

**Management Discussion and Analysis for the  
second quarter of the Financial Year 2008-09  
Ended 30<sup>th</sup> Sep, 2008  
Revenue Figures – Consolidated**

[Rs. in millions]

Particulars	Q2 FY 2008-09			H1 FY 2008-09		
	2008-09	2007-08	Growth %	2008-09	2007-08	Growth %
<b>Generics Business</b>						
US	1761.29	810.72	117.25%	3670.07	1636.94	124.20%
Europe	31.63	-	-	31.63	-	-
Latin America (Argentina)	142.99	95.84	49.19%	214.12	157.48	35.97%
API	539.26	425.82	26.64%	940.46	820.97	14.56%
<b>Total Generics Business [A]</b>	<b>2475.17</b>	<b>1332.38</b>	<b>85.77%</b>	<b>4856.28</b>	<b>2615.39</b>	<b>85.68%</b>
<b>Speciality Business</b>						
Latin America ( Brazil & Others)	562.08	474.55	18.45%	874.17	964.88	-9.40%
Semi Regulated Markets [SRM]	704.61	545.02	29.28%	1098.72	991.40	10.82%
Europe	295.90	68.05	334.83%	419.61	161.20	160.30%
India	1559.43	1328.99	17.34%	2956.66	2529.68	16.88%
<b>Speciality Formulation [1]</b>	<b>3122.02</b>	<b>2416.61</b>	<b>29.19%</b>	<b>5349.16</b>	<b>4647.16</b>	<b>15.11%</b>
<b>Out-licensing Revenue [2]</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Speciality Business [B = (1+2)]</b>	<b>3122.02</b>	<b>2416.61</b>	<b>29.19%</b>	<b>5349.16</b>	<b>4647.16</b>	<b>15.11%</b>
<b>Consolidated Revenue [A + B]</b>	<b>5597.19</b>	<b>3748.99</b>	<b>49.30%</b>	<b>10205.44</b>	<b>7262.55</b>	<b>40.52%</b>
<b>Consolidated Net Profit</b>	<b>1173.60</b>	<b>751.26</b>	<b>56.21%</b>	<b>2327.37</b>	<b>1322.77</b>	<b>75.94%</b>

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

For the second quarter of FY'2009, Glenmark's consolidated revenue increased to Rs. 5597.19 Mn [USD 131.02 Mn] as against Rs. 3748.99 Mn [USD 91.62 Mn] registering growth of 49.30%. Revenue from the generics business was at Rs. 2475.17 Mn (USD 57.94 Mn), as against Rs.1332.38 Mn (USD 32.56 Mn), registering growth of 85.77%. The Speciality business registered revenue of Rs. 3122.02 Mn (USD 73.08 Mn) as against Rs. 2416.61 Mn (USD 59.06 Mn) for the quarter of the previous year, registering growth of 29.19%. Consolidated Net profit for the second quarter increased to Rs. 1173.60 Mn [USD 27.47 Mn] from Rs. 751.26 Mn [USD 18.35 Mn] for the previous corresponding quarter, an increase of 56.21 %. For the Generics business, Profit From Operations (before Other Income and Interest) was Rs. 871.90 Mn [USD 20.41 Mn] and for the Speciality Business Profit From Operations(before Other Income and Interest) was Rs.596.85 Mn [USD 13.97 Mn] for the second quarter.

For the first six months of FY'2009, Glenmark's consolidated revenue increased to Rs.10205.44 Mn [USD 238.89 Mn] as against Rs. 7262.55 Mn [USD 177.48 Mn] registering growth of 40.52%. Revenue from the generics business was at Rs. 4856.28 Mn (USD 113.68Mn), as against Rs.2615.39 Mn (USD 63.91Mn), registering growth of 85.68 %. The Speciality business registered revenue of Rs.5349.15 Mn ( USD 125.21 Mn) as against Rs. 4647.16 Mn (USD 113.57 Mn) for the six-month period, registering growth of 15.11 %. Consolidated Net profit for the first six months increased to Rs. 2327.37 Mn [USD 54.47 Mn] from Rs. 1322.77 Mn [USD 32.32 Mn] for the previous year, an increase of 75.94 %. For the Generics business, Profit From Operations(before Other Income and Interest)was Rs. 1817.01Mn [USD 42.53 Mn] and for the Speciality Business Profit From Operations(before Other Income and Interest) was Rs.858.91 Mn [USD 20.10 Mn] for the six month period from April'08 to September'08

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<sup>1</sup> Average conversion rate for Q2 FY 2008-09 of Rs. 42.72 / USD 1.00

<sup>2</sup>Average conversion rate for Q2 FY 2007-08 of Rs..40.92 / 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. 1559.43 Mn [USD 36.50 Mn] for the second quarter of this financial year as compared to Rs.1328.99 Mn [USD 32.48 Mn] in the previous corresponding quarter, recording a growth of 17.34 %. According to the latest ORG-IMS data the company is ranked 26<sup>th</sup> in the market registering value growth of 17.7 %, vis-à-vis that of the industry [11.1 %] [ORG :Jan- Sep 2008].

In the India formulations business, Glenmark launched 3 new products during the quarter. The key brands continued to register good growth in the dermatology, respiratory and cardiovascular segments. 'Telma', the leading brand in telmisartan entered the list of top 300 brands of the industry as reported by IMS. Flexilor continued to hold its leadership position in the lornoxicam market. Glenmark's flagship brands "Candid" and "Ascoril" registered good growth for the quarter.

The new products launched were Asmita, which marked our entry into the oral contraceptive market further strengthening our gynaecology portfolio. Asmita is a combined oral contraceptive (COC) with fourth generation progestin Drospirenone and an estrogen component EthinylEstradiol. LRN is the second brand of Lornoxicam targeted at the pain segment which has been launched to have better reach in all specialties like Physician, ENT, Surgeon. Milivo is the second brand of Levofloxacin, fastest growing molecule in Quinolone (Antibiotic) segment, launched with focus on General Practitioners.

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

For the second quarter of the financial year, revenue from Africa, Asia and CIS region was Rs. 704.61 Mn [USD 16.49 Mn] as against Rs. 545.02Mn [USD 13.32Mn] for the previous corresponding quarter, recording an increase of 29.28 %.

### **CIS Region**

In the first quarter, the company had launched Klenzit, Klenzit C, Momate Cream and Momate Ointment in the Russian market. The initial response for these products has been encouraging and the company expects these products to continuously generate good sales. The company also received approvals for two new products i.e. Glevo Tablets and Powercort Cream. In CIS, the company is focusing on building its business in Ukraine, Kazakhstan and Uzbekistan. Earlier this year Glenmark's Nasik plant successful passed a GMP audit of the Ukraine Ministry of Health.

### **Africa**

The Africa region has registered impressive secondary sales growth in the second quarter in all key markets viz Kenya, Sudan, S. Africa, and Nigeria. During the quarter, the company initiated operations in Egypt and UAE. In Kenya the company launched the Oncology range and Deriva –C and Perigard range was launched in Mauritius. The company has received four new registrations in Nigeria and has launched Glevo Tab, Maclar and Ascorex.

### **Asia-Pacific**

For the Asia region also, overall secondary sales growth has been satisfactory. In Vietnam, Glenmark made its entry in the hospital segment which comprises of 85% of the total Vietnam Pharma market, with the listing of Glenmark products in most of the key hospitals. In Malaysia also, the company made its entry in the Hospital segment with Budesonide Inhaler, our first product launch.

The company has received product approval for Perigard (perindopril) for Philippines and Telma (telmisartan) for Vietnam. Both these products will be the first branded

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generic in these markets. The launch of these products scheduled in the next quarter will further strengthen the foothold of Glenmark in the Chronic Care segment.

For the entire Africa, Asia and Russia/CIS region, Glenmark has filed 12 product dossiers during the quarter and have received 53 product approvals.

### **Latin America**

Glenmark's revenue from its Latin American and Caribbean operations were Rs. 562.08 Mn [USD 13.15Mn] for the second quarter of 2008-09 as against Rs. 474.55 Mn [USD 11.60Mn] a growth of 18.45%.

As per IMS figures for Q2'FY09, the Brazilian subsidiary has grown by 90% and improved its ranking in two main segments viz. Dermatology (50th position in YTD Sept'07 to 21st position in YTD Sept'08) and Endocrinology (85th position in YTD Sept'07 to 22nd position in YTD Sep'08). This is mainly attributed to the excellent performance of Saccette(Sibutramine) and AdacneClin(Adapalen+Clindamycin). Other products viz Flutican (fluticasone), Ginec (triple combination to vaginal infection) and Aerocort S (salbutamol+beclomethasone) have also shown satisfactory growth during the quarter. The subsidiary has launched two new products POSPRAND (Repaglinide) and ORAMEDIC (aloe-vera oral rinsing)

The company initiated operations in Mexico and started strengthening its operations in Peru and Venezuela by establishing offices, building sales teams and also training of personnel. The company launched Glevo 500 in Peru during the quarter

For the entire LatAm region, Glenmark has filed 9 product dossiers during the quarter and received 12 product approvals.

### **Europe**

Glenmark Europe's operations registered revenue growth of 334.83% at Rs. 295.90Mn [USD 6.93Mn] as compared to Rs. 68.05 Mn [USD 1.66 Mn] for the previous corresponding quarter.

During the quarter, Glenmark has started operations in Poland and Romania. The growth in revenues is largely attributed to the products acquisitions in Poland. The company is actively pursuing in-licensing opportunities and introduction of its own products which are currently under registration to scale up its European operations. Glenmark has established a sales team in Romania and launched Aflen, an innovative product for the prevention of strokes and acute ischaemic attacks. Glenmark has successfully manufactured, delivered and released its first own product development (Topimark) from India for sale in Europe.

### **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.

### **NCEs**

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

Glenmark's lead PDE4 inhibitor molecule, Oglemilast GRC 3886, a treatment for a variety of important inflammatory disorders, continues to progress well in the clinics. The multi-center Phase II study in COPD has been initiated by our partner Forest Labs in the US and is progressing as per plan. The company also recently announced that a multi-center Phase II study for the treatment of Asthma for Oglemilast has also been initiated. This 12-Week randomised, double-blind, parallel group, placebo-controlled dose range finding Phase II study will evaluate the efficacy of Oglemilast in the treatment of Asthma and will enroll approximately 230 patients in about 30 centers.

Glenmark is currently in active discussions with European partners for licensing rights for the Europe region.

**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 a Phase IIB study. This large, multicentre, dose ranging, double-blind, placebo controlled clinical study is ongoing and patient enrolment is proceeding as per plan.

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 and other well known oral anti-diabetic treatments

Glenmark is in advanced discussions with several potential partners to outlicense this molecule.

**GRC 6211:**

Glenmark recently announced that its partner Eli Lilly has suspended further clinical development for GRC 6211 in Osteoarthritis pain. Glenmark and Lilly are currently in discussions on the way forward. Under the terms of the agreement signed in Oct'07, Lilly had acquired the rights to a portfolio of transient receptor potential vanilloid sub-family 1 (TRPV1) antagonist molecules, including GRC 6211 which was in early clinical Phase II development at the time. The collaboration between Glenmark and Lilly covers all TRPV1 antagonist molecules discovered by either company.

**GRC 4039:**

Glenmark's other potent PDE4 inhibitor, GRC 4039, a candidate for a variety of important inflammatory disorders, including Rheumatoid Arthritis and Multiple Sclerosis is progressing well. Glenmark has completed Phase 1 dosing. The early results from the Phase I study are encouraging and support continued development. The company expects this molecule to enter Phase II in the near future.

**GRC 10693:**

Glenmark's cannabinoid-2 [CB-2] receptor agonist GRC 10693 a candidate for Neuropathic Pain, Osteoarthritis and other Inflammatory Pain disorders has entered Phase I trials and is progressing well. The company intends to develop GRC 10693 in

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neuropathic pain as the primary indication. GRC 10693 belongs to a novel and exciting class of analgesic agents and Glenmark is an early entrant in this category. Glenmark expects to enter Phase II before the end of FY'09. Glenmark is currently in discussions with several partners to outlicense this molecule.

### **GRC 15300 (Formally GRC 17173) :**

Glenmark has decided to pursue a better candidate GRC 15300 in the TRPV3 class than GRC 17173. This change would not significantly impact the timelines of entering the clinics. Glenmark's TRPV3 lead candidate GRC 15300 for pain is currently undergoing IND enabling studies. Glenmark expects to file a Phase 1 application in December 08. Currently GRC 15300 is a first in class molecule and addresses a large market for various types of pain. Over the years Glenmark has developed a significant expertise in the TRP area and would continue to leverage this expertise.

### **GRC 9332**

Glenmark's SCD1 inhibitor, GRC 9332, a novel treatment for the common and increasingly prevalent problems of obesity and non-alcoholic fatty liver disease, is also in IND enabling studies. Glenmark intends to file a Phase 1 application by the end of this financial year or early next year.

### **NBEs**

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 the "first in class" with this target and has established proof of concept in animals. Glenmark has filed an IND application with the US FDA for initiation of Phase I trials. Phase I will be 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 with animal proof of concept already established and toxicity studies currently underway. Glenmark expects to file for Phase 1 in March 09.

**Generics Business:**

**USA Formulations**

Glenmark Generics Inc., U.S.A. posted revenue of Rs. 1761.29 Mn [USD 41.23 Mn] for the second quarter of FY'09 against revenue of Rs. 810.72 Mn [ USD 19.81 Mn] registering an increase of 117.25 % over the second quarter of the previous year.

The Company received ANDA approval for Betamethasone Dipropionate Cream, 0.05% (Augmented). Betamethasone Dipropionate is a high-potency corticosteroid indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. During the quarter, the company filed 6 ANDAs with the US FDA and intends to file at least 5 ANDAs in Q3-FY09. In the forthcoming quarter, the company plans to launch at least 5 new products. The existing product portfolio continues to grow and sustain market share.

The Company now has a portfolio of 35 generic products for the US market. The Company currently has over 40 ANDAs in various stages of the approval process with the US FDA. Further, there are four potential first to file Para 4 applications filed by Glenmark. 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 made significant progress in its Europe business plans, both in terms of market entry and regulatory submission/approvals. The company achieved a major milestone in Europe by commencing shipments for its first product launch into the UK. This was in addition to a second product shipped for launch by Glenmark's subsidiaries in Central & Eastern Europe. In addition, the company plans to further launch products in two markets in H2 FY08-09.

On the regulatory front, the second quarter saw approvals for two Glenmark products in five EU markets. Till date, the Company has filed eight MAAs and is on track to make further eight product submissions via the DCP / MRP / Centralized routes in the second half of FY08-09. Glenmark continues to invest in differentiated products and two out of the eight submissions planned for H2 FY08-09 will consist of dermatology products.

The quarter also saw the culmination of licensing/supply deals with European generic companies for Glenmark's products and progress on plans to establish Glenmark's own presence in selected key markets

The Company posted revenue of Rs. 31.63 Mn [USD 0.74 Mn] in Europe for the second quarter of FY 09.

## **Oncology**

Glenmark Generics S.A. filed three dossiers in Argentina and 18 Extra-company\* dossiers in the second quarter (between April 08 – Sep 08 the company filled 4 dossiers in Argentina & 31 in Extra company\*). For the third quarter, the company plans to file one more dossier in Argentina and 30 Extra company\* dossiers.

The Company will aim to launch 50 products & 64 fillings in existing semi-regulated markets in the current financial year. Argentina, Ecuador, Uruguay, Peru, Bolivia, Venezuela, Colombia, El Salvador, Mexico, Pakistan, Yemen & Egypt will also witness

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several product launches in the coming quarter. Glenmark's revenue from the Argentina operations were Rs. 142.99 Mn [USD 3.35 Mn] in the second quarter of 2008-09 against Rs.95.85 Mn [ USD 2.34 Mn] for the second quarter of the previous year reflecting an increase of 49.19 %.

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

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

The Company has filed 32 DMFs till date. The Company intends to file three to four DMFs in the third quarter and 10 for the entire financial year. In the quarter, the Company extended its reach in 8 new markets in South America.

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 273.88 Mn [USD 6.41 Mn] for Q2 FY09 against Rs.131.12 Mn [USD 3.20 Mn] for Q2 of the previous year, recording an increase of 108.87 %. Revenue from the domestic API and co-marketing business amounted to Rs.265.38Mn [USD 6.21Mn] in Q2 FY09 against Rs.294.70Mn [USD 7.20 Mn ] for Q2 of the previous year, recording a decline of 9.95 %.

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