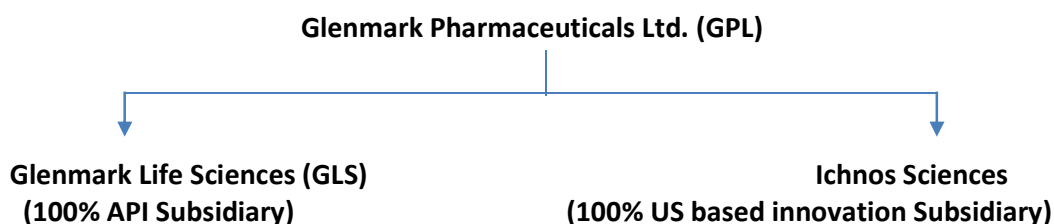


## Management Discussion & Analysis for the Third Quarter of FY 2020-21

Glenmark has reorganised its businesses into three separate entities.



Each of these three entities are operating independently with separate Management Teams and Board of Directors. We have provided an update on each of these entities separately.

### Revenue Figures for the Consolidated Glenmark Pharmaceuticals Ltd.

*(Rs. In Millions)*

	Third quarter ended December 31			Nine months ended December 31		
	FY 2020-21	FY 2019-20	Growth (%)	FY 2020-21	FY 2019-20	Growth (%)
<b>India</b>	<b>8,821.19</b>	7,888.39	11.82%	<b>27,127.05</b>	24,374.14	11.29%
<b>North America</b>	<b>7,803.87</b>	7,998.28	-2.43%	<b>22,752.06</b>	23,785.46	-4.34%
<b>Rest of the World (ROW)</b>	<b>3,360.37</b>	3,413.74	-1.56%	<b>9,286.42</b>	9,488.97	-2.13%
<b>Europe</b>	<b>3,133.29</b>	3,089.36	1.42%	<b>9,053.30</b>	8,368.80	8.18%
<b>Latin America</b>	<b>1,285.65</b>	1,563.18	-17.75%	<b>2,927.17</b>	3,586.84	-18.39%
<b>API</b>	<b>3,200.70</b>	2,621.56	22.09%	<b>8,762.35</b>	7,625.38	14.91%
<b>Total</b>	<b>27,605.07</b>	26,574.51	3.88%	<b>79,908.35</b>	77,229.59	3.47%
<b>Other Revenue</b>	<b>262.56</b>	781.11	-66.39%	<b>931.94</b>	1,505.21	-38.09%
<b>Consolidated Revenue</b>	<b>27,867.63</b>	27,355.62	1.87%	<b>80,840.29</b>	78,734.80	2.67%

Average conversion rate in 9M FY 2020-21 considered as **INR 74.40/USD 1.00**

Average conversion rate in 9MFY 2019-20 considered as INR 70.25/USD 1.00

USD figures are only indicative

## **Review of Operations for the quarter ended December 31, 2020**

For the third quarter of FY 2020-21, Glenmark's consolidated revenue was at Rs. 27,867.63 Mn. (USD 378.08 Mn.) as against Rs. 27,355.62 Mn. (USD 385.64 Mn.) recording an increase of 1.87 %.

For the third quarter of FY 2020-21, Glenmark's consolidated sales (excluding other revenue) was at Rs. 27,605.07 Mn. (USD 374.50 Mn.) as against Rs. 26,574.51 Mn. (USD 374.57 Mn.) recording an increase of 3.88 %.

For the nine months ended December 31, 2020, Glenmark's consolidated revenue was at Rs.80,840.29 Mn. (USD 1,086.54 Mn.) as against Rs. 78,734.80 Mn. (USD 1,120.78 Mn.) recording an increase of 2.67 %.

Glenmark issued U.S.\$ 200,000,000, 4.5% Senior Notes on 1 August 2016 maturing on 2 August 2021. These Senior Notes were redeemable (all or part of the notes) at the option of the company at any time on or after 2 August 2019 by paying the redemption price, subject to fulfilment of certain conditions. The Senior Notes were listed on the Singapore stock exchange. The organisation tied up a syndicated loan to refinance the Senior Notes. In Dec 2020 and Jan 2021, the company elected to redeem the entire principal amount of the Senior Notes under optional redemption. The company paid a redemption premium of 101.125% as well as accrued & unpaid interest and the notes were delisted.

## **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 Third Quarter of FY 2020-21 was at Rs. 8,821.19 Mn. (USD 119.78 Mn.) as against Rs. 7,888.39 Mn. (USD 111.08Mn.) in the previous corresponding quarter, recording growth of 11.82 %.

The India business continues to significantly outperform industry growth rates, continuing the trend of the past several years. As per IQVIA data, Glenmark remains the second fastest growing company in the industry among the Top 20 players on a MAT Dec 2020 basis with growth of 15.8% as compared to IPM (Indian Pharma market) growth of 6.12% . On a quarterly basis, as per IQVIA, the business recorded growth of 15.11% as compared to 9.75% for the market.

In terms of market share, Glenmark's India business further strengthened its position in its core therapy areas such as Cardiac, Diabetes and Respiratory. As per IQVIA MAT Dec 2020, the Cardiac segment market share increased from 4.68% to 4.72%; the Respiratory segment market share rose from 5.03 % to 5.07 %; the Anti-diabetic segment market share increased from 1.71% to 1.86%; the

Antiviral segment market share has increased to 18.5 %; and the Derma segment market share changed from 8.92% to 8.66%. Glenmark is ranked 2<sup>nd</sup> in the overall Dermatology market, 4<sup>th</sup> in the overall Respiratory market and 6<sup>th</sup> in the cardiology market in India. As per IQVIA data, the overall favipiravir market has seen a significant decline in this quarter as compared to the previous quarter. Thus the revenue for FabiFlu in the third quarter dropped substantially as compared to the second quarter.

Glenmark's novel, patent protected and globally-researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin etabonate (Remogliflozin) indicated for the treatment of Type 2 diabetes in adults continues to do well in India. Glenmark is the first company in the world to launch Remogliflozin and the response from KOLs has been positive. As per IQVIA Dec 2020 data, Glenmark's Remogliflozin ranks first in terms of prescription with Rx share of 22.8 % and fifth in terms of value with a market share of 6.50 %.

Further Glenmark became the first company to launch Remogliflozin + Vildagliptin fixed dose combination, at an affordable price for adults with Type 2 Diabetes in India. The FDC is marketed under two brand names Remo V and Remozen V. With this launch, the company aims to increase patient access to SGLT2 inhibitors & DPP4 inhibitors which have proven benefits in the effective management of diabetes. Glenmark's Remo V and Remozen V is priced around 65% lower than the other available SGLT2 & DPP4 combination brands in India.

## **India – Glenmark Consumer Care Business**

Glenmark's Consumer Care business continued to perform well in the third quarter of the financial year. Despite the challenging economic environment especially in discretionary consumption categories, the GCC business recorded value sales of Rs. 265.7 mn in the third quarter registering growth of 29% (excluding VWash sales). Candid Powder continues to drive growth for this category recording value sales growth in excess of 30 % for the quarter. The other major brand of the consumer business Scalpe Plus also recorded growth in excess of 25 % for the quarter. The strategic media investment and trade activities conducted for these brands resulted in better sales traction and saliency for the brands.

## **North America**

Glenmark Pharmaceuticals Inc., USA registered revenue from sale of finished dosage formulations of Rs.7,803.87 Mn. (USD 105.88 Mn.) for the quarter ended Dec 31, 2020 as against revenue of Rs.7,998.28 Mn. (USD 112.70 Mn.) for the previous corresponding quarter, recording decline in revenue by (2.43%). However, the business recorded quarter on quarter growth of 4.4 % in USD terms. The North America business registered sales of USD 101.42 mn in the second quarter of this financial year.

In the third quarter of fiscal year 2020-21, Glenmark received final approval and launched Sirolimus Tablets and Tacrolimus Capsules, USP. Additionally, final approval was received for Dimethyl

Fumarate Delayed-Release Capsules and Tadalafil Tablets, USP; and tentative approvals were received for Apremilast Tablets, Axitinib Tablets, Dabigatran Etxilate Capsules and Gabapentin Enacarbil Extended-Release Tablets. The Company is on track to file in excess of 15 ANDAs in this financial year.

Glenmark recently received final approval from the USFDA for Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg, the generic version of Qudexy®1 XR Capsules, of Upsher-Smith Laboratories, LLC. According to IQVIA sales data for the 12 month period ending December 2020, the Qudexy® XR Capsules, achieved annual sales of approximately \$120.8 million. Glenmark has launched the product and as on date remains the sole generic in the market.

Glenmark's marketing portfolio through December 31, 2020 consists of 167 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 22 are Paragraph IV applications.

## **Africa, Asia and CIS Region (ROW)**

For the third quarter of FY 2020-21, revenue from Africa, Asia and CIS region was at Rs.3,360.37 Mn. (USD 45.56Mn.) as against Rs. 3,413.74 Mn. (USD 48.15Mn.) for the previous corresponding quarter, recording decline in revenue of (1.56%).

As per IQVIA MAT December'20 data, Glenmark Russia recorded value growth of 3.5 % vis-a-vis overall retail market growth of 10 %. In terms of units the subsidiary witnessed sales decline 2.6 % as compared to overall retail market growth of 0.7 % in units. While Glenmark Russia ranks 51 in the market, it is ranked 11th in the dermatology segment and 3rd in the expectorants segment.

Further the Russian subsidiary entered into a definitive agreement with Dr. Reddy's Laboratories Ltd. to divest its brand Momat Rino (for Russia, Kazakhstan and Uzbekistan), Momat Rino Advance (for Russia), Momat A (for Kazakhstan and Uzbekistan), Glenspray and Glenspray Active (for Ukraine), along with rights to the trademarks, dossiers and patents for the territories mentioned. The divested brand and its extensions represent two types of products, (a) Mometasone mono product and (b) combination of Mometasone with Azelastine, and are indicated for the treatment of Seasonal and Perennial Allergic Rhinitis. This divestment is in line with our strategy to launch Ryaltris, our global anti-allergy brand, in markets of Russia and other CIS countries. We look forward to strengthening our respiratory franchise in Russia/CIS region.

The challenging conditions continued to persist across CIS markets. As per Morion MAT Dec 2020 data, Glenmark Ukraine sales declined by 9.3 %.

The Asian markets continued to remain under pressure due to the lockdown on account of the pandemic. The Philippines and Malaysian unit continued to struggle with decline in secondary sales that was reported for the quarter.

For the quarter, the Middle East and Africa region recorded growth as number of markets witnessed signs of recovery due to the easing of lockdown measures. Secondary sales growth for the region was in excess of 20 %. The growth across major MEA markets including Kenya and South Africa units was positive.

## Europe

Glenmark Europe's operations revenue for the third quarter of FY 2020-21 was at Rs.3,133.29 Mn. (USD 42.51 Mn.) as against Rs. 3,089.36 Mn. (USD 43.59 Mn) recording growth of 1.42%.

Glenmark's European business remained weak in the third quarter mainly impacted by the enhanced lockdown measures due to heightened pandemic concerns in most key markets. This resulted in sales decline recorded in both the Central Eastern European region and the Western European region. Glenmark continues to increase penetration across major markets in Western Europe. For the financial year, the European region signed 12 major contracts for in-licensing products from various companies across its operating markets in the region. The Czech and Slovak subsidiaries launched three products during the quarter. The German subsidiary launched two products and the Spain unit launched one product during the third quarter

## Latin America

Glenmark's revenue from its Latin American & Caribbean operations was at Rs. 1,285.65 Mn. (USD 17.39 Mn.) for the third quarter of FY 2020-21 as against Rs. 1,563.18 Mn. (USD 22.10 Mn.), recording revenue decline of 17.75 %. The pandemic continues to impact the Brazilian business and the unit once again recorded decline in sales for the quarter as compared to the previous corresponding quarter. The Mexico subsidiary performed relatively better recording sales growth for the quarter. The entire region continues to witness a challenging environment on account of the pandemic.

## 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.

During the quarter, Glenmark and Menarini entering into an Exclusive Licensing Agreement for commercializing Ryaltris™ Nasal Spray across numerous markets throughout Europe. The licensing agreement will be effective in 33 countries throughout the European region including France, Italy, and Spain. Under the terms of the agreement, Glenmark will be responsible for the development and regulatory approval of Ryaltris™ by relevant European Regulatory Authorities, while Menarini Group will be responsible for the commercialization of Ryaltris™ across these markets.

Ryaltris sales continues to progress well in Australia, after the successful launch earlier in this financial year by Glenmark's partner, Seqirus Pty. Ltd. During the second quarter, Ryaltris® was launched in South Africa. Glenmark is planning to initiate the commercial launch in Ukraine and Uzbekistan in the fourth quarter of this financial year. The company is awaiting regulatory approvals for its filings in various markets across Europe, Canada, Russia, Brazil, Malaysia, Saudi Arabia and several other emerging markets.

During the quarter, Glenmark's partner in China, Grand Pharmaceutical (China) Co. Ltd., received feedback from the CDE on the Pre-IND meeting application outlining the development and registration strategy for Ryaltris™ in China. IND submission in China is targeted for mid-2020. Also, a paediatric efficacy supplement was submitted to the TGA in Dec 2020. Glenmark is working with its partner in South Korea, Yuhan Corporation to submit the paediatric efficacy supplement in the fourth quarter of this financial year.

### **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 (RORyt inhibitor)**

GRC 39815 is a NCE currently being evaluated as an inhaled compound for the possible treatment of Chronic Obstructive Pulmonary Disorder (COPD). It is an inhibitor of the Retinoid-related Orphan Receptor gamma-t (RORyt). The company recently received an IND approval from the USFDA to commence a phase 1 first in human study.

### **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).**

For the third quarter of the financial year, Glenmark Life Sciences Limited registered consolidated revenue including captive sales of Rs. 5,006 Mn (USD 67.86 Mn) as against Rs. 4,092 Mn (USD 57.67 Mn), recording growth of 22.35 %. For the first nine months of the financial year, Glenmark Life Sciences consolidated revenue including captive sales was Rs. 14,185 Mn (USD 190.65 Mn) as against Rs. 11,124 Mn. (USD 158.35 Mn), recording growth of 27.52 %. The EBITDA Margin for Glenmark Life Sciences was 29.78 % for first nine months of this financial year.

For the third quarter of FY 2020-21, external sales for Glenmark Life Sciences was at Rs 3,200.70 Mn (USD 43.39 Mn) as against Rs. 2,621.56 Mn. (USD 36.95Mn.), recording growth of 22.09% over the corresponding period last year.

The external sales for the API business performed well in the third quarter recording strong growth. The India API business grew over 50 % and the Latam business grew in excess of 30 % in the third quarter. GLS continues to look for opportunities for the Favipiravir API and has already started supplying in a few countries. During the quarter, GLS submitted nine new DMFs across various operating markets. The company is looking to file at least 10 -12 DMFs in the fourth quarter of the financial year.

## **ICHNOS Sciences**

For the third quarter of the financial year, Glenmark invested Rs 1713 Mn (USD 23.3 Mn) as compared to Rs. 2,108 Mn ( USD 30.01 Mn) invested in the corresponding quarter of the previous financial year. For the first nine months of the current financial year, Glenmark has invested Rs 5693 Mn (USD 76.26 Mn) as compared to Rs 5,943 Mn ( USD 85.03 Mn) invested in the corresponding period of the previous financial year.

For further updates on the pipeline and the organisation, please log on to [www.ichnossciences.com](http://www.ichnossciences.com). The pipeline update for the third quarter of this financial year is published on this site.

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**Investor Relations Update** : We would like to inform you that Jason D'Souza would be leaving the organisation and Ravi Agrawal would now take charge of the Investor Relations function. We would like to thank Jason for his long-standing service to the company

You can reach Ravi at [Ravi.Agrawal2@glenmarkpharma.com](mailto:Ravi.Agrawal2@glenmarkpharma.com)

## **Disclaimer**

This document has been prepared by Glenmark Pharmaceuticals Ltd. The information, statements and analysis made in this document describing company's objectives, projections and estimates are forward looking statements and progressive within the meaning of applicable Security Laws and Regulations. The analysis contained herein is based on numerous assumptions. Actual results may vary from those expressed or implied depending upon economic conditions, government policies and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this presentation. This presentation should not be regarded by recipients as a substitute for the exercise of their own judgment.

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## 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 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.

	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

\*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. There was one death due to pre-existing hypertension in a patient in the telazorlimab group, considered by the investigator to be unrelated to study drug.
- A US IND to conduct studies of telazorlimab in additional autoimmune diseases, including Rheumatoid Arthritis (RA), is active and Ichnos plans to out-license this asset for further development.

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## ISB 880 (IL-1RAP ANTAGONIST)

- ISB 880 is a fully human, high-affinity, monoclonal antagonist antibody against human IL-1RAP that blocks signalling via three key disease drivers, IL1R, IL36R, and IL33R, reducing downstream inflammatory responses. ISB 880 is expected to impact diseases where multiple cytokines may concurrently play a role and, thus, has the potential to deliver superior and sustained clinical efficacy in a broad range of indications.
- A US IND in autoimmune disease indication(s) is targeted for the second half of calendar year 2021.

## **PAIN**

### ISC 17536 (TRPA1 ANTAGONIST)

- A Phase 2a proof-of-concept (PoC) study of the oral inhibitor of transient receptor potential ankyrin-1 (TRPA1), ISC 17536, was previously completed at sites in Europe and India in adult patients with painful diabetic peripheral neuropathy (DPN).
- While the primary endpoint of change from baseline to week 4 in average pain intensity was not met in the overall study population, a statistically significant reduction in this endpoint was seen for ISC 17536 compared to placebo in the prespecified subgroup of patients who had preserved small nerve fiber function at baseline.
- At a Type C meeting with FDA in March 2020, agreement was reached regarding the proposed preclinical plan that would enable a randomized, double-blind, placebo-controlled, Phase 2b, dose-range-finding study for painful DPN. A preclinical toxicology study in dogs and a formulation study in healthy volunteers have recently been completed.
- Intellectual property rights and oversight of future development of ISC 17536 are being transferred to Ichnos' parent company, Glenmark. Future out-licensing activities for the product will be conducted by Glenmark Business Development.

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**ONCOLOGY SMALL MOLECULES**

ISC XXXXX HEMATOPOIETIC PROGENITOR KINASE 1 (HPK1, MAP4K1)  
INHIBITOR

- Multiple immunogenic syngeneic models have demonstrated (in vivo) anti-tumor activity associated with HPK1 gene deletion, kinase dead HPK1, and small molecule inhibitors.
- Enhanced anti-tumor efficacy may be achieved by combining HPK1 inhibition with checkpoint inhibitors (CPIs) like anti-PD-1, anti-PD-L1, or anti-CTLA4 antibodies.
- Ichnos plans to focus on biologics for the treatment of cancer and will out-license this program prior to starting IND-enabling studies.