

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

Revenue Figures – Consolidated

(Rs. in Millions)

	Fourth quarter ended March 31, 2015			Twelve months ended March 31, 2015		
	FY 2014 – 15	FY 2013 – 14	Growth	FY 2014 – 15	FY 2013 – 14	Growth
India	4405.71	3829.96	15.03%	17489.53	15104.89	15.79%
US	5363.44	5008.52	7.09%	20397.66	20270.24	0.63%
Rest of the World (ROW)	2198.41	3425.34	-35.82%	8123.29	9869.01	-17.69%
Europe	2433.00	1932.00	25.93%	6445.33	5060.70	27.36%
Latin America	1810.35	1061.74	70.51%	7640.00	4045.54	88.85%
API	1547.22	1530.63	1.08%	6052.82	5353.46	13.06%
Total	17751.30	16788.19	5.74%	66141.80	59703.84	10.78%
Out-Licensing Revenue		247.41		299.05	365.51	
Consolidated Revenue	17758.13	17035.60	4.24%	66447.68	60069.35	10.62%

Average conversion rate in 12M FY 2014 – 15 considered is Rs. 61.17/ USD 1.00

Average conversion rate for 12M FY 2013 – 14 considered is Rs. 60.43/ USD 1.00

USD figures are only indicative

Review of Operations for the quarter ended March 31, 2015

For the fourth quarter ended March 31, 2015, Glenmark's consolidated revenue was at Rs. 17,758.13 Mn (USD 285.38 Mn) as against Rs. 17035.60 Mn (USD 276.86 Mn). For the year ended March 31, 2015, Glenmark's consolidated revenue was at Rs. 66,447.68 (USD 1086.19 Mn) as against Rs. 60,069.35 (USD 994.09 Mn) recording an increase of 10.62%.

India

Sales for the formulation business in India for the fourth quarter ended March 31, 2015, was at Rs. 4405.71 Mn (USD 70.71 Mn) as against Rs. 3,829.96 Mn (USD 62.05 Mn) in the previous corresponding quarter, recording a growth of 15.03%.

As per IMS MAT March 2015, Glenmark Pharmaceuticals Ltd. moved up to 17th rank from 19th compared to MAT March 2014 with increase in market share by 0.09%, exhibiting value growth of 18% vis-à-vis IPM growth of 13%. For the month March 2015, the business registered growth of 19% vis-a-vis market growth of 16%. Glenmark presently has 8 brands in the Top 300 Brands in the Indian Pharmaceutical Market.

The India business strengthened itself in the following therapeutic segments with significant growth in market share from IMS MAT March 2014 to MAT March 2015 respectively. The Cardiac segment market share increased from 3.69% to 3.80%; the Respiratory segment market share rose from 3.49% to 3.80%; Anti-infective segment market share rose from 1.68% to 1.81%; the Anti-diabetic segment market share rose from 1.64% to 2.07%; and the Derma segment market share changed from 8.07% to 8.04%.

USA Formulations

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was at Rs. 5,363.44 Mn (USD 86.16 Mn) for the quarter ended March 31, 2015 against revenue of Rs. 5,008.52 Mn (USD 81.09 Mn) for the previous corresponding quarter, recording an increase of 7.09%.

In the fourth quarter of fiscal year 2015, Glenmark was granted a final approval for Levonorgestrel/Ethinyl Estradiol Tablets, 0.15mg/0.03mg and Ethinyl Estradiol Tablets, 0.01 mg (Seasonique®). During the financial year, Glenmark has filed 18 ANDA applications with the US F.D.A.

As of March 31, 2015 Glenmark's portfolio consists of 95 generic products authorized for distribution in the U.S. market. The Company currently has 70 applications pending in various stages of the approval process with the US FDA, of which 33 are Paragraph IV applications.

Africa, Asia and CIS Region (ROW)

For the fourth quarter, revenue from Africa, Asia and CIS region was Rs. 2198.41 Mn (USD 35.34 Mn) as against Rs. 3,425.34 Mn (USD 55.93 Mn) for the previous corresponding quarter, recording a decrease of 35.82%.

The currency devaluation and subdued business environment continued to impact the Russia business. However, as per IMS MAT March 2015, Glenmark Russia rank improved to 46 from 51 MAT March 2014. The Ukraine business continues to remain challenging due to the unstable economic and political environment. The Asia and Africa region continued to record good secondary sales growth. The good secondary sales growth for Asia and Africa augurs well for FY 2015 – 16.

Europe Formulations

Glenmark Europe's operations revenue for the fourth quarter ended March 31, 2015 was at Rs. 2,433.00 Mn (USD 39.37 Mn) as against Rs. 1,932.00 Mn (USD 31.60 Mn) recording growth of 25.93%.

During the quarter, Glenmark launched 6 products in the European region driven mainly by in-licensed products. Glenmark launched 2 products in Czech and Germany and 1 product each in Romania, Slovak and Poland.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,810.35 Mn (USD 29.00 Mn) for the fourth quarter ended March 31, 2015 as against Rs. 1,061.74 Mn (USD 17.22 Mn), recording an increase of 70.51%.

For the quarter, in local currency, the Mexico and Venezuela unit recorded growth in excess of 100% respectively. The growth in Mexico was backed by the respiratory line of products.

Active Pharmaceutical Ingredients (API)

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1,547.22 Mn (USD 24.84 Mn), for the quarter ended March 31, 2015 against Rs. 1,530.63 Mn (USD 24.88 Mn) for the previous corresponding quarter, recording an increase of 1.08%.

During the quarter Glenmark has filed for 6 US DMFs including 3 targeting FTF molecules. The good growth was bagged by continued strong sales of Amiodarone, Lercanidipine, Adapalene and Perindopril. The Ankleshwar and Dahej manufacturing facilities were successfully inspected by the US FDA during the quarter.

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. Phase 2 enabling toxicology studies have been initiated. Glenmark intends to open an IND in Q2 FY 2015 – 16 for a Phase 2b dose range finding study.

GRC 27864

Glenmark’s Novel Chemical Entity (NCE) 'GRC 27864' 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 has approval for Phase I first-in-human trial from MHRA, UK. A single ascending dose study has been completed with no safety concerns. Multiple ascending dose study is 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.

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 Phase I study is currently on-going in Netherlands, Europe. Glenmark intends to open an IND in Q2 FY 2015 – 16.

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. Glenmark is currently putting together a submission package for initiating clinical trials for GBR 1302 and expects to obtain approval by Q3 FY 15-16.

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 successfully filed Crofelemer in 13 countries and also received approval in Ecuador, Zimbabwe and Botswana. Fillings are planned in several more countries in this fiscal year. Glenmark is also in discussion to expand the supply of Crofelemer API.

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