Glenmark Pharmaceuticals Ltd

Management Discussion and Analysis for the Financial Year Q2 FY 2011-12

Revenue Figures – Consolidated

	Second quarter ended 30 Sep			Six months ended Sep 30		
	Q2 - FY 2011-12	**Q2- FY 2010-11**	**Growth %**	**H1 – FY 2011-12**	**H1 – FY 2010-11**	**Growth %**
Speciality Business						
India	2538.97	2121.90	19.66 %	4792.77	3999.46	19.84 %
Rest of the World (ROW)	1479.33	810.98	82.41 %	2526.11	1544.36	63.57 %
Latin America	738.17	492.76	49.80 %	1330.10	858.93	54.85 %
Europe	377.58	351.49	7.42 %	592.70	563.39	5.20 %
Total	**5134.05**	**3777.13**	**35.92 %**	**9241.68**	**6966.14**	**32.67 %**
Out-Licensing Revenue	1184.55	-	-	2296.89	895.10	156.61 %
Total Speciality Business	**6318.60**	**3777.13**	**67.29 %**	**11538.57**	**7861.24**	**46.78 %**
Generics Business						
US	3000.55	2237.86	34.08 %	5512.13	4067.80	35.51 %
Europe	185.41	134.44	37.91 %	360.77	214.92	67.86 %
Latin America	41.34	115.17	- 64.1 %	70.32	190.49	-63.09 %
API	762.92	786.69	- 3.02%	1408.55	1420.57	- 0.85 %
Total Generics Business	**3990.22**	**3274.16**	**21.87 %**	**7351.77**	**5893.78**	**24.74 %**
Others	245.65	184.46	33.17 %	346.67	298.44	16.16 %
Consolidated Revenue	**10554.47**	**7235.75**	**45.87%**	**19237.01**	**14053.46**	**36.88%**

Average conversion rate for H1 FY 2011-12 considered is Rs 45.74. / USD 1.00
Average conversion rate in H1 FY 2010-11 considered is Rs. 46.20 / USD 1.00

USD figures are only indicative

Review of Operations for the quarter ended September 30, 2011

For the second quarter ended Sep 30, 2011, Glenmark's consolidated revenue was at Rs. 10554.47 mn [USD 230.74 Mn] as against Rs. 7235.75 Mn [USD 156.62 mn], an increase of 45.87 %. Revenue from the generics business was at Rs. 3990.22 Mn (USD 87.23 Mn), as against Rs. 3274.16 Mn (USD 70.87 Mn), a growth of 21.87 %. The Speciality formulation business revenue was at Rs. 6318.59 Mn (USD 138.14 Mn) as against Rs. 3777.14 Mn (USD 81.76 Mn) for the corresponding previous quarter, registering a growth of 67.29 %

For the six month ended Sep 30, 2011, Glenmark's consolidated revenue was at Rs. 19237.01 Mn [USD 420.58 Mn] as against Rs. 14053.46 Mn [USD 304.18 mn], an increase of 36.88 %. Revenue from the generics business was at Rs. 7351.77 Mn (USD 160.73 Mn), as against Rs. 5893.78 Mn (USD 127.57 Mn), a growth of 24.74 %. The Speciality formulation business revenue was at Rs. 11538.58 Mn (USD 252.27 Mn) as against Rs. 7861.24 Mn (USD 170.15 Mn) for the corresponding previous six month period, registering growth of 46.78 %

Specialty Business:

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

India

Sales for the formulation business in India for the second quarter ended September 30, 2011 increased to Rs. 2538.97 Mn [USD 55.51 Mn] as compared to Rs.2121.90 Mn [USD 45.93 Mn] in the previous corresponding quarter, recording a growth of 19.66 %.

As per ORG-IMS data, the company registered value growth of 16 % vis-à-vis that of the industry growth which was 15 % [July – Sep 11 v/s July – Sep'10].

For the first six months of the financial year, ORG-IMS reported Glenmark growth at 16.5 % v/s Industry growth at 14.7 %. During the second quarter, Glenmark launched four new products which were Azifine – C indicated for Typhoid, Flexilor – SP for pain management, Milixim – O for acute care and Casfung for invasive fungal infections.

Africa, Asia and CIS Region

For the second quarter, revenue from Africa, Asia and CIS region was Rs. 1479.33 Mn [USD 32.34] as against Rs. 810.98 Mn [USD 17.55 Mn] for the previous corresponding quarter, recording an increase of 82.41 %.

In the region, Glenmark filed 16 product dossiers during the quarter and received 11 product approvals.

Russia/CIS Region

The secondary sale for the Russian subsidiary has shown good growth in the second quarter. According to Pharmexpert data, on a MAT basis, the company is growing at a rate of 22% (Overall pharma market MAT Sept 2011 growth is 7%) and has consistently improved rankings in the market to the current rank of 55 in Sept 2010 (MAT Sept 2011 rank is 60). In this quarter the company has received approval of four Dermatology products – Ureative, Mannative, Fisiotive and Melanativ. The products will be launched in January 2012 and will help Glenmark to consolidate its position in the dermatology segment. With a growth rate of 33% (Pharmexpert MAT Sept 2011 data) we continue to be the fastest growing company in the dermatology segment with healthy growth rates for all the Derma brands.

In the other CIS markets, Ukraine, Kazakhstan and Uzbekistan are continuing to show positive trend in secondary sales. In Ukraine Glenmark has shown strong growth in secondary sales in Q2 driven primarily by the focus brands.

Africa/Middle East

The Africa and the Middle East region continued its strong growth momentum by recording secondary sales growth of 37% fuelled by its focus on developing leadership in select therapy areas through focussed approach on brand building.

South Africa, Kenya and Egypt further built on the new products launched in the last quarter and achieved good secondary sales performance. Supiroban (Mupirocin) continued its robust secondary growth in South Africa while Flexilor (Lornoxicam) became one of the leading brands in pain management in Kenya. Glenmark UAE launched dermatology products to consolidate its presence in the therapy area. Despite the unrest and political

instability, the Middle East/ North Africa region recorded good secondary sales primarily due to Sudan , Egypt and GCC countries.

Asia

For the Asia region, secondary sales growth was 30 % over corresponding period last year. The Malaysia , Vietnam and Myanmar unit are growing at an average of 50% over last year where as Philippines is growing by 25% . The power and focus brands continue to drive the business in Asia. Asia also had successful launch of Glemont - Monteleukast in Malaysia and launch of Dervia MS / Klenzit MS (Adapalene in Microsphere technology) in Malaysia , Philippines and Vietnam

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 738.17 Mn [USD 16.14 Mn] for the second quarter ended September 30, 2011 as against Rs. 492.76 Mn [USD 10.67 Mn] a growth of 49.80 %

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, Mexico launched two products, Venezuela unit launched three products and the Caribbean unit launched four products. Glenmark Venezuela gained 21 ranks in the IMS ranking and is now ranked 74 in the country

Europe

Glenmark Europe's operations revenue for the second quarter ended September 30, 2011 was at Rs. 377.58 Mn [USD 8.25 Mn] as compared to Rs. 351.49 Mn [USD 7.61 Mn] for the previous corresponding quarter, an increase of 7.42 %.

During the second quarter, the Europe region recorded good secondary sales growth of double digit vis-à-vis industry growth which remained flat. Two new products were launched in key markets. In the second quarter, all the countries experienced industry changes – new pricing and reimbursement law were announced in Poland, Romania coupled

with continued price cuts in Slovakia. The Romania unit announced its entry into the CNS segment with the launch of Olanzapine

Research & Development

The company has a pipeline of 6 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. The pivotal study in adult acute watery diarrhoea is expected to begin soon in India and Bangladesh. 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.

During the quarter, Glenmark Pharmaceuticals received USD 15 million from Salix Pharmaceuticals, Inc, USA 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.

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

approval for conducting Phase IIb trials for Revamilast in Asthma and Rheumatoid Arthritis in the UK (MHRA), India (DCGI) & other regulatory bodies to commence multi-centric Phase IIb studies. These Phase IIb studies being carried out will determine the efficacy and safety of the molecule and will also provide dose range finding for Revamilast.

Dosing has been initiated for Revamilast in asthma patients. Glenmark plans to file an IND for Revamilast in the US in Q4 FY 12. In parallel to these two clinical studies, Glenmark is also conducting various other clinical and non-clinical studies to ensure timely entry into Phase III trials. Glenmark intends to initiate Phase III trials for at least one indication in the second half of FY 2012-13

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/Q4 Financial Year 2011-2012.

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. Single ascending doses have been well tolerated with expected pharmacokinetic profile. Dosing for multiple ascending doses is currently ongoing. Glenmark plans to initiate Phase II filing for proof-of-concept in respiratory and pain indications in Q3/Q4 FY 2011-12.

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/Q4 Financial Year 2011-2012 to initiate a PoC trial in Ulcerative Colitis/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.

Generics Business:

USA Formulations

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations of Rs. 3,000.55 Mn (USD 65.60 Mn) for the second quarter ended September 30, 2011 against revenue of Rs. 2,237.86 Mn (USD 48.44 Mn), an increase of 34.08 % in Rs. term over the previous corresponding quarter.

During the second quarter, Glenmark received final ANDA approvals for three products and filed four ANDAs with the U.S. FDA. The Company successfully launched 4 products in the U.S. market including the exclusive launch of Atovaquone Proguanil tablets 250mg/100mg, their generic version of Malarone® tablets, under a royalty-bearing license from GSK. Glenmark believes that it is entitled to 180 days of exclusivity as the first generic to file an ANDA for the product. The Company also launched the authorized generic version of Malarone® tablets, Pediatric

In July, Glenmark Pharmaceuticals Limited, Glenmark Generics Limited and Glenmark Generics Inc., USA ("Glenmark") announced the settlement of litigation with Daiichi Sankyo,

Inc. and Genzyme Corporation ("Daiichi Sankyo and Genzyme") regarding Glenmark's ANDA filed with the U.S. FDA for Colesevelam Hydrochloride. Daiichi Sankyo and Genyzme filed a patent infringement suit in November 2010 in the U.S.District Court for the District of Delaware seeking to prevent Glenmark from commercializing its ANDA prior to expiration of the Orange Book patents. Glenmark has received a license from Daiichi Sankyo and Genzyme that will permit Glenmark to launch its generic Colesevelam Hydrochloride products on April 2, 2015, or earlier under certain circumstances.

At end of the second quarter, the Company has a portfolio of 73 generic products authorized for distribution in the US market as well as 41 ANDAs in various stages of the approval process with the U.S. FDA.

During the quarter, the Company made a payment of US$ 28.8 Mn in exercise of its purchase option election with respect to its royalty agreement with Paul Capital Partners' Royalty Fund ("Paul Capital"). As stated in the June 2005 release when the deal was entered, Paul Capital invested funds for the development of dermatological products for the US market. In return, Paul Capital received royalties. With the exercise of the purchase option election, Glenmark Generics Limited has no further obligation to pay royalties to Paul Capital.

EU Formulations

The European business continued to steadily expand through product sales and licensing income. The UK entity continued to build on the business through addition of new accounts. It also launched a product in Republic of Ireland through a distributor for the first time. In the UK and other European markets, three new products were launched in this quarter. The Netherlands business continued supplying four Products to the pharmacies through the continuation of the health insurance contracts. The German Business won a tender for a product from two insurance companies and supplies for these are expected to commence from the next quarter. The out-licensing business successfully signed five more deals for licensing out and supply of products in EU markets. During the quarter, Glenmark Generics (Europe) Limited, UK 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 September 30, 2011 were Rs. 185.41 Mn (USD 4.05 Mn) against revenue of Rs. 134.44 Mn (USD 2.91 Mn), an increase of 37.91 %, in Rs. term, over the previous corresponding quarter.

Latin America - Oncology

Glenmark's revenue from the Argentina operations was Rs. 41.34 Mn [USD 0.90Mn] in the second quarter ended September 30, 2011 as against Rs. 115.17 Mn [USD 2.49 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 filed four product dossiers of which two were for the LATAM region.

Active Pharmaceutical Ingredients [API]

Glenmark has filed one US DMF this quarter taking the total number of US DMF's to 48. It was the first company to launch Colistimethate in the domestic market and received 2 new product registrations in Russia. The API division also achieved leadership position in Bupropion in Latin America

For the second quarter of FY 12 revenues were Rs. 762.92 Mn [USD 16.68Mn] against Rs. 786.69 Mn [USD 17.03 Mn] for the previous corresponding quarter, recording a decline of 3.02 % in Rs. term.

Disclaimer

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