Glenmark Pharmaceuticals Ltd

# Management Discussion and Analysis for the Fourth quarter of FY 2013-14

## Revenue Figures – Consolidated

**INR in Millions**

| | Fourth quarter ended Mar 31 | | | Twelve months ended Mar 31 | | |
|---|---|---|---|---|---|---|
| | **FY 2013-14** | **FY 2012-13** | **Growth %** | **FY 2013-14** | **FY 2012-13** | **Growth %** |
| India | 3,829.96 | 3,550.32 | 7.88% | 15,104.89 | 13,095.79 | 15.34% |
| US | 5,008.52 | 4,291.36 | 16.71% | 20,270.24 | 16,887.40 | 20.03% |
| Rest of the World (ROW) | 3,425.34 | 2,293.84 | 49.33% | 9,869.01 | 8,493.00 | 16.20% |
| Europe | 1,932.00 | 1,491.78 | 29.51% | 5,060.70 | 3,723.68 | 35.91% |
| Latin America | 1,061.74 | 792.73 | 33.93% | 4,045.54 | 3,467.91 | 16.66% |
| API | 1,530.63 | 938.58 | 63.08 % | 5,353.46 | 3,976.41 | 34.63 % |
| **Total** | **16,788.19** | **13,358.61** | **25.67%** | **59,703.84** | **49,644.19** | **20.26%** |
| Out-Licensing Revenue | 247.41 | - | | 365.51 | 493.03 | -25.86% |
| **Consolidated Revenue** | **17,035.60** | **13,358.61** | **27.53%** | **60,069.35** | **50,137.22** | **19.81%** |

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

Average conversion rate for 12M FY 2012-13 considered is Rs 54.55 / USD 1.00

USD figures are only indicative

**Review of Operations for the quarter ended Mar 31, 2014**

For the fourth quarter ended Mar 31, 2014, Glenmark's consolidated revenue was at Rs. 17,035.60 Mn (USD 276.86 Mn) as against Rs. 13,358.61 Mn (USD 245.95 Mn) an increase of 27.53 % For the year ended Mar 31, 2014, Glenmark's consolidated revenue was at Rs. 60,069.35 Mn (USD 994.09 Mn) as against Rs. 50,137.22 Mn (USD 919.11 Mn) an increase of 19.81% .

**India**

Sales for the formulation business in India for the fourth quarter ended Mar 31, 2014, was at Rs. 3,829.96 Mn (USD 62.05 Mn) as against Rs. 3,550.32 Mn (USD 65.38 Mn) in the previous corresponding quarter, recording a growth of 7.88%.

As per IMS MAT Mar 2014, Glenmark gained 1 rank from 20$^{th}$ to 19$^{th}$ as compared to MAT Mar 2013 exhibiting value growth of 17.65% vis-a-vis IPM growth of 10.07%.

For the month Mar 14, the business registered growth of 19.64% vis a vis market growth of 9.27%.

The India business strengthened itself in the following therapeutic segments with significant growth in market share from IMS MAT Mar'13 to MAT Mar'14 respectively. The cardiac segment market share went from 3.28% to 3.62%; the respiratory segment market share went from 3.33% to 3.48%; Anti-infective segment market share went from 1.51% to 1.69%; Gynaecology segment market share went from 1.37% to 1.52%; the Derma segment market share went from 8.60% to 8.05% and the Anti-diabetic segment market share went from 1.27% to 1.61%

**USA Formulations**

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations was Rs. 5,008.52 Mn (USD 81.09 Mn) for the quarter ended Mar 31, 2014 against revenue of Rs. 4,291.36 Mn (USD 79.05 Mn) for the previous corresponding quarter, recording an increase of 16.71% .

In the fiscal year 2014, Glenmark was granted approval of 8 Abbreviated New Drug Applications (ANDA), comprised of 7 final approvals and 1 tentative approval. In the fourth quarter, Glenmark filed seven ANDA's with the U.S. FDA, and plans to file an additional ten applications in the first quarter of the FY 2014-15.

Glenmark completed the successful launches of 7 products during fiscal year 2014, consisting of a mix of semi-solid preparations, delayed release, and immediate release items. The total number of ANDAs filed during FY 2014 was 20. During the year, we filed 3 dermatology products, 4 Oncology injectables; 4 oral contraceptives; 4 complex OSD (Oral solid dosage) and have also filed 2 immunosuppressant's which is a new therapeutic area for the organisation. In addition, we have filed in this year one complex injectable (New Therapeutic Area) and we plan to file another 6 complex injectable in FY 2014-15. In this year, we have filed only 2 immediate release (OSD).

As of March 31, 2014, our portfolio consists of 90 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 US FDA, of which 32 are Paragraph IV applications.

**Africa, Asia and CIS Region (ROW)**

For the fourth quarter, revenue from Africa, Asia and CIS region was Rs. 3,425.34 Mn (USD 55.93 Mn) as against Rs. 2,293.84 Mn (USD 42.19 Mn) for the previous corresponding quarter, recording an increase of 49.33%.

According to IMS Health, Glenmark Russia ranks 50 as per IMS MAT March'14 from rank 52 in March'13, which sustains Glenmark's position in the list of TOP-50 companies in the retail segment of the Russian pharmaceutical market. In the dermatology segment, the company continues to secure its position in the TOP-15 derma companies, with MAT March 2014 rank being 14. Glenmark Russia growth in this segment was 48.3% in value MAT March 2014 vs 19.1% market growth. Registered growth in units was 8.5% vs dermatology market de-growth of -1.1% MAT March 2014.

In the other CIS markets, Ukraine continues to show positive trends in secondary sales, driven primarily by the key brands. Glenmark Ukraine secondary sales grew by 75 % in Q4 (vs same period last year). Ukrainian GMP certificate has also been granted to the Baddi plant by Ukrainian authorities in February 2014.

The Africa/Middle East region posted good secondary sales growth in the fourth quarter. All subsidiaries in the region recorded good growth. Glenmark South Africa's secondary sales recorded growth of 138% & grew by 45% as compared to last year for the quarter. The South Africa unit is the largest in the Africa region

The Asia region grew 20 % in secondary sales for the fourth quarter and 25% for the entire financial year. The units in Malaysia, Cambodia and Myanmar grew by 40%, 42% & 33% in fourth quarter

**Europe Formulations**

Glenmark Europe's operations revenue for the fourth quarter ended Mar 31, 2014 was at Rs. 1,932.00 Mn (USD 31.60 Mn) as against Rs. 1,491.78 Mn (USD 27.42 Mn) recording growth of 29.51%.

The Central Eastern Europe region continued its strong sales growth in the fourth quarter. The region significantly outpaced the market with a 27% growth in secondary sales while the market stagnated. Glenmark is within top 40 players of overall pharma market in core countries and within Top 10 players in 'Glenmark Therapeutic Areas' market. The key launches in the region include Revitasens, Diorex +, Telmisartan+HCTZ, Ederix while building on the launches of Capecitabine, Temozolomide and Zoledronic acid in the last quarter. The growth in the fourth quarter and year as a whole is the combination of new launches with a high effectiveness of sales and marketing activities coupled with disciplined P&L and cash management. During the year, the region in-licensed around 15 product for various operating markets

The Western European business launched two in-Licensed products in Germany and three products in the UK comprising of one in-licensed product and two in-house products. In the Netherlands, there were two more in-house product launches. The German business won four more exclusive tenders and one semi-exclusive tender for five different products. The Netherlands and German entity continued supplying products through existing and new health insurance contracts. The Out-licensing business successfully signed one new deal for two products. Applications for Marketing Authorisations (MA) for four new products were filed through the decentralised procedure. MA approval for eight different products in different countries were also received this quarter. During the year, the region in-licensed 8 products for these markets

**Latin America**

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,061.74 Mn (USD 17.22 Mn) for the fourth quarter ended Mar 31, 2014 as against Rs. 792.73 Mn (USD 14.61 Mn) an increase of 33.93 %.

The Mexico, Venezuela and the Caribbean subsidiary performed well recording good growth during the quarter while the Brazil subsidiary recorded moderate growth at 10 % in local currency for the fourth quarter. The Mexico subsidiary launched Generic Seretide during the quarter

**Active Pharmaceutical Ingredients [API]**

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1,530.63 Mn (USD 24.88 Mn), for the quarter ended Mar 31, 2014 against Rs. 938.58 Mn (USD 17.30 Mn) for the previous corresponding quarter, recording an increase of 63.08%. The API plant in Ankleshwar completed the successful inspection from EU authorities. In Japan, 2 new product filings were undertaken and 3 new USDMF's were filed targeting FTF molecules.

**Research & Development**

The company has a pipeline of 3 NCE and 3 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. In addition, when tested in in-vivo model of asthma, it showed promising effect on airway inflammation, bronchoconstriction and cough. GRC 17536 has showed good safety in the Phase 1 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.

Glenmark is currently recruiting patients for a Phase II proof of concept study in pain indication in Europe and India.

Additionally, Glenmark has completed recruitment for a Phase I/IIa study for respiratory indications in the UK (MHRA). Topline data shows that inhaled doses of GRC 17536, upto maximum dose tested, were well tolerated in mild asthmatics. Glenmark is currently recruiting patients for a Phase IIa study in patients with chronic cough.

**GRC 15300**

GRC 15300, a first in class TRPV3 inhibitor for chronic pain did not meet the primary endpoint in the Phase II proof of concept trial. Sanofi and Glenmark Pharmaceuticals S.A, a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd had entered in April 2010 in a licensing agreement for the development and commercialization of GRC 15300. Glenmark received USD 25 Mn in upfront and milestone payments during the course of the agreement.

**mPGES-1 inhibitor**

Glenmark entered into an option agreement with Forest Laboratories, Inc on a collaboration for the development of novel mPGES-1 inhibitor to treat chronic inflammatory conditions, including pain. Forest has an exclusive option to obtain license rights to the program upon the completion of Phase 1 clinical trials. Glenmark has completed preclinical studies and Phase 1 enabling GLP studies for its selected lead molecule has been completed. It has filed a Phase 1 application for first-in-human trial with the MHRA, UK. The Phase 1 studies are to be initiated soon and are likely to get completed by January 2015.

Glenmark received USD 4 million as research fee payment from Forest Laboratories Inc. in the fourth quarter. Under the terms of the agreement signed in FY 2012-13, Forest made USD 6 million upfront payment and also provided an additional USD 3 million to support the next phase of work. In September 2013, Glenmark received an additional amount of USD 2 million as research fee payment from Forest Laboratories Inc. Hence, the total amount received by Glenmark from Forest Laboratories Inc towards its novel mPEGS-1 inhibitors program is USD 15 million

**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.

While Sanofi has terminated the Ulcerative Colitis Phase II POC study, it has announced a new phase II POC study for Multiple Sclerosis and has paid Glenmark USD 5 million as a milestone payment in the first quarter of FY 2014-15.

**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 1 enabling toxicity studies for GBR 900 have been completed successfully. A Phase 1 clinical trial application has been filed with the UK MHRA. 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 1 enabling toxicity studies for GBR 830 have been completed and Glenmark plans to file for a Phase 1 study in FY 2015.

**Crofelemer**

Supported by Salix's US 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 additional filings based on the regulatory filing data requirements within each of these markets. The recruitment in the pivotal C-Forward trial in adult acute watery diarrhoea has been completed and represents a significant milestone for the Crofelemer program with results of the trial expected in FY 2015. Glenmark has also submitted the protocol of a Proof-Of-Concept Pediatric clinical trial for acute watery diarrhoea and is awaiting approval of protocol.