Management Discussion & Analysis for the First Quarter of FY 2021-22

Glenmark operates its businesses through three separate entities.

Glenmark Pharmaceuticals Ltd. (GPL)

Glenmark Life Sciences (GLS)
(82.84% API Subsidiary)

Ichnos Sciences
(100% US based innovation Subsidiary)

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

Revenue figures for consolidated Glenmark Pharmaceuticals Ltd.

(Rs. In Millions)

	For the first quarter ended June 30		
	FY 2021-22	**FY 2020-21**	**Growth (%)**
India	12,250	7,799	57.1%
North America	7,878	7,426	6.1%
Rest of the World (ROW)	2,686	2,120	26.7%
Europe	3,059	2,739	11.7%
Latin America	675	658	2.5%
API	3,040	2,348	29.4%
Total	**29,587**	**23,091**	**28.1%**
Other Revenue	62	357	
Consolidated Revenue	**29,649**	**23,448**	**26.4%**

Average conversion rate in 3M FY 2021-22 considered as **INR 73.68 /USD 1.00**
Average conversion rate in 3MFY 2020-21 considered as INR 75.39 /USD 1.00
USD figures are only indicative

Review of Operations for the quarter ended June 30, 2021

For the First Quarter of FY 2021-22, Glenmark's consolidated revenues from operations was at Rs. 29,649 Mn (USD 402 Mn) as against Rs. 23,448 Mn (USD 311 Mn) recording an increase of 26.4%

GLENMARK PHARMACEUTICALS LTD. (GPL)

GPL is primarily focused on building a global Generics, Specialty and OTC business 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 First Quarter of FY 2021-22 was at Rs. 12,250 Mn as against Rs. 7,799 Mn in the previous corresponding quarter, recording a growth of 57.1%.

Q1FY22 was a landmark quarter for the India business, with both the COVID and non-COVID portfolios of the company performing well. The India business outperformed industry growth; continuing the trend of the past several years. As per IQVIA MAT June '21, Glenmark's India business recorded growth of 35.4% as compared to the IPM growth of 14.7%. Glenmark's India Formulations is ranked 13th, an increase of 1 rank with market share of 2.6% as compared to 2.24% in Q1 last year. Glenmark is the fastest growing company (among top 20 companies) on MAT June 2021 basis.

As per IQVIA MAT June '21, Glenmark's India business further strengthened its position in its core therapy area in respiratory with market share increasing to 5.25% as compared to 5.16% in Q1 last year. Similarly, market share in antivirals increased to 31.3% in the period. Glenmark is ranked 1st in antivirals, 2nd in dermatology market, 4th in respiratory and 6th in the cardiology market in India. The company launched 7 new products during the quarter.

Glenmark's novel, patent protected and globally-researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin etabonate (Remogliflozin) continues to do well in India. Glenmark is the first company in the world to launch Remogliflozin and has launched multiple brand extensions, including combinations to leverage its positioning around the product. This strategy is showing results with total Remogliflozin sales, including brand extensions growing in strong double digits during the quarter.

Glenmark has recently signed an exclusive long term agreement with Canadian biotech SaNOtize to commercialize Nitric Oxide Nasal spray for COVID-19 treatment in Indian and other Asian markets. Studies show that Nitric Oxide nasal spray is safe and highly effective in reducing viral load in COVID-19 patients and reduces onward transmission. Phase III clinical trial is expected to be completed, followed by commercial launch under the brand name FabiSpray® in India later during the calendar year

During the quarter, Glenmark became one of the first companies in the world to launch Ryaltris®-AZ nasal spray, a novel fixed dose combination of Mometasone furoate and Azelastine for the treatment of moderate to severe allergic rhinitis in India for patients above 12 years of age. Launched at an affordable cost, the product provides a far more convenient, cost effective treatment option in the country and reinforces the company's strength in its respiratory franchise.

During the quarter, the company announced interim data of 503 patients from its Post Marketing Surveillance (PMS) study on Favipiravir in India. Glenmark is the only organization from India to conduct a Phase 3 study with a 1000+ patient PMS study in mild to moderate COVID 19. The interim data revealed no new safety signals or concerns till date supporting the safety and effectiveness of Fabiflu® in real-world settings.

India – Glenmark Consumer Care Business

Secondary sales of Glenmark's Consumer Care business grew by 24% YoY during the quarter. Candid Powder recorded its highest ever secondary sales in June '21. Similarly, LaShield and Scalpe Plus both recorded their highest secondary sales in the quarter. As mentioned earlier, Candid Powder is the first brand in the Consumer Care Business to enter the "Rs. 100 Cr" club. The company also successfully launched Candid Cream during the quarter which is available in more than 30,000 outlets currently.

North America

North America registered revenue from the sale of finished dosage formulations of Rs. 7,878 Mn (USD 107 Mn) for the quarter ended June 30, 2021 as against revenue of Rs. 7,426 Mn (USD 99 Mn) for the previous corresponding quarter, recording a growth of 6.1%. On a constant currency basis revenues grew 8.5% YoY during the quarter.

In the first quarter of fiscal year 2021-22, Glenmark was granted final approval and launched Theophylline Extended-Release Tablets, 300 mg and 450 mg. Glenmark has been granted a competitive generic therapy (CGT) designation for Theophylline Extended-Release Tablets USP, 450 mg. With this approval, Glenmark is the first approved applicant for such competitive generic therapy and is eligible for 180 days of CGT exclusivity upon commercial marketing of the 450 mg strength. Glenmark also received approval and laiunched Arformoterol Tartrate Inhalation Solution. Arformoterol is manufactured at the company's North American manufacturing facility based in Monroe, North Carolina, and marks the company's first nebulizer approval.

In addition, Glenmark launched the previously approved product Rufinamide Tablets, as one of the first available generics on the market. The Company filed eight ANDA applications with the U.S. FDA including three filings from Monroe, and is on track to file 18-20 ANDAs in FY22 including 4-5 filings from Monroe.

Glenmark's marketing portfolio through June 30, 2021 consists of 172 generic products authorized for distribution in the U.S. market. The Company currently has 44 applications pending in various stages of the approval process with the US FDA, of which 21 are Paragraph IV applications.

Africa, Asia and CIS Region (ROW)

For the First Quarter of FY 2021-22, revenue from Africa, Asia and CIS region was Rs. 2,686 Mn (USD 36 Mn) as against Rs. 2,120 Mn (USD 28 Mn) for the previous corresponding quarter, recording growth of 26.7%.

In Russsia and CIS markets, the company is witnessing recovery as compared to the previous quarters with secondary sales having grown 42% YoY in the region. In Russia, as per Q1 IQVIA, Glenmark's revenues grew 29% in value terms vis-à-vis 13.2% growth in the overall retail market. Also during the quarter, the company successfully commercialized Ryaltris™ in Russia with indications of seasonal and perennial allergic rhinitis in patients over 12 years of age, strengthening our respiratory franchise in the market. We are currently focused on building the distribution of the product across the region.

In the Asia region, a strong second wave of COVID especially in South East Asian countries impacted marketing activities. Despite these challenges, secondary sales of the company grew 20% YoY during the quarter in the region, with strong growth in key markets like Philippines and Sri Lanka. The company also witnessed recovery in the Middle East/Africa region with secondary sales growth of 52% YoY with growth witnessed in markets like Kenya, South Africa and Saudi Arabia.

Europe

Glenmark Europe's operations revenue for the First Quarter of FY 2021-22 was at Rs. 3,059 Mn (USD 42 Mn) as against Rs. 2,739 Mn (USD 36 Mn) recording a growth of 11.7 %.

The company witnessed a mixed performance in the Western European region. While growth was affected by continued COVID restrictions in some countries, key markets like UK and Netherlands witnessed positive growth, The Central Eastern European region witnessed healthy growth across most key markets. Amongst the key launches, the company launched one product each in UK, Germany and Spain during the quarter respectively.

In-line with our global focus on the respiratory segment, Glenmark became one of the first generic companies to successfully launch Tiotropium Dry Powder Inhaler, the bioequivalent version of Spiriva® Handihaler® under the brand name of Tiogiva® in the UK during the quarter. Company has a strategic exclusive in-licensing agreement to market Tiotropium DPI in Western Europe. Glenmark is planning subsequent launches of the product across markets in Western Europe under the brand name Tiogiva® in Ireland, Sweden, Finland and Norway; Tavulus® in Denmark, Spain and Netherlands; and Tiotropium Glenmark® in Germany.

In this quarter, Glenmark concluded the DCP procedure for Ryaltris™ in Europe, enabling approval in 17 countries across EU and UK with launch planned in current year.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 675 Mn (USD 9.2 Mn) for the First Quarter of FY 2021-22, as against Rs. 658 Mn (USD 8.7 Mn), recording growth of 2.5 %. Revenue growth was impacted by Brazil where the market remained challenging due to the pandemic. However, we have begun to witness recovery in this region with most of the other markets recording positive growth momentum during the quarter including Mexico which grew 63% YoY during the quarter.

GPL Specialty/Innovative R&D Pipeline

Ryaltris™

Ryaltris™ (olopatadine hydrochloride and mometasone furoate) Nasal Spray, the company's respiratory pipeline asset, is currently under review with the U.S. Food and Drug Administration (FDA) as a treatment for seasonal allergic rhinitis in the USA. Glenmark's response to the Agency's Complete Response Letter (CRL) was submitted to the US FDA in July 2021 with the PDUFA goal date in Q4FY22

In Apr 2021, Glenmark concluded the DCP procedure in Europe, enabling approval in 17 countries across EU and UK. During the first quarter, Glenmark also received regulatory approval for Ryaltris™ in Zambia, Ecuador and Peru. Ryaltris™ sales continue to progress well in Australia, South Africa, Ukraine and Uzbekistan. Glenmark initiated the commercial launch in Russia in the first quarter of FY21-22. Glenmark is targeting launch in key European markets in H2 FY21-22. The company is awaiting regulatory approvals for its filings in various markets across Canada, Brazil, Malaysia, Saudi Arabia and several other emerging markets.

In Q1 FY21-22, Glenmark's partner in China, Grand Pharmaceutical (China) Co. Ltd., finalized the Phase 3 protocol for China, and submitted the IND application in July 2021. In South Korea, Glenmark is working with its partner Yuhan Corporation, to potentially launch the product by H2 FY22. Also, the company is working to submit the application for paediatric efficacy supplement in the country. In June 2021, Glenmark's partner in Australia, Seqirus Pty Ltd. received positive initial feedback from the TGA for the pediatric indication expansion.

GBR 310

Glenmark had announced successful Phase 1 results for GBR 310 that suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between GBR 310, and the reference product, Omalizumab, marketed in the U.S. under the brand name Xolair®. The Company is in discussions with potential partners and is targeting to conclude a deal before initiating Phase 3

studies.

GRC 39815 (RORγt inhibitor)

GRC 39815 (RORγt antagonist) is the company's respiratory pipeline asset being developed as an inhaled therapy for treatment of mild to moderate COPD. It is currently under Phase 1 clinical development with a single ascending dose study in the US. The Phase 1 study is expected to be completed in the next few quarters.

GRC 17536

GRC 17536 (TRPA1 antagonist) is the company's pain pipeline asset being developed as an orally administered treatment for pain in patients with painful diabetic peripheral neuropathy. A regulatory submission to DCGI for conducting the Phase 2b DRF study in India was done in Q1 FY22 and the study is scheduled to be initiated in Q2 FY22. The company is evaluating further options including out licensing for the molecule.

GRC 54276

GRC 54276 (HPK1 Inhibitor) is being developed as an orally administered IO-adjuvant treatment for patients with solid tumors in oncology. Pre-clinical in-vitro and in-vivo profiling was completed in Q1 FY22 and Pre-clinical DMPK and non-GLP Toxicology studies are currently underway. Further evaluation of GRC 54276 is ongoing to advance towards clinical studies.

GLENMARK LIFE SCIENCES LTD. (GLS)

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

The equity shares of GLS were listed on BSE Ltd and NSE Ltd on 6th August, 2021 following a successful Initial Public offering (IPO). Pursuant to the IPO, GLS published its unaudited financial results for the first quarter of the financial year on August 13, 2021.

For the first quarter of the financial year, GLS registered revenue from operations including captive sales of Rs. 5,249 Mn as against Rs. 3,969.7 Mn during the same quarter of the last financial year, recording growth of 32.2% YoY. The EBITDA Margin for Glenmark Life Sciences including captive sales was 31.3% for the first quarter of this financial year.

For the first quarter of FY 2021-22, external sales for Glenmark Life Sciences was at Rs. 3,040 Mn as against Rs. 2,348 Mn, recording growth of 29.5% over the corresponding period last year.

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

ICHNOS Sciences

Glenmark has invested Rs. 1,617 Mn (USD 21.9 Mn) in the first quarter of the financial year as compared to Rs. 1,735 Mn (USD 23.0 Mn) Q1 last year. The company had invested Rs. 7,570 Mn (USD 102.3 Mn) in FY 21.

For further updates on the pipeline and the organization, please log on to www.ichnossciences.com.The pipeline update for the first quarter is published on this site.

Key objectives for FY22

- Revenue growth of 10-15% during the year
- Sustain EBITDA margin performance at similar levels of FY21
- Reduce debt by at least Rs. 16 Bn through a combination of free cash generation and IPO proceeds during the year
- Post FY22, strategic priority to enhance free cash generation for further debt reduction; prioritizing over R&D investments and capital expenditure
- Close 1-2 out-licensing agreements at Ichnos

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ICHNOS SCIENCES INC.

AUGUST 2021 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 and autoimmune diseases. The company, headquartered in New York City, with discovery and manufacturing at two sites in Switzerland, has approximately 225 employees and strong capabilities in the research and development of new biological entities (NBEs).

The first wave of Ichnos' bi-/trispecific antibody oncology pipeline consists of five programs, including a clinical-stage, potentially first-in-class T-cell engager, ISB 1342 (CD38 x CD3), which is in Phase 1 for the treatment of relapsed/refractory multiple myeloma.

Ichnos' proprietary BEAT® technology platform[1] enables the company to develop novel immune cell engagers and modulators in oncology, with the goal of realizing its mission to provide breakthrough, potentially curative therapies that will hopefully extend and improve lives, writing a new chapter in healthcare.

Beyond oncology, Ichnos has a pipeline of two first-in-class therapeutics addressing autoimmune diseases. ISB 830 (telazorlimab, OX40 antagonist) is in Phase 2b, and ISB 880 (anti-IL-1RAP antagonist) is in IND-enabling studies. Both compounds have potential across a range of autoimmune diseases and are available for out-licensing, enabling Ichnos to focus on oncology moving forward.

Officially launched on October 15, 2019, Ichnos has an experienced executive leadership team and board of directors. The company is a subsidiary of Glenmark Holding SA, which is currently funding operating expenses until additional investors come on board.

[1] Bispecific Engagement by Antibodies based on the T-cell receptor

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QUARTERLY HIGHLIGHTS

BUSINESS UPDATES

Ichnos' pipeline continues to grow. Enrollment in a Phase 1 study for ISB 1342 is ongoing and preclinical-stage assets focused on CD38 x T-cell engagers and macrophage modulators are advancing.

Ichnos has entered into advanced out-licensing discussions with potential partners for the autoimmune disease portfolio, which includes the Phase 2b OX40 antagonist telazorlimab (formerly known as ISB 830) and the IL-1RAP antagonist ISB 880, which is currently in IND-enabling studies.

The opening of the global headquarters at One World Trade Center in New York City is planned for mid-September 2021.

FISCAL YEAR 2022 OBJECTIVES

- Establish clinical proof of concept for ISB 1342 and the BEAT® platform
- File an IND for ISB 1442
- Finalize out-licensing of ISB 830 and ISB 880
- Continue to prepare for equity capital raise

UPDATE ON ICHNOS ONCOLOGY BIOLOGICS PIPELINE

MOLECULE MECHANISM/CLASS	PHASE/STATUS	LEAD INDICATION
ISB 1342 CD38 x CD3 BEAT® 1.0 bispecific antibody	Phase 1	Relapsed/Refractory Multiple Myeloma
ISB 1442 CD38 x CD47 BEAT® 2.0 bispecific antibody	IND-Enabling Studies	Relapsed/Refractory Multiple Myeloma
ISB 2001 TREAT™ trispecific antibody	Discovery	Hematologic Malignancies
ISB 2004 BEAT® 2.0 bispecific antibody	Discovery	Hematologic Malignancies/ Solid Tumors
ISB 2005 TREAT™ trispecific antibody	Discovery	Hematologic Malignancies

OVERVIEW OF SELECT ONCOLOGY COMPOUNDS

ISB 1342 (CD38 X CD3 BISPECIFIC ANTIBODY)

- A Phase 1, open-label, dose-escalation, first-in-human study of ISB 1342 in patients with relapsed/refractory multiple myeloma is ongoing.
  - Enrollment of patients receiving biweekly dosing was closed in March 2020 following clinical pharmacology evaluation in 29 subjects.
  - Enrollment of patients receiving a weekly dosing regimen is ongoing.
  - Number of sites participating in the study was recently expanded to enhance enrollment. New locations in the US were added and a clinical trial application has been approved in France.
- 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 anti-myeloma activity of ISB 1342 according to the International Myeloma Working Group response criteria (Part 2 dose expansion).
- Preclinical data on ISB 1342 were presented at the 2021 ASCO Annual Meeting and EHA 2021 Virtual Congress.
- Orphan Drug Designation for multiple myeloma was granted by the FDA in September 2019.
- The bulk drug substance is manufactured at the site in La Chaux-de-Fonds, Switzerland.

ISB 1442 (CD38 X CD47 BISPECIFIC ANTIBODY)

- This first-in-class CD38 x CD47 biparatopic bispecific antibody was generated using the BEAT® 2.0 technology developed 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-SIRPα axis to increase antibody-dependent cellular phagocytosis (ADCP) and enhance antibody-dependent cellular cytotoxicity through CDC and ADCC, enabled by the architecture and engineered Fc of the molecules.
- IND-enabling studies are proceeding, and a Phase 1/2 first-in-human dose-finding study of ISB 1442 in relapsed/refractory multiple myeloma is currently planned to start in 2022.
- The bulk drug substance will be manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland.

ICHNOS TO OUT-LICENSE ASSETS IN AUTOIMMUNE DISEASE

MOLECULE MECHANISM/CLASS	POTENTIAL INDICATIONS	PHASE	STATUS
ISB 830 Telazorlimab OX40 Antagonist Antibody	Atopic Dermatitis	Phase 2b	Achieved the primary endpoint of EASI[2] score, % change from baseline to Week 16, at the two highest doses tested (300 mg and 600 mg q 2 weeks) versus placebo. Numerical improvements were also seen at the two higher dose arms of telazorlimab for the secondary endpoints of EASI-75[3] and Investigator Global Assessment[4] as compared to placebo, but most of these differences were not statistically significant.
	Other autoimmune diseases, including Rheumatoid Arthritis	US IND for RA and other autoimmune indications is active.	
ISB 880 IL-1RAP Antagonist Monoclonal Antibody	Autoimmune Diseases	Pre-clinical	IND-enabling studies are ongoing and IND filing is on track to be completed by end of calendar year 2021.

AUTOIMMUNE DISEASE

ISB 830 (TELAZORLIMAB, OX40 ANTAGONIST)

- The double-blind portion of a two-part, randomized, controlled, multicenter, Phase 2b clinical trial, assessing four doses and two dosing schedules of telazorlimab versus placebo in adults with moderate-to-severe atopic dermatitis (AD), has been completed. An open-label extension is ongoing across study sites in the US, Canada, Germany, Czech Republic, and Poland.
- Results from the double-blind portion of the study are summarized below.
  - **Efficacy:** The primary endpoint of EASI score, % change from baseline to Week 16, was achieved for the two highest doses of telazorlimab tested (300 mg and 600 mg q 2 weeks) versus placebo. Numerical improvements were also seen for the two higher dose arms of telazorlimab compared to placebo in the secondary endpoints of EASI-75 and Investigator Global Assessment, but most of the differences were not statistically significant.

[2] EASI: Eczema Area and Severity Index
[3] Proportion of patients with ≥75% improvement in EASI score from baseline to Week 16
[4] Proportion of patients with Investigator Global Assessment of clear or almost clear (0 or 1) and ≥2-point reduction from baseline at Week 16

	PART 1				PART 2	
	TELAZORLIMAB 300 MG Q2W (n=76*)	TELAZORLIMAB 300 MG Q4W (n=78*)	TELAZORLIMAB 75 MG Q4W (n=77*)	PLACEBO (n=80*)	TELAZORLIMAB 600 MG Q2W (n=75*)	PLACEBO (n=74*)
EASI Score % Change from Baseline to Week 16 Mean (SD)	-57.59 (36.20)	-56.73 (32.54)	-38.10 (39.69)	-42.14 (38.19)	-59.74 (27.12)	-43.25 (41.24)
P-value	0.008	0.061	0.691	n/a	0.008	n/a

Q2W, every 2 weeks; Q4W, every 4 weeks; n/a, not applicable

*Includes subjects who were randomized and dosed. Subjects who received rescue medication for atopic dermatitis during the study are considered non-responders in the efficacy analyses.

  - **Safety:** Telazorlimab was well tolerated. The most commonly reported adverse events (>5%) were: atopic dermatitis, nasopharyngitis, upper respiratory tract 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.

- In addition to data from the 16-week primary analysis period, preliminary results from the open-label extension and ongoing follow-up period of this study are available and were recently presented at the 2021 Society for Investigative Dermatology Virtual Meeting and are accessible here. Of note:
  - Clinical efficacy continued to improve after Week 16, with maximal impact achieved several weeks later
  - Reduction in AD disease activity was maintained after discontinuation of telazorlimab, through three months of follow-up
- A US IND to conduct studies of telazorlimab in autoimmune diseases, including Rheumatoid Arthritis (RA), is active and Ichnos plans to out-license this asset for further development.

ISB 880 (IL-1RAP ANTAGONIST)

- ISB 880, a fully human, high-affinity, monoclonal antibody blocking IL-1RAP signalling, is in the IND-enabling phase 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 are expected to enable IND filing by end of calendar year 2021.
- 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.
- To date there is no IL-1RAP antagonist approved or under clinical development for autoimmune disease, positioning ISB 880 as a potential first-in-class therapeutic.