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

Revenue Figures – Consolidated

(Rs. In Millions)

	Third Quarter ended December 31			Nine Months ended December 31		
	FY 2015-16	**FY 2014-15**	**Growth**	**FY 2015-16**	**FY 2014-15**	**Growth**
India	4,880.30	4,330.73	12.69%	15,695.02	13,083.82	19.96%
US	6,088.68	5,072.01	20.04%	17,683.41	15,034.22	17.62%
Rest of the World (ROW)	2,363.39	2,071.49	14.09%	6,052.12	5,924.88	2.15%
Europe	1,763.53	1,729.54	1.97%	4,465.56	4,012.33	11.30%
Latin America	1,237.26	2,344.40	-47.23%	5,078.73	5,829.65	-12.88%
API	1,449.80	1,464.90	-1.03%	4,454.23	4,505.60	-1.14%
Total	17,782.96	17,013.07	4.53%	53,429.07	48,390.50	10.41%
Out-Licensing Revenue	-	-		-	299.05	
Consolidated Revenue	17,782.96	17,013.07	4.53%	53,429.07	48,689.55	9.73%

Average conversion rate for 9M FY 2015-16 considered is Rs 64.64/ USD 1.00

Average conversion rate for 9M FY 2014-15 considered is Rs 60.80/ USD 1.00

USD figures are only indicative

Review of Operations for the quarter ended December 31, 2015

For the third quarter ended December 31, 2015, Glenmark's consolidated revenue was at Rs. 17,782.96 Mn (USD 270.15 Mn) as against Rs. 17,013.07 Mn (USD 274.80 Mn) recording an increase of 4.53%.

India

Sales for the formulation business in India for the third quarter ended December 31, 2015, was at Rs. 4,880.30 Mn (USD 73.99 Mn) as against Rs. 4,330.73 Mn (USD 69.82 Mn) in the previous corresponding quarter, recording growth of 12.69%.

As per IMS MAT December 2015, Glenmark Pharmaceuticals Ltd. gained one rank from 18th to 17th compared to MAT December 2014 with increase in market share by 0.11%, exhibiting value growth of 21% vis-à-vis IPM growth of 14%. For the month December 2015, as per IMS, the business registered growth of 23% vis-a-vis market growth of 17%. Glenmark presently has 9 brands among the Top 300 Brands in the Indian Pharmaceutical Market.

The India business strengthened itself in the following therapeutic segments with growth in market share from IMS MAT December 2014 to MAT December 2015 respectively. The Cardiac segment market share increased from 3.74% to 3.87%; the Respiratory segment market share rose from 3.65% to 4.02%; Anti-infective segment market share rose from 1.78% to 1.81%; the Anti-diabetic segment market share rose from 1.95% to 2.28%; and the Derma segment market share rose from 7.97% to 8.40%.

During this financial year, Glenmark launched Teneligliptin, a DPP-4 Inhibitor, for the first time in India under the brand names Ziten and Zita Plus. As per IMS for the nine months ended Dec 31, 2015, Glenmark has been able to achieve sales of more than Rs. 230 million for this molecule and its combination. This is one of the most successful launches in India in the recent few years.

USA Formulations

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was at Rs. 6,088.68 Mn (USD 92.58 Mn) for the third quarter ended December 31, 2015 against revenue of Rs. 5,072.01 Mn (USD 81.82 Mn) for the previous corresponding quarter, recording an increase of 20.04%.

During the third quarter of fiscal year, Glenmark was granted final approval for two products and tentative approval for two products. Glenmark received the final approval for Clotrimazole and Betamethasone Dipropionate Cream USP, 1%|0.05% and Linezolid Tablets, 600 mg. Glenmark

received tentative approval for Lacosamide Tablets, 50 mg, 100 mg, 150 mg and 200 mg and Dronedarone Tablets, 400 mg. For the nine months ended Dec 31, 2015, Glenmark received 13 ANDA approvals (including 3 tentative approvals) from the U.S. FDA.

During the past nine months, Glenmark filed 6 ANDA applications with the U.S. FDA and intends to file another 6-8 ANDA applications with the U.S. FDA during the next quarter.

As of December 31, 2015 Glenmark's portfolio consists of 104 generic products authorized for distribution in the U.S. market. The Company currently has 63 applications pending in various stages of the approval process with the U.S. FDA, of which 26 are Paragraph IV applications.

Africa, Asia and CIS Region (ROW)

For the third quarter, revenue from Africa, Asia and CIS region was Rs. 2,363.39 Mn (USD 36.05 Mn) as against Rs. 2,071.49 Mn (USD 33.48 Mn) for the previous corresponding quarter, recording an increase of 14.09%.

The Russia business continues to remain challenging. While demand conditions are still weak, the currency continues to create turbulence for the business. For the third quarter of the previous financial year the average currency for the Rouble to the dollar was 47.7 as compared to 66.1 in this current quarter. In local currency the business grew by 5 % for the third quarter and was 10% for the nine months ended Dec 31, 2015. Secondary sales growth for the Russia subsidiary was at 16 % for the third quarter. The CIS region ex Russia also continues to be under pressure.

The Asia business recorded strong secondary sales growth of 24% during the quarter. The Asia business continues to record strong growth. The regions of Malaysia, Sri Lanka, Philippines and Cambodia recorded secondary sales growth in excess of 20%. During the quarter, Glenmark launched 1 product in Sri Lanka, 4 products in Philippines, and 4 products in Vietnam.

The Africa region recorded secondary sales growth in excess of 30% for the third quarter. The good growth for the quarter was led by the performance of South Africa, Nigeria and Kenya subsidiaries. During the quarter, Glenmark launched 3 new products in the region.

Europe Formulations

Glenmark Europe's operations revenue for the third quarter ended December 31, 2015 was at Rs. 1,763.53 Mn (USD 26.91 Mn) as against Rs. 1,729.54 Mn (USD 28.08 Mn) in the previous corresponding quarter recording growth of 1.97%.

The secondary sales growth for the Europe region continues to remain very strong and the German business continues to perform well. In the third quarter, there were quite a few launches, driven mainly by in-licensed products. In the CEE region Glenmark launched Bortezomib, Pregabalin, Aripiprazole, Dexpanthenol, Magnesium Complex B, Eztom (Mometasone) Spray, Rekarnival. In the Western Europe region Glenmark launched Lansoprazole, Losartan, Memantine oral drop, Omeprazole in UK and in Spain Glenmark launched its first product, Desloratadine (in house), in Nov and in-licensed Product – Irbesartan and Irbesartan HCTZ which was launched in December.

During the quarter, Glenmark entered into a Strategic Development & Licensing Agreement with Celon Pharma S.A. (Celon) to develop and market a generic version of GlaxoSmithKline's Seretide Accuhaler® product - Fluticasone/Salmeterol dry powder Inhaler in Europe upon commercialization. As per the terms of the agreement; Glenmark has obtained Semi-exclusive Marketing & Distribution rights of the product across 15 European countries including Great Britain, Germany, Belgium, the Netherlands, Italy, Sweden, Norway and Romania among others. Celon on the other hand, shall receive an upfront payment; followed by certain milestone payments during various stages of the product's development from Glenmark; including Royalties on sales. The distribution agreement was concluded for a period of 10 years, with an option of a two-year extension.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,237.26 Mn (USD 18.61 Mn) for the third quarter ended December 31, 2015 as against Rs. 2,344.40 Mn (USD 38.00 Mn), recording a decrease of 47.23%.

In local currency, the subsidiaries of Brazil and Mexico grew 10% and 50% respectively for the third quarter. Glenmark stopped supplying to the Venezuela subsidiary from the month of November and is evaluating the situation on a constant basis. The Brazil currency depreciated significantly as compared to the previous corresponding quarter. For the third quarter of the previous year, the Brazil Real was at an average of 2.5 to the dollar as compared to 3.8 to the dollar in the third quarter of this financial year.

During the quarter, Glenmark launched DIRNELID (Mometason NS 50 mcg) in Mexico and Glemont IR 10 in Caribbean region.

Active Pharmaceutical Ingredients (API)

Revenue from sale of API business globally was Rs. 1,449.80 Mn (USD 22.01 Mn), for the quarter ended December 31, 2015 as against Rs. 1,464.90 Mn (USD 23.60 Mn) for the previous corresponding quarter, recording an decrease of 1.03%.

Glenmark has filed three new products in US and one each in Japan & Europe. The sales of API were driven by Lercanidipine, Amiodarone and Perindopril.

Research & Development

The company has a pipeline of 3 NCE and 5 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 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 US FDA. The Agency has requested additional information with some additional 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 is currently on going in France. Glenmark is planning a Pre-IND meeting with the U.S. FDA in Q4 FY 2015-16.

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.

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 to initiate dosing for Phase 2 study in atopic dermatitis.

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, a HER2xCD3 bi-specific 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. Glenmark has submitted an application to conduct Phase 1 clinical trials for GBR 1302 with the Paul Ehrlich Institute (PEI), Germany, and expects to initiate dosing in this financial year. 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.

Crofelemer

Glenmark is the sole supplier of Crofelemer API for Salix's Fulyzac brand in the US. Glenmark continues to expand the filing of Crofelemer 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. We expect to receive additional approvals over the next quarters.