Glenmark Pharmaceuticals Ltd

# Management Discussion and Analysis for the Financial Year Q3 FY 2011-12

## Revenue Figures – Consolidated

**INR in Millions**

| | Third quarter ended Dec 31 | | | Nine months ended Dec 31 | | |
|---|---|---|---|---|---|---|
| | **Q3 - FY 2011-12** | **Q3- FY 2010-11** | **Growth %** | **9M – FY 2011-12** | **9M – FY 2010-11** | **Growth %** |
| | | | | | | |
| **Speciality Business** | | | | | | |
| India | 2546.71 | 2287.89 | 11.31 % | 7339.50 | 6287.34 | 16.73 % |
| Rest of the World (ROW) | 1571.37 | 1062.00 | 47.96 % | 4097.48 | 2606.36 | 57.21 % |
| Latin America | 824.75 | 559.05 | 47.53 % | 2154.85 | 1417.98 | 51.97 % |
| Europe | 664.14 | 447.69 | 48.35 % | 1256.84 | 1011.08 | 24.31 % |
| **Total** | **5606.97** | **4356.63** | **28.70%** | **14,848.67** | **11,322.76** | **31.14 %** |
| Out-Licensing Revenue | 238.35 | - | | 2535.24 | 895.10 | 183.24% |
| **Total Speciality Business** | **5845.32** | **4356.63** | **34.17 %** | **17383.91** | **12217.86** | **42.28%** |
| | | | | | | |
| **Generics Business** | | | | | | |
| US | 3190.28 | 2040.89 | 56.32 % | 8702.41 | 6108.69 | 42.46 % |
| Europe | 306.73 | 194.25 | 57.91 % | 667.50 | 409.17 | 63.14 % |
| Latin America | 35.51 | 42.90 | - 17.23 % | 105.83 | 233.39 | -54.66 % |
| API | 835.84 | 728.26 | 14.77 % | 2244.39 | 2148.83 | 4.45 % |
| **Total Generics Business** | **4368.36** | **3006.30** | **45.31 %** | **11,720.13** | **8900.08** | **31.69 %** |
| Others | 97.18 | 123.53 | 21.33% | 443.83 | 421.98 | 5.18 % |
| | | | | | | |
| **Consolidated Revenue** | **10310.86** | **7486.46** | **37.73 %** | **29,547.87** | **21,539.92** | **37.18 %** |

Average conversion rate for 9M FY 2011-12 considered is Rs 47.67 / USD 1.00
Average conversion rate in 9M FY 2010-11 considered is Rs. 45.9/ USD 1.00

USD figures are only indicative

**Review of Operations for the quarter ended December 31, 2011**

For the third quarter ended Dec 31, 2011, Glenmark's consolidated revenue was at Rs. 10,310.86 Mn [USD 201.25 Mn] as against Rs. 7,486.46 Mn [USD 164.97 Mn], an increase of 37.73 %. Revenue from the generics business was at Rs. 4368.36 Mn (USD 85.11 Mn), as against Rs. 3006.30 Mn (USD 66.33 Mn), a growth of 45.31 %. The Speciality formulation business revenue was at Rs. 5845.32 Mn (USD 114.41 Mn) as against Rs. 4356.63 Mn (USD 95.90 Mn) for the corresponding previous quarter, registering a growth of 34.17 %

For the nine month ended Dec 31, 2011, Glenmark's consolidated revenue was at Rs. 29,547.87 Mn [USD 621.83 Mn] as against Rs. 21,539.92 Mn [USD 469.28 Mn], an increase of 37.18 %. Revenue from the generics business was at Rs. 11720.13 Mn (USD 245.84 Mn), as against Rs. 8900.08 Mn (USD 193.90 Mn), a growth of 31.69 %. The Speciality formulation business revenue was at Rs. 17,383.91 Mn (USD 366.68 Mn) as against Rs. 12,217.86 (USD 266.18 Mn) for the corresponding previous nine month period, registering growth of 42.28 %

**Specialty Business:**

**ROW Markets: India, Africa, Asia, CIS & Latin America region**

**India**

Sales for the formulation business in India for the third quarter ended Dec 31, 2011, increased to Rs. 2546.71 Mn [USD 49.17 mn] as compared to Rs. 2287.89 Mn [USD 50.41 Mn] in the previous corresponding quarter, recording a growth of 11.31 %.

As per ORG IMS MAT Dec 2011 data, Glenmark gained two ranks from 25th to 23rd registering value growth of 22.1% v/s. IPM growth of 14.9%. As per ORG IMS Nov 11 MAT data, Glenmark market share increased in Dermatalogy from 8.3% to 8.4%, Cardiac from 2.4% to 2.5%, and Respiratory from 1.2% to 2.7%,

## Africa, Asia and CIS Region

For the third quarter, revenue from Africa, Asia and CIS region was Rs. 1571.37 Mn [USD 30.72 Mn] as against Rs. 1062.00 Mn [USD 23.36 Mn] for the previous corresponding quarter, recording an increase of 47.96 %.

## Russia/CIS Region

According to Pharmexpert MAT Dec 2011 data, the Russian subsidiary registered 28% value growth (Overall pharma market MAT December 2011 growth is 13%). In this quarter, the company has launched two Dermatology products – Supirocin and Supirocin B, thus strengthening Glenmark's position in this segment and leading to the establishment of the Glenmark "Institute of healthy skin". The secondary sales of dermatology products recorded 34% growth, and Pharmexpert MAT December 2011 rank of the company in the derma segment in Russia is 16 (MAT December 2010 rank is 19).

In the other CIS markets, Ukraine, Kazakhstan and Uzbekistan are continuing to show positive trend in secondary sales. In Ukraine Glenmark has shown a strong growth in the secondary sales of 90% in Q3 driven primarily by the focus brands.

## Africa/Middle East

Africa and Middle East recorded strong secondary sales increase of 36% despite the reigning politically sensitive environment, particularly in the Middle East. The growth is driven mainly by its top 9 Power Brands which have all shown strong growth and enjoy high equity in the markets. South Africa and Kenya were the prime growth drivers accompanied by Egypt, Nigeria and Sudan. A number of new product registrations were received in UAE which will go a long way in terms of building Glenmark business in the country.

## Asia

For the Asia region, secondary sales growth in the third quarter has been very good. All countries in the region performed well. The Power and Focus brands continue to drive the demand in the market and presently contribute to nearly 70% of the total business. The focus is on building competencies of field staff employees in the region. Towards that, regional training program for Area Managers and Medical Rep training programs were initiated in all countries.

## Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 824.75 Mn [USD 16.12 Mn] for the third quarter ended December 31, 2011 as against Rs. 559.05 Mn [USD 12.30 Mn] a growth of 47.53 %

All subsidiaries in the region viz. Brazil, Venezuela, Mexico, Caribbean and Peru continued to record good growth. During the quarter, the Mexico subsidiary launched two products in the dermatology segment while the Venezuela unit launched three products.

## Europe

Glenmark Europe's operations revenue for the third quarter ended December 2011 was at Rs. 664.14 Mn [USD 13.41 Mn] as compared to Rs. 447.69 Mn [USD 9.83 Mn] recording growth of 48.35 %

Secondary sales grew by over 20% in a stagnant market which witnessed several challenges especially in Poland, where recent changes in legislation have resulted in severe price cuts and massive value de-growth of the pharmaceutical market as a whole.
In Romania, the team entered the CNS segment by launching several new products with the flagship launch of Olanzapine. In Poland, the team geared up for entry into a new therapeutic area viz. Dermatology. Czech and Slovak saw the successful launches of Trimetazidine MR and Perindopril-Inadapamide. In Hungary where the company recently established presence, the company witnessed business growth in its core area – cardiovascular.

## Research & Development

The company has a pipeline of 6 NCE and NBE molecules in clinical trials including the in-licensed molecule "Crofelemer".

### Revamilast (GRC 4039)

Glenmark's PDE4 inhibitor, Revamilast (GRC 4039); a candidate for a variety of respiratory and inflammatory disorders is progressing well in the clinics. Glenmark has obtained approval for conducting Phase IIb trials for Revamilast in Asthma and Rheumatoid Arthritis in the UK (MHRA), India (DCGI) & other regulatory bodies. Both studies are actively recruiting patients in these countries and dosing has been initiated. The Phase IIb studies being carried out will determine the efficacy and safety of the molecule and will also provide dose range finding for Revamilast.

In parallel to these two clinical studies, Glenmark is also conducting various other clinical and non-clinical studies to ensure timely entry into Phase III trials. Glenmark plans to file an IND for Revamilast in the US in Q3 FY 13. Glenmark intends to initiate Phase III trials for at least one indication by end of FY 13

### 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 initiated Phase 1 study in the Netherlands. Single and multiple ascending doses have been well tolerated with expected pharmacokinetic profile. Glenmark plans to initiate Phase II filing for proof-of-concept in pain indications in Q3'FY 2012 and respiratory indication in FY 2012-13

**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 in June 2011 to Sanofi. An application is planned to be filed in the coming quarter to initiate a PoC trial in Ulcerative Colitis in US and other countries.

**GRC 15300**

GRC 15300, a TRPV3 inhibitor for Neuropathic pain, Osteoarthritic pain and other inflammatory pain has completed Phase 1 trials in the UK. Globally, this is the only reported TRPV3 specific antagonist molecule to enter clinical trials. The PK and safety profile of the Phase I study results support further clinical development. A development and commercialisation license for GRC 15300 has been granted to Sanofi. PhIIa proof of concept studies for neuropathic and osteoarthritic pain are planned to be initiated in Q1 and Q2 Financial Year 2012-2013.

**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.

**GBR 401**

GBR 401, an anti-CD19 antibody, is currently under development for the target indications of B cell leukemias/lymphomas. The target CD19 is present on all B cells and shows up early during haematopoiesis. CD19 is more broadly expressed than CD20, hence providing potential to be used for patients with CD20 negative B cell tumours. GBR 401 is a human specific antibody that has shown good in vitro and in vivo properties. Glenmark had a successful Pre-IND meeting with the US FDA. Glenmark will file for Phase I trials in Q1 FY 13.

**Crofelemer**

Glenmark's in-licensed molecule Crofelemer - for multiple diarrhoeal conditions including HIV associated diarrhoea, acute adult and paediatric diarrhoea - successfully completed Phase 3 clinical testing for HIV associated diarrhoea The trial was conducted by Salix Pharmaceuticals Inc. in the USA. Glenmark also successfully completed a proof of concept, phase II study in adult acute diarrhoea in India. The pivotal study in adult acute watery diarrhoea has started recruiting in India and awaiting approval for trial in Bangladesh. Glenmark is further working on a developmental and regulatory strategy towards obtaining approvals in Glenmark territories. This could be the first innovative product launch for Glenmark across 140 countries where it has exclusive marketing and distribution rights.

With respect to Napo's purported termination of the Collaboration Agreement, the Arbitration Panel granted an interim order which prohibits Napo from terminating the Collaboration Agreement or treating the Collaboration Agreement as terminated unless and until the Panel amends the order. The Arbitration hearing is scheduled for end of March' 2012.

**Generics Business:**

**USA Formulations**

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations of Rs. 3190.28 Mn (USD 62.03 Mn) for the third quarter ended December 31, 2011 against revenue of Rs. 2040.89 Mn (USD 45.04 Mn), an increase of 56.32 % in Rs. term over the corresponding quarter of the previous year.

During the third quarter, Glenmark filed two ANDA's with the U.S. FDA and received tentative approval on Montelukast Sodium 10 mg tablets. IMS Health has recorded sales of Singulair® 10 mg tablets for the 12 month period ending September 2011, as USD 3.2 billion. Based on the tentative approval for Montelukast Sodium tablets, Glenmark should be able to launch the product upon patent expiry in August 2012.

At the end of third quarter, the Company has a portfolio of 73 generic products authorised for distribution in the US market as well as 43 ANDAs in various stages of the approval process with the U.S. FDA.

**EU Formulations**

The European business continued to steadily expand through product sales and licensing income. The UK entity continued to add new accounts in UK and also continued product supply in Republic of Ireland through distribution arrangements. We also launched four products this quarter in UK and two additional products in the other European market. The Netherlands business won tenders for three New Products and continued supplying Products to the pharmacies through the health insurance contracts. The German Business also launched one product this quarter and continued product supplies of other product through Tender Contract. The out-licensing business successfully signed one deal for licensing out and supply of products in EU markets.

Revenues for the quarter ended December 31, 2011 were Rs. 306.73 Mn (USD 6.11 Mn) against revenue of Rs. 194.25 Mn (USD 4.26 Mn), an increase of 57.91 %, in Rs. term, over the corresponding quarter of the previous year.

**Latin America - Oncology**

Glenmark's revenue from the Argentina operations were Rs 35.51 Mn [USD 0.68 Mn] in the third quarter ended December 31, 2011 as against Rs. 42.90 Mn [USD 0.96 Mn], a decrease of 17.23%, in Rs. term, over the corresponding quarter of the previous year. The unit in Argentina serves as a supply hub for Glenmark's oncology business worldwide. During the quarter, Glenmark Argentina filed sixteen product dossiers of which ten were for the LATAM region

## Active Pharmaceutical Ingredients [API]

Glenmark has filed total number of 49 US DMF's.

For the third quarter of FY 12 revenues were Rs. 835.84 Mn [USD 16.28 Mn] against Rs. 728.26 Mn [USD 16.07 Mn] , an increase of 14.77 %, in Rs. term, over the corresponding quarter of the previous year.

## Disclaimer

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