Management Discussion & Analysis for the Second Quarter of FY 2019-20

Revenue Figures for the Consolidated Glenmark Pharmaceuticals Ltd.

(Rs. In Millions)

	Second quarter ended September 30			Six months ended September 30		
	FY 2019-20	**FY 2018-19**	**Growth (%)**	**FY 2019-20**	**FY 2018-19**	**Growth (%)**
India	8963.56	7783.57	15.16 %	16485.75	14416.47	14.35 %
US	8478.26	8102.47	4.64%	15787.18	15139.95	4.27 %
Rest of the World (ROW)	3487.98	3051.16	14.32 %	6075.24	5505.29 %	10.35 %
Europe	2850.90	2607.76	9.32 %	5279.44	4805.63	9.86%
Latin America	1212.41	985.03	23.08 %	2023.66	1961.13	3.19 %
API	2697.81	2512.08	7.39 %	5003.82	4612.86	8.48%
Total	**27690.92**	**25042.07**	**10.58 %**	**50655.09**	**46441.33**	**9.07 %**
Other Revenue	459.48	771.25	-40.42 %	724.10	1028.16	-29.57%
Consolidated Revenue	**28150.42**	**25813.32**	**9.05 %**	**51379.20**	**47469.49**	**8.24 %**

Average conversion rate in 6M FY 2019-20 considered as INR 69.89 /USD 1.00
Average conversion rate in 6M FY 2018-19 considered as INR 68.43 /USD 1.00
USD figures are only indicative

Review of Operations for the quarter ended September 30, 2019

For the second quarter of FY 2019-20, Glenmark's consolidated revenue was at Rs. 28,150.42 Mn. (USD 400.92 Mn.) as against Rs. 25,813.32 Mn. (USD 369.96 Mn.) recording an increase of 9.05%.

For the six months ended September 30, 2019, Glenmark's consolidated revenue was at Rs. 51,379.20 Mn. (USD 735.14 Mn.) as against Rs. 47,469.49 Mn. (USD 693.72 Mn.) recording an increase of 8.24%.

GLENMARK PHARMACEUTICALS LTD. (GPL)

GPL is primarily focused on building a global Innovative/Specialty, Generics 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 second quarter of FY 2019-20 was at Rs. 8,963.56 Mn. (USD 127.65 Mn.) as against Rs. 7,783.57 Mn. (USD 111.52 Mn.) in the previous corresponding quarter, recording a growth of 15.16%.

The India business continued to outperform the industry growth; as per IQVIA Q2 FY 2019-20, Glenmark's India business recorded growth of 15.3% compared to IPM growth of 12.6%. As per IQVIA MAT September 2019, the India business recorded growth of 12.3% compared to IPM growth of 10.3%. Glenmark's India formulation business is ranked 14th, with market share of 2.19%. Glenmark has 9 brands among the 'Top 300 Brands in the IPM'.

In terms of market share, Glenmark's India business further strengthened itself in core therapy areas such as Cardiac and Respiratory. As per IQVIA MAT September 2019, the Cardiac segment market share increased from 4.40% to 4.63%; the Respiratory segment market share rose from 4.69% to ~5%; the Anti-diabetic segment market share increased from 1.64% to 1.66%; and the Derma segment market share changed from 9.11% to 9%.

In April 2019, Glenmark announced the launch of its novel, patent protected and globally-researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin etabonate (Remogliflozin) in India. Glenmark is the first Company in the world to launch Remogliflozin and the response from KOLs has been extremely positive. As per IQVIA September 2019, the sales for Remogliflozin is tracking at more than INR 3 Cr. per month. Remogliflozin is the most successfully launched SGLT2 inhibitor in the Indian market in the first few months from launch, with Glenmark attaining 5% market share in terms of value and 20% market share in terms of volume in the overall SGLT2 market in India.

In July 2019, Glenmark announced that it has entered into a non-exclusive sub-licensing agreement with Torrent Pharmaceuticals Limited to co-market Remogliflozin etabonate in India.

Glenmark received regulatory approval to market a combination of Remogliflozin and Metformin Hydrochloride (Metformin) film coated tablets in India in August 2019. The Company subsequently launched the product under the brand names 'Remo-M' and 'Remozen-M'. Glenmark is also targeting to launch further various line-extensions of Remogliflozin over the next 12 months.

Glenmark has consistently grown ahead of the overall respiratory market in India through niche product launches such as Glycopyrronium and multiple novel platforms such as Digihaler and Nebzmart. This is reflective in our performance as per IQVIA data; as of MAT September 2016, Glenmark was ranked 6th in the respiratory market in India, while as per MAT September 2019, the Company is now ranked 3rd in the market with 5% market share as per IQVIA Sep 2019. This is a significant improvement in the respiratory segment driven by differentiated product launches accompanied by innovative devices for the Indian market.

India – Glenmark Consumer Care Business

Glenmark's Consumer Care business consolidated its sales growth trajectory in Q2, despite some headwinds in the larger discretionary consumption categories. The consumer business grew at almost 20% to around Rs. 553 Mn. in the second quarter. The strong sales on brands were also reflected externally as per IQVIA. Key brands VWash & Candid Powder registered 24.2% and 22.6% respectively in the second quarter as per IQVIA data. The key brands also gained market share Q-o-Q with VWash Plus gaining 6.6% while Candid Powder gaining 2.6% in Q2 as per IQVIA. Growth remained strong across all sales channels; particularly modern trade & e-commerce continued to grow aggressively, clocking 34% growth in Q2.

USA

Glenmark Pharmaceuticals Inc., USA registered revenue from the sale of finished dosage formulations of Rs. 8,478.26 Mn. (USD 120.72 Mn.) for the quarter ended Sep 30, 2019 as against revenue of Rs. 8,102.47 Mn. (USD 116.05 Mn.) for the previous corresponding quarter, recording an increase of 4.64%.

In the second quarter of fiscal year 2019-20, Glenmark was granted final approval and launched Ranolzine Extended-Release Tablets, Pimecrolimus Cream, 1% and Clobetasol Propionate Foam, 0.05% [Emulsion Formulation]. In addition, Glenmark launched the previously approved product HAILEY® 1.5/30 [Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1.5 mg/30 mcg]. Glenmark also received approval for Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) which was its first injectable approval. In the six months of FY 2019-20, the Company has received 9 ANDA approvals including 8 final approvals and 1 tentative approval. The generic industry continues to be subdued with the overall generic topical dermatology market continuing to witness price erosion of 6-7% on a Q-o-Q basis.

The Company filed one ANDA application with the U.S. FDA, and plans to file an additional three applications in the forthcoming quarter. As of September 30, 2019 Glenmark's portfolio consists of 161 products authorized for distribution in the U.S. marketplace and 49 ANDA's pending approval with the U.S. FDA.

Glenmark has 5 U.S. FDA approved formulation manufacturing facilities (Goa, Indore, Baddi, Aurangabad and Monroe). In July 2019, the U.S. FDA inspected the manufacturing facility in Monroe, North Carolina. The inspection covered the OSD, injectable and nebulizer units and concluded with the facility receiving one observation. The Company has received the EIR for the Monroe facility. During the second quarter, the U.S. FDA also completed GMP audits at Glenmark's Goa and Indore manufacturing facilities. The inspections concluded with the Goa facility receiving two observations and the Indore facility receiving zero observations.

During the first quarter, the Company had earlier informed that the inspection conducted at Glenmark's Baddi facility was classified as ''Official Action Indicated'' vide a letter by U.S. FDA. With regards to the same inspection, U.S. FDA had issued a ''Warning Letter'' to the Baddi facility. The Company is committed to work along with U.S. FDA to implement all the necessary corrective actions required to address the concerns raised in the letter and has submitted a detailed response on the same. The Company believes that the existing manufacturing & the sale of products from this facility will not be impacted. The Baddi facility is expected to contribute USD 30 Mn. in total sales for FY 2019-20 which is approximately 7% of total sales for the US market. There are no major pending approvals from this facility in the next 12 months. There will be no financial impact on the organisation on account of this development.

Africa, Asia and CIS Region (ROW)

For the second quarter of FY 2019-20, revenue from Africa, Asia and CIS region was Rs. 3,487.98 Mn. (USD 49.70 Mn.) as against Rs. 3,051.16 Mn. (USD 43.77 Mn.) for the previous corresponding quarter, recording an increase of 14.32%.

As per IQVIA data for MAT September 2019, Glenmark Russia recorded growth of 8.7% in value vis-à-vis overall retail market growth of 5.2%; Glenmark's overall rank is 47 in Russian pharmaceutical market. As per IQVIA, Glenmark grew by 3.1% in value vis-à-vis overall market growth of 3.4% in the dermatology segment. Amongst the companies present in the expectorants market, Glenmark secures a strong position and ranks 4 as per IQVIA MAT September 2019. During the second quarter, Glenmark received approval from the Ministry of Healthcare, Russia to market Montlezir (Levocetirizine Dihydrochloride 5mg + Montelukast Sodium 10mg) film-coated tablets as a prescription product for the treatment of seasonal and perennial allergic rhinitis in patients above 15 years of age. Montlezir is expected to be available in the Russian market in Q3 FY 2019-20. Amongst other CIS markets, Glenmark Ukraine showed secondary sales growth of 46.5% in value in the second quarter of FY 2019-20. In units, Glenmark Ukraine showed growth of 33.2% compared to relevant market growth of 0.9%.

The Asia region recorded moderate performance in the second quarter of FY 2019-20, with secondary sales growth of 6%. Growth remained subdued across all major Asian markets for Glenmark. The Africa region also recorded moderate growth in the second quarter. The South Africa and the Kenya subsidiary continued to record good growth in the second quarter.

Europe

Glenmark Europe's operations revenue for the second quarter of FY 2019-20 was at Rs. 2,850.90 Mn. (USD 40.60 Mn.) as against Rs. 2,607.76 Mn. (USD 37.37 Mn.) recording an increase of 9.32%.

During the second quarter, the CEE region of Europe witnessed double-digit secondary sales growth which was higher than the total market; this was aided by new product launches as well as key tenders in markets such as Czech. The Western European business continued expanding through increased penetration of UK, Germany, Spain and NL. Growth for the second quarter in Western European markets was 11%, mainly contributed by Germany and Spain.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,212.41 Mn. (USD 17.28 Mn.) for the second quarter of FY 2019-20, as against Rs. 985.03 Mn. (USD 14.07 Mn.), recording an increase of 23.08%. The Company expanded its presence in the Brazil respiratory market through the exclusive partnership with Novartis for three respiratory brands. The launch of the three in-licensed respiratory brands from Novartis has enabled the Brazil subsidiary to record good growth in the second quarter. Growth remained subdued in other LATAM markets such as Mexico and the Caribbean.

GPL Specialty/Innovative R&D Pipeline

Ryaltris™

Ryaltris™ (olopatadine hydrochloride and mometasone furoate) Nasal Spray is the Company's respiratory pipeline asset and is currently under review with the U.S. Food and Drug Administration (FDA) as a treatment for seasonal allergic rhinitis in the USA. The Company is currently in the process of bringing in a partner to commercialize Ryaltris™ in the US market. Additionally, Glenmark is also working to close a partnership deal for Ryaltris™ for the EU markets. The Company has already completed partnership deals for Ryaltris™ in other markets such as Australia, New Zealand, South Korea and China. The Company will continue evaluating partnership opportunities in various markets and also launch the product in some of our key operating markets.

During the first quarter of FY 2019-20, the U.S. FDA issued a Complete Response Letter (CRL) pertaining to the New Drug Application(NDA) for Ryaltris. We continue to work with the agency to resolve the issues raised in the CRL.

Note: All brand names and trademarks are the property of their respective owners.

GBR 310

During FY 2018-19, Glenmark announced results from a Phase 1 study that suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between GBR 310, and the reference product, omalizumab, marketed in the US 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 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 (RORγt).
- The compound is currently in pre-clinical development and the Company plans to initiate a Phase 1 study in FY 2019-20.

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 second quarter of FY 2019-20, external sales for Glenmark Life Sciences was at Rs. 2,697.81 Mn. (USD 38.42 Mn.) as against Rs. 2,512.08 Mn. (USD 36.01 Mn.), recording growth of 7.39% over the corresponding period last year.

Domestic and ROW regions led the growth in the second quarter, with both regions recording 20+% growth over the corresponding period last year. The Company also expanded its presence in the Japanese market. GLS continued to sustain its leadership position in products like Lercanidipine, Atovaquone, Perindopril, Olmesartan, and Aprepitant. GLS is on-track to file 4-5 DMFs in the upcoming quarters and continues to register multiple products in other ROW markets.

GLS has 3 U.S. FDA approved API manufacturing facilities (Ankleshwar, Dahej and Mohol). In July 2019, the U.S. FDA and Health Canada jointly inspected the Ankleshwar manufacturing facility of GLS. Subsequently the U.S. FDA has issued the EIR for the facility and Health Canada has rated the facility as “Compliant”. During August 2019, the PMDA of Japan also conducted an audit of the Ankleshwar manufacturing site; no major/critical observations were reported. Response to the minor observation has been submitted and approval for the facility is awaited.

ICHNOS Sciences

As part of its strategy to create a leading and cutting edge biotech organisation, Glenmark announced the spin-off of its innovation business into a new company headquartered in the US. Setting up this new company would provide enhanced focus to the business and help accelerate the pipeline towards commercialization. In October 2019, the new innovation company was launched as Ichnos (‘īk-nōz) Sciences. A spin-off of Glenmark Holding SA, with a track-record of improving patients’ lives by providing affordable medicines, the newly formed company was first approved in principle by the Glenmark Board of Directors in February 2019 and now operates with its own Board of Directors and executive team. Former Gilead executive, Alessandro Riva, MD, is CEO of Ichnos Sciences. The innovation pipeline of Ichnos will include five novel, first-in-class clinical-stage assets in oncology, autoimmune disease and pain. The assets will also include BEAT® (Bispecific Engagement by Antibodies based on the T cell receptor), a proprietary

platform; a development site, two research centers; a GMP biologics manufacturing facility and ~350 employees worldwide.

During the first quarter of FY 2019-20, Glenmark invested Rs. 1,900 Mn. (USD 27.34 Mn.) in innovation business. For the second quarter of the financial year, Glenmark has invested Rs 1,935 (USD 27.68 Mn.) totalling to Rs. 3,835 Mn. (USD 55.02 Mn.) for the first half of this financial year. During the financial year 2018-19, Glenmark invested approximately USD 113 Mn. in the innovation business and the Company expects to invest a similar amount in FY 2019-20. Ichnos Sciences would initiate the process to raise capital in the US starting Q4 FY 2019-20 to fund the development of its pipeline and for future growth plans.

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

Disclaimer

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