

Management Discussion and Analysis for the Second quarter of FY 2014 – 15

Revenue Figures – Consolidated

	Second quarter ended September 30, 2014			Six months ended September 30, 2014		
	FY 2014 – 15	FY 2013 – 14	Growth (%)	FY 2014 – 15	FY 2013 – 14	Growth (%)
India	4,781.50	4,176.80	14.48	8,753.09	7,462.63	17.29
US	5,075.51	5,578.60	-9.02	9,962.21	10,048.12	-0.85
Rest of the World (ROW)	1,740.30	1,739.65	0.04	3,853.39	3,428.78	12.38
Europe	1,305.53	1,043.90	25.06	2,282.79	1,770.35	28.95
Latin America	2,308.80	966.00	139.01	3,485.25	1,844.49	88.95
API	1,595.44	1,010.75	57.85	3,040.70	2,343.76	29.74
Total	16,807.08	14,515.70	15.79	31,377.43	26,898.13	16.65
Out-Licensing Revenue		118.10		299.05	118.10	
Consolidated Revenue	16,807.08	14,633.80	14.85	31,676.48	27,016.23	17.25

(Rs. in Millions)

Average conversion rate in 6M FY 2014 – 15 considered is Rs. 60.21/ USD 1.00

Average conversion rate for 6M FY 2013 – 14 considered is Rs. 59.04 / USD 1.00

USD figures are only indicative



Review of Operations for the quarter ended September 30, 2014

For the second quarter ended September 30, 2014, Glenmark's consolidated revenue was at Rs. 16,807.08 Mn (USD 277.50 Mn) as against Rs. 14,633.80 Mn (USD 235.68 Mn) an increase of 14.85%.

India

Sales for the formulation business in India for the second quarter ended September 30, 2014, was at Rs. 4,781.50 Mn (USD 78.98 Mn) as against Rs. 4,176.80 Mn (USD 67.51 Mn) in the previous corresponding quarter, recording a growth of 14.48%.

As per IMS MAT September 2014, Glenmark Pharmaceuticals Ltd. maintained 19th rank as compared to MAT September 2013, exhibiting value growth of 19.3% vis-à-vis IPM growth of 11.60%. For the month September 2014, the business registered growth of 27.20% vis-a-vis market growth of 15.50%.

The India business strengthened itself in the following therapeutic segments with significant growth in market share from IMS MAT September 2013 to MAT September 2014 respectively. The Cardiac segment market share increased from 3.50% to 3.81%; the Respiratory segment market share rose from 3.46% to 3.59%; Anti-infective segment market share rose from 1.57% to 1.79%; the Anti-diabetic segment market share rose from 1.40% to 1.85%; Gynaecology segment market share rose from 1.45% to 1.47%; and the Derma segment market share changed from 8.26% to 8.07%.

USA Formulations

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations was Rs. 5,075.51 Mn (USD 83.76 Mn) for the quarter ended September 30, 2014 against revenue of Rs. 5,578.60 Mn (USD 90.09 Mn) for the previous corresponding quarter, recording a decrease of 9.02%.

In the second quarter of fiscal year 2015, Glenmark was granted a final approval for Telmisartan Tablets – 20 mg, 40 mg and 80 mg and Fluocinonide Cream USP, 0.1%. During the quarter, Glenmark filed one ANDA with the U.S. FDA, and plans to file four additional applications in the forthcoming quarter. During the first six months of the financial year, Glenmark has filed for 11 ANDAs.

As of September 30, 2014 Glenmark's portfolio consists of 93 generic products authorized for distribution in the U.S. market. The Company currently has 72



applications pending in various stages of the approval process with the US FDA, of which 30 are Paragraph IV applications.

Africa, Asia and CIS Region (ROW)

For the second quarter, revenue from Africa, Asia and CIS region was Rs. 1,740.30 Mn (USD 28.67 Mn) as against Rs. 1,739.65 Mn (USD 26.70 Mn) for the previous corresponding quarter, recording an increase of 0.04%.

Though Glenmark Russia performed reasonably well in the local market, the devaluation of the currency and the subdued business environment is having an overall impact on the Russia business. Glenmark continues to do well as reported by IMS. As per IMS YTD August 2014, Glenmark Russia grew by 21.4% in value vs overall market growth of 11.8%. As per IMS YTD August 2014 Glenmark Russia growth in the dermatology segment was 31.7% in value vs 13.3% derma market growth. During the quarter, Glenmark launched Kerwort (imiquimod) and Sertamykol (sertaconazole). These are two important product launches and as these products ramp up, it will enable the Russia business to record good growth in the following financial year. The Ukraine business even though it's a very small portion of the overall ROW business was impacted severely due to the economic crisis and devaluation of the Ukraine currency. Glenmark launched two new products in Ukraine during the quarter.

The Africa region posted good secondary sales growth and performed well in the second quarter. The units in South Africa, Nigeria and Kenya grew by 67%, 54% and 82% respectively.

The Asia region grew 12% in secondary sales. The performance of the Asia region was subdued during the quarter. Glenmark received 6 product approvals in the region including Combiwave SF, an inhaler product which was approved in Malaysia.

Europe Formulations

Glenmark Europe's operations revenue for the second quarter ended September 30, 2014 was at Rs. 1,305.53 Mn (USD 21.57 Mn) as against Rs. 1,043.90 Mn (USD 16.97 Mn) recording growth of 25.06%.

The UK region achieved remarkable sales growth of over 50% via increasing the sales portfolio and effectiveness of account management despite the lack of new launches and price cuts. Glenmark launched three new products during this quarter.

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Excluding Romania where the business environment is extremely challenging, Eastern Europe recorded good growth. The Poland subsidiary has been the primary contributor to this performance.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 2,308.80 Mn (USD 38.21 Mn) for the second quarter ended September 30, 2014 as against Rs. 966.00 Mn (USD 15.50 Mn), recording an increase of 139.01%.

The Mexico, Venezuela and the Caribbean subsidiaries performed well recording good growth during the quarter. The Mexico and Venezuela subsidiary grew more than 200% and 300% respectively; the Brazil subsidiary recorded moderate growth of 12% for the second quarter. During the quarter, Glenmark launched two new oncology products in the Mexico market. The Venezuela subsidiary received three new product approvals and Brazil subsidiary received one product approval during the quarter.

Active Pharmaceutical Ingredients (API)

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1,595.44 Mn (USD 26.34 Mn), for the quarter ended September 30, 2014 against Rs. 1,010.75 Mn (USD 16.92 Mn) for the previous corresponding quarter, recording an increase of 57.85%. Glenmark continues to record good sales growth for Amiodarone, Perindopril and Telmisartan. The good growth during this quarter is also on account of the Crofelemer API supplies.

Research & Development

The company has a pipeline of 3 NCE and 4 NBE molecules in clinical trials or ready to enter clinical trials soon, including the in-licensed molecule "Crofelemer".

GRC 17536

GRC 17536, a TRPA1 antagonist, has proven highly efficacious in treating inflammatory and neuropathic pain in animal models. GRC 17536 has showed good safety in the Phase I enabling GLP safety pharmacology and toxicology studies performed. Glenmark has completed Phase 1 study in the Netherlands. Single and multiple ascending doses have been well tolerated with expected pharmacokinetic profile. 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.

GRC 27864

Glenmark's Novel Chemical Entity (NCE) 'GRC 27864' has entered human trials in this quarter. This NCE program targets Microsomal Prostaglandin E synthase-1 (mPGES-1) as a novel therapeutic target in pain management. Selective mPGES-1 inhibitors are expected to inhibit increased prostaglandin E2 (PGE2) production in the disease state without affecting other prostanoid metabolites and, consequently, may be devoid of the GI (gastrointestinal) and cardiovascular side effects seen with NSAIDs and COX-2 inhibitors, respectively.

Glenmark has completed preclinical studies and Phase I enabling GLP studies for its selected lead molecule, GRC 27864 and filed a Phase I application for first-in-human trial with the MHRA, UK. The Phase I studies are currently on-going.

Vatelizumab (GBR 500)

GBR 500, a monoclonal antibody, is an antagonist of the VLA-2 (alpha2-beta1) integrin. It has the potential to be a broadly applicable anti-inflammatory compound in diseases like Crohn's disease (CD) and Multiple Sclerosis. It is a 'first-in-class' monoclonal antibody therapeutic with this target and has established proof of concept in animals. Phase I studies for GBR 500 have been completed in the US. GBR 500 has been licensed to Sanofi. The Phase II studies which are conducted by Sanofi are currently on-going for Multiple Sclerosis.

GBR 900

Glenmark licensed from Lay Line Genomics, Italy, exclusive intellectual property rights for monoclonal antibodies against the neuronal growth factor receptor TrkA. TrkA is part of the NGF-TrkA axis, a validated and novel pain receptor system for treatment of chronic pain. Pre-clinical research on the GBR 900 project is being carried out at Glenmark's Biologics Research (GBR) centre at La Chaux-de-Fonds, Switzerland and is progressing well. 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.

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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. Phase I enabling toxicity studies for GBR 830 have been completed and Glenmark has initiated a Phase I study in the Netherlands, Europe.

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 the Glenmark's first clinical candidate targeting oncology indications. The BEAT[®] antibody technology platform facilitates the efficient development and manufacture of antibodies with dual specificities called bispecific antibodies. GBR 1302 is presently in preclinical development and Glenmark expects to obtain approval for the initiation of clinical studies during FY 14 – 15.

Crofelemer

Supported by Salix's U.S. FDA approval of Crofelemer, Glenmark has already filed Crofelemer in the some of the key markets within the 140 Countries where it has exclusive marketing and distribution rights. Glenmark has lined up additional filings based on the regulatory filing data requirements within each of these markets. The Aurangabad API manufacturing site also received the US FDA approval in August 2014.

Disclaimer

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