Glenmark Pharmaceuticals Ltd

Management Discussion and Analysis for the First quarter of the Financial Year 2010 - 11 Ended 30th June 2010

Revenue Figures – Consolidated

[Rs. in millions]

	Q1 FY 2010-11		
	2010-11	**2009-10**	**Growth %**
Speciality Business			
India	1,936.10	1,659.20	17%
Rest of the World (RoW)	733.38	786.02	-7%
Latin America	406.17	335.41	21%
Europe	211.90	269.25	-21%
Total Speciality Business	**3,287.55**	**3,049.88**	8%
Out-Licensing Revenue	895.10	-	
Total Speciality Business	**4,182.65**	**3,049.88**	37%
Generics Business			
US	1,829.94	1,720.54	6%
Europe	103.85	41.40	151%
Latin America	75.32	68.24	10%
API	626.84	556.81	13%
Total Generics Business	**2,635.95**	**2,387.00**	10%
Consolidated Revenue	**6,818.60**	**5,436.88**	25%

Average conversion rate in FY 2009-10 considered is Rs. 49.29 / USD 1.00
Average conversion rate in FY 2010-11 considered is Rs. 45.72 / USD 1.00

USD figures are only indicative

Review of Operations for the First Quarter of the Financial Year 2010-11

For the First Quarter of FY'2011, Glenmark's consolidated revenue was at Rs. 6,818.60 Mn [USD 149.13 Mn] as against Rs. 5,436.88 Mn [USD 110.30 Mn], an increase of 25%. Revenue from the generics business was at Rs. 2,635.95 Mn (USD 57.65 Mn), as against Rs. 2,387.00 Mn (USD 48.43 Mn), a growth of 10%. The Speciality formulation business revenue was at Rs. 4,182.65 Mn (USD 91.48 Mn) as against Rs. 3,049.88 Mn (USD 61.88 Mn) for the corresponding quarter of the previous year, registering a growth of 37%. The specialty revenue in the first quarter of FY 2011 includes out-licensing revenue of Rs. 895.10 Mn (USD 19.58 Mn).

Specialty Business:

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

India

Sales for the formulation business in India increased to Rs. 1,936.10 Mn [USD 42.34 Mn] for the First Quarter of this financial year as compared to Rs. 1,659.20 Mn [USD 33.66 Mn] in the previous corresponding quarter, recording a growth of 17%.

According to the latest ORG-IMS data it was reported that the company registered value growth of 27.23 % vis-à-vis that of the industry 21.26% [ORG: Apr'10 – Jun'10]

For the first quarter, all Glenmark brands in the top 300 i.e. Ascoril, Candid B, Telma, & Telma H registered strong growth rates. The India formulations business launched five products during the quarter. Prasugrel (Aplet), which was launched in the last quarter has performed very well. Some of the significant product launches were Paxib targeting

dermatologists and GPs, D'acne another product targeting dermatologists, 'Wunder Eye' an under eye cream, and Onabet Shampoo

Africa, Asia and CIS Region

For the First quarter of the financial year, revenue from Africa, Asia and CIS region was Rs. 733.38 Mn [USD 16.04 Mn] as against Rs. 786.02 Mn [USD 15.95 Mn] for the previous corresponding quarter, recording a decline of 7%. The decline is mainly on account of channel re-stocking in the first quarter of the previous year and higher than normal sales in Q4 of the previous year.

In the region, Glenmark filed 20 product dossiers during the quarter and received 26 product approvals.

Russia/CIS Region

The robust secondary sales momentum which got built in last two quarters of the previous financial year continued in the first quarter of the new financial year. For the first quarter, the region registered secondary sales growth of 64%. According to pharmexpert data on a MAT basis the company is growing at a rate of 50% which has improved rankings in the market to the current rank of 69 in May 2010. Klenzit (Anti-acne drug) has become the fifth brand for the company to cross USD 1 Million (MAT). With this the company has further consolidated its position in the dermatology segment and is one of the fastest growing companies in this segment.

In the other CIS markets, Ukraine, Kazakhstan and Uzbekistan are continuing to show positive trend in secondary sales.

Africa/Middle East

The Africa Middle East has achieved secondary sales growth of 30% in quarter ended June 2010, aided by robust growth in South Africa, Nigeria, Kenya, Sudan, Mauritius, Tanzania as well as a rise in sales from francophone markets.

The quarter was also included several first-to-market products across key therapeutic categories: (a) South Africa introduced a novel gastrointestinal agent CEC for treatment of IBS and GORD, (b) Egypt initiated its entry into the cosmeceutical segment with the launch of Elovera cream, (c) The Mauritius market saw the introduction of the Telma Range of products, thus offering the widest range of Cardio-metabolic products in the country.

Asia

The efforts undertaken on marketing activities to strengthen relationship with KOLs and create more awareness for power and focus brands is beginning to pay off - the region recorded secondary sales growth in excess of 25%. The region received new registrations of Tacroz Forte and Stilloz 50 in Sri Lanka, Sibutrim and Saferon Drops in Malaysia, Momate S and Stilloz 50,100 for Myanmar, Momate S in Vietnam and Tazret gel in the Philippines. The Philippine subsidiary continued to register strong sales growth while the Vietnam unit entered the insurance list of many hospitals in the country.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 406.17 Mn [USD 8.88 Mn] for the First Quarter of 2009-10 as against Rs. 335.41 Mn [USD 6.80 Mn] a growth of 21%.

The growth in the Latin American region reflects the impact of the restructuring of operations in Brazil in FY 2010-11 and the contribution from newer markets like Mexico and Venezuela.

Europe

Glenmark Europe's operations registered first quarter revenue of Rs. 211.90 Mn [USD 4.63 Mn] as compared to Rs. 269.25 Mn [USD 5.46 Mn] for the previous corresponding quarter, a decline of 21%.
The decline in the region is mainly on account of higher channel inventory in Poland. Going forward, we expect the region to record growth on the strength of new product introductions in the cardiology and CNS segments.

During the quarter, Glenmark successfully launched 'Clopidogrel' in the Czech Republic, Slovakia and Poland to strengthen its cardiology portfolio. The Romania subsidiary also launched "Donepezil", which is used for the symptomatic treatment of mild to moderately severe Alzheimer's dementia, strengthening its CNS portfolio.

The company continues to focus on the search for new in-licensing opportunities and the launch of its own products that are currently under registration to scale up its European operations

Research and Development

The company has a pipeline of 7 NCE and NBE molecules in clinical trials. In addition, the company has one in-licensed molecule, Crofelemer

Crofelemer:

Glenmark's in-licensed molecule Crofelemer (for HIV associated diarrhoea) continues to progress well in Phase 3 clinical testing in the US. A Phase 2b study in acute infectious diarrhoea patients is also progressing well in India. Glenmark expects to initiate the launch of this product in Calendar Year 2011 in 'Rest of the World' markets. This would be the first innovative product launch for Glenmark globally. Peak sales from ROW markets are estimated to be around $80 million for HIV associated Diarrhoea.

Melogliptin (GRC 8200):

Glenmark's DPPIV inhibitor, Melogliptin (GRC 8200), completed Phase IIb studies and will enter Phase III trials. Glenmark is in discussions with potential partners to out-license this molecule.

Revamilast (GRC 4039):

Glenmark's other potent PDE4 inhibitor, Revamilast (GRC 4039), a candidate for a variety of respiratory and inflammatory disorders is progressing well in the clinics. The company expects to initiate multiple Phase II trials for Revamilast in the Q3 of Financial Year 2010-11.

Tedalinab (GRC 10693):

Glenmark's cannabinoid-2 [CB-2] receptor agonist GRC 10693 a candidate for Neuropathic Pain, Osteoarthritis and other Inflammatory Pain disorders has successfully completed Phase 1 studies. The company intends to develop GRC 10693 in 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. Additional Phase 1 extension studies are in progress. Glenmark expects to initiate Phase II studies in the Q3 of Financial Year 2010-11.

GRC 15300:

GRC 15300 for Osteoarthritic pain, Neuropathic pain, and other inflammatory pain conditions is undergoing Phase 1 trials in the UK. Globally, this is the only reported TRPV3 specific antagonist molecule to enter clinical trials. So far, the trial is progressing well in the single ascending dose phase with good oral availability and no safety concerns. A development and commercialisation license for GRC 15300 has been granted to Sanofi-Aventis. Under the terms of the agreement, Glenmark received an upfront payment of US $20 million, and is eligible for development, regulatory and commercial milestone payments which could aggregate U.S. $ 325 million. In addition, Glenmark is eligible to receive tiered double-digit royalties on sales of products commercialized under

the license. Sanofi-aventis will have exclusive marketing rights for North America, European Union and Japan subject to Glenmark's right to co-promote the products in the United States and five Eastern European countries. Sanofi- aventis will also have co-marketing rights in 10 other countries including Brazil, Russia, and China, whereas Glenmark will retain exclusive rights in India and other countries in the rest of the world.

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 Multiple Sclerosis (MS). 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 are ongoing in the US and are progressing as per plan. We expect to initiate a proof-of-concept trial in MS in the second half of FY’11.

GBR 600:

GBR 600, an anti-platelet monoclonal antibody, has shown good results in pre-clinical testing and has received approval from MHRA, UK to commence Phase I studies. We are in the process of initiating the Phase 1 study.

Glenmark Generics Limited:

For the First Quarter of FY’2011, Company’s consolidated revenue was at Rs. 2,635.95 Mn [USD 57.65 Mn] as against Rs. 2,387.00 Mn [USD 48.43 Mn], an increase of 10% in rupee terms over the corresponding quarter of the previous year.

USA Formulations

Glenmark Generics Inc., U.S.A. (GGI) registered revenue from sale of finished dosage formulations of Rs. 1,829.94 Mn (USD 40.02 Mn) for the first quarter of FY’11 as against revenue of Rs. 1,720.54 Mn (USD 34.91 Mn), an increase of 6% in rupee terms over the corresponding quarter of the previous year.

During the first quarter, the Company was granted final approval by the Food and Drug Administration (FDA) for three strengths of Trandolapril and Verapamil Hydrochloride extended-release tablets, the generic version of Abbott's Tarka® and commenced marketing and distribution of 4 mg/240mg, 2 mg/240mg and 2 mg/180mg towards the end of the quarter. Glenmark is the first and only generic company to be granted tentative and final approval by the FDA on Trandolapril and Verapamil Hydrochloride extended-release tablets. According to IMS Health, Tarka® achieved sales of $58 million for the 12-month period ending March 2010.

During the quarter, GGI received ANDA approval for Norethindrone tablets 0.35mg. The product was also launched during the quarter under the trade name Heather®. This marks the first launch by Glenmark in the hormone segment and these products will be manufactured at the USFDA approved hormone facility at Goa. Glenmark has an exciting pipeline of pending ANDAs in the hormone segment.

During the quarter, Glenmark filed 4 ANDAs with the USFDA. In the second quarter, Glenmark plans to launch the following products: Norethindrone tablets 0.35mg (AB2), Norethindrone Acetate 5mg tablets, Theophylline extended-release tablets, Adapalene Gel 0.1%, Ciclopirox Olamine gel and a dermatology proprietary product.

Glenmark's current marketing portfolio consists of 56 generic products authorized for distribution in the U.S. market. The Company currently has over 50 applications pending in various stages of the approval process with the US FDA. Also, the Company has filed 11 Para IV applications till date of which Glenmark is the sole first-to-file for four products.

The summary of Glenmark's Paragraph IV ANDA filings with sole exclusivity is shown below:

Product	Brand Name	Plaintiff	Sales	Litigation Status	Approval Status
Ezetimibe	Zetia®	Schering Plough	US$ 1.4Bn	Case Settled	Tentative Approval Received
Trandolapril + Verapamil	Tarka®	Abbott/ Sanofi-Aventis	US$ 58Mn	Jury trial date to be scheduled	Final approval received for three of the 4 dosage strengths. All three dosage strengths launched
Fluticasone Lotion 0.005%	Cutivate®	Nycomed	US$ 45Mn	Case to be scheduled	Awaited
Atovaquone + Proguanil Hcl	Malarone®	Glaxo-Smithkline	US$ 58 Mn	Case Settled	Awaited

*Sales are IMS for FY ending March 2010

EU Formulations

The European business continued to grow through a mix of product sales, out-licensing and in-Licensing income. During the quarter, Glenmark Generics BV was incorporated in Amsterdam, Netherlands. The entity booked Sales in the First month itself through the award of a tender by a leading health insurance company in the Netherlands. The UK business also expanded its coverage of the market by adding several new important accounts across the wholesaling and retail channels.

The out-licensing business successfully signed three more deals for licensing and supply of products in various EU markets. In this quarter, we also shipped out products for new launches by our third party clients in five additional EU markets.

During the quarter, GGEL filed MA Applications as eCTDs via the DCP procedure for one new product and received three MAs for products in different markets.

Overall, the EU formulation business posted revenue of Rs. 103.85 Mn (USD 2.27 Mn) for the quarter against revenue of Rs. 41.40 Mn (USD 0.84 Mn), an increase of 151 % in rupee terms, over the corresponding quarter of the previous year.

Oncology

During the quarter, the oncology business submitted 28 product dossiers worldwide. Glenmark's revenue from the Argentina operations were Rs. 75.32 Mn [USD 1.65 Mn] in the first quarter of 2010-11 as against Rs. 68.24 Mn [USD 1.38 Mn] for the first quarter of the previous year, an increase of 10 % in rupee terms.

Active Pharmaceutical Ingredients [API]

The API business continued to strengthen its presence in regulated and Rest of the World (RoW) markets.

Revenue from sale of API to regulated and Rest of the World (RoW) markets globally was Rs. 626.84 Mn [USD 13.71 Mn] for Q1 FY11 against Rs. 556.81 Mn [USD 11.30 Mn] for Q1 of the previous year, recording an increase of 13% in rupee terms.

Disclaimer

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