Glenmark Pharmaceuticals Ltd

# Management Discussion and Analysis for the Financial Year Q1 FY 2012-13

## Revenue Figures – Consolidated

**INR in Millions**

| | Q1 - FY 2012-13 | Q1- FY 2011-12 | Growth % |
|---|---|---|---|
| | | | |
| **Speciality Business** | | | |
| India | 2797.88 | 2253.82 | 24.14% |
| Rest of the World (ROW) | 1348.40 | 1046.78 | 28.81% |
| Latin America | 630.51 | 591.93 | 6.52 % |
| Europe | 269.66 | 215.12 | 25.36% |
| **Total** | **5046.45** | **4107.65** | **22.85 %** |
| Out-Licensing Revenue | - | 1112.34 | |
| **Total Speciality Business** | **5046.45** | **5219.99** | **-3.32%** |
| | | | |
| **Generics Business** | | | |
| US | 3923.58 | 2511.58 | 56.22 % |
| Europe | 332.27 | 175.36 | 89.48% |
| Latin America – Oncology | 39.44 | 28.98 | 36.08% |
| API | 1004.71 | 645.63 | 55.62% |
| **Total Generics Business** | 5300.00 | 3361.55 | 57.67% |
| Others | 57.62 | 101.00 | - 42.95% |
| | | | |
| **Consolidated Revenue** | **10,404.07** | **8682.54** | **19.83%** |

Average conversion rate for 3M FY 2012-13 considered is Rs 54.579/ USD 1.00

Average conversion rate in 3m FY 2011-12 considered is Rs. 45.28 / USD 1.00

USD figures are only indicative

**Review of Operations for the quarter ended June 31, 2012**

For the First quarter ended June 30, 2012, Glenmark's consolidated revenue was at Rs. 10404.07 Mn (USD 190.62 mn) as against Rs. 8682.54 Mn (USD 191.75) an increase of 19.83 % . Revenue from the generics business was at Rs. 5300.00 Mn (USD 97.11 Mn), as against Rs. 3361.55 Mn (USD 74.24 Mn), a growth of 57.67 %. The Speciality formulation business excluding outlicensing revenue was at Rs. 5046.45 Mn (USD 92.46 Mn) as against Rs. 4107.65 Mn (USD 90.72 Mn) for the corresponding previous quarter, recording a growth of 22.85%.

**Specialty Business:**

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

**India**

Sales for the formulation business in India for the first quarter ended June 30, 2012, increased to Rs. 2797.88 Mn [USD 51.26 mn] as compared to Rs. 2253.82 Mn [USD 49.77 Mn] in the previous corresponding quarter, recording a growth of 24.14 %

As per ORG IMS MAT June 2012 data, Glenmark gained three ranks from 24$^{th}$ to 21$^{st}$ registering value growth of 28.6% v/s. IPM growth of 13.9 %. As per ORG IMS MAT June 2012 data, Glenmark market share increased in Dermatalogy from 8.22% to 8.84%, Cardiac from 2.41% to 3.05%, and Respiratory from 2.71 % to 2.92%,

**Africa, Asia and CIS Region**

For the first quarter, revenue from Africa, Asia and CIS region was Rs. 1348.40 Mn [USD 24.71 Mn] as against Rs. 1046.78 Mn [USD 23.12 Mn] for the previous corresponding quarter, recording an increase of 28.81 %.

For the first quarter, the secondary sales growth for the Russian subsidiary is at 36%. The Russian subsidiary improved its ranking to 58 in June'12 as compared to 67 in June'11. The respiratory and dermatology segment registered strong growth in the quarter. In other CIS markets, Ukraine, Kazakhstan and Uzbekistan are continuing to show positive trend in secondary sales. In Ukraine Glenmark has shown good growth in secondary sales at 65 % in the first quarter

The Africa/Middle East region posted healthy secondary sales growth of 44 % for the first quarter due to significant contributions from the power brands. South Africa, Kenya and Egypt achieved highest ever secondary sales value for the quarter while Nigeria, Tanzania, Ethiopia, and Yemen also continued to record good value growth. The political and economic environment in the Africa/Middle East region continues to be uncertain.

The Asia region continued to perform well with secondary sales growth in excess of 30 % for the quarter. All power brands and key units are performing well in the region. The focussed strategy of brand building is driving the performance in Asia

**Latin America**

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 630.51 Mn [USD 11.55 Mn] for the first quarter ended June 30, 2012 as against Rs. 591.93 Mn [USD 13.07 Mn] a growth of 6.52 %

All subsidiaries in the region viz. Brazil, Venezuela, Mexico, Caribbean and Peru continued to record good secondary sales growth. During the quarter, the Brazil subsidiary launched one product.. The Mexico subsidiary received approvals for two dermatology products. The Venezuela unit launched one product during the quarter..

**Europe**

Glenmark Europe's operations revenue for the first quarter ended June 30, 2012 was at Rs. 269.66 Mn [USD 4.94 Mn] as compared to Rs. 215.12 Mn [USD 4.75 Mn] recording growth of 25.36 %. Secondary sales growth for the region was 17 % against a de-growing pharma industry. The company launched several products successfully, further validating the marketing capabilities and prescription generation effort. Products such as Trimetazidine, Pramipexole are the leading generics in Czech. Topiramate is the market leader in Slovakia. Quetiapine was launched and is the second generic in Romania. Several successful new launches in the countries: Levetiracetam across the region, Betahistine in RO, Temozolamide in CZ/ RO, Anastrozole in SK, differentiated packs of Telmisartan/ Nebivolol in CZ/ SK.

## Generics Business:

### USA Formulations

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations of Rs. 3923.58 Mn (USD 71.89 Mn) for the first quarter of FY 2012-13 against revenue of Rs. 2511.58 Mn (USD 55.47 Mn) for the first quarter of the previous year, an increase of 56.22 % in Rs. term over the corresponding quarter of the previous year.

In the first quarter of FY 2012-13, Glenmark was granted approval of three Abbreviated New Drug Applications (ANDA), comprised of two final and one tentative approval. Final approvals were granted for Desogestrel and EthinylEstradiol tablets (Viorele®), Norgestimate and EthinylEstradiol tablets and Lamotrigine immediate release tablets; Tentative approval was granted for Zolmitriptan orally disintegrating tablets. The Company filed one ANDA with the U.S. FDA. During the quarter, the company launched five oral contraceptive products and also launched Imiquimod, a derma product.

Glenmark's marketing portfolio as on June 30, 2012 consists of 80 generic products authorized for distribution in the U.S. market. The Company currently has 39 applications pending in various stages of the approval process with the US FDA.

### EU Formulations

The European business continued to steadily expand through product sales and licensing income and by expanding its presence through Distribution Partners in more European Countries. An innovative, only supplier, new pack size of an existing one product and one new product was launched in this quarter in UK. One additional product in three European Markets through partners was also launched. Two products in Nordic Markets were launched through a distributor. The Germany business launched two products during the quarter, one being supplied through tenders. Netherlands and Germany Entity continued supplying products through the existing health insurance contracts.

Overall, the business posted revenues of Rs. 332.27 Mn (USD 6.09Mn) for the First quarter of FY 2012-13 against revenue of Rs. 175.36_ Mn (USD 3.87 Mn), for the first quarter of the previous year , an increase of 89.48 % in Rs. term over the corresponding quarter of the previous year.

**Oncology**

During the first quarter, the oncology business based out of Argentina filed 2 product dossiers in Brazil and Venezuela. Glenmark's revenues from the Argentina operations were Rs. 39.44Mn [USD 0.72 Mn] in the first quarter of 2012-13 as against Rs. 28.98 Mn [USD 0.64 Mn] for the first quarter of the previous year

**Active Pharmaceutical Ingredients [API] :**

The business continues it's leadership position through major product drivers- Lercanidpine, Amiodarone, Telmisartan, Perindopril, Adapalene. The company has also continued to expand presence in the US, Europe and Brazil through new molecules. The company has also maintained acceptable audit status for facilities.

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1004.71 Mn [USD 18.41 Mn] for the First quarter of FY 2012-13 against Rs. 645.63 Mn [USD 14.26 Mn] ), for the first quarter of the previous year, recording an increase of 55.62 % in Rs. term.

**Research & Development**

The company has a pipeline of 5 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 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 in Europe and Asia. The Asthma study is currently recruiting patients in these countries. Recruitment for the Rheumatoid Arthritis study is nearing completion. 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 both the indications.

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 completed Phase 1 study in the Netherlands. Single and multiple ascending doses have been well tolerated with expected pharmacokinetic profile. Glenmark has obtained approval for Phase II proof of concept study in pain indication in the UK (MHRA) and awaiting approval in Germany (BfArM). Additionally, Glenmark has filed for a Phase I/IIa study for respiratory indications in the UK (MHRA) and is awaiting approval.

**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. A development and commercialisation license for GRC 15300 has been granted to Sanofi. A PhIIa proof of concept study in neuropathic pain has been initiated in Q1 FY 2012-2013 and is currently ongoing.

**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 has been successfully filed in Q1 FY 2013 to initiate a PoC trial in Ulcerative Colitis in US and other countries.

**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 initiated. Glenmark plans to file for a Phase I study in Q1 FY 14.

**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 and the PDUFA date issued by the USFDA is Sep 5, 2012.

The pivotal study in adult acute watery diarrhoea conducted in India and Bangladesh by Glenmark is actively recruiting patients. 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. The final Arbitration hearing has been concluded and the order is awaited.

**Disclaimer**

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