

**Management Discussion and Analysis for  
Fourth quarter of the Financial Year 2007 - 08  
Ended 31st March, 2008**

**Revenue Figures – Consolidated**

**[Rs. in millions]**

Particulars	Quarter 4			Financial Year		
	2007-08	2006-07	Growth %	2007-08	2006-07	Growth %
<b>Generics Business</b>						
US	1962.57	803.35	144.30%	5640.27	2207.52	155.50%
Europe	9.20	-		9.20	-	
Latin America (Argentina)	60.19	55.54	8.37%	309.90	265.24	16.84%
API	590.87	355.93	66.01%	1959.34	1318.36	48.62%
<b>Total Generics Business [A]</b>	<b>2622.83</b>	<b>1214.82</b>	<b>115.90%</b>	<b>7918.71</b>	<b>3791.13</b>	<b>108.87%</b>
<b>Speciality Business</b>						
Latin America ( Brazil & Others)	432.71	620.31	-30.24%	1917.55	1155.41	65.96%
Semi Regulated Markets [SRM]	532.63	454.42	17.21%	2045.74	1883.97	8.59%
Europe	83.46	-	-	368.55	-	-
India	1540.88	1292.03	19.26%	5453.54	4289.72	27.13%
<b>Speciality Formulation [1]</b>	<b>2589.68</b>	<b>2366.76</b>	<b>9.42%</b>	<b>9785.39</b>	<b>7329.10</b>	<b>33.51%</b>
<b>Out-licensing Revenues [2]</b>	<b>609.84</b>	<b>-</b>	<b>-</b>	<b>2402.73</b>	<b>1395.12</b>	<b>72.22%</b>
<b>Speciality Business [B = (1+2)]</b>	<b>3199.52</b>	<b>2366.76</b>	<b>35.19%</b>	<b>12188.12</b>	<b>8724.22</b>	<b>39.70%</b>
<b>Consolidated Revenues [A + B]</b>	<b>5822.35</b>	<b>3581.58</b>	<b>62.56%</b>	<b>20106.83</b>	<b>12515.34</b>	<b>60.66%</b>

## **Review of Operations for the Fourth quarter of the Financial Year 2007- 08**

During the fourth quarter of FY2008, Glenmark's consolidated revenues increased to Rs. 5822.35 Mn [USD<sup>1</sup> 144.55 Mn] against Rs. 3581.58 Mn [USD<sup>2</sup> 81.14 Mn] for the fourth quarter of the previous year, recording a growth of 62.56 % .Revenues from Generics business, Glenmark Generics Ltd. ( GGL ), presently a subsidiary of Glenmark Pharmaceuticals Ltd.(GPL) were Rs. 2622.83 Mn (USD 65.11 Mn ), as against Rs. 1214.82 Mn (USD 27.52 Mn ) which was reported in the same quarter of previous year, registering a growth of 115.9%. The Speciality business (including out licensing revenues a part of GPL), had revenues of Rs.3199.52 Mn ( USD 79.43 Mn) as against Rs. 2366.76 Mn (USD 53.62 Mn) for the quarter of the previous year, recording a growth of 35.19%.

Consolidated profits for the fourth quarter increased to Rs. 2189.63 Mn [USD 54.36 Mn] from Rs. 622.03 Mn [USD 14.09 Mn] for the previous year, an increase of 252%.

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<sup>1</sup> Average conversion rate for Q4 FY 2007-08 of Rs. 40.28 / USD 1.00

<sup>2</sup> Average conversion rate for Q4 FY 2006-07 of Rs.44.14 / USD 1.00

## **Specialty Business:**

### **ROW Markets:**

#### **India**

Glenmark's formulation business in India increased to Rs. 1540.88 Mn [USD 38.25 Mn] in the fourth quarter of FY 08 against Rs. 1292.03 Mn [USD 29.27 Mn] in the previous year, recording a growth of 19.26%. According to the latest ORG IMS SSA data the company is ranked 24<sup>th</sup> in the market registering a value growth of 23%, vis-à-vis that of the industry [17%] [ORG Feb 2008]. In terms of volume, the company registered a growth of 17%, vis-à-vis that of the industry [9%].

Glenmark launched eight new products in the fourth quarter. Four of which were first to launch products. Glenmark plans to launch another 23 products in the next year.

The company has further received USFDA, approval for its plant in Baddi. This is the third Glenmark manufacturing plant to have been approved by USFDA

#### **Semi Regulated Markets (Africa, Asia and CIS)**

Revenues from the export of branded formulations increased to Rs. 532.63 Mn [USD 13.22 Mn] in the fourth quarter of FY 08 against Rs. 454.42 Mn [USD 10.29 Mn] for the fourth quarter of the previous year, recording a growth of 17.2%.

Glenmark filed 25 products and obtained registrations for 63 formulation products in several of its export markets in the fourth quarter.

A total of 104 fillings and 88 approvals were obtained in Africa and Middle east, 42 fillings with 66 approvals in Asia and 21 fillings with 42 approvals in Russia & CIS in

the year ended 07 – 08. A total of 173 filings were made in the year ended 07 – 08 with a total of 199 approvals.

During this time the company launched Klenzit C (Adapalene with Clindamycin) in Kenya, Glevo (Levofloxacin) in Philippines and Perigard (Perindopril) in Malaysia.

The company has established its operations in Egypt for the development of its branded formulations business in the country. Glenmark has further initiated operations in Indonesia, Thailand, Australia and China.

## **Latin America**

Glenmark's revenues from its Latin American and Caribbean operations, comprising Glenmark Farmacêutica Ltda [GFL], the wholly owned Brazilian subsidiary of Glenmark and commercial operations in 10 other Latin American and Caribbean countries, were Rs. 432.71 Mn [USD 10.74 Mn] in the fourth quarter of 2007-08 against Rs. 620.31 Mn [USD 14.05 Mn] for the fourth quarter of the previous year reflecting a decline of 30.2%.

Seven products were launched, three in Jamaica (Glevo 250 and 500mg, Glimulin 2mg), and four in Dominican Republic (Maclar, Glevo 250 and 500mg, Tacroz). Glenmark filed 15 products in the fourth quarter and obtained registrations for 10 formulation products and is on track to achieve its target. The total of 98 filings were done in the year ended 07 -08 receiving a total of 25 approvals.

## **Europe**

Medicamenta, Glenmark's wholly owned subsidiary, posted revenue of Rs.83.46 mn (USD 2.07mn) for the fourth quarter of 2008. Medicamenta management and processes are now aligned with Glenmark practices. The company has established its base in Romania through Glenmark Pharmaceuticals s.r.l. in February '08, thereby creating its third commercial country operation in Europe. In Romania, Glenmark hopes to achieve net revenues of up to \$50m within 5 years, based on its portfolio of

branded generic and Specialty products. Glenmark Pharmaceuticals Ltd. has further initiated commercial operations in Poland, Bulgaria and Hungary.

## **Research and Development**

Glenmark today has a pipeline of 13 NCE and NBE molecules in the pipeline, with three molecules in Phase II clinical development.

### **NCEs:**

#### **Oglemilast (GRC 3886):**

Glenmark received USD 15 million as milestone payment from Forest Laboratories for Oglemilast, GRC 3886. USFDA has provided a favourable response to the submission made by Forest, allowing it to initiate an additional Phase II study in COPD for Oglemilast (GRC 3886), Glenmark's lead PDE4 inhibitor molecule. The approval came after Forest satisfactorily addressed FDA's outstanding non-clinical questions. Glenmark is working closely with Forest Labs, which is Glenmark's North American partner for Oglemilast, to detail out plans for further long term development, Glenmark views this as an important positive step in continuing overall clinical development of Oglemilast.

#### **Melogliptin (GRC 8200):**

Glenmark's DPPIV inhibitor, Melogliptin , GRC 8200 , a treatment for Type II diabetes has completed Phase IIA studies and is currently undergoing Phase IIB studies. Glenmark plans to complete all Phase II's on Monotherapy by the mid 2009 and would initiate Phase III's by end of 2009. Glenmark also plans to develop Melogliptin in combination with various other diabetes therapies.

Merck recently announced that it plans to move out of the diabetes space for strategic reasons. In light of this development Glenmark and Merck Serono , a division of Merck kGaA , have reached a mutually amicable settlement to terminate their on-going agreement on GRC-8200 . Glenmark has received the global rights back from Merck Serono for Glenmark’s DPPIV inhibitor, Melogliptin , GRC 8200 , a treatment for Type II diabetes. Glenmark had out-licensed Melogliptin to Merck kGaA in October 2005. The company has initiated discussions with other partners to out-license Melogliptin.

#### **GRC 6211:**

Glenmark Pharmaceuticals S.A. (GPSA) a wholly owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL) has out licensed its molecule GRC 6211 to Eli Lilly and Company. Under the terms of the agreement, Lilly will acquire the rights to a portfolio of transient receptor potential vanilloid sub-family 1 (TRPV1) antagonist molecules, including a clinical compound, GRC 6211. GRC 6211 is currently in early clinical Phase II development as a potential next-generation treatment for various pain conditions, including osteoarthritic pain.

As per the terms of the agreement, Glenmark has received an upfront fee of \$45 million and could receive up to an additional \$215 million in potential development and sales milestones for the initial indication, as well as royalties on sales if GRC 6211 is successfully commercialized. If other indications are successfully developed, Glenmark would be entitled to additional milestones up to \$90 million. Lilly will have marketing rights for North America, Europe and Japan, while Glenmark will retain the marketing rights in all other countries. Further Glenmark will have the right to co-promote GRC 6211 in the United States.

**GRC 4039:**

Glenmark's candidate for Rheumatoid Arthritis, Inflammation and Multiple Sclerosis, GRC 4039, a PDE 4 inhibitor, is expected to complete Phase I trials in the coming quarters.

**GRC 10693:**

Glenmark's candidate for Neuropathic Pain, Osteoarthritis and other Inflammatory Pain, GRC 10693, a CB 2 agonist, is in its pre-clinical development stage and is expected to enter the clinics in Q1 FY 2009.

**Biologics**

Glenmark Pharmaceuticals S.A., the wholly-owned Swiss subsidiary of Glenmark Pharmaceuticals Ltd. (Glenmark) is developing its pipeline for NBE's focusing on inflammatory disorders.

**GBR 500:**

GBR 500, a monoclonal antibody is an antagonist of the VLA-2 (Alpha2 beta1) integrin has completed crucial IND-enabling preclinical studies. VLA -2 mediates interactions of cells with the extra cellular matrix.

Glenmark intends to file an IND application with the US FDA by August 2008 for initiation of Phase I trials and expects to complete Phase I in this fiscal year immediately followed by a proof of Concept Phase IIa study.

This is Glenmark's first NBE to enter the clinics from the pipeline of 13 NCEs and NBEs , and demonstrates steady progress in the drug discovery space .

## **GBR 600:**

GBR 600 an antithrombolytic humanized monoclonal antibody is showing good results in pre-clinical testing and is being scaled up for further IND enabling studies.

## **Generics Business:**

### **USA Formulations**

Glenmark Generics Inc., U.S.A. [GGI], Glenmark's wholly owned US subsidiary posted revenues of Rs. 1962.57 Mn [USD 48.72] for the fourth quarter of FY 08 against revenues of Rs. 803.35 Mn [USD 18.20 Mn] registering an increase of 144.3 % over the fourth quarter of the previous year.

The Company commenced marketing and distribution of five Clobetasol Propionate dermatology products, namely, Clobetasol Propionate Cream, Clobetasol Propionate E Cream, Clobetasol Propionate Gel, Clobetasol Propionate Ointment, Clobetasol Propionate Topical Solution in Q4 FY08. The Company also initiated marketing and distribution of Nabumetone tablets, Hydroxyzine Hydrochloride tablets and Nystatin tablets and continues to gain share across the board in this quarter.

Glenmark filed nine ANDA's during Q4 which brings it FY08 total to 25 (23 internal/2 external). The Company now has a portfolio of 28 generic products in the US market. The Company currently has over 34 ANDAs undergoing USFDA approval process/launch. Further, there are three potential first to file Para 4 applications filed by Glenmark.

## **EU Formulations**

This quarter, the Company initiated an MRP for one product and a DCP procedure covering several EU markets for another. The Company also received Duplex MAs for one of its products. Glenmark has so far filed six MAAs in total. The Company plans to launch three products and file for eight during the next financial year.

The Company is actively pursuing acquisition opportunities in the Western European markets.

Glenmark's revenues from EU operations were Rs. 9.20 Mn [USD 0.23 Mn] in the fourth quarter of 2007-08

## **Oncology**

Glenmark filed two dossiers in Argentina, 11 dossiers in the rest of Latin America and has received two approvals. The Company intends to file two dossiers in Argentina and at least 30 in the rest of Latin America in near quarters

The Company launched one product [Anastrozole 1 mg tab] in Ecuador, five in Uruguay [Carboplatin 150 & 450mg Inj, Paclitaxel 30 mg & 100 mg & 150mg & 300 mg, Oxaliplatin 50mg & 100 mg, Etoposide 100 mg Inj, Epirubicin 10 mg & 50 mg] and three in Pakistan [Leucovorin 50 mg Inj, Paclitaxel 150 mg Inj, Pamidronate 30 mg & 90 mg]. The total number of products launched by the Company in FY08 is 50.

Glenmark's revenues from Argentina operations were Rs. 60.19 Mn [USD 1.49 Mn] in the fourth quarter of 2007-08 against Rs. 55.54 Mn [USD 1.26 Mn] for the fourth quarter of the previous year reflecting an increase of 8.4%.

## Active Pharmaceutical Ingredients [API]

The Company has filed two DMFs in this quarter. This takes the total DMF filing for FY08 to eight and the total DMFs filed till date to 31. The Company intends to file another four DMFs in the ensuing quarter and targets entering China and South Africa.

## International

Revenues from sale of API to regulated and semi-regulated markets globally were Rs. 283.17 Mn [USD 7.03 Mn] for Q4 FY 08 against Rs. 187.79 Mn [USD 4.25 Mn] for Q4 of the previous year, recording an increase of 50.8 %.

## Domestic

Revenues from the domestic API and co-marketing business amounted to Rs. 307.70 Mn [USD 7.64 Mn] in Q4 FY 08 against Rs. 168.14 Mn [USD 3.81 Mn] for Q4 of the previous year, recording an increase of 83.0%.

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