

Management Discussion and Analysis for the First quarter of FY 2015 – 16

Revenue Figures – Consolidated

(Rs. In Millions)

	Q1 FY 2015-16	Q1 FY 2014-15	Growth %
India	4,729.30	3,971.59	19.08%
US	5,610.46	4,886.70	14.81%
Rest of the World (ROW)	1,580.00	2,113.09	-25.23%
Europe	1,098.53	977.26	12.41%
Latin America	2,184.76	1,176.45	85.71%
API	1,349.43	1,445.26	-6.63%
Total	16,552.48	14,570.35	13.60%
Out-Licensing Revenue	-	299.05	-
Consolidated Revenue	16,552.48	14,869.40	11.32%

Average conversion rate in Q1 FY 2015 – 16 considered is 63.29 /USD 1.00

Average conversion rate in Q1 FY 2014 - 15 considered is 59.81 / USD 1.00

USD figures are only indicative

The net sales mentioned herein are inclusive of duty and taxes to the extent of Rs. 75.05 million.



Review of Operations for the quarter ended June 30, 2015

For the first quarter ended June 30, 2015, Glenmark's consolidated revenue excluding out-licensing revenue was at Rs. 16552.48 Mn (USD 261.53 Mn) as against Rs. 14570.35 Mn (USD 243.61 Mn) recording an increase of 13.60%.

India

Sales for the formulation business in India for the first quarter ended June 30, 2015, was at Rs. 4729.30 Mn (USD 74.72 Mn) as against Rs. 3971.59 Mn (USD 66.40 Mn) in the previous corresponding quarter, recording growth of 19.08%.

As per IMS MAT June 2015, Glenmark Pharmaceuticals Ltd. moved up to 17th rank from 18th compared to MAT June 2014 with increase in market share by 0.09%, exhibiting value growth of 19% vis-à-vis IPM growth of 14%. For the month June 2015, as per IMS the business registered growth of 23% vis-a-vis market growth of 16%. 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 significant growth in market share from IMS MAT June 2014 to MAT June 2015 respectively. The Cardiac segment market share increased from 3.72% to 3.76%; the Respiratory segment market share rose from 3.49% to 3.84%; Anti-infective segment market share rose from 1.74% to 1.83%; the Anti-diabetic segment market share rose from 1.76% to 2.12%; and the Derma segment market share rose from 8.01% to 8.07%.

During the quarter, Glenmark launched Teneligliptin, a DPP-4 Inhibitor, for the first time in India under the brand names Ziten and Zita Plus. With the launch of Teneligliptin, Glenmark is the only company manufacturing gliptins in India right from API to formulations.

USA Formulations

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was at Rs. 5610.46 Mn (USD 88.65 Mn) for the quarter ended June 30, 2015 against revenue of Rs. 4886.70 Mn (USD 81.70 Mn) for the previous corresponding quarter, recording an increase of 14.81%.

In the first quarter of fiscal year 2015, Glenmark was granted final approval for six products – Norethindrone Acetate/Ethinyl Estradiol Tablets USP, 1 mg/5 mcg & 0.5 mg/2.5 mcg, Levonorgestrel/Ethinyl Estradiol Tablets USP, 0.9 mg/0.02 mg, Desmopressin Acetate Tablets, Calcipotriene Cream, 0.005%, Levonorgestrel/Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg and



Ezetimibe Tablets, 10 mg. Glenmark also received tentative approval for the product Rufinamide Tablets. During the quarter, Glenmark filed one ANDA application with the U.S. FDA. Glenmark intends to file 17 – 20 ANDA application with the U.S. FDA in FY 2016.

As of June 30, 2015 Glenmark's portfolio consists of 100 generic products authorized for distribution in the U.S. market. The Company currently has 65 applications pending in various stages of the approval process with the U.S. FDA, of which 28 are Paragraph IV applications.

Africa, Asia and CIS Region (ROW)

For the first quarter, revenue from Africa, Asia and CIS region was Rs. 1580.00 Mn (USD 24.96 Mn) as against Rs. 2113.09 Mn (USD 35.33 Mn) for the previous corresponding quarter, recording a decrease of 25.23%.

The overall business environment in Russia continues to remain challenging. The sales numbers for Russia were further impacted due to currency devaluation. The average rate for the Ruble to USD was 52.68 in first quarter of FY 2016 compared to 34.95 in the first quarter of FY 2015. As per IMS MAT May 2015, Glenmark Russia grew by 8.8% in value vs overall market growth of 11.6%. Glenmark's rank improved to 47 as per MAT May 2015 from 49 as per MAT May 2014. During the quarter Glenmark launched Oflomil nail lacquer, the first generic amorolfine in the Russian market. The Ukraine business, though a minuscule portion of the overall business, continues to be challenging.

The Asia business recorded secondary sales growth of 20% during the quarter. The regions of Malaysia, Myanmar, Sri Lanka, Philippines and Cambodia registered secondary sales growth of 18%, 18%, 17%, 27% and 53% respectively. The Africa region recorded strong secondary sales growth in the first quarter led by South Africa, Nigeria and Kenya.

Europe Formulations

Glenmark Europe's operations revenue for the first quarter ended June 30, 2015 was at Rs. 1098.53 Mn (USD 17.36 Mn) as against Rs. 977.26 Mn (USD 16.34 Mn) recording growth of 12.41%.

The strong sales growth for the Europe region was driven primarily by the German and the Czech subsidiary. During the quarter, Glenmark launched 4 new products in the European region driven mainly by the in-licensed products.

The Western Europe region recorded a strong growth mainly driven by the good performance of the German region. In the first quarter Glenmark launched Cilostazol and Paricalcitol, both niche



products, in Germany. The products Aripiprazole and Pregabalin are the core sales growth drivers for Germany. Glenmark also launched Mometasone Ointment in Netherlands.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 2184.76 Mn (USD 34.52 Mn) for the first quarter ended June 30, 2015 as against Rs. 1176.45 Mn (USD 19.67 Mn), recording an increase of 85.71%. The subsidiaries of Brazil, Mexico and Venezuela continued to record good sales growth in local currency. Brazil recorded growth of 20% in the quarter and launched Levolukast, the first product in the market with combination of Levocetrizine and Montelukast. The subsidiaries of Mexico and Venezuela recoded very good sales growth in the quarter.

Active Pharmaceutical Ingredients (API)

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1349.43 Mn (USD 21.32 Mn), for the quarter ended June 30, 2015 against Rs. 1445.26 Mn (USD 24.16 Mn) for the previous corresponding quarter, recording a decrease of 6.63%. Glenmark successfully received acceptable status for all the API manufacturing facilities.

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 completed. Glenmark intends to open an IND in Q2 FY 2015 – 16 for a Phase 2b dose range finding study along with regulatory submissions in India and EU.



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 study has been completed in the UK 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, conducted by Sanofi, are currently on-going for Multiple Sclerosis.

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. All subjects in the clinical Phase I study have



been dosed successfully. GBR 830 proved safe and was well tolerated. Glenmark intends to open an US IND in Q2 FY 2015 – 16 for clinical studies in patients.

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. 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 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 has also received approval in 4 countries - Ecuador, Zimbabwe, Botswana and Brazil. Fillings are planned in several more countries during this fiscal year. Glenmark is the sole supplier of Crofelemer API for Salix's Fulyzac brand in the US.

Disclaimer

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