Glenmark Pharmaceuticals Ltd

Management Discussion and Analysis for the Financial Year Q1 FY 2011-12

Revenue Figures – Consolidated

[Rs. in millions]

	First Quarter Ended 30 June		
	Q1 - FY 2011-12	**Q1- FY 2010-11**	**Growth %**
Speciality Business			
India	2253.82	1877.55	20 %
Rest of the World (ROW)	1046.78	733.38	43 %
Latin America	591.93	366.17	62 %
Europe	215.12	211.90	2 %
Total	**4107.65**	**3189.01**	**29 %**
Out-Licensing Revenue	1112.34	895.10	24 %
Total Speciality Business	**5219.99**	**4084.11**	**28 %**
Generics Business			
US	2511.58	1829.94	37 %
Europe	175.36	80.48	118 %
Latin America	28.98	75.32	-62 %
API	645.63	633.88	2 %
Total Generics Business	**3361.54**	**2619.62**	**28 %**
Others	**101.02**	**113.98**	
Consolidated Revenue	**8682.54**	**6817.71**	**27 %**

Average conversion rate in FY 2011-12 considered is Rs. 45.28 / 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 quarter ended June 30, 2011

For the first quarter ended June 30, 2011, Glenmark's consolidated revenue was at Rs. 8682.54 Mn [USD 191.75 Mn] as against Rs. 6817.71 Mn [USD 149.11 mn], an increase of 27%. Revenue from the generics business was at Rs. 3361.54 Mn (USD 74.24 Mn), as against Rs. 2619.62 Mn (USD 57.29 Mn), a growth of 28 %. The Speciality formulation business revenue was at Rs. 5219.99 Mn (USD 115.28 Mn) as against Rs. 4084.11 Mn (USD 89.32 Mn) for the corresponding previous quarter, registering a growth of 28%.

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, 2011 increased to Rs. 2253.82 Mn [USD 49.77 Mn] as compared to Rs. 1877.55 Mn [USD 41.06 Mn] in the previous corresponding quarter, recording a growth of 20 %.

As per ORG-IMS data, the company registered value growth of 18.9 % vis-à-vis that of the industry growth which was 14.0 % [Apr-Jun 11 v/s Apr-Jun'10]. During the quarter, the India business launched two new products and consolidated its position across all focus brands. The two new products launched were Vorth TP and Doriglen. "Vorth- TP" is India's first brand of Tapentadol and will help the business strengthen its presence in the orthopaedic segment.

Africa, Asia and CIS Region

For the first quarter, revenue from Africa, Asia and CIS region was Rs. 1046.78 Mn [USD 23.12 Mn] as against Rs. 733.38 Mn [USD 16.04 Mn] for the previous corresponding quarter, recording an increase of 43 %.

In the region, Glenmark filed 18 product dossiers during the quarter and received 5 product approvals.

Russia/CIS Region

Due to several government regulations implemented in the year 2010, the Russian pharma market growth has slowed down considerably to 5.6 % MAT (Pharmexpert May 2011). Against this backdrop, Glenmark recorded good growth of 28% MAT (Pharmexpert May 2011). Glenmark Russia continues to gain ranks and market share. Our current MAT rank is 61 against 70 in Q1 last year. We now have a strong position in the respiratory and dermatology segment.

In the other CIS markets, Ukraine, Kazakhstan and Uzbekistan are continuing to show positive trend in secondary sales. In Ukraine which is the largest market in the CIS region (excluding Russia) we recorded secondary sales growth of 88%.

Africa/Middle East

The Africa and Middle East region continued to show robust secondary sales increase between April to June 2011, recording an impressive 46% growth over the same period last year. This was contributed mainly by strong performance in South Africa, Kenya, Egypt, Tanzania and Sudan. The growth was driven through extensive brand building efforts focused on nine power brands which are responsible for contributing around 80% of the sales. The quarter also saw some important product launches including Supiroban (Mupirocin ointment) in South Africa and Levoctivan (Levocetirizine) in Egypt. Supiroban is the first branded generic in the market and therefore has excellent potential. UAE also saw a range of dermatology products getting launched which will further consolidate its position in this therapeutic segment. Glenmark, which is a leading player in Kenya made a strong entry in the pain management market by launching Flexilor(Lornoxicam) which is a first of its kind product in Kenya.

Asia

The Asia region continued to perform well due to focused marketing activities which were the main drivers for the 40% increase in secondary off take over corresponding quarter for the last year. Klenzit MS was launched in Malaysia, Vietnam and Philippines. Glemont(Monteleukast) was successful launched in Malaysia and has provided us an entry

in the respiratory segment. With the increased focus on power brands, these brands now constitute 70 % of the business for the Asia region.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 591.93 Mn [USD 13.07 Mn] for the first quarter ended June 30, 2011 as against Rs. 366.17 Mn [USD 8.01 Mn] a growth of 62 %.

All the subsidiaries in the region viz. Brazil, Venezuela, Mexico, Caribbean and Peru recorded impressive sales growth for the quarter. During the quarter, the Brazil unit launched one product, Venezuela unit launched three products and the Peru unit launched five products.

In the region, Glenmark filed 13 product dossiers during the quarter and received one product approval.

Europe

Glenmark Europe's operations revenue for the first quarter ended June 30, 2011 was at Rs. 215.12 Mn [USD 4.75 Mn] as compared to Rs. 211.90 Mn [USD 4.63 Mn] for the previous corresponding quarter, an increase of 2%.

During the quarter, the Czech/Slovak unit registered good sales growth. The Romania and Poland unit performed well despite the uncertain economic environment prevailing in respective countries. The Czech/Slovak unit launched one product during the quarter

Research & Development

The company has a pipeline of 5 NCE and NBE molecules in clinical trials including the in-licensed molecule "Crofelemer".

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. Glenmark also successfully completed a proof of concept, phase II study in adult acute diarrhoea in India. 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. Peak sales from ROW markets are estimated to be around $80 million for HIV associated diarrhoea.

Today, Glenmark Pharmaceuticals limited received USD 15 million from Salix Pharmaceuticals, Inc, USA. This is as per an Agreement for Advance against Commitment fee which is to cover Glenmark's risks associated with upgrading its manufacturing facilities to meet Salix's anticipated increased requirements in demand for Crofelemer.

Through an agreement between the two companies, Salix agreed to pay Glenmark a $21.6 million commitment fee in five equal annual installments, with the first annual installment in July 2012, in view of Glenmark's investment in, and risks associated with, upgrading its manufacturing facilities to increase the production capacity of crofelemer. The commitment fee is in addition to the compound purchase price payable by Salix to Glenmark.

After remitting the advance of USD 15 million to Glenmark, Salix will pay Glenmark the remaining $6.6 million of the commitment fee in five equal annual installments.

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. The PK and safety profile of the Phase I study results support further clinical development. A development and commercialisation license for GRC 15300 has been granted to Sanofi. PhIIa proof of concept study in neuropathic pain is planned to be initiated in Q3 Financial Year 2011-2012.

Revamilast (GRC 4039)

Glenmark's PDE4 inhibitor, Revamilast (GRC 4039); a candidate for a variety of respiratory and inflammatory disorders is progressing well in the clinics. Glenmark has obtained UK-MHRA approval for conducting Phase IIb trials for Revamilast in Asthma and Rheumatoid Arthritis in the UK, and is awaiting approval from DCGI, India & other regulatory bodies to commence multi-centric Phase IIb studies. These Phase IIb studies that will be carried out

will determine the efficacy and safety of the molecule and will also provide dose range finding for Revamilast.

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 initiated Phase 1 study in the Netherlands and initial dose has been well tolerated with showed expected pharmacokinetic profile. Glenmark plans to complete Phase I trials and initiate Phase II filing for proof-of-concept in respiratory and pain indications in Q3 FY 2011-12.

Novel Biologics Entity (NBE)

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. Once the ongoing technology transfer is completed Sanofi will file a new IND in Q3 Financial Year 2011-2012 to initiate a PoC trial in Crohn's disease.

GBR 401:

GBR 401, an anti-CD19 antibody, is currently under development for the target indications of B cell leukemias/lymphomas. The target CD19 is present on all B cells and shows up early during haematopoiesis. CD19 is more broadly expressed than CD20, hence providing potential to be used for patients with CD20 negative B cell tumours. GBR 401 is a human specific antibody that has shown good in vitro and in vivo properties. Glenmark will file for Phase I trials in Q4 FY 2011-12

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.

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. Preclinical studies with GBR 600 in a novel baboon model of TTP (Thrombotic Thrombocytopenic Purpura) have demonstrated that GBR 600's ability to prevent and treat TTP.

Generics Business:

USA Formulations

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations of Rs. 2511.58 Mn (USD 55.47 Mn) for the first quarter ended June 30,2011 against revenue of Rs. 1829.94 Mn (USD 40.02 Mn), an increase of 37 % in Rs. term over the previous corresponding quarter.

During the first quarter, the Company received final ANDA approvals for four products and filed three ANDAs with the U.S. FDA. In the forthcoming quarter, the company plans to file four new products and anticipates successful launch of seven new products which are a mix of oral solids, oral contraceptives, semi-solids as well as an exclusive launch. The existing product portfolio continues to grow and sustain market share.

At end of the first quarter, the Company has a portfolio of 69 generic products authorized for distribution in the US market as well as 40 ANDAs in various stages of the approval process with the U.S. FDA.

Two of Glenmark's paragraph IV filings, Fluticasone Propionate lotion and Hydrocortisone Butyrate cream, reached settlement agreements in the first quarter. Glenmark believes that it is entitled to 180 days of exclusivity for both products, as the first generic company to file an ANDA.

Fluticasone Propionate lotion is Glenmark's generic version of Nycomed US Cutivate® lotion. Under the terms of the Settlement Agreement, Glenmark will be able to market and distribute its Fluticasone propionate lotion under a royalty-bearing license from Nycomed US in March 2012, or earlier in certain circumstances. IMS Health reported sales of Cutivate® lotion for the 12 month period ending March 2011 at USD 44 million.

Hydrocortisone Butyrate is Glenmark's generic version of Astellas and Triax's Locoid Lipocream®. Subject to the terms of the settlement and license Agreement, Glenmark will be permitted to market and distribute Glenmark's 0.1% hydrocortisone butyrate cream under a royalty-bearing license from Astellas and Triax in the United States near the end of CY 2013. Locoid Lipocream® garnered sales of USD 38 million in the 12 month period ending March 2011 according to IMS Health.

EU Formulations

The European business continued to steadily expand with the turnover growing on the back of revenue streams of product sales and licensing income. The UK entity continued to build on the business through addition of new accounts and for the first time, the quarter also saw the commencement of distribution of a proprietary product in the UK. The Netherlands business continued supplying the pharmacies through the continuation of the health insurance contracts which were secured for several products. The out-licensing business successfully signed two more deals for licensing out and supply of products in EU markets.

During the quarter, GGEL was granted six Marketing authorizations in different markets and the company also filed a MA Application for one product across several EU markets through the DCP procedure route.

Revenues for the quarter ended June 30,2011 were Rs. 175.36 Mn (USD 3.87 Mn) against revenue of Rs. 80.48 Mn (USD 1.76 Mn), an increase of 118 %, in Rs. term, over the previous corresponding quarter.

Latin America - Oncology

Glenmark's revenue from the Argentina operations was Rs. 28.98 Mn [USD 0.64 Mn] in the first quarter ended June 30, 2011 as against Rs. 75.32 Mn [USD 1.65 Mn] for the previous corresponding quarter. The unit in Argentina serves as a supply hub for Glenmark's oncology business worldwide. During the quarter, Glenmark Argentina ten product dossiers of which six were for Brazil.

Active Pharmaceutical Ingredients [API]

The API business filed its first DMF in Japan and also recorded its first sale in the market. The business also filed one USDMF while it continued to consolidate its market position in the four product launched in the last financial year

For the first quarter of FY 12 revenues were Rs. 645.63 Mn [USD 14.26 Mn] against Rs. 633.88 Mn [USD 13.86 Mn] for the previous corresponding quarter, recording an increase of 2 % in Rs. term.

Disclaimer

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