

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

Revenue Figures for the Consolidated Glenmark Pharmaceuticals Ltd.

(Rs. In Millions)

	First quarter ended June 30		
	FY 2019-20	FY 2018-19	Growth
India	7,522.19	6,632.90	13.41%
US	7,308.93	7,037.48	3.86%
Rest of World (ROW)	2,587.27	2,454.14	5.43%
Europe	2,428.54	2,197.86	10.50%
Latin America	811.24	976.11	-16.89%
API	2,306.01	2,100.78	9.77%
Total	22,964.18	21,399.26	7.31%
Other Revenue	264.61	256.92	3.00%
Consolidated Revenue	23,228.79	21,656.17	7.26%

Average conversion rate in 3M FY 2019-20 considered as INR 69.50/USD 1.00

Average conversion rate in 3M FY 2018-19 considered as INR 66.89/USD 1.00

USD figures are only indicative

Review of Operations for the quarter ended June 30, 2019

For the first quarter of FY 2019-20, Glenmark's consolidated revenue was at Rs. 23,228.79 Mn (USD 334.22 Mn) as against Rs. 21,656.17 Mn (USD 323.76 Mn) recording an increase of 7.26%.

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 2019-20 was at Rs. 7,522.19 Mn (USD 108.23 Mn) as against Rs. 6,632.90 Mn (USD 99.16 Mn) in the previous corresponding quarter, recording a growth of 13.41%.

The India business continued to outperform the industry growth; as per IQVIA Q1 FY 2019-20, Glenmark's India business recorded growth of ~12% compared to IPM growth of ~10%. As per IQVIA MAT June 2019, Glenmark's India formulation business is ranked 14th, with market share of 2.18%. Glenmark now 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 June 2019, the Cardiac segment market share increased from 4.34% to 4.57%; the Respiratory segment market share rose from 4.78% to 4.81%; the Anti-diabetic segment market share changed from 1.66% to 1.62%; and the Derma segment market share changed from 9.19% to 9.07%.

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. The response from KOLs has been extremely positive, which has resulted in this being one of the most successful product launches for the India business. As per IQVIA June 2019, the sales for Remogliflozin is already tracking ~INR 2 cr per month, in less than 2 months from launch.

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 is also targeting to close one more co-marketing deal for Remogliflozin in the second quarter. The Company is also developing various line-extensions for Remogliflozin which would be launched over the next 12 months.

India – Glenmark Consumer Care Business

Glenmark's consumer care business continued its strong growth trajectory in Q1 FY 2019-20. The consumer business grew around 27% to record sales of Rs. 556.30 Mn in the first quarter. Multiple line-extensions were launched in the first quarter of FY 2019-20, such as VWash Bikini Line & Scalpe Pro Anti-Dandruff shampoo. The business growth was observed in all retail channels across chemists, modern trade & e-commerce.

In the first quarter, the consumer care business recorded high growth on Candid Powder as well as on VWash. As per IQVIA, Candid Powder clocked Rs. 100 Mn sales in a single month in June 2019. Overall, Candid Powder recorded growth of 17% while VWash recorded growth of 23% as per IQVIA. Both these brands continue to hold a dominant market share in their respective covered markets; as per IQVIA, Candid Powder recorded 1.2% share gain and VWash recorded 4.4% share gain in Q1 FY 2019-20.

USA

Glenmark Pharmaceuticals Inc., USA registered revenue from the sale of finished dosage formulations of Rs. 7,308.93 Mn (USD 105.16 Mn) for the quarter ended June 30, 2019 as against revenue of Rs. 7,037.48 Mn (USD 105.21 Mn) for the previous corresponding quarter, recording an increase of 3.86%.

Generics Business:

In the first quarter of FY 2019-20, Glenmark was granted final approval and launched Solifenacin Succinate Tablets. The Company also obtained three additional approvals during the first quarter: Esomeprazole Magnesium Delayed-Release Capsules USP, Aspirin and Extended-Release Dipyridamole Capsules, and Ezetimibe and Simvastatin Tablets. During the first quarter, Glenmark launched the previously approved products Clobetasol Propionate Foam, 0.05% and Clindamycin and Benzoyl Peroxide Gel, 1%|5%. As part of a distribution agreement with Elite Laboratories, Glenmark also launched Isradipine Capsules.

Even though the Company has normalized supplies of Mupirocin cream, the product sales have been impacted due to changes in the reimbursement environment and higher patient co-pay for Mupirocin cream, which is reflecting in the increasing share of prescriptions for Mupirocin ointment as against Mupirocin cream. As per IQVIA, in June 2018, total prescriptions for Mupirocin ointment were 8,51,865 (94%) and total prescriptions for Mupirocin cream were 56,490 (6%); in June 2019, total prescriptions for Mupirocin ointment were 8,79,978 (97%) and total prescriptions for Mupirocin cream were 31,068 (3%). The overall generic topical dermatology market also continues to witness significant price erosion for the third consecutive quarter. Despite the decline of Mupirocin cream, the Company witnessed flat growth in Q1.

The Company anticipates two significant generic approvals (a limited competition injectable product and a topical product with CGT designation) in the second quarter of FY 2019-20 which would provide impetus to the US generics business. The Company filed three ANDA applications with the U.S. FDA in the first quarter, and plans to file an additional four applications in the forthcoming quarter.

Glenmark's marketing portfolio through June 30, 2019 consists of 157 generic products authorized for distribution in the U.S. market. The Company currently has 58 applications pending in various stages of the approval process with the US FDA, of which 32 are Paragraph IV applications.

Glenmark has 5 US FDA approved formulation manufacturing facilities (Goa, Indore, Baddi, Aurangabad and Monroe). In July 2019, the US 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 will respond to the observation as per the regulatory timelines. Since this inspection was also a pre-approval inspection (PAI), it is expected to facilitate the approval of Glenmark's first in-house injectable product in the fourth quarter of FY 2019-20.

The Company has received a letter from the US FDA classifying the inspection conducted at its Baddi facility from 15th to 20th April 2019 as Official Action Indicated (OAI). The Company has responded in detail to all the observations made in the Form 483 and is awaiting further information and clarity from the US FDA. The Company is committed to implement the necessary corrective actions required to address the procedural deficiencies raised by the US FDA and will resolve them as soon as possible. The manufacturing and sale of existing products from this facility will not be impacted. Glenmark has no other outstanding observations of the US FDA at any of its other formulation manufacturing facilities.

Specialty Business: Glenmark Therapeutics Inc., USA (GTI)

Dermatology

In FY 2018-19, Glenmark announced its foray into the branded dermatology segment in the US when GTI acquired rights to seven branded dermatology products from Exeltis USA, Inc. During the first quarter of FY 2019-20, the sales from this franchise has been insignificant and the response from the market has been far below expectations.

Ryaltris™

Ryaltris™ (olopatadine hydrochloride and mometasone furoate) Nasal Spray is the company's leading 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 close to concluding 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, the U.S. FDA issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for Ryaltris™. The CRL cited deficiencies in the Drug Master File (DMF) pertaining to one of the active pharmaceutical ingredients (APIs) and in the manufacturing

facilities. The CRL did not specify any deficiencies with the clinical data supporting the NDA for Ryaltris™. The Company is targeting to resolve the issues pertaining to the CRL in the next 6 to 9 months by working closely with the FDA and will continue to pursue regulatory approval for Ryaltris™.

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

Africa, Asia and CIS Region (ROW)

For the first quarter of FY 2019-20, revenue from Africa, Asia and CIS region was Rs. 2,587.27 Mn (USD 37.23 Mn) as against Rs. 2,454.14 Mn (USD 36.69 Mn) for the previous corresponding quarter, recording an increase of 5.43%.

As per IQVIA data for MAT June 2019, Glenmark Russia recorded growth of 7.2% in value vis-à-vis overall retail market growth of 3.8%; Glenmark's overall rank is 46 in Russian pharmaceutical market. As per IQVIA, Glenmark grew by 5.1% in value vis-à-vis overall market growth of 2.1% in the dermatology segment. Glenmark retains its position amongst the top-10 companies in the dermatology segment in Russia. Amongst the companies present in the expectorants market, Glenmark secures a strong position and ranks 4 as per IQVIA MAT June 2019. Launch of Momate Rhino OTC has helped to further strengthen Glenmark's respiratory franchise in the Russian market.

Amongst other CIS markets, Glenmark Ukraine showed secondary sales growth of 44% in value in the first quarter of FY 2019-20. In units, Glenmark Ukraine showed growth of 34.4% compared to relevant market growth of 2.2%. The other CIS subsidiaries recorded a moderate performance during the quarter.

The Asia region recorded moderate performance in the first quarter of FY 2019-20, with secondary sales growth of -3%. In spite of the Philippines recording double-digit secondary sales growth, the regional performance was affected due to relatively weak performance in Malaysia, Sri Lanka and Myanmar. The Africa region also recorded moderate growth in the first quarter, and witnessed new product launches in markets such as Kenya and Egypt.

Europe

Glenmark Europe's operations revenue for the first quarter of FY 2019-20 was at Rs. 2,428.54 Mn (USD 34.94 Mn) as against Rs. 2,197.86 Mn (USD 32.86 Mn) recording an increase of 10.50%.

During the first quarter, the western European business continued expanding through increased penetration in the UK, Germany, Spain and NL while Nordic countries witnessed some de-growth. Overall the western European business recorded a growth of 10%. The central and eastern European business recorded moderate growth in the first quarter. During the first quarter, multiple new products were launched across all major countries of the Europe region. The Company also signed two in-licensing agreements during the first quarter.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 811.24 Mn (USD 11.67 Mn) for the first quarter of FY 2019-20, as against Rs. 976.11 Mn (USD 14.59 Mn), recording a decrease of -16.89%. The Company's overall performance remained subdued for the region in the first quarter.

In June 2019, Glenmark announced that its Brazilian subsidiary has entered into an exclusive partnership agreement with Novartis AG, for three respiratory products indicated towards treatment of the symptoms of chronic obstructive pulmonary disease (COPD) in Brazil. The products involved in the agreement are Seebri® (Glycopyrronium bromide), Onbrize® (Indacaterol) and Ultibro® (combination of Indacaterol and Glycopyrronium). Under the terms of the agreement, Novartis remains the holder of the registration of these medicines and will be responsible for manufacture and supply. Glenmark will be responsible for exclusively promoting, commercializing and distributing of these products in Brazil. This deal is expected to strengthen Glenmark's respiratory franchise and further consolidate the Company's position in this segment in Brazil.

GPL Specialty/Innovative R&D Pipeline

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 active discussions with potential partners and is targeting to conclude a deal before initiating Phase 3 studies.

GSP 304

- GSP 304 is a long-acting muscarinic antagonist administered by nebulization being studied for the long term, once-daily, maintenance treatment of bronchospasm associated with COPD.
- The GSP 304 program is ongoing and is currently in Phase 2 for patients with mild to moderate COPD as established by the Global Initiative for Chronic Obstructive Lung Disease.

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 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 first quarter of FY 2019-20, external sales for Glenmark Life Sciences was at Rs. 2,306.01 Mn (USD 33.18 Mn) as against Rs. 2,100.78 Mn (USD 31.41 Mn), recording growth of 9.77% over the corresponding period last year.

Domestic and LATAM regions led the growth in the first quarter, with both regions recording 20+% growth over the corresponding period last year. GLS' top-10 APIs contributed to 55% of the total sales and GLS continued to sustain its leadership position in products like Lercanidipine, Atovaquone, Perindopril, Olmesartan, and Aprepitant. During the first quarter, GLS filed 1 DMF each in the US (Atomoxetine) and Canada (Mirabegron). In addition, GLS also filed several products in key ROW markets including China.

GLS has 3 US FDA approved API manufacturing facilities (Ankleshwar, Dahej and Mohol). In July 2019, the US FDA and Health Canada jointly inspected the Ankleshwar manufacturing facility of GLS. Subsequently the US FDA issued a Form-483 with 4 observations. GLS has responded to the observations within the specified time period.

INNOVATION NEW COMPANY (NewCo)

NewCo is focused on discovery and development of novel, first-in-class treatments in the therapeutic areas of Immunology, Oncology and Pain. The NewCo has strong capabilities both in new biological entities (NBE) as well as new chemical entities (NCE).

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. The new innovation company will be a wholly-owned subsidiary of Glenmark.

The subsidiary creation process is on track with various work streams such as HR, Finance/Legal, Branding, and IT systems transition currently under progress. The Company expects to announce the name of the new innovation organization by mid-October 2019. During this period, NewCo would also announce the strategic blueprint for the new innovation organization with the objective of becoming a leading, cutting-edge biotech company in the near future. NewCo has also instituted an independent board of directors which would govern the functioning of the new innovation organization.

During the first quarter of FY 2019-20, Glenmark invested INR 1,900 Mn (USD 27.34 Mn) in the NewCo innovation business. 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 for NewCo. NewCo 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.

Quarterly Highlights: Innovation Assets

NewCo’s current innovation pipeline consists of 6 assets, including new chemical entities (NCEs) and new biological entities (NBEs), in various stages of development in the areas of immunology, oncology and pain management.

Amongst the 5 assets in clinical development, 2 assets are currently in Phase 2b studies (GBR 830 and GRC 27864), 1 asset is gathering data in anticipation of entering Phase 2b (GRC 17536), and 2 oncology assets are in Phase 1a/1b. The remaining asset (GRC 5xxxx) is currently in pre-clinical development. Of the 6 assets, 2 assets have shown positive clinical proof-of-concept (GBR 830 and GRC 17536).

Update on Clinical Pipeline

Clinical Asset	Therapy	MoA/Class	Potential Indication	Current Stage	Expected Data Readout	Comments
GBR 830	Immunology	OX40 Antagonist	Atopic Dermatitis	Phase 2b ongoing	H1 CY 2020	225 ⁱ /312 patients enrolled
			Systemic Lupus Erythematosus	Phase 2b/3 to be initiated	H2 CY 2021	Initiating trial in CY 2020
GRC 27864	Pain	mPGES-1 Inhibitor	Osteoarthritic Pain	Phase 2b ongoing	Q1 CY 2020	519 ⁱ /624 patients enrolled
GRC 17536		TRPA1 Antagonist	Painful Diabetic Neuropathy	Phase 2a completed	--	Initiating Phase 2b in CY 2020
GBR 1302	Oncology	HER2xCD3	Breast Cancer	Phase 1a/1b ongoing	H1 CY 2021	Initiating weekly dosing
GBR 1342		CD38xCD3	Multiple Myeloma	Phase 1a/1b ongoing	H2 CY 2022	Initiating weekly dosing

Note: GBR – biologics; GRC – chemical entities

Update on Pre-clinical Pipeline

Pre-clinical Asset	Therapy	MoA/Class	Potential Indication	Comments
GRC 5xxxx	Oncology	MAP4K1 Inhibitor	TBD	Initiate Phase 1 in H2 CY 2020

NewCo will continue to leverage its capabilities in NBEs and NCEs, particularly through the BEAT® (Bispecific Engagement by Antibodies based on the T cell receptor) platform and is planning to bring additional biological and small molecule clinical candidates in CY 2021 and CY 2022.

Immunology

GBR 830 (OX40 antagonist)

- A Phase 2b study of GBR 830 has been initiated and will enrol 312 adult patients with moderate-to-severe atopic dermatitis (AD). As of July 2019, 225 patients have been recruited with 80 sites actively open to enrol patients in the US, Canada, Germany, Czech Republic and Poland. Of the 225 enrolled patients, 71 subjects have completed the 16-week treatment period and 60 subjects have rolled over in to a 52-week Open Label Extension (OLE) study.
- Top-line results of the Phase 2b study in AD are expected to be available in H1 CY 2020.
- Abstract to the 2019 American College of Rheumatology (ACR) submitted showing that GBR 830 is a suitable drug candidate for treatment of systemic lupus erythematosus (SLE). Initiation of Phase 2b/3 study in patients with SLE is expected in CY 2020.
- In addition, evaluation of GBR 830 for the treatment of multiple immunology indications such as Rheumatoid Arthritis (RA), systemic sclerosis/scleroderma (SSc), Hidradenitis Suppurativa (HS), Lupus Nephritis (LN), Ulcerative Colitis (UC), is ongoing.

Pain Management

GRC 27864 (mPGES-1 inhibitor)

- GRC 27864 is a non-opioid, selective, and orally bioavailable inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1). Enrolment for a Phase 2b study in 624 patients with osteoarthritic pain of the knee and hip, is progressing as per plan with 47 active sites and 519 patients recruited for the study as of July 2019.
- Top-line results of the Phase 2b study are expected to be available in Q1 CY 2020

GRC 17536 (TRPA1 antagonist)

- A positive Phase 2a proof of concept study of GRC 17536 conducted in Europe and India in patients with painful diabetic neuropathy has been completed.
- The Company is targeting to initiate a Phase 2b dose range finding study in neuropathic pain in CY 2020.

Oncology

GBR 1302 (HER2xCD3 bsAb)

- The GBR 1302 Phase 1, first-in-human study with bi-weekly dosing to determine the maximum tolerated dose (MTD) in patients with HER2-positive cancers has completed enrolment as of May 2019.
- The company plans to initiate a GBR 1302 Phase 1 study to evaluate a weekly dosing regimen in H2 CY 2019.

GBR 1342 (CD38xCD3 bsAb)

- For GBR 1342, a Phase 1, first-in-human study to determine the MTD in a bi-weekly dosing regimen in patients with refractory multiple myeloma is ongoing. Cohorts 1-9 have been completed, and the study continues with the enrolment of patients into Cohort 10.
- The company has amended the current protocol to include a weekly dosing regimen in the current study and enrolment into the weekly dosing regimen is expected to begin in H2 CY 2019.

GRC 5xxxx

- The Company is developing GRC 5xxxx, a MAP4K1 inhibitor compound which has the potential to be used as a monotherapy or in combination with approved therapies to address unmet needs in cancer treatment.
- The compound is currently progressing through pre-clinical studies. The Company is targeting to initiate Phase 1 studies in H2 CY 2020.

Non-core assets include GBR 1372, GBR 500 and GRC 4039. These molecules are candidates for out-licensing.

¹As of July 25, 2019

FY 2019-20 OBJECTIVES FOR GLENMARK PHARMACEUTICALS LTD.

- Target revenue growth in the range of 10-15%
- Manpower cost as % to sales to trend lower as compared to FY 2018-19
- Conclude at least one partnership on innovative/specialty assets
- Total R&D expenditure to be lower in absolute value as compared to FY 2018-19
- Bring in a minority investor in to Glenmark Life Sciences Ltd.
- Divest other non-core global assets

Disclaimer

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