJ involving historical pricing practices by former employees relating to the generic drug Pravastatin between 2013 and 2015. The Company has entered into a three-year Deferred Prosecution Agreement, and if the Company adheres to the terms of the agreement, including the payment of \$30 million, payable in six installments, the DOJ will dismiss the pending Superseding Indictment.

EUROPE

Glenmark Europe operations' revenue for the second quarter of FY24 was at Rs. 5,997 Mn (USD 72.5 Mn) as against Rs. 3,785 Mn (USD 47.6 Mn) recording a growth of 58.4%. Europe business contributed 16.7% of the total revenues in Q2 FY24 compared to 11.2% in Q2 FY23.

Glenmark's European operations continued their strong trajectory, driven by a robust uptick of the branded business and sustained growth in the generics business. The Western European business clocked 30%+ growth for Q2 mainly led by the United Kingdom (UK), which recorded strong growth on the back of key launches in the generics business as well as increasing uptake from the branded Respiratory pipeline.

Further, Glenmark continues to be ranked 16th in the generic market of Germany as per IQVIA MAT August 2023 data. The Czech and Poland markets in the CEE region recorded strong double digit secondary sales growth during the quarter. Glenmark (~23%) outperformed the Czech market (6.4%) in terms of growth as per IQVIA MAT September 2023. The Respiratory portfolio launched by Glenmark in Europe continues to do well. Key brands such as RYALTRIS[®] and Salmex[®] / Asthmex[®] continue to sustain their market share, both, in terms of volume as well as value, across the CEE markets. During the second quarter, Glenmark launched RYALTRIS[®] in Slovakia. Menarini, Glenmark's partner for RYALTRIS[®] in the European markets, recorded strong growth across multiple markets where it has launched the product.

In Q2 FY24, Cosmo Pharmaceuticals N.V. ("Cosmo") and Glenmark Specialty S.A., a subsidiary of Glenmark, announced the signing of distribution and license agreements for Winlevi[®] (clascoterone cream 1%) in Europe and South Africa. Under the terms of the agreements, Glenmark will receive from Cassiopea, a subsidiary of Cosmo, the exclusive right to commercialize Winlevi[®] in 15 EU countries (Bulgaria, the Czech Republic, Denmark, Finland, France, Hungary, Iceland, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain and Sweden) as well as in South Africa and the UK. Cassiopea shall be responsible for the Centralized Marketing Authorization at the European Medicines Agency (EMA), and Glenmark will undertake the registration of the product in South Africa and in the UK. Cosmo will be the exclusive supplier of the product. Cassiopea will receive an upfront payment of USD 5 million, further double-digit regulatory and sales milestones and agreed double-digit royalties on net sales.

ROW REGION (ASIA, MEA, LATAM & RCIS)

For the second quarter of FY24, revenue from the ROW region was Rs. 7,324 Mn (USD 88.6 Mn) as against Rs. 6,154 Mn (USD 77.7 Mn) for the corresponding quarter last year, recording a growth of 19.0%. For the second quarter of FY24, the ROW business contribution was at 20.4%, compared to 18.2% in Q2 FY23. The Company continues to witness strong growth in the base business across all sub-regions of the ROW market.

As per IQVIA Q2 FY24 and MAT September 2023 data, Glenmark's Russia business recorded 16% and 17% growth in value, respectively. This has been driven by all key brands, including RYALTRIS[®], Ascoril[®] and Montlezir[™]. RYALTRIS[®] sustained its momentum and gained further market share during the quarter. In terms of key therapeutic areas, Glenmark recorded growth of 21.8% in value in the Dermatology segment versus the overall Dermatology market growth of 9.6% as per MAT September 2023. Amongst the Dermatology companies in Russia, Glenmark ranks 8th as per MAT September 2023. Amongst the companies present in the Expectorants market in Russia, Glenmark continues to maintain a strong position, ranking 2nd as per MAT September 2023. Key recent launches in Russia include Ascoril LS (ambroxol + guaifenesin + levosalbutamol) solution and Fenismart (Dimetindene gel).

The Asia region recorded 10% growth in secondary sales which was driven by markets like the Philippines, Sri Lanka and Vietnam. Dermatology and Respiratory are key therapy areas for Glenmark in Asia, contributing significantly to the overall sales. RYALTRIS[®], launched by Glenmark in Malaysia in Q1 FY24, has seen very strong pick-up in the market. RYALTRIS[®] in Australia holds 18.1% share in value across the top allergic rhinitis products. RYALTRIS[®] is ranked 1st in the combination prescription market and 4th in the overall prescription market, for inhaled nasal sprays in South Korea (as per IQVIA September 2023 data) where the product has been launched by Yuhan Corporation, Glenmark's partner for that region.

The Middle East and Africa region recorded 15%+ growth in sales during the second quarter of FY24. Glenmark continued to be ranked 3rd in the overall Kenya Pharmaceutical Market and has recorded 25% growth in secondary sales. Further, the Company continued to achieve strong secondary sales growth in South Africa, UAE and other African markets. Respiratory and Dermatology together contributed ~60% to the overall sales of the MEA region. RYALTRIS[®] was launched in Saudi Arabia in Q1 FY24 and the product has received good response in the market; the product will be launched in other MEA markets in Q3 FY24.

LATAM witnessed double digit growth for Q2 FY24. The Respiratory portfolio remains the key contributor for Glenmark in this region. Glenmark Brazil achieved 20%+ growth in the covered market as per IQVIA YTD August 2023. The Company maintained its rank amongst the top companies in the covered market of the chronic respiratory segment in Brazil as per IQVIA MAT August 2023. Secondary sales growth remained strong in Mexico, with Glenmark's business having 8% market share and growing by ~18% in value in the Glenmark covered market (IQVIA YTD August 2023).

RESPIRATORY – CREATING GLOBAL SCALE

Following are the key business updates for Glenmark's global respiratory business in Q2 FY24:

RYALTRIS[®]

- As of the end of the second quarter of FY24, marketing applications for RYALTRIS[®] have been submitted in more than 70 countries across the world. The product has been commercialized in 29 markets, including major markets like the USA, Canada, Europe (the UK and multiple markets across the EU), Australia, Russia, South Africa, South Korea and Saudi Arabia.
- Glenmark's partner in the EU, Menarini, intends to launch the product in additional EU markets in FY24 and consolidate its position in the markets where the product has been already launched.
- Glenmark's commercial partner in the USA, Hikma, continued to see strong new prescriptions and repeat prescriptions growth as the allergy season progressed in the country

- Glenmark’s partner in Mainland China, Grand Pharmaceutical (China) Co. Ltd., has successfully completed the Phase 3 clinical trial with the product meeting the primary endpoint. NDA submission to the National Medicines Product Administration (NMPA) is targeted for December 2023.
- Below are the value market shares of RYALTRIS® across key geographies (Top 10 products within “R1A1 – Nasal Corticosteroids without Anti Infectionives” category as per IQVIA + RYALTRIS®):

MARKET	MARKET SHARE
Poland	26.1%
Australia	18.1%
Czech	15.5%
South Africa	14.3%
Italy	13.1%
Austria	7.7%
France	6.6%
Spain	6.0%
Ireland	4.8%
Peru	4.7%

**Data as of, for each respective market: Australia – May 2023; South Africa, Peru – June 2023; Poland, Czech, Italy, Austria, Spain, Ireland – August 2023; France – September 2023

Other Key Products

- Clinical trial ongoing for generic Flovent pMDI; expect to file in FY24
- Plan to file at least one more generic respiratory pMDI in the U.S. in FY25 and continue filing momentum beyond FY25

INNOVATIVE R&D PIPELINE

GRC 54276

GRC 54276 (HPK1 Inhibitor) is being developed as an orally administered IO-adjuvant treatment for patients with solid tumors. Hematopoietic progenitor kinase 1 (HPK1), is a negative regulator of T and B cell receptor signaling and an attractive therapeutic strategy for immuno-oncology based treatment in cancers. GRC 54276 is a novel, orally active HPK1 inhibitor that demonstrates stand-alone efficacy and enhances current immunotherapy efficacy. GRC 54276 is currently being evaluated in the First in Human (FIH) Phase 1 clinical study (GRC 54276-101).

Part 1a monotherapy phase of the study is ongoing in India since July 2022. Additional subjects are being recruited in the 50 mg monotherapy backfill cohort of the study to further assess safety, and tolerability for GRC 54276 monotherapy. The Phase 1, Part 1b combination study of GRC 54276 with pembrolizumab and atezolizumab was initiated in India and the U.S. in Q1 FY24 and Q2 FY24 respectively. As of Q2 FY24, two dose cohorts of GRC 54276 with pembrolizumab and atezolizumab have been completed in the Phase 1, Part 1b combination study and the study is currently ongoing.

GRC 39815

GRC 39815 (ROR γ t inhibitor) is the Company's respiratory pipeline asset being developed as an inhaled therapy for treatment of mild-to-moderate Chronic Obstructive Pulmonary Disorder (COPD). It is currently under Phase 1 clinical development in the U.S.

GLENMARK LIFE SCIENCES LTD. (GLS)

Glenmark Life Sciences is focused on manufacturing and marketing of Active Pharmaceutical Ingredients (API) products across all major markets globally. It also includes captive sales (i.e. use of API by GPL for its own formulations).

External sales for GLS in Q2 FY24 were at Rs. 3,930 Mn (USD 47.5 Mn) as against Rs. 3,744 Mn (USD 47.1 Mn) in Q2 FY23, recording a growth of 5.0% YoY.

In September 2023, Glenmark announced that it has entered into a definitive agreement with Nirma Limited to divest 75% stake in its subsidiary, Glenmark Life Sciences Limited (GLS) at a price of Rs. 615/- per share for an aggregate consideration of Rs. 56,515 Mn, subject to closing adjustments. Glenmark would own 7.84% in GLS after the divestment. The transaction is subject to customary closing conditions precedent, including receipt of regulatory and shareholder approvals.

For further updates on the organization, please log on to www.glenmarklifesciences.com.

ICHNOS SCIENCES Inc.

Glenmark invested Rs. 1,613 Mn (USD 19.6 Mn) in Ichnos in the second quarter of FY24 compared to Rs. 1,727 Mn (USD 22 Mn) in the corresponding quarter last year. For the first six months of FY24, Glenmark has invested Rs. 3,030 Mn (USD 36.8 Mn) compared to Rs. 3,363 Mn (USD 43 Mn) invested in the corresponding period of the previous financial year.

For further updates on the pipeline and the organization, please log on to www.ichnoscience.com.
The pipeline update for the second quarter of FY23 is published on the Ichnos website.

KEY OBJECTIVES FOR FY24*

- **Consolidated Revenue Growth: 10-11%**
- **Consolidated R&D Investment: 8-8.5% of total sales**
- **Consolidated EBITDA Margin: 19-20%+**
- **Consolidated Capex: INR 6-7 Bn**
- **Priority to enhance free cash generation for further debt reduction**
- **Close at least 1 out-licensing deal in innovation pipeline**

*inclusive of GLS

Disclaimer:

This document has been prepared by Glenmark Pharmaceuticals Ltd. The information, statements and analysis made in this document describing Company's 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 which could cause actual outcomes and results to differ materially from these statements, depending upon economic conditions, government policies and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this document. This document should not be regarded 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.

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ICHNOS SCIENCES INC.

NOVEMBER 2023 UPDATE



















ABOUT ICHNOS

Ichnos Sciences aims to shift the way the world thinks about innovation in medicine by developing potentially transformative biologic treatments in immuno-oncology. The company, currently a subsidiary of Glenmark Holding, SA, plans to pursue external financing following the achievement of clinical proof of concept for its lead assets.

Headquartered in New York City, Ichnos has research and manufacturing operations at two sites in Switzerland. As a fully integrated biotechnology company with approximately 151 employees following the recent restructuring of the Research group, Ichnos has strong capabilities in research, antibody engineering, CMC, and clinical development of biotechnologies.

Ichnos is guided by an accomplished management team with experience developing immune cell engagers within the biopharmaceuticals industry, and is led by Cyril Konto, M.D., President and Chief Executive Officer.

In October 2023, Ichnos promoted Dean Thomas to the role of General Counsel.

<p>CYRIL KONTO, M.D. President and Chief Executive Officer</p> <p>  </p>	<p>LIDA PACAUD, M.D. Chief Medical Officer</p> <p>  </p>	<p>EUGENE ZHUKOVSKY, Ph.D. Chief Scientific Officer</p> <p>    </p>
<p>MICHAEL D. PRICE Chief Financial Officer</p> <p> </p>	<p>ROBERTO GIOVANNINI, Ph.D. Chief Process and Manufacturing Officer</p> <p> </p>	<p>DEAN THOMAS General Counsel</p> <p></p>
<p>PATRICIA JAQUET Head of Human Resources</p> <p> </p>		

...ichnos...

The proprietary BEAT[®] technology platform¹ is the basis for Ichnos' clinical-stage oncology pipeline. Using this technology, coupled with the proprietary common light chain library, the company is developing novel multispecific immune cell engagers and modulators, with the goal of realizing its mission to provide breakthrough, potentially curative therapies that may extend and improve lives, writing a new chapter in healthcare.

ONCOLOGY PIPELINE

Ichnos' multispecific antibody pipeline consists of four assets. This includes ISB 2301 which is in the discovery stages for application in solid tumors and ISB 2001, ISB 1342 and ISB 1442, each of which are orphan drug designated by the U.S. Food and Drug Administration (FDA) and currently in Phase 1 clinical studies for relapsed/refractory multiple myeloma. Updates of note in the last quarter are outlined below:

- Each asset has had an associated abstract accepted for presentation at the 65th ASH Annual Meeting on December 9-12, 2023, in San Diego, California, and online.
- Ichnos has initiated its first-in-human clinical trial for ISB 2001, dosing the first patient with Ichnos' TREAT[™] trispecific antibody in November 2023.

MOLECULE MECHANISM/CLASS	PHASE/STATUS	LEAD INDICATION
ISB 1342 CD38 x CD3 BEAT [®] bispecific antibody ²	Phase 1	Relapsed/Refractory Multiple Myeloma; T-Cell Acute Lymphoblastic Leukemia(T-ALL) is also under consideration
ISB 1442 CD38 x CD47 BEAT [®] biparatopic bispecific antibody	Phase 1	Relapsed/Refractory Multiple Myeloma; Phase 1 study in Acute Myeloid Leukemia (AML) is planned by early 2024
ISB 2001 BCMA x CD38 x CD3 TREAT [™] trispecific antibody ³	Phase 1	Relapsed/Refractory Multiple Myeloma
ISB 2301 NK-cell engaging multispecific platform	Discovery	Solid Tumors

Ichnos is looking for asset-level and platform-level collaboration partners in development and research. For more information, visit <https://ichnos.com/contact/>.

¹ Bispecific Engagement by Antibodies based on the TCR

² Future clinical development will be advanced by a partner

³ Trispecific Engagement by Antibodies based on the TCR

OVERVIEW OF SELECT ONCOLOGY DRUG PRODUCT CANDIDATES

ISB 1342 (CD38 X CD3 BEAT® BISPECIFIC ANTIBODY)

- A Phase 1, open-label, dose-escalation, first-in-human study of ISB 1342 in patients with relapsed/refractory multiple myeloma
 - + The study has been suspended and the strategy is to out-license the asset and allow a potential partner to continue the escalation/expansion now that clinical proof-of-mechanism and proof-of-concept have been established with acceptable immunogenicity on par with other bispecifics.
 - + Database lock and site closures are ongoing while preparing for a potential out-licensing and handover to a partner
 - + The first partial response in this study was observed in Cohort 109 intravenous (dose level 8 µg/kg) and a second partial response was observed in Cohort 110 intravenous (dose level 16 µg/kg). The responses are supported by translational data, where higher T-cell activation has been observed with increasing doses
- The primary objectives of the study are to:
 - + Determine maximum tolerated dose and/or recommended Phase 2 dose of ISB 1342 (Part 1 dose escalation).
 - + Assess the anti-myeloma activity of ISB 1342 according to the International Myeloma Working Group response criteria (Part 2 dose expansion).
- Clinical safety remains on par with earlier results presented in a poster session at the 2022 American Society of Hematology (ASH) Annual Meeting in December with data cut-off October 26, 2022:
 - + Observed CRS events were moderate and manageable with supportive care
 - + No increased risk of infection has been observed
- ISB 1342 was granted Orphan Drug Designation for multiple myeloma by the U.S. Food and Drug Administration.
- The bulk drug substance is manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland.
- In July 2023, a research article, Preclinical characterization of ISB 1342, a CD38 x CD3 T-cell engager for relapsed/refractory multiple myeloma, was published in Volume 142, Issue 3, of the American Society of Hematology's *Blood* journal.
 - + One of the figures from this publication was prominently featured on the cover of the print edition of the journal.
- An abstract for the 2023 ASH Annual Meeting with the latest clinical data has been



accepted for presentation:

- + **Dose Escalation of ISB 1342, a Novel CD38xCD3 Bispecific Antibody, in Patients with Relapsed / Refractory Multiple Myeloma (RRMM)**
- + Sunday, December 10, 2023, 6:00 PM-8:00 PM
San Diego Convention Center, Halls G-H
Session Name: 652. Multiple Myeloma: Clinical and Epidemiological: Poster II
Publication Number: 3339

ISB 1442 (CD38 X CD47 BEAT® BISPECIFIC ANTIBODY)

- This first-in-class biparatopic bispecific antibody targeting CD38 and CD47 was generated by scientists in Ichnos' laboratories in Lausanne at the Biopole life sciences campus.
- ISB 1442 is designed to kill CD38-expressing tumor cells through inhibition of the CD47-SIRP α axis to increase antibody-dependent cellular phagocytosis (ADCP) and enhance antibody-dependent cellular cytotoxicity (ADCC) as well as complement-dependent cytotoxicity (CDC).
- After receiving approval from the HREC in Australia and the U.S. Food and Drug Administration, a Phase 1 / 2 first-in-human dose-finding study of ISB 1442 in relapsed/refractory multiple myeloma is now actively enrolling patients in Cohort 5 (300 mg SQ weekly) in both countries.
- Ichnos is also considering the potential development of ISB 1442 in acute myeloid leukemia (AML).
- The preclinical data package for ISB 1442 shows:
 - + Higher potency in vitro for ISB 1442 relative to daratumumab in CD38 high/low tumor models as measured by a multiple antibody-dependent mechanisms of action killing assay
 - + Higher tumor growth inhibition for ISB 1442 than daratumumab in CD38 high and low preclinical in vivo xenograft models
 - + Low on-target off-tumor binding with ISB 1442 compared to anti-CD47 mAb (hu5F9), is anticipated to result in lower red blood cell depletion in clinic, and potentially a better therapeutic index than anti-CD47 bivalent monoclonal antibodies
- Additional information on the ongoing Phase 1 study and on preclinical models in other hematologic malignancies were most recently presented at the 2022 ASH Annual Meeting in December:
 - + **A Phase 1/2, First-in-Human, Multicenter, Open-Label, Dose Escalation and**

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Dose-Expansion Study of Single-Agent ISB 1442 in Patients with Relapsed/Refractory Multiple Myeloma; Poster presentation that describes the design of the ongoing study [may be viewed here](#).

- + **Preclinical Evaluation of ISB 1442, a First-in-Class CD38 and CD47 Bispecific Antibody Innate Cell Modulator for the Treatment of AML and T-ALL**; Poster presentation that shows the rationale for advancing to a clinical study in relapsed/refractory AML [may be viewed here](#), specifically:
 - In AML cell lines in multiple *in vitro* assays, ISB 1442 induces killing, including ADCP and ADCC
 - Superior activity to daratumumab in AML cell lines having intermediate or low CD38 expression
- ISB 1442 was granted Orphan Drug Designation for multiple myeloma by the FDA in March 2023.
- The bulk drug substance is manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland.
- An abstract for the [2023 ASH Annual Meeting](#) with the latest clinical data has been accepted:
 - + **Initial Results From the Dose Escalation Phase1/2 of ISB 1442, a Novel CD38 Biparatopic x CD47 Bispecific Antibody, in Patients with Relapsed / Refractory Multiple Myeloma (RRMM)**
 - + Monday, December 11, 2023, 6:00 PM-8:00 PM
San Diego Convention Center, Halls G-H
Session Name: 652. Multiple Myeloma: Clinical and Epidemiological: Poster III
Publication Number: 4707

ISB 2001 TREAT™ TRISPECIFIC ANTIBODY

- ISB 2001 is a first-in-class T cell-engaging antibody that targets BCMA and CD38 on multiple myeloma cells. It is a trispecific antibody based on Ichnos' proprietary BEAT® platform, allowing maximal flexibility and excellent manufacturability of full-length multispecific antibodies. Additional ISB 2001 details include:
 - + ISB 2001 combines three proprietary Fab antigen-binding arms, each targeting a different antigen, with one arm binding to the epsilon chain of CD3 on T cells, and the other two binding BCMA and CD38 on multiple myeloma cells. Its Fc domain was fully silenced to suppress Fc effector functions.

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- + In vitro studies showed that ISB 2001 exhibited increased killing potency of tumor cells compared to all tested antibodies that are either currently approved for the treatment of multiple myeloma or are being tested in ongoing clinical studies. In vivo studies in the multiple myeloma models also demonstrated superior potency of ISB 2001 relative to approved antibody treatments of multiple myeloma.
- + ISB 2001 redirects CD3+ T lymphocytes to kill tumor cells expressing low to high levels of both BCMA and CD38. With two different tumor-associated antigens instead of one, ISB 2001 is expected to be more resistant to antigen escape associated with treatment of multiple myeloma patients.
- The preclinical data package for ISB 2001 was selected for a presentation at the 2023 American Association for Cancer Research (AACR) Annual Meeting in April, as well as an oral presentation at the ASH Annual Meeting in December 2022:
 - + In this presentation, **Overcoming Mechanisms of Escape from Treatments for Multiple Myeloma by ISB 2001, a first-in-Class Trispecific BCMA and CD38 targeted T Cell Engager**, the following data were highlighted:
 - Increased killing of tumor cells across variable levels of expression of both BCMA and CD38 compared to teclistamab, alnuctamab and EM-801
 - Higher potency *in vitro* when compared to the combination of daratumumab and teclistamab
 - Superior cytotoxicity over teclistamab in *ex vivo* assays with Multiple Myeloma cells from patients at different stages of progression of the disease
 - Superior efficacy over teclistamab in *in vivo* models with low level of expression of CD38 and BCMA demonstrating 100% complete responses
- In April 2023, Ichnos received approvals from HREC in Australia and the FDA to initiate a Phase 1 first-in-human study of ISB 2001 for the treatment of relapsed/refractory multiple myeloma. Ichnos is considering expansion of clinical studies to additional countries in parallel.
- In July 2023, Ichnos received Orphan Drug Designation from the FDA for ISB 2001 for the treatment of multiple myeloma.
- First patient was dosed in November 2023.
- The bulk drug substance is manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland.
- An abstract for the 2023 ASH Annual Meeting has been accepted:

- + **Trial in Progress: A Phase 1, First-in-Human, Dose Escalation and Dose-Expansion Study of a BCMAxCD38xCD3 Targeting Trispecific Antibody ISB 2001 in Subjects with Relapsed/Refractory Multiple Myeloma**
- + Sunday, December 10, 2023, 6:00-8:00 p.m.
San Diego Convention Center, Halls G-H
Session: 653. Multiple Myeloma: Prospective Therapeutic Trials: Poster II
Publication Number: 3396

AUTOIMMUNE DISEASES

Ichnos has two monoclonal antibody drug product candidates addressing autoimmune diseases in the pipeline. To enhance the company's focus on oncology, future development of both assets will be overseen by out-licensing partners.

The first asset, ISB 880, an anti-IL-1RAP antagonist, was licensed to Ammirall, S.A. in December 2021. The initiation of dosing in a Phase 1 study of ISB 880/ALM27134 was announced by Ammirall in September 2022.

The second antibody, ISB 830 (telazorlimab) and its follow-on molecule ISB 830-X8, was licensed to Astria Therapeutics in October 2023. Telazorlimab is an OX40 antagonist that successfully completed a Phase 2b study in moderate to severe atopic dermatitis in 2021. Both compounds have potential across a range of autoimmune diseases.

ASSETS IN AUTOIMMUNE DISEASES

MOLECULE MECHANISM/CLASS	POTENTIAL INDICATIONS	PHASE	STATUS
ISB 880 (ALM 27134) IL-1RAP Antagonist Monoclonal Antibody	Autoimmune Diseases	Phase 1	Licensed to Ammirall S.A. in December 2021. Dosing of participants in the Phase 1 study was announced by Ammirall in September 2022.
ISB 830 Telazorlimab OX40 Antagonist Antibody	Atopic Dermatitis	Phase 2b	Licensed to Astria Therapeutics in October 2023. Successfully completed a Phase 2b study in Atopic Dermatitis.
	Other autoimmune diseases, including Rheumatoid Arthritis	U.S. IND for Rheumatoid Arthritis and other autoimmune indications is active.	

ISB 880 (IL-1RAP ANTAGONIST)



- Ichnos entered an exclusive global licensing agreement for ISB 880 in autoimmune diseases with Ammirall in December 2021. Within the terms of the agreement, Ammirall

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assumed full cost and responsibility for the global development and commercialization of the compound. Ichnos received an upfront payment of €20.8 million. The deal includes development and commercial milestone payments and tiered royalties based upon future global sales. As part of the agreement, Ichnos is also being paid to manufacture batches of ISB 880 to support early clinical studies to be sponsored by Almirall and realized revenue this year for drug supplies for the ongoing Phase 1 study.

- ISB 880, a fully-human, high-affinity, monoclonal antibody blocking IL-1RAP signaling, has completed IND-enabling studies for patients with autoimmune diseases. The optimal antibody profile, the strong *in vitro* and *in vivo* data package, as well as toxicology, CMC, and clinical pharmacology plans enabled Almirall to complete a U.S. IND filing in Q2 of 2022. A Phase 1 study began September 2022 and is currently underway. Blockade of IL-1RAP simultaneously abrogates multiple disease drivers among the IL-1 family of proinflammatory cytokine receptors, including IL-1R, IL-33R, and IL-36R, differentiating ISB 880 from single cytokine blockade therapies. These cytokines have been implicated in numerous autoimmune conditions, opening opportunities for ISB 880 to be positioned across broad disease indications.
- Ichnos retains rights for antibodies acting on the IL-1RAP pathway for oncology indications.

ISB 830 (TELAZORLIMAB, OX40 ANTAGONIST)



- Ichnos entered an exclusive global licensing agreement for ISB 830 in autoimmune diseases with Astria Therapeutics in October 2023.
- Previously, Ichnos had received FDA clearance to study Telazolimab in seropositive autoimmune diseases (Rheumatoid Arthritis, Systemic Lupus Erythematosus, Sjogren's Syndrome, Multiple Sclerosis, Type I Diabetes Mellitus, Myasthenia Gravis).
- The database for the ISB 830-204 Phase 2b clinical study in atopic dermatitis was locked in October 2021, and the final results were posted on [ClinicalTrials.gov](https://clinicaltrials.gov). This study, which was conducted in the U.S., Canada, Germany, Czech Republic, and Poland, had a randomized, controlled, multicenter design and assessed three doses and two dosing schedules of telazolimab versus placebo in adults with moderate-to-severe atopic dermatitis.
- Results from the double-blind portion of the study are summarized below:
 - + **Efficacy:** The primary endpoint of the EASI score, % change from baseline to Week 16, was achieved for the two highest doses of telazolimab tested (300 mg and 600 mg q 2 weeks) versus placebo.
 - + **Safety:** Telazolimab was well tolerated. The most commonly reported adverse events (>5%) were atopic dermatitis, nasopharyngitis, upper respiratory tract

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infection, and headache. One patient with pre-existing hypertension in the telazorlimab group died due to a presumed cardiovascular event during the treatment period. The investigator considered the death to be unrelated to the study drug.

- For more information, visit <https://ichnos.com/contact/>.