

Management Discussion and Analysis for the First quarter of FY 2018 – 19

Revenue Figures - Consolidated

(Rs. In Millions)

	First quarter ended June 30		
	FY 2018 – 19	FY 2017 – 18	Growth (%)
India	6,632.90	6,164.04	7.61%
US	7,037.48	10,450.29	-32.66%
Rest of the World (ROW)	2,454.13	2,264.63	8.37%
Europe	2,197.86	1,620.78	35.61%
Latin America	976.11	845.11	15.50%
API	2,100.78	2,047.70	2.59%
Total	21,399.25	23,392.55	-8.52%
Other Revenue	256.92	237.47	8.19%
Consolidated Revenue	21,656.17	23,630.02	-8.35%

Average conversion rate in 3M FY 2018 – 19 considered as INR 66.89/USD 1.00 Average conversion rate in 3M FY 2017 – 18 considered as INR 64.38/USD 1.00

USD figures are only indicative

^{*}The sales are not comparable to the corresponding quarter of the previous financial year as Glenmark through its partner Endo had launched Ezetimibe, generic version of ZETIA® (Merck) in the United States in December 2016 and was entitled to an exclusivity on the product



Review of Operations for the quarter ended June 30, 2018

For the first quarter ended June 30, 2018, Glenmark's consolidated revenue was at Rs. 21,656.17 Mn (USD 323.76 Mn) as against Rs. 23,630.02 Mn (USD 367.05 Mn) recording a decrease of -8.35%.

India

Sales from the formulation business in India for the first quarter ended June 30, 2018 was at Rs. 6,632.90 Mn (USD 99.16 Mn) as against Rs. 6,164.04 Mn (USD 95.74 Mn) in the previous corresponding quarter, recording a growth of 7.61%.

As per IQVIA MAT June 2018, Glenmark Pharmaceuticals is ranked 13th with a market share of 2.31%. Glenmark is the fastest growing company as per MAT June 2018 (among top 20 companies). Glenmark continues to have 8 brands among the 'Top 300 Brands in the Indian Pharmaceutical Market.'

The India business gained market share in the following segments, as per IQVIA MAT June 2017 to MAT June 2018 respectively. The Derma segment market share increased from 9.15% to 9.19%. Respiratory segment market share rose from 4.6% to 4.77%; The Cardiac segment market share increased from 4.04% to 4.35%; The Anti-diabetic segment market share changed from 1.65% to 1.66%.

Glenmark recently launched AKYNZEO®, an oral fixed dose combination of netupitant 300mg and palonosetron 0.5mg in the Indian market as a 5-day prophylaxis from both the acute and delayed phases of chemotherapy-induced nausea and vomiting (CINV). Glenmark had earlier announced an exclusive licensing agreement with Helsinn Group ("Helsinn"), a Swiss pharmaceutical group, to introduce AKYNZEO® with exclusive marketing rights in India and Nepal.

Glenmark announced that it has entered into a collaboration agreement with leading, home-grown private equity firm True North for its orthopaedic and pain management business for the India and Nepal market. Glenmark's orthopaedic and pain management business, consisting of brands such as Esoz, Bon K2, Collasmart, and Lizolid, clocked revenue of Rs. 1,558 Mn in FY 2017 – 18. Under this collaboration, Glenmark's orthopaedic and pain management business will be transferred to a new entity to-be incorporated by True North, which will market the product portfolio in India and Nepal. The transaction is expected to be completed in 2-3 months.

India – Glenmark Consumer Care Business

Glenmark's consumer care business continued its robust growth trajectory with 25% growth in the first quarter of FY 2018 – 19. As per IQVIA data for the first quarter, Glenmark's leading brand in the Consumer Healthcare business Candid Powder recorded 5.6% value growth and market share of 46.6%.

Likewise, VWash Plus brand continued to be the dominant market leader in the intimate hygiene category with a market share of 46.7% in the first quarter, a gain of 4% in market share over last year and value growth of 21.5%. Scalpe Anti Dandruff Shampoo is also



ranked no. 1 in its operating market with a market share of 25.9% and a value growth of 23.5% in the first quarter.

USA Formulations

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations of Rs. 7,037.48 Mn (USD 105.21 Mn) for the quarter ended June 30, 2018 against revenue of Rs. 10,450.29 Mn (USD 162.32 Mn) for the previous corresponding quarter, recording a decrease of -32.66%. The sales are not comparable to the corresponding quarter of the previous financial year as Glenmark through its partner Endo had launched Ezetimibe, a generic version of ZETIA® (Merck) in the United States in December 2016 and was entitled to an exclusivity on the product.

In the first quarter of FY 2018 – 19, Glenmark was granted final approval and launched Clobetasol Propionate Topical Solution USP, 0.05%, Colesevelam Hydrochloride Tablets, 625 mg and Tacrolimus Ointment, 0.1%. The company also received approvals for Clobetasol Propionate Cream USP, 0.05%, HAILEY™ 1.5/30 (Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1.5 mg/30 mcg) and HAILEY™ Fe 1.5/30 (Norethindrone Acetate and Ethinyl Estradiol Tablets USP and Ferrous Fumarate Tablets, 1.5 mg/30 mcg).

In the first quarter, Glenmark filed three ANDA's with the U.S. FDA, and plans to file three ANDA applications in the second quarter.

During the quarter, the U.S. Food & Drug Administration (FDA) provided its first supplemental Abbreviated New Drug Application (sANDA) approval for Glenmark's manufacturing facility in Monroe, North Carolina. The approval covers Atovaquone and Proguanil Hydrochloride Tablets, 250 MG/100 MG and 62.5 MG/25 MG, a generic version of GlaxoSmithKline's Malarone® (atovaquone and proguanil hydrochloride) Tablets.

The Monroe facility is Glenmark's first manufacturing site in the U.S., designed to manufacture a variety of dosage forms. Glenmark has invested more than \$100 million into the facility with plans for further expansion in the coming years. At peak capacity, the site is anticipated to produce 300-400 million tablets and capsules, 20-25 million vials and prefilled syringes and 25-30 million ampoules for inhaled formulations.

Glenmark's marketing portfolio through June 30, 2018 consists of 137 generic products authorized for distribution in the U.S. market. The Company currently has 63 applications pending in various stages of the approval process with the US FDA, of which 30 are Paragraph IV applications.

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



Africa, Asia and CIS Region (ROW)

For the first quarter, revenue from Africa, Asia and CIS (ROW) region was Rs. 2,454.13 Mn (USD 36.69 Mn) as against Rs. 2,264.63 Mn (USD 35.18 Mn) for the previous corresponding quarter, recording an increase of 8.37%.

According to IQVIA MAT June 2018 data, Glenmark's Russia business showed de-growth of -5.5% in value vs. overall market growth of 3.7%, and growth of 0.1% in units vs. overall market de-growth of -2.9%. Glenmark ranks 42 as of MAT June 2018 in the retail segment of the Russian pharmaceutical market.

As a result of the strong position of Glenmark Russia in the dermatology segment (retail), the company continues to ranks in the Top-10 of all derma companies present in the market, with MAT June 2018 rank being 10. In the respiratory space, Glenmark is ranked 4 as of MAT June 2018 amongst the companies present in the expectorants market (retail segment) of the local pharmaceutical market. Key markets across the CIS region such as Ukraine and Kazakhstan recorded high double-digit secondary sales growth for the company.

The Asia region secondary sales growth was led by key subsidiaries such as Malaysia, the Philippines and Myanmar. The Glenmark Africa region also posted strong secondary sales growth of ~50% in the first quarter aided by robust growth in most of the key markets.

Europe Formulations

Glenmark Europe's operations revenue for the first quarter FY 2018 – 19 was at Rs. 2,197.86 Mn (USD 32.86 Mn) as against Rs. 1,620.78 Mn (USD 25.18 Mn), recording an increase of 35.61%.

The Western European business continued expanding, led by very strong growth from the Nordic countries due to launch of SALMEX (generic Seretide) in Denmark and Norway. While the UK market growth was impacted due to one-off supply chain issues, the overall growth was compensated with strong performance in Spain, Germany and the Netherlands. The Central Eastern European region recorded strong secondary sales growth in spite of significant pricing pressures during the quarter.

The overall regional growth was led by multiple new product launches across all key markets. Glenmark launched 4 products in Spain, 2 products each in the UK, the Netherlands, Germany, Spain and Sweden. Maloff Protect (250mg/100mg atovaquone/proguanil film-coated tablets), anti-malarial medication, launched as a pharmacy license in the United Kingdom during Q2 FY18 continues to gain market share.

During the fourth quarter FY 2017-18, Glenmark had become the first generic company to receive regulatory approval for substitution in Denmark for its generic of Seretide® Accuhaler®, and the company has subsequently launched the product in Denmark and Norway.



Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 976.11 Mn (USD 14.59 Mn) for the first quarter FY 2018 - 19, as against Rs. 845.11 Mn (USD 13.13 Mn), recording a growth of 15.50%. The overall performance in the region was led by the larger markets such as Brazil and Mexico.

Active Pharmaceutical Ingredients (API)

Glenmark forayed in to the API business in 2003 and over the last 15 years has built a large business based on strong product selection, focus on key regulated markets, maintaining high operational efficiency and a strong compliance culture. The company has robust R&D capabilities in API for developing an attractive pipeline and achieving cost efficiencies to overcome external market challenges.

Revenue from sale of API globally was Rs. 2,100.78 Mn (USD 31.41 Mn), for the quarter ended June 30, 2018 against Rs. 2,047.70 Mn (USD 31.81 Mn) for the previous corresponding quarter, recording a growth of 2.59%. In spite of a challenging external environment, the Company recorded robust sales in some of its key APIs such as Perindopril, Lercanidipine and Aprepitant.

Research & Development

The company has a pipeline of 7 new molecular entities (NMEs), which includes 2 new chemical entities (NCEs), 4 new biological entities (NBEs) and a biosimilar candidate, in various stages of clinical development focused in the therapeutic areas of oncology, respiratory and dermatology.

Quarterly Highlights on the R&D Pipeline

RESPIRATORY ASSETS

Ryaltris™

- Glenmark announced the filing and acceptance of the company's first New Drug Application (NDA) for Ryaltris™ (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg]), an investigational fixed-dose combination nasal spray of an antihistamine and a steroid, indicated for treatment of seasonal allergic rhinitis (SAR) in patients 12 years of age and older.
 - The filing includes efficacy and safety results from two pivotal trials in more than 2,000 patients with SAR and another long-term safety study in more than 600 adults with perennial allergic rhinitis.
 - The Prescription Drug User Fee Act (PDUFA) target action date for completion of the FDA review is March 21, 2019



- Glenmark also entered in to an exclusive licensing agreement with Seqirus Pty. Ltd. (Seqirus), part of Australia-based specialty biotechnology company CSL Ltd., to commercialize Ryaltris in Australia and New Zealand. Glenmark will receive an upfront payment as well as regulatory and commercial milestone payments from Seqirus. Glenmark will continue to explore commercial partnerships for Ryaltris in markets where it doesn't have direct presence.
- Ryaltris represents the continued commitment towards building a global branded business in the specialty respiratory segment. The company plans to commercialize Ryaltris in several key markets globally and has already initiated product filings in certain markets.

GBR 310

- Glenmark recently announced results from a Phase 1 study that suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between Glenmark's proposed biosimilar, GBR 310, and the reference product omalizumab, marketed in the U.S. under the brand name Xolair.
- Glenmark expects to meet with the US FDA in H2 CY 2018, with the goal of advancing the development of GBR 310. The company targets to file/initiate the Phase 3 study in Q4 FY19.

GRC 39815

• GRC 39815 continues to progress well in pre-clinical development and the company plans to initiate a Phase 1 study in FY20.

ONCOLOGY ASSETS

GBR 1302

- For GBR 1302, a Phase 1, first in human study to determine maximum tolerated dose (MTD) in patients with HER2 positive cancers is ongoing. Dose escalation continues at 9 participating clinical trial sites across Germany and the U.S. The study is currently enrolling patients in Cohort 9 and will continue until MTD is reached.
 - Translational data in trastuzumab-resistant cancers were presented at the 2018
 Annual Meeting of the American Society of Clinical Oncology (ASCO), and updated
 results on early biomarker data was accepted for presentation at the European
 Society of Medical Oncology (ESMO) conference slated in October 2018.
- The Company recently announced an exclusive license agreement with Harbour Biomed for the Greater China territory to develop, manufacture and commercialize GBR 1302.
 - Under the terms of the agreement, Glenmark will receive an upfront payment and is eligible to receive payments for achieving pre-specified milestones, as well as tiered royalties on net sales for any approved products from Harbour BioMed.
 - The agreement is potentially worth more than \$120 million in addition to royalties for Glenmark.
 - Harbour BioMed will lead the clinical development and commercialization of GBR 1302, with the option to manufacture GBR 1302 for the Greater China market. The



companies will collaborate on the generation of clinical data to support the registration of GBR 1302 in HER2-positive indications in their respective territories.

GBR 1342

- For GBR 1342, a Phase 1, first in human study to determine MTD in patients with multiple myeloma is ongoing. The study is currently enrolling patients in Cohort 6 with patients being already identified for enrolment into Cohort 7. Up to 10 cohorts are planned for this MTD portion of the study.
 - The study's primary objective is to assess the safety and tolerability of increasing doses of GBR 1342. Additional study objectives include assessment of biomarkers, immunogenicity and measures of anti-tumor activity.
 - At ASCO 2018, Glenmark presented a trial-in-progress poster about GBR 1342 for treatment of refractory multiple myeloma, including patients who are nonresponders to daratumumab.

GBR 1372

• GBR 1372 is currently in pre-clinical development.

IMMUNO/DERMA ASSET

GBR 830

- A Phase 2b study of GBR 830, which is being evaluated for treatment of moderate-to-severe atopic dermatitis, has been initiated with 13 active sites in the US. Glenmark will be activating sites in Canada in August and in EU later in the year.
- Glenmark is currently evaluating GBR 830 for a study in patients with systemic lupus erythematosus (SLE).
- The Company has also initiated pre-clinical ex-vivo translational studies to evaluate GBR 830 in patients suffering from ulcerative colitis (UC).

PAIN ASSET

GRC 27864

• The Phase 2b study of GRC 27864 is progressing as per plan, with 30 active sites in India and 70 patients recruited for the study. Glenmark plans to complete trial recruitment by end of FY19.

Overview of Glenmark's R&D Capabilities

Glenmark's clinical development centre is based in Paramus, New Jersey, and research centres are based in Navi Mumbai, India and Neuchâtel, Switzerland. Spread over 125,000 square feet the R&D centre in India has end-to-end capabilities for discovery and development of NCEs from target selection to clinical development. The research facility is



equipped with state-of-the-art infrastructure required to carry out research activities including medicinal chemistry, process and analytical chemistry, in vitro and in vivo studies and project management. Glenmark's dedicated R&D centre for biologics in Switzerland has end-to-end capabilities to discover NBE's and to support clinical development and the centre is also fully equipped to manufacture and supply clinical trial material.

BEAT® Technology

BEAT® (Bispecific Engagement by Antibodies based on the T cell receptor) is Glenmark's proprietary technology for the production of bispecific antibodies (bsAbs). With BEAT® technology, Glenmark's scientists have been able to overcome past production obstacles encountered with bsAbs and efficiently manufacture these molecules on a clinical and commercial scale. Preclinically, BEAT® bsAbs demonstrate the potential for more potent activity compared to existing therapeutic antibodies. Additionally, structural similarity to naturally-occurring antibodies may result in a normalized IgG half-life and less immunogenicity.

PIPELINE DETAILS BY ASSET

RESPIRATORY ASSETS

Ryaltris (mometasone furoate [25 mcg] and olopatadine hydrochloride [665 mcg]) nasal spray

Ryaltris, an investigational product, is a combination of a steroid and an antihistamine administered intranasally intended for the treatment of seasonal allergic rhinitis.

Glenmark's first new drug application (NDA) to the FDA for Ryaltris for the treatment of patients 12 years of age and older with seasonal allergic rhinitis (SAR) was accepted for review with a target Prescription Drug User Fee Act (PDUFA) date of March 21, 2019. The filing included efficacy and safety results from two pivotal, randomized, multicentre, double-blind, placebo-controlled trials in adults and adolescents 12 years of age and older with SAR. The similarly designed trials lasted two weeks and enrolled 2,352 patients. Assessment of efficacy was based on patient-reported reflective total nasal symptom score (rTNSS), along with other patient-reported measures of nasal and ocular symptoms. Across the two studies, treatment with Ryaltris resulted in statistically significant improvements in rTNSS compared to placebo.

The incidence of adverse reactions in four placebo-controlled studies was 13.9% in the Ryaltris treatment groups versus 9.5% of patients in the placebo groups.

According to the most recent data, over 17 million adults in the U.S. are affected by seasonal allergic rhinitis, also called hay fever, every year. Currently, there is only one product available in the U.S. that combines a steroid and antihistamine in a single spray.

GBR 310



GBR 310 is a biosimilar candidate being developed for the treatment of allergic asthma and chronic idiopathic urticaria (CIU). Results from a Phase 1 study suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between Glenmark's GBR 310 proposed biosimilar and reference product omalizumab. GBR 310 has the potential to be among the first biosimilar candidates to be submitted to the FDA for approval for a respiratory or allergic disease in the U.S.

Asthma is one of the most common diseases in children and affects more than 18 million people older than 18 in the U.S. Allergic asthma is unique because it is triggered by exposure to year-round allergens like pet dander and dust mites. Allergies trigger asthma attacks in 60-90 percent of children and in approximately 50 percent of adults with asthma.

Urticaria is a common skin disease that presents as spontaneously recurring hives or welts. It occurs across all age groups and about one percent of the population suffers from a chronic form of the disease. Among this group, 70% of people report symptoms that last for more than one year and 14% report symptoms that last for more than five years.

GRC 39815

GRC 39815 is a NCE currently in preclinical studies. It is 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 (ROR y t).

Based on the most recent estimates COPD affects approximately 64 million people worldwide. COPD is an incurable disease and based on the most recent data is the third leading cause of death worldwide.

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.

ONCOLOGY ASSETS

GBR 1302

GBR 1302, a HER2xCD3 bsAb, is the first clinical candidate based on Glenmark's proprietary BEAT® platform. Preclinical study results from redirected lysis assays suggest GBR 1302, in comparison to current 1st and 2nd line HER2-targeted monoclonal antibodies, exhibits faster and more complete killing of HER2+ tumor cells. If confirmed in clinical trials, GBR 1302 will constitute an innovative treatment for HER2 positive cancers, including treatment-resistant cancers. A Phase 1 study is underway to determine MTD.

Patients enrolled in the study receive intravenous GBR 1302 on Day 1 and Day 15 in 28-day treatment cycles at escalating doses until maximum-tolerated dose is achieved. Preliminary biomarker data demonstrate modulation of peripheral T cell populations and cytokines.



Some subjects treated at the higher doses experienced cytokine release syndrome, which was mild and transient. Dose escalation is ongoing.

GBR 1342

GBR 1342, a CD38xCD3 bsAb based on Glenmark's proprietary BEAT® platform targets CD38, a clinical target in multiple myeloma and other malignancies of hematopoietic origin, as well as a variety of solid tumors. Results from preclinical assays in comparison to daratumumab, an FDA-approved monoclonal antibody targeting CD38, suggest that GBR 1342 has a potent antitumor effect on patient derived multiple myeloma cell lines. A Phase 1 study is underway.

GBR 1372

GBR 1372 is an EGFRxCD3 bsAb based on Glenmark's proprietary BEAT® platform. It targets epidermal growth factor receptor, a proven target in several cancers including squamous cell carcinoma of the head and neck and colorectal cancer. GBR 1372 is currently in preclinical development.

IMMUNO/DERMA ASSET

GBR 830

GBR 830, an anti-OX40R monoclonal antibody, was discovered at the Glenmark Biologics Research Centre located in Switzerland and is in clinical development in the U.S. GBR 830 is being developed to target and inhibit pathologically activated T cells and effector memory T cells which are key drivers in a variety of autoimmune and chronic inflammatory disorders. The lead indication being evaluated for GBR 830 is moderate-to-severe atopic dermatitis (AD). Additional indications are under evaluation.

Glenmark has completed a Phase 2a study evaluating GBR 830, relative to placebo, in adults with moderate-to-severe AD with history of inadequate response to topical therapies. Although not powered for statistical differences between GBR 830 versus placebo, data from this study suggest clinically meaningful improvement of symptoms that is continuous and sustained, with consistency observed between biological and clinical response. The overall safety profile of GBR 830 was similar to placebo. The most common treatment-related adverse event was headache, with no clinically meaningful differences between GBR 830 and placebo (4 percent and 6 percent, respectively).

A randomized, double-blind placebo-controlled, parallel-group Phase 2b clinical trial in adults with moderate-to-severe AD inadequately responding to topical therapies was started in June 2018 in the U.S. and Europe. Glenmark is targeting a BLA filing for GBR 830 in 2022.

Atopic dermatitis is the most common inflammatory skin disease, affecting up to 3% of the adult population and its prevalence has increased 2-3 fold over the last 100 years. Biologic



agents in moderate-to-severe atopic dermatitis offer promise to both control the disease and prevent the occurrence of new skin lesions.

PAIN ASSET

GRC 27864

GRC 27864 is a potent, selective, and orally bioavailable inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1), a novel therapeutic target in pain management, which is upregulated under inflammatory conditions. A Phase 1 single ascending dose and a multiple ascending dose study have been completed in the UK with no safety concerns.

Glenmark announced in January 2018 the initiation of a Phase 2b dose finding study in patients with moderate osteoarthritic pain. The Phase 2 study has been initiated in India and planned to enrol 624 patients with osteoarthritis of the knee and hip to evaluate the safety, efficacy and biomarkers associated with GRC 27864 compared to existing NSAID and selective COX-2 inhibitors.

Non-core assets include GRC 17536, GBR 900 and GBR 500. These 3 molecules and GRC 27864 are candidates for out-licensing.

¹Xolair is a registered trademark of Genentech USA, Inc. and Novartis Pharmaceuticals Corporation indicated for the treatment of moderate to severe persistent asthma in patients six years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled via inhaled corticosteroids; and for the treatment of chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Disclaimer

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