

Management Discussion and Analysis for the Second quarter of FY 2016 – 17

Revenue Figures - Consolidated

(Rs. In Millions)

	Second quarter ended September 30			Six months ended September 30		
	FY 2016 – 17	FY 2015 – 16	Growth (%)	FY 2016 – 17	FY 2015 – 16	Growth (%)
India	6749.31	6085.42	10.91%	12099.71	10814.72	11.88 %
US	7712.06	5984.27	28.87 %	14693.91	11594.73	26.73 %
Rest of the World (ROW)	2538.48	2108.73	20.38 %	4487.48	3688.73	21.65 %
Europe	1346.94	1603.50	- 16.00 %	2846.46	2702.03	5.35 %
Latin America	1337.91	1656.71	-19.24 %	2894.14	3841.47	-24.66 %
API	2213.41	1655.00	33.74 %	4176.28	3004.43	39.00 %
Total	21898.11	19093.63	14.69 %	41197.98	35646.11	15.57 %
Other Revenue	342.98	-		736.92	-	
Consolidated Revenue	22241.09	19093.63	16.48 %	41934.90	35646.11	17.64 %

Average conversion rate in Q2 FY 2016 – 17 considered is $66.85 \, \text{/USD} \, 1.00$

Average conversion rate in Q2 FY 2015 – 16 considered is 64.06 / USD 1.00

USD figures are only indicative



Review of Operations for the quarter ended September 30, 2016

For the second quarter ended September 30, 2016, Glenmark's consolidated revenue was at Rs. 22241.09 Mn (USD 336.55 Mn) as against Rs. 19093.63 Mn (USD 295.45 Mn) recording an increase of 16.48%. Glenmark's consolidated revenue excluding other revenue was at Rs. 21898.11 Mn (USD 331.42 Mn) as against Rs. 19093.63 Mn (USD 295.45 Mn) recording an increase of 14.69%.

For the six months ended September 30, 2016, Glenmark's consolidated revenue was at Rs. 41934.90 Mn (USD 627.29 Mn) as against Rs. 35646.11 Mn (USD 556.45 Mn) recording an increase of 17.64%. Glenmark's consolidated revenue excluding other revenue was at Rs. 41197.98 Mn (USD 616.27 Mn) as against Rs. 35646.11 Mn (USD 556.45 Mn) recording an increase of 15.57%.

India

Sales for the formulation business in India for the second quarter ended September 30, 2016, was at Rs. 6749.31 Mn (USD 104.12 Mn) as against Rs. 6085.42 Mn (USD 94.09 Mn) in the previous corresponding quarter, recording growth of 10.91%.

As per IMS MAT September 2016, Glenmark improved its ranking at the market place to 16 as compared to 17 as on MAT Sep 2015 with increase in market share by 0.10%, exhibiting value growth of 18% vis-à-vis IPM growth of 13%. Glenmark presently has 8 brands among the Top 300 Brands of the Indian Pharmaceutical Market.

The India business strengthened itself in the following therapeutic segments with growth in market share from IMS MAT Sep 2016 to MAT Sep 2015 respectively. The Cardiac segment market share increased from 3.73% to 3.95%; the Respiratory segment market share rose from 3.89% to 4.26%; the Anti-diabetic segment market share changed from 2.23% to 1.90%; and the Derma segment market share rose from 8.25% to 9.0%.

As per IMS Sep 2016 data, Glenmark's India business has outperformed industry growth every month for the last 60 months. Among the top 20 companies, Glenmark is probably the only company to consistently outperform IPM growth for such a long period in time. The Indian business completed the launch of 'Digihaler', the first Digital Dose Inhaler' across the country. The products launched on the 'Digihaler' device have gained good acceptance among patients across the country.

USA Formulations

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was at Rs. 7712.06 Mn (USD 115.33 Mn) for the quarter ended Sep 30, 2016 against



revenue of Rs. 5984.27 Mn (USD 92.34 Mn) for the previous corresponding quarter, recording an increase of 28.87%.

In the second quarter of fiscal year 2016, Glenmark was granted final approval for 6 products which were Rosuvastatin Calcium Tablets, Triamcinolone Acetonide Ointment USP, 0.5%; Lidocaine Ointment USP, 5%; Diclofenac Sodium Gel, 3%; Potassium Chloride Extended-Release Tablets USP, 10 mEq & 20 mEq; and Triamcinolone Acetonide Cream USP, 0.1%. For the first six months of this financial year, Glenmark received 11 approvals (8 final approvals and 3 tentative approvals) from the FDA.

During the quarter, Glenmark filed 2 ANDA applications with the U.S. FDA. In the next quarter, Glenmark intends to file seven ANDA applications with the U.S FDA. The total number of ANDA applications filed in this financial year is six.

Glenmark's marketing portfolio through September 30, 2016 consists of 110 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 U.S. FDA, of which 23 are Paragraph IV applications.

Africa, Asia and CIS Region (ROW)

For the second quarter, revenue from Africa, Asia and CIS region was Rs. 2538.48 Mn (USD 37.96 Mn) as against Rs. 2108.73 Mn (USD 32.92 Mn) for the previous corresponding quarter, recording in an increase 20.38%.

In the second quarter of the financial year, Glenmark Russia's secondary sales growth was at 46% vis-a-vis the same period last year. YTD Sep'16 secondary sales growth for the subsidiary was at 52%. For the second quarter of FY 2017, the average deprecation of the Rouble to the US dollar was 3% as compared to the corresponding period last year. For the second quarter of this financial year, constant currency growth for the Russia business was 20%. As per IMS MAT August 2016, in the dermatology segment, Glenmark grew by 64.4% in value vs overall dermatology market growth of 7.1%. The strong growth witnessed by the dermatology business continues on account of the good growth in Oflomil nail lacquer and Klenzit-C which has gained good traction across the country. The respiratory business also continues to benefit from the success of Momat Rino Advance nasal spray (mometasone and azelastine combination) in the country

The Asia business recorded secondary sales growth of 26% during the second quarter. The subsidiaries of Malaysia, Philippines and Vietnam recorded secondary sales growth of 52%, 31% and 35% respectively. The Africa business performed well during the quarter. The largest subsidiary i.e. South Africa recorded secondary sales growth of 56%. The Kenya subsidiary recorded secondary sales growth on 7%.



Europe Formulations

Glenmark Europe's operations revenue for the second quarter ended September 30, 2016 was at Rs. 1346.94 Mn (USD 20.14 Mn) as against Rs. 1603.50 Mn (USD 24.82 Mn) recording decrease of 16%.

During the quarter, the Europe business was severely impacted on account of the depreciation of the British pound and the weak performance of the Central & Eastern European markets. The German business performed well during the quarter. On a constant currency, even the UK business recorded sales growth.

During the first six months of the quarter, Glenmark launched over ten new products in the region through a mix of in-licensing and in house development. During the first six months, the German subsidiary launched 3 new products; the UK subsidiary launched 3 products and the other European subsidiaries launched another 6 products cumulatively.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1337.91 Mn (USD 20.01 Mn) for the second quarter ended September 30, 2016 as against Rs. 1656.71 Mn (USD 25.44 Mn), recording decrease of 19.24%. During the quarter, the Venezuela subsidiary sales dropped significantly as compared to the previous corresponding quarter. The Brazil and Mexico subsidiary did not perform as per expectations during the quarter. Due to the uncertain economic situation, the Latam region continues to struggle.

Active Pharmaceutical Ingredients (API)

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 2213.41 Mn (USD 33.86 Mn), for the quarter ended September 30, 2016 against Rs. 1655.00 Mn (USD 25.84 Mn) for the previous corresponding quarter, recording an increase of 33.74%. Glenmark filed two US DMF during the quarter. The good growth was contributed by sale of Lercanidipine, Adapalene, Amiodarone.

Research & Development

The company has a pipeline of 8 molecules – 2 NCEs and 6 NBEs molecules in clinical trials or ready to enter clinical trials soon.



GRC 17536

GRC 17536, a TRPA1 antagonist, has been proven highly efficacious in treating inflammatory and neuropathic pain in animal models. GRC 17536 has shown positive data in a Phase 2a proof of concept study in patients with painful diabetic neuropathy conducted in Europe and India. Phase 2 enabling toxicology studies have been completed and GRC 17536 has shown a good safety profile supporting further development. Glenmark has submitted an IND for a Phase 2b dose range finding study with the U.S. FDA. The Agency has requested additional information with some changes to the clinical protocol. Glenmark is working to address the questions and ensure minimal delay in the start-up of the study.

GRC 27864

Glenmark's Novel Chemical Entity (NCE) '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. Selectively blocking the mPGES-1 enzyme is a novel strategy and expected to selectively inhibit increased prostaglandin E2 (PGE2) production during the disease state, without affecting other prostanoids of physiological importance and, consequently, may be devoid of the gastrointestinal and cardiovascular side effects seen with NSAIDs and COX-2 inhibitors, respectively.

Glenmark has successfully completed preclinical studies and Phase I enabling toxicity studies for GRC 27864. A Phase I first-in-human single ascending dose and a multiple ascending dose study has been completed in the UK with no safety concerns. A relative bioavailability study with a tablet formulation has been completed.

Vatelizumab (GBR 500)

GBR 500, a monoclonal antibody, is an antagonist of the VLA-2 (alpha2-beta1) integrin. GBR 500 has been licensed to Sanofi for testing in a Multiple Sclerosis (MS) Phase II clinical study.

Sanofi has made the decision not to pursue further Vatelizumab as a potential Relapsing-Remitting MS therapy, following the results of a pre-planned interim analysis that revealed the primary efficacy endpoint was not met. This decision is not due to safety concerns. Glenmark will continue to pursue the relicensing of GBR 500 after it is returned from Sanofi. The termination of the contract with Sanofi has become effective in Q1 FY 2017 and Glenmark is now free to pursue the relicensing of GBR 500.

GBR 900

Glenmark licensed the exclusive intellectual property rights for monoclonal antibodies against the neuronal growth factor receptor TrkA from Lay Line Genomics, Italy. TrkA is part of the NGF-TrkA axis, a validated and novel pain receptor system for treatment of chronic pain. Phase I



enabling toxicity studies for GBR 900 have been completed successfully. A Phase I clinical trial has been initiated in the UK. GBR 900 is the first anti-TrkA monoclonal antibody to enter clinical development.

GBR 830

GBR 830, the first anti-OX40 monoclonal antibody, was discovered at the Glenmark Biologics Research Centre located in Switzerland. The development of OX40 antagonists has been very challenging and Glenmark has achieved a significant milestone with the successful generation of an antagonistic OX40 monoclonal antibody coupled with generation of data validating the role of OX40 in autoimmune diseases. GBR 830 shows great promise to emerge as a valuable therapeutic option to treat patients suffering from autoimmune diseases.

GBR 830 completed the clinical Phase 1 dosing successfully in The Netherlands. GBR 830 was well tolerated and its safety & pharmacokinetics profile in healthy volunteers fully support the transition into clinical Phase 2 studies. Glenmark has an open IND at the U.S. FDA and Health Canada approval under which a Phase 2 study in atopic dermatitis is currently ongoing.

GBR 1302

GBR 1302, a HER2xCD3 bispecific antibody, is the first clinical candidate based on Glenmark's proprietary best in class BEAT® platform and also GBR 1302 is Glenmark's first clinical candidate targeting oncology indications. The BEAT® antibody technology platform facilitates the efficient development and manufacturing of antibodies with dual specificities called bispecific antibodies.

GBR 1302, antibody has successfully completed the preclinical evaluation phase. In pre-clinics, GBR 1302 has demonstrated superiority over current antibody therapies against most HER2 positive cancers, including breast cancer. Dosing of patients has been successfully initiated and the antibody has been well tolerated. If confirmed in clinical trials, GBR 1302 could constitute an innovative treatment for HER2 positive cancers, potentially superior to the currently available monoclonal antibody treatments.

GBR 1342

GBR 1342 is a CD38xCD3 bi-specific antibody based on Glenmark's proprietary BEAT® platform. GBR 1342 is the second clinical development candidate based on the BEAT® technology. It is also Glenmark's second clinical candidate targeting oncology indications. GBR 1342 targets CD38, a target for multiple myeloma and potentially other malignancies of haematopoietic origin. Glenmark has initiated IND-enabling studies for GBR 1342 and is committed to moving GBR 1342 rapidly into clinical trials.



GBR 1372

GBR 1372 is an EGFRxCD3 bispecific antibody based on Glenmark's proprietary BEAT® platform targeting epidermal growth factor receptor EGFR through redirected killing by T-cells. GBR 1372 has the potential to target EGFR expressing cancer cells independent of RAS-family mutations which drive resistance to current EGFR targeting drugs. Glenmark has initiated IND-enabling studies for GBR 1372.

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