Glenmark Pharmaceuticals Ltd

Management Discussion and Analysis for the Third quarter of FY 2012-13

Revenue Figures – Consolidated

INR in Millions

	Third quarter ended Dec 31,			Nine months ended Dec 31		
	FY 2012-13	**FY 2011-12**	**Growth %**	**FY 2012-13**	**FY 2011-12**	**Growth %**
Specialty Business						
India	3307.33	2546.71	29.87	9545.47	7339.50	30.06
Rest of the World (ROW)	2619.50	1571.37	66.70	5908.90	4097.48	44.21
Latin America	963.86	824.75	16.87	2531.19	2154.85	17.46
Europe	466.95	664.14	-29.69	1115.93	1256.84	-11.21
Total	**7357.64**	**5606.97**	**31.22**	**19101.49**	**14848.67**	**28.64**
Out-Licensing Revenue	493.03	238.35	106.85	493.03	2535.24	-80.55
Total Specialty Business	**7850.67**	**5845.32**	**34.31**	**19594.52**	**17383.91**	**12.72**
Generics Business						
US	4365.25	3190.28	36.83	12596.04	8702.41	44.74
Europe	395.16	306.73	28.83	1115.97	667.50	67.19
Latin America	50.83	35.51	43.14	143.99	105.83	36.06
API	998.61	835.84	19.47	3037.83	2244.39	35.35
Total Generics Business	**5809.85**	**4368.36**	**33.00**	**16893.83**	**11720.13**	**44.14**
Others	152.07	97.18	56.48	280.22	443.83	-36.86
Consolidated Revenue	**13812.59**	**10310.86**	**33.96**	**36768.57**	**29547.87**	**24.44**
Consolidated Revenue excluding Out-licensing income	**13319.56**	**10072.51**	**32.24**	**36275.54**	**27012.63**	**34.29**

Average conversion rate for 9M FY 2012-13 considered is Rs 54.64/ USD 1.00

Average conversion rate in 9M FY 2011-12 considered is Rs. 47.67/ USD 1.00

USD figures are only indicative

Review of Operations for the quarter ended Dec 31, 2012

For the third quarter ended Dec 31 2012, Glenmark's consolidated revenue was at Rs. 13812.59 Mn (USD 254.45 Mn) as against Rs. 10310.86 Mn (USD 201.25 Mn) an increase of 33.96 % . Excluding out-licensing income received in the third quarter, Glenmark's consolidated revenue for the third quarter grew by 32.24 %.

Revenue from the generics business was at Rs. 5809.85 Mn (USD 107.13 Mn), as against Rs. 4368.36 Mn (USD 85.10 Mn), a growth of 33.00 %. The Specialty formulation business excluding out-licensing revenue was at Rs. 7357.64 Mn (USD 135.50 Mn) as against Rs. 5606.97 Mn (USD 109.42 Mn) for the corresponding previous quarter, recording a growth of 31.22 %.

Specialty Business:

India

Sales for the formulation business in India for the third quarter ended Dec 31, 2012, was Rs. 3307.33 Mn [USD 60.98 Mn] as compared to Rs. 2546.71 Mn [USD 49.17 Mn] in the previous corresponding quarter, recording a growth of 29.87 %. As per IMS MAT Dec'12 data Glenmark recorded growth of 24.5 % vis-a-vis industry growth of 11.1 % .

Africa, Asia and CIS Region (ROW)

For the third quarter, revenue from Africa, Asia and CIS region was Rs. 2619.50 Mn [USD 48.18 Mn] as against Rs. 1571.37 Mn [USD 30.72 Mn] for the previous corresponding quarter, recording an increase of 66.70 %.

The secondary sales for the Russian subsidiary continued to show good growth in the third quarter at 43 % vis-a-vis the same period last year. According to Pharmexpert YTD December 2012 data, the company recorded growth of 35.6 % as compared to pharma industry growth of 24.2 %. Glenmark Russia ranking improved by three positions to 56 in Dec'12 from 59 in Dec'11. The company continues to remain a dominant player in dermatology and is ranked among the top 15 in the segment, with December 2012 rank being 14.

In the other CIS markets, Ukraine, Kazakhstan and Uzbekistan are continuing to show positive trends in secondary sales. In Ukraine, registration was obtained for Elovera IMF Cream and Elovera IMF lotion, strengthening the company's position in the dermatology

segment. Overall, Glenmark Ukraine has shown good growth in secondary sales of 104% in Q3 (vs same period last year), driven primarily by the focus brands.

The Africa/Middle East region posted healthy secondary sales growth of 23 % for the third quarter. South Africa, Kenya, Egypt, Nigeria and Sudan were significant contributors to the strong growth achieved by the region. Specially developed I-pad detailing for key brands substantially improved the in-clinic time of reps and image of the company in South Africa, Kenya, Mauritius and UAE.

The Asia region achieved secondary sales growth of 20 % for the third quarter of this financial year. The subsidiaries in Vietnam, Myanmar and Cambodia contributed strongly to the performance of the Asia region.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs.963.86 Mn [USD 17.75 Mn] for the third quarter ended Dec 31, 2012 as against Rs. 824.75 Mn [USD 16.12 Mn] a growth of 16.87 %.

During the quarter, the Mexico subsidiary received another dermatology product approval thus making it five dermatology product approvals for the subsidiary in the first nine months of the financial year. The Peru subsidiary received an approval for an oncology product whereas the Ecuador subsidiary received an approval for a dermatology product

Europe

Glenmark Europe's operations revenue for the third quarter ended Dec 31, 2012 was at Rs. 466.95 Mn [USD 8.59 Mn] as compared to Rs. 664.14 Mn [USD 13.41 Mn] recording decline of 29.69% .

For the third quarter, all units in the region recorded secondary sales growth in a declining market. There were several new successful launches in the markets. An important launch in the region across various subsidiaries was Diosmin+Hesperedin. This was a project taken up and completed end-to-end at the local Vysoke Myto facility. Another key launch was Zoledronic acid where we are in the first wave of generics.

Generics Business:

USA Formulations

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations was Rs. 4365.25 Mn (USD 80.48 Mn) for the quarter ended Dec 31, 2012 against revenue of Rs. 3190.28 Mn (USD 62.03 Mn) for the previous corresponding quarter, recording an increase of 36.83% .

In the third quarter of fiscal year 2013, Glenmark was granted approval of two Abbreviated New Drug Applications (ANDAs), comprised of one final, and one tentative approval. Final approval was granted for Rizatriptan benzoate immediate release tablets; tentative approval was granted for Telmisartan Tablets.

The Company filed 5 ANDAs with the U.S. FDA in the third quarter. The total ANDAs filed with the USFDA for the first nine months is now 11.

Glenmark's marketing portfolio through December 31, 2012 consists of 83 generic products authorized for distribution in the U.S. market. The Company currently has 46 applications pending in various stages of the approval process with the US FDA, of which 18 are Paragraph IV applications.

EU Formulations

The European business continued to steadily expand through product sales and licensing income and by expanding its presence through Distribution Partners in more European Countries. We launched two in-house products and two products were in-licensed from partners in the UK. During this quarter, we launched four new in-house products and one in-licensed product in Germany and one in-house product in the Netherlands. Through products licensed out to partners, we also launched three additional products in five European Markets. The Netherlands and the Germany entity continued supplying products through the existing health insurance contracts. The Out-licensing business successfully signed one new deal for licensing out and supply of product in EU markets.

During the quarter, the region in-licensed three products thus taking the tally to five for the first nine months of the financial year. Overall, the business posted revenues of Rs. 395.16 Mn (USD 7.28 Mn) for the quarter ended Dec 31, 2012 against revenue of Rs. 306.73 Mn (USD 6.11 Mn), for the previous corresponding quarter, recording an increase of 28.83 %.

Oncology (LatAm)

The Oncology business based out of Argentina is the manufacturing hub for oncology products worldwide. During the third quarter, the oncology business based out of Argentina filed 1 product dossier each in Brazil, Ukraine and Mexico.

Glenmark's revenues from the Argentina operations was Rs. 50.83 Mn [USD 0.94 Mn] for the third quarter ended Dec 31, 2012 as against Rs. 35.51 Mn [USD 0.68 Mn] for the previous corresponding quarter, recording a increase of 43.14%.

Active Pharmaceutical Ingredients [API]

During the quarter, two products were launched in Canada and in Europe with use of Glenmark API. Also two new products were launched in Japan. Glenmark continued dominant position for Amiodarone supplying large generic companies in US and Europe.

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 998.61 Mn [USD 18.42 Mn] for the quarter ended Dec 31, 2012 against Rs. 835.84 Mn [USD 16.28 Mn]), for the previous corresponding quarter, recording an increase of 19.47 %.

Research & Development

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

Revamilast (GRC 4039)

Glenmark's PDE4 inhibitor, Revamilast (GRC 4039); a candidate for variety of respiratory and inflammatory disorders, has completed a Phase IIb trial for Rheumatoid Arthritis in Europe and Asia. Topline data from this study has shown a favourable side effect profile but failed to show evidence of competitive efficacy for the primary end-point (percentage of patients achieving ACR20 response at 12 weeks relative to placebo). In depth analysis of the data from this study is currently ongoing. Based on this outcome, Glenmark is unlikely to continue development of Revamilast in Rheumatoid Arthritis.

Glenmark anticipates topline data from another Phase IIb trial for Revamilast in Asthma in Q2 2012. Glenmark has an open IND for Revamilast in the US and is conducting a safety and PK study in geriatric subjects under this IND. Glenmark is also conducting various other studies as part of the overall development plan.

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 completed Phase 1 study in the Netherlands. Single and multiple ascending doses have been well tolerated with expected pharmacokinetic profile. Glenmark has obtained approval for Phase II proof of concept study in pain indication in the UK (MHRA), Germany (BfArM), and India (DCGI) and recruitment has been initiated for the study. Additionally, Glenmark has initiated a Phase I/IIa study for respiratory indications in the UK (MHRA).

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. A development and commercialisation license for GRC 15300 has been granted to Sanofi. A PhIIa proof of concept study in neuropathic pain has been initiated in Q1 FY 2013 and is currently ongoing.

mPGES-1 inhibitors

Microsomal prostaglandin E synthase 1 (mPGES-1) is a key enzyme in the pathway responsible for inflammation. This provides a strong rationale for exploring inhibitors for mPGES-1 in the treatment of chronic inflammatory conditions, including pain. Glenmark has entered into an option agreement with Forest Laboratories, Inc on a collaboration for the development of novel mPGES-1 inhibitors to treat chronic inflammatory conditions, including pain. Glenmark has identified clinical candidates and is currently conducting pre-clinical studies and other development activities required to support the initiation of first-in-human dosing. Under the terms of the agreement, Forest will make a $6 million upfront payment to Glenmark and provide an additional $3 million to support the next phase of work. Forest will make other future payments in FY 2014 to support the advancement of the ongoing mPGES-1 inhibitors program. Forest has an exclusive option to obtain license rights to the program upon the completion of Phase 1 clinical trials.

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. A PhII proof of concept study in ulcerative colitis has been initiated in Q2 FY 2012-13 and is currently ongoing.

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. Phase 1 enabling toxicity studies for GBR 900 have been initiated. Glenmark plans to file for a Phase I study in Q1 FY 14.

Crofelemer

Crofelemer, Glenmark's in-licensed molecule, obtained USFDA approval for marketing authorisation in the US on 31st December 2012. Salix Pharmaceuticals Limited, Glenmark's partner in US, received a response from the FDA approving the use of Crofelemer for symptomatic relief of non-infectious diarrhoea in patients with HIV/AIDS on anti retro viral therapy. This is a significant milestone in the development of this molecule and will pave the way for further Glenmark filings and approvals in the 140 emerging markets where Glenmark has exclusive marketing and distribution rights. Glenmark continues to make progress on the Phase 3 trial in adult acute watery diarrhoea with recruitment ongoing in India and Bangladesh. Glenmark is also finalising a clinical development plan for the product in the paediatric acute watery diarrhoea setting.

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