Management Discussion and Analysis for the Second quarter of FY 2017 – 18

Revenue Figures – Consolidated

(Rs. In Millions)

	Second quarter ended September 30			Six months ended September 30		
	FY 2017 – 18	**FY 2016 – 17**	**Growth (%)**	**FY 2017 – 18**	**FY 2016 – 17**	**Growth (%)**
India	7106.77	6749.31	5.30	13270.80	12099.71	9.68
US	7270.95	7712.06	-5.72	17721.24	14693.91	20.60
Rest of the World (ROW)	2520.93	2538.48	-0.69	4785.56	4487.48	6.64
Europe	2000.24	1346.94	48.50	3621.02	2846.46	27.21
Latin America	1047.23	1337.91	-21.73	1892.34	2894.14	-34.61
API	2366.14	2213.41	6.90	4413.84	4176.28	5.69
Total	**22312.26**	**21898.11**	1.89	**45704.80**	**41197.98**	10.94
Other Revenue	253.64	342.98		491.11	736.92	
Consolidated Revenue	**22565.90**	**22241.09**	1.46	**46195.92**	**41934.90**	10.16

Average conversion rate in 6M FY 2017 – 18 considered as 64.31/USD 1.00
Average conversion rate in 6M FY 2016 – 17 considered as 66.85/ USD 1.00
USD figures are only indicative

Review of Operations for the quarter ended September 30, 2017

For the second quarter ended September 30, 2017, Glenmark's consolidated revenue was at Rs. 22,565.90 Mn (USD 351.29 Mn) as against Rs. 22,241.09 Mn (USD 336.55 Mn) recording an increase of 1.46%.

India

Sales for the formulation business in India for the second quarter ended September 30, 2017, was at Rs. 7,106.77 Mn (USD 110.62 Mn) as against Rs. 6,749.31 Mn (USD 104.12 Mn) in the previous corresponding quarter, recording a growth of 5.30%.

As per IMS MAT September 2017, Glenmark Pharmaceuticals (IF) is ranked 13th with market share of 2.27%. Glenmark is among the top 3 fastest growing companies as per MAT September 2017. Glenmark has 6 brands among the 'Top 300 Brands of the Indian Pharmaceutical Market.' The India business strengthened itself in the following segments with growth in market share from IMS MAT September 2016 to MAT September 2017 respectively. The Cardiac segment market share increased from 3.9% to 4.1%; the Respiratory segment market share rose from 4.2% to 4.6%; the Anti-diabetic segment market share changed from 1.9% to 1.5%; and the Derma segment market share changed from 9% to 9.2%.

The India revenue numbers for the previous year includes excise and for this quarter of the financial year, the revenue reported is net of GST. Thus on a like to like basis the India business grew by around 8% in the second quarter of the financial year. During the second quarter, the market was still recovering post the implementation of GST.

USA Formulations

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was Rs. 7,270.95 Mn (USD 113.24 Mn) for the quarter ended September 30, 2017 against revenue of Rs. 7,712.06 Mn (USD 115.33 Mn) for the previous corresponding quarter, recording a decrease of 5.72%.

In the second quarter of fiscal year 2017-18, Glenmark was granted final approval for Acyclovir Ointment USP, 5% and Nitroglycerin Sublingual Tablets USP, 0.3 mg, 0.4 mg, and 0.6 mg; Amlodipine and Olmesartan Medoxomil Tablets, 5 mg/20 mg, 5 mg/40 mg, 10 mg/20 mg and 10 mg/40 mg, Desonide Cream, 0.05%, Triamcinolone Acetonide Ointment USP, 0.1%, Propafenone Hydrochloride Extended-Release Capsules USP, 225 mg, 325 mg, and 425 mg, Desonide Ointment, 0.0% and Desonide Lotion, 0.05%. During the second quarter, the company received eight final approvals taking the tally to 13 final approvals for the first half of this financial year. The Company filed three ANDA applications with the U.S. FDA, and plans to file an additional seven applications in the forthcoming quarter. The company has thus filed five ANDA applications in the first half of this financial year.

Glenmark's marketing portfolio through September 30, 2017 consists of 126 generic products authorized for distribution in the U.S. market. The Company currently has 61 applications pending in various stages of the approval process with the US FDA, of which 28 are Paragraph IV applications.

During the quarter, Glenmark entered into a development, license, manufacture and commercial supply agreement with Cyndea Pharma S.L., granting exclusive rights to use their technology for developing generic, soft-gelatin capsule formulations of certain pharmaceutical products. Under this agreement, Glenmark receives exclusive rights to the United States and Canada markets for these soft-gelatin formulations in exchange for sharing development costs and profits from future sales. In addition, the agreement provides for the companies to add further soft-gelatin product candidates for development and commercialization, as new branded, soft-gelatin, capsule-based drug products become available in the marketplace.

Africa, Asia and CIS Region (ROW)

For the second quarter, revenue from Africa, Asia and CIS region was Rs. 2,520.93 Mn (USD 39.23 Mn) as against Rs. 2,538.48 Mn (USD 37.96 Mn) for the previous corresponding quarter, recording a decrease of 0.69%.

During the second quarter of the financial year, Glenmark Russia secondary sales recorded degrowth of 0.14 % as compared to the previous corresponding quarter. The second quarter was relatively tough for the Russia business. However as per IMS Health MAT August 2017 data, Glenmark ranks 40 as compared to 44 in Aug 2016, sustaining Glenmark's position in the list of TOP-40 companies in the retail segment of the Russian pharmaceutical market.

During the second quarter, the Asia region secondary sales growth was just 1%, with most of the subsidiaries posting an average performance in the second quarter.

In the Africa region, for the second quarter, Glenmark recorded growth in the region. The subsidiaries of Kenya and Sudan recorded good secondary sales growth. During the quarter, Glenmark launched Teneligliptin & its combination with Metformin in Mauritius and Sertaconazole (Onabet) in Sudan.

Europe Formulations

Glenmark Europe's operations revenue for the second quarter ended September 30, 2017 was at Rs. 2000.24 Mn (USD 31.13 Mn) as against Rs. 1346.94 Mn (USD 20.14 Mn) recording an increase of 48.50%.

The Western European region recorded good growth during the quarter. Glenmark launched 7 products in UK, 2 products in Germany, 4 products in Netherlands, 1 product in Poland, Sweden and Finland each. During the quarter, we expanded our footprint to the Nordic region in Europe. We launched Bupronorphine in Sweden and won the tender for Desloratadine and Escitalopram.

During the quarter, Glenmark was granted final approval by the MHRA (Medicines and Healthcare products Regulatory Agency) for Maloff Protect (250mg/100mg atovaquone/proguanil film-coated tablets), anti-malarial medication, as a pharmacy license in the United Kingdom. Maloff Protect contains atovaquone and proguanil hydrochloride, and has been available only as a prescription medicine in the UK. Under this approval, this is the first approval of the molecule as OTC wherein patients will be able to purchase Maloff Protect without a prescription.

The Central Eastern European region also recorded secondary sales growth of 26% during the quarter. The Czech and the Polish subsidiary performed well during the quarter. During the quarter, the Czech and the Slovak subsidiary launched one product each.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,047.23 Mn (USD 16.30 Mn) for the second quarter ended September 30, 2017 as against Rs. 1337.91 Mn (USD 20.01 Mn), recording decrease of 21.73%. As Venezuela sales is present in the second quarter of the previous financial year, this has resulted in sales declining for the Latam region

The Latam region excluding Venezuela recorded growth in excess of 20% in constant currency during the second quarter of this financial year. The Brazil subsidiary recorded growth of 14% and the Mexico subsidiary recorded growth of 70% on a much smaller base. The Caribbean region also performed well during the quarter.

Active Pharmaceutical Ingredients (API)

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 2366.14 Mn (USD 36.82 Mn), for the quarter ended September 30, 2017 against Rs. 2213.41 Mn (USD 33.86 Mn) for the previous corresponding quarter, recording an increase of 6.90%.

During the second quarter, Glenmark filed 2 US DMFs and 1 EU CEP and completed several other regulatory filings in other key markets including Brazil and South Korea. The sales was contributed majorly by Perindopril, Lercanidipine, Etoricoxib, Adapalene and Amiodarone.

Research & Development

The company has a pipeline of 7 new molecular entities (NMEs), which includes 2 new chemical entities (NCEs) and 5 new biological entities (NBEs), in various stages of clinical development focused in the therapeutic areas of oncology, respiratory and dermatology. The company also has 3 specialty products in clinical development targeting key indications in the respiratory therapy area.

Glenmark's research centers are based in Navi Mumbai, India and Neuchâtel, Switzerland. Spread over 125,000 square feet the R&D center 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 like medicinal chemistry, process and analytical chemistry, *in vitro* and *in vivo* studies and project management. Glenmark's dedicated R&D center for biologics in Switzerland has end-to-end capabilities to discover NBE's and to support clinical development. It 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 an industrial 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.

ONCOLOGY Pipeline

Quarterly Highlights:

- GBR 1302 HER2xCD3 bsAb, is actively enrolling in Phase 1, first-in-human study to determine maximum tolerated dose (MTD) in patients with HER2 positive cancers. Dose escalation continues with clinical sites open in Europe and the U.S., and several additional sites slated to be opened in November 2017. The study is currently recruiting HER2 positive patients in cohort 7. So far, 21 patients have been screened and 15 patients (including patients with gastric cancer, bladder cancer and breast cancer) have been dosed.
    - In addition, GBR 1302 interim biomarker data and preclinical data is expected to be presented at medical meetings in CY 2018.
- GBR 1342 CD38xCD3 bsAb, in Phase 1, first-in-human study to determine MTD in patients with multiple myeloma is currently in study start-up activities. The first U.S. site has been initiated and the first patient first visit occurred on October 25, 2017, with dosing expected to begin early November 2017. Glenmark is also evaluating GBR 1342 for solid tumors.
- GBR 1372 EGFRxCD3 bsAb – preclinical evaluation is in progress, nearing completion. GBR 1372 is being evaluated as a potential treatment for head and neck cancers, lung cancer and colorectal cancer. Phase 1 trials are likely to start around Q2 of FY19

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. Dosing escalation is continuing.

GBR 1342

GBR 1342, a CD38xCD3 bsAb based on Glenmark's proprietary BEAT® platform targets CD38, a clinically proven target in multiple myeloma. 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. GBR 1342 is targeting multiple myeloma and other malignancies of hematopoietic origin. Glenmark received clearance from the FDA on an Investigational New Drug Application (IND) for GBR 1342 in May 2017 and initiation of the Phase 1 study is underway.

New treatments have improved the survival rate in multiple myeloma patients, but the disease remains incurable. Based on the most recent data, globally there are more than 100,000 new cases of multiple myeloma diagnosed every year.

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.

GBR 8383

GBR 8383 is a new type of highly potent OX40R antibody based agonist in preclinical studies. OX40R is an immuno-oncology target and member of the TNFR superfamily. It is expressed on activated CD4 and CD8 T cells as well as a number of other lymphoid and non-lymphoid cells. GBR 8383 is currently in preclinical studies.

IMMUNO-DERMATOLOGY PIPELINE

Quarterly Highlights:

- Promising results demonstrated in a Phase 2a study of GBR 830, an investigational anti-OX40R monoclonal antibody, with 17 out of 23 patients treated with GBR 830 experiencing greater than 50% reduction in Eczema Area and Severity Index score.
- 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).
- Glenmark is submitting these data for presentation at the American Academy of Dermatology Annual Meeting taking place in February, 2018.
- A Phase 2B study in moderate to severe patients with Atopic Dermatitis is set to begin in Q1 of FY 2019 in the U.S. and Europe.
- Glenmark also intends to initiate a Phase 2A study in patients with lupus nephritis in Q1 FY 2019

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 by Glenmark USA. The molecular target of GBR 830 is to inhibit pathologically activated T cells and effector memory T cells which are involved in a variety of autoimmune and chronic inflammatory disorders. The lead indication being evaluated for GBR 830 is moderate-to-severe atopic dermatitis (AD).

Glenmark recently 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). Based on the results of this Phase 2a study, Glenmark is firmly committed to advancing GBR 830 for patients with AD and plans to initiate a Phase 2b trial in the U.S. and Europe in Q2 of CY 2018.

Glenmark is targeting a BLA filing for GBR 830 in 2022. Evaluation of GBR 830 for the treatment of other autoimmune disorders is also underway.

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.

RESPIRATORY PIPELINE

Quarterly Highlights:

- Glenmark recently presented GSP 301 data at the American College of Allergy, Asthma and Immunology Annual Meeting.
- Continuing to move toward Glenmark's first NDA submission for GSP 301 in CY 2018
- GBR 310, the biosimilar candidate for omalizumab (trade name XOLAIR®) intended for the treatment of asthma and chronic idiopathic urticaria (CIU), Phase 1 study continues with 55 patients currently enrolled
- GSP 304 – phase 2b studies are currently underway. Glenmark hopes to initiate Phase 3 in FY 19.

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).

GSP 301

GSP 301 is a combination of a steroid and an anti-histamine administered intranasally for the treatment of seasonal allergic rhinitis in adults and children. Glenmark reported positive results from a Phase 3 trial where GSP 301 demonstrated statistically significant and clinically meaningful improvement from baseline for the primary endpoint of average morning and evening patient-reported reflective Total Nasal Symptom Score, compared to placebo ($p < 0.001$), oloapatadine ($p = 0.028$) and mometasone ($p = 0.019$). All investigational treatments administered in the trial were well-tolerated, and showed no meaningful differences in reported adverse events (AEs) across treatments. The most common AE occurring in at least two percent of patients was dysgeusia.

Glenmark recently received confirmation from the FDA that the data from this Phase 3 trial is sufficient and no further studies are needed to support a New Drug Application (NDA) filing for GSP 301. Glenmark plans to submit a 505(b)(2) NDA in early CY 2018.

According to the most recent data, over 17 million adults and 6 million children 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. This limits treatment options for people with hay fever and can increase the cost and complexity of treatment.

GSP 304

GSP 304 is a long-acting muscarinic antagonist for administration by nebulization for the long term, once-daily, maintenance treatment of bronchospasm associated with COPD. Glenmark has initiated a Phase 2 study for patients with mild to moderate COPD as established by the Global Initiative for Chronic Obstructive Lung Disease.

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.

GBR 310

GBR 310 is a biosimilar candidate being developed for the treatment of asthma and chronic idiopathic urticaria (CIU). Glenmark has initiated a Phase 1 single center study which will assess the pharmacokinetics of GBR 310 in comparison to the reference product. Currently 48 subjects of a planned total of 168 have been randomized. GBR 310 has the potential to be among the first biosimilar candidates to be submitted for approval for a respiratory or allergic disease in the U.S.

Asthma affects an estimated 300 million people worldwide and the morbidity and economic burden is significant, with approximately 240,000 asthma-related deaths per year.

CIU is a common skin disease that presents as spontaneously occurring hives or welts. It occurs across all age groups and about one percent of the population suffers from a chronic form of the disease.

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 up-regulated 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.

The Phase 2 study is planned in India in 624 patients of osteoarthritis of the knee and hip to evaluate safety, efficacy and; biomarkers to characterize novel mechanism differentiated from existing NSAID's and selective COX-2 inhibitors. Primary objective of the study is to evaluate safety

and tolerability of GRC 27864 given orally at daily doses of 10mg, 25 mg and 75 mg for 12 weeks compared to placebo, in patients with moderate osteoarthritis pain.

The proposal for the Phase 2 study has been deliberated in the IND committee and the final DCGI approval is awaited. The dose-range finding Phase 2 study is planned to be initiated in India in December 2017. The therapeutic dose selected from the study will be taken forward for Pivotal Phase 3 trials.

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

Disclaimer

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