

**Management Discussion and Analysis for the  
First quarter of the Financial Year 2008-09  
Ended 30<sup>th</sup> June, 2008**

**Revenue Figures – Consolidated**

[Rs. in millions]

Particulars	Quarter 1		
	2008-09	2007-08	Growth %
<b>Generics Business</b>			
US	1908.79	826.22	131.03 %
Europe	-	-	
Latin America (Argentina)	71.14	62.41	13.99%
API	426.07	395.15	7.83 %
<b>Total Generics Business [A]</b>	<b>2406.00</b>	<b>1283.78</b>	<b>87.42 %</b>
<b>Speciality Business</b>			
Latin America ( Brazil & Others)	312.09	490.33	-36.35%
Semi Regulated Markets [SRM]	394.09	446.38	-11.71 %
Europe	123.71	93.15	32.80 %
India	1428.61	1280.60	11.56%
<b>Speciality Formulation [1]</b>	<b>2258.50</b>	<b>2310.46</b>	<b>- 2.25 %</b>
<b>Out-licensing Revenue [2]</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Speciality Business [B =(1+2)]</b>	<b>2258.50</b>	<b>2310.46</b>	<b>- 2.25 %</b>
<b>Consolidated Revenue [A + B]</b>	<b>4664.50</b>	<b>3594.24</b>	<b>29.78 %</b>
<b>Consolidated Net Profit</b>	<b>1153.76</b>	<b>571.51</b>	<b>101.88 %</b>

## **Review of Operations for the First Quarter of the Financial Year 2008-09**

For the first quarter of FY'2009, Glenmark's consolidated revenue increased to Rs. 4664.50 Mn [USD<sup>1</sup> 112.07 Mn] as against Rs. 3594.24 Mn [USD<sup>2</sup> 87.01 Mn] registering growth of 29.78 %. Revenue from the generics business, Glenmark Generics Ltd (GGL) was at Rs. 2406.00 Mn (USD 57.81 Mn ), as against Rs. 1283.78 Mn (USD 31.08 Mn ), registering growth of 87.42 %. The Speciality business (including out licensing revenues), had revenues of Rs. 2258.50 Mn ( USD 54.26 Mn) as against Rs. 2310.46 Mn (USD55.93 Mn) for the quarter of the previous year, a marginal decline of 2.25 % - This was due to the decline in primary sales for the LatAm and the (Africa, Asia and CIS) Region. The secondary sales growth in these markets continues to be strong above 40% as per third party data sources. We expect primary sales growth from these markets from the second quarter.

Consolidated Net profit for the quarter increased to Rs. 1153.76 Mn [USD 27.72 Mn] from Rs. 571.51 Mn [USD 13.83 Mn] for the previous year, an increase of 101.88 %. For the Generics business, Net profit was Rs. 681.76 Mn [USD 16.38 Mn] and for the Speciality Business (including out licensing revenues) Net Profit was Rs. 472.0 Mn [USD 11.34 Mn] for the quarter.

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<sup>1</sup> Average conversion rate for Q1 FY 2008-09 of Rs. 41.62 / USD 1.00

<sup>2</sup> Average conversion rate for Q1 FY 2007-08 of Rs. 41.31 / USD 1.00

## **Specialty Business:**

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

#### **India**

Sales for the formulation business in India increased to Rs. 1428.61 Mn [USD 34.32 Mn] for the first quarter of this financial year as compared to Rs. 1280.60 Mn [USD 31.00 Mn] in the previous corresponding quarter, recording a growth of 11.56 %. According to the latest ORG-IMS data the company is ranked 26<sup>th</sup> in the market registering value growth of 16.4 %, vis-à-vis that of the industry[12%] [ORG:Jan-June 2008].

In the India formulations business, Glenmark continued to grow and strengthen its position in the dermatology, respiratory and cardiovascular segments. The business made a strong comeback in the pain segment with its product Flexilor(Lornoxicam), which not only registered strong sales growth but also emerged as the leader in this particular molecule segment.

The India formulations division launched 12 new products during the quarter. Some major product launches during the quarter were Onabet(Sertaconazole) cream, a derma product which is a first of its kind product in the country. Onabet, a benzothioephene imidazole agent reduces the chances of relapse by offering better penetration and long-term residency within the skin. The active ingredient in Onabet, sertaconazole nitrate, has been approved by USFDA and is marketed in over 24 countries. Onabet cream is a significant product launch for the India formulations division. Deriva CMS, a unique combination of Retinoid adapalene and Antimicrobial clindamycin is another major launch in the derma segment. This combination has been introduced for the first time by the company using microsphere technology which leads to more sustained release of Adapalene, resulting in significantly lesser irritation while improving efficacy. The third major launch has been Hair4U, a Aminexil+Minoxidil combination product, another first in the market specifically targeting perfollicular fibrosis while improving the quality and density of hair.

## **Africa, Asia and CIS Region**

For the first quarter of the financial year, revenue from the export of branded formulations was Rs. 394.09 Mn [USD 9.47 Mn] as against Rs. 446.38 Mn [USD 10.81 Mn] for the previous corresponding quarter, recording a decline of 11.71%.

The Russian operations performed well in the quarter. Glenmark also strengthened its presence in key markets in Asia viz. Malaysia and Philippines. Both these countries have registered strong secondary sales growth in the branded generic space.

During the quarter for the SRM region, the company has filed 5 product approvals with regulatory authorities in the region and have received 31 product approvals.

During the quarter, the company launched Perigard (Perindopril) in Vietnam – this is the first branded generic version in the country, In Russia, Glenmark launched 3 new products Klenzit(Adapalene), Klenzit C(Adapalene with Clindamycin) and Momet(Mometazone). Klenzit and Momet are the first branded generic version to be launched in the country

Glenmark has initiated the process of building its front ends in China and Australia. The China market which is valued at around USD 15 bn and the Australia market at around USD 8 bn have significant potential. Glenmark has recently appointed country managers for both these countries.

## **Latin America**

Glenmark's revenue from its Latin American and Caribbean operations, comprising Glenmark Farmacêutica Ltda [GFL], the wholly owned Brazilian subsidiary of Glenmark and commercial operations in other Latin American and Caribbean countries, were Rs. 312.09 Mn [USD 7.50 Mn] in the first quarter of 2008-09 as against Rs. 490.33 Mn [USD 11.87 Mn] a decline of 36.35 %.

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The decline is mainly attributed to the tender business and hospitals/institutional sales reflected in the first quarter of the previous financial year. Brazil, the largest subsidiary in the region registered impressive secondary sales growth for the quarter. As per IMS figures for Q1 FY09, the Brazilian subsidiary has grown by 89%. As per IMS figures for the first six months of the current calendar year, the Brazilian subsidiary showed an increase in market share to 0.132% as compared to 0.098 % for the previous corresponding period. In value terms, as per IMS the subsidiary is now ranked at 77 in the marketplace as compared to 88 at the same time the previous year. Saccette, the weight loss product and Adacne Clin, an innovative acne product which was launched in the last financial year have registered impressive sales growth in the first quarter. The subsidiary has in-licensed two products RadiaPlex and OraMedic during the quarter - Both are quality of life products for the use in Oncology. These new additions have strengthened the Oncology portfolio of the Brazilian subsidiary.

For the region, the company has filed 12 product approvals with regulatory authorities in the region and received 1 product approval during the quarter. In Q2 FY'09, the LatAm region plans to launch at least 10 new products in various markets

### Europe

Glenmark Europe's operations registered revenue growth of 32.80 % at Rs. 123.71 Mn [USD 2.97 Mn] as compared to Rs. 93.15 Mn [USD 2.25 Mn] for the previous corresponding quarter. All sales in Q1 were generated through Glenmark's wholly owned subsidiary, Medicamenta, through its sales activities in Czech Republic and Slovakia.

Glenmark continues to invest in Medicamenta primarily in the areas of quality release and packaging. The manufacturing site in Vysoke Myto, Czech Republic, is being developed as an EU centre for packaging, batch release and distribution. In the second quarter, Medicamenta will launch the first product in Europe to have been developed and manufactured by Glenmark - 'Topiramate', for the treatment of epilepsy. The Czech subsidiary is currently focusing its activities in the areas of Cardiovascular, CNS and Dermatology.

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Glenmark also announced that it has established a new company in Poland and acquired a product portfolio of seven branded products from Actavis. Glenmark's estimated annualised sales of the acquired product portfolio for FY09 will be USD 15 million. Under the terms of the agreement, Glenmark has received through its subsidiary all Marketing Authorisations and Trademark rights in Poland for the products, and will sell the products directly to the Polish market through its appointed distributors.

The Polish subsidiary will also launch another 4-5 products by the end of the year in the cardiovascular and CNS segments. The subsidiary has begun hiring sales force and should have around 30 representatives before the end of Q2. By the end of the 2008, Glenmark will also assume full control for the sales, marketing and distribution of the acquired brands, which are currently being promoted and distributed on its behalf by its partner, Actavis.

In Romania, another key market for the European region, Glenmark has acquired the rights for an original product, Aflen, in the cardiovascular area. The subsidiary is launching the product this month and, being an innovative drug, it expects a good sales response from physicians. The subsidiary also plans to launch Glenmark manufactured and developed products during the latter half of the year.

Overall, the Central & East European region will be the major growth driver for the European region. Glenmark will focus on building its front-end in these key CEE markets and will continue to launch products in the branded generic and innovative product space. For the financial year 2008-09, the estimated sales for the European region should be in the range of USD 26 – 30 mn.

### **Research and Development**

The discovery program at Glenmark continues to investigate new targets and is actively yielding new hits for further development. Presently, the company has a pipeline of 13 NCE and NBE molecules. Five are in clinics, four in pre-clinical and four are in the discovery stage.

## **NCEs**

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

Glenmark's lead PDE4 inhibitor molecule, GRC 3886 continues to progress well in the clinics. The Phase II for COPD has been initiated by our out-licensing partner Forest Labs in the US and is progressing as per plan. The Phase II for asthma also remains on track. Glenmark continues active discussions with European partners for licensing rights for the Europe region.

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

Glenmark's DPP4V inhibitor, Melogliptin (GRC 8200), a treatment for Type II diabetes completed Phase IIA studies and is currently undergoing Phase IIB studies. The clinical study is ongoing and clinical trial enrolment is proceeding as per plan. We are glad with the progress made by the molecule so far and the results continue to remain encouraging. As per the current timelines, Melogliptin monotherapy is expected to enter Phase III in the second half of calendar 2009. Glenmark is also developing several combinations with Melogliptin.

Since we have received global rights for the molecule back from Merck Serono, Glenmark has initiated several discussions with other potential partners. Some of these are likely to conclude over the next 6-12 months.

### **GRC 6211:**

Glenmark's molecule GRC 6211 for the treatment of pain which was out-licensed to Eli Lilly for developing and marketing in North America, Europe and Japan is also progressing as per plan in Phase II studies.

### **GRC 4039:**

Glenmark's candidate for Rheumatoid Arthritis, Inflammation and Multiple Sclerosis, GRC 4039, a PDE 4 inhibitor, is progressing well. The early results from the Phase I study are encouraging and support continued development. We expect the molecule to enter phase II in Q3 FY'09

**GRC 10693:**

Glenmark's candidate GRC 10693 for Neuropathic Pain, Osteoarthritis and other Inflammatory Pain has entered Phase I trials. The company intends to develop GRC 10693, a cannabinoid-2 [CB-2] receptor agonist, in neuropathic pain as the primary indication. GRC 10693 belongs to a novel exciting class and Glenmark is an early entrant in this category. Glenmark expects to complete Phase I trials for GRC 10693 and initiate Phase II before the end of FY 09.

**GRC 17173 and GRC 9332 :**

Glenmark's TRPV3 lead candidate GRC 17173 for pain is currently undergoing IND enabling studies. Glenmark expects to file a Phase 1 application in November'08. Currently GRC 17173 is first in class and addresses a large market for various types of pain.

Further Glenmark obesity candidate GRC 9332 which is an SCD1 inhibitor is also in IND enabling studies. Glenmark intends to file for Phase 1 by the end of the financial year.

**NBE (Biologics)**

Glenmark Pharmaceuticals S.A., the wholly-owned Swiss subsidiary of Glenmark Pharmaceuticals Ltd. 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. VLA -2 mediates interactions of cells relevant for inflammatory processes with the extracellular matrix. Hence GBR 500 has the potential to be a broadly applicable anti-inflammatory compound. Glenmark is on track 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 will be Glenmark's first NBE to enter the clinics.

**GBR 600 :**

GBR 600 an anti platelet monoclonal antibody is showing good results in pre-clinical testing and is being scaled up for further IND enabling studies. The program is making good progress and Glenmark plans to file for Phase 1 in the US by March 2009.

**Innovative R&D restructuring at Glenmark:**

Given the breadth of Glenmark's pipeline and the competencies required for conducting world class R&D, Glenmark recently restructured its R&D activities. Every molecule is now driven by global project teams coordinated from India.

Glenmark has also regrouped its R&D activities into four centers of excellence.

**India R&D:**

All NCE discovery and pre clinical development (in vivo, DM/PK and toxicology) for the entire firm will be conducted/coordinated out of Glenmark's Mumbai R&D facility.

**Switzerland:**

All Glenmark's novel biologic's discovery activities, process development and scale up of Biologics would be conducted/coordinated out of Glenmark's Switzerland facility

**Oxford UK:**

All Glenmark's clinical R&D development for both small molecules and Biologics would be conducted/coordinated out of the UK

**New Jersey USA:**

Glenmark's global regulatory and global business development activities will be conducted/coordinated out of the US.

Glenmark has also recently hired the following eminent individuals in the R&D space to head various functions:

**Dr. John Efthimiou**

Dr. John Efthimiou has joined Glenmark as President - Clinical R&D and Chief Medical Officer. John will be based at our new office in Oxford, UK. He brings with him over thirty years of experience in medical practice and clinical research & development. He has worked with companies like GSK, Chugai Pharma, Novartis and Almirall (as CMO). John's last position was with Phynova as Head Research, Development & CMO.

**Dr. Vijay Baragi**

Dr. Vijay Baragi has joined Glenmark as Senior Vice President – Biology. Vijay will head the in-vivo pharmacology, toxicology and Drug metabolism/Pharmacokinetics groups globally that would support both NCE's and NBE's. Vijay is a Ph.D from Auburn University and has over 25 years of work experience most of which was with Pfizer / Parke-davis. His last assignment was with Atlantos Pharmaceuticals as Director of Pre-Clinical research. Vijay will be based in India

## **Generics Business:**

### **USA Formulations**

Glenmark Generics Inc., U.S.A. posted revenue of Rs. 1908.79 Mn [USD 45.86 Mn] for the first quarter of FY 09 against revenue of Rs. 826.22 Mn [USD 20 Mn] registering an increase of 131.03 % over the first quarter of the previous year.

The Company received ANDA approvals for Trandolapril tablets USP 1mg, 2mg and 4 mg; Mometasone Furoate Ointment USP, 0.1%, Mometasone Furoate Cream USP, 0.1% and Metformin Hydrochloride Tablets USP 500 mg, 850 mg and 1000 mg. The company has already commenced marketing and distribution for these products in the second quarter. Glenmark also launched Nystatin Oral Suspension and Oxycodone Oral solution in Q1. All these new launches will drive growth for the business in the remaining part of the year. The existing product portfolio continues to grow and sustain market share.

The Company now has a portfolio of 33 generic products for the US market. The Company currently has over 35 ANDAs undergoing US FDA approval process/launch. Further, there are three potential first to file Para 4 applications filed by Glenmark. During the quarter, the company filed 4 ANDAs with the US FDA and intends to file at least 8 ANDAs in Q2-FY09.

The company expects at least 4-5 approvals in the second quarter. Glenmark Generics Inc., U.S.A. is on course to launch at least 20 products in this financial year and complete filings of over 30 ANDAs.

### **EU Formulations**

Glenmark Generics (Europe) Ltd. has initiated discussions with selected potential M&A targets in Western Europe. The Company is also gearing up to launch its first generic product in the UK in Q2 in association with a partner.

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Till date, the Company has filed seven MAAs and will further make at least 8 product submissions in this financial year. The Company is developing over 28 solid dose products and has initiated development of 6 new products in this quarter. The Company further has 6 semi-solids and one hormone under development.

The Company is currently in discussions with more than 20 clients for entering into dossier partnerships and expects to conclude 2-3 agreements in the following quarter.

### **Oncology**

Glenmark Generics S.A. filed one dossier in Argentina and 13 Extra-company\* dossiers. The Company intends to file two dossiers in Argentina and over 40 Extra-company dossiers in the second quarter.

The Company launched one product in Ecuador and Venezuela each and will aim to launch over 50 products in existing semi-regulated market in the current financial year. Argentina, Ecuador, Uruguay, Peru, Bolivia will also see several product launches in the coming quarter.

Glenmark's revenue from Argentina operations were Rs. 71.14 Mn [USD 1.71 Mn] in the first quarter of 2008-09 against Rs.62.41 Mn [USD 1.51 Mn] for the first quarter of the previous year reflecting an increase of 13.99 %.

*\*Extra-company excludes Brazil, Trinidad & Tobago, ROW and any other intra-company operations*

### **Active Pharmaceutical Ingredients [API]**

The Company has filed 31 DMFs till date. The Company intends to file three DMFs in the second quarter and 15 for the entire financial year. The Company extended its reach to Egypt in the quarter and targets entering other African countries in the next quarter.

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 210.40 Mn [USD 5.06 Mn] for Q1 FY09 against Rs. 196.70 Mn [USD 4.76 Mn] for Q1 of



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the previous year, recording an increase of 6.97 %. Revenue from the domestic API and co-marketing business amounted to Rs. 215.67 Mn [USD 5.18 Mn] in Q1 FY09 against Rs. 198.45 Mn [USD 4.80 Mn] for Q1 of the previous year, recording an increase of 8.68 %.

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### **Disclaimer**

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