Glenmark Pharmaceuticals Ltd

Management Discussion and Analysis for the Financial Year Q4 FY 2011-12

Revenue Figures – Consolidated

INR in Millions

	Fourth quarter ended			Annual Result		
	Q4 - FY 2011-12	**Q4- FY 2010-11**	**Growth %**	**FY 2011-12**	**FY 2010-11**	**Growth %**
Speciality Business						
India	2681.80	2159.54	24 %	10021.30	8446.88	19 %
Rest of the World (ROW)	1828.04	1463.30	25 %	5925.52	4069.66	46 %
Latin America	714.28	500.88	43 %	2869.13	1918.86	50 %
Europe	719.63	516.57	39 %	1976.47	1527.65	29 %
Total	**5943.75**	**4640.29**	**28 %**	**20792.42**	**15963.05**	**30 %**
Out-Licensing Revenue	-	-	-	2535.24	895.10	183%
Total Speciality Business	**5943.75**	**4640.29**	**28 %**	**23327.66**	**16858.15**	**38 %**
Generics Business						
US	3434.52	2242.87	53 %	12136.93	8351.56	45 %
Europe	363.86	134.44	171%	1031.36	543.61	90%
Latin America	36.60	167.49	- 78 %	142.43	400.88	- 64 %
API	850.05	618.22	37 %	3094.44	2767.05	12 %
Total Generics Business	**4685.03**	**3163.02**	**48%**	**16405.16**	**12063.10**	**36 %**
Others	29.78	147.47	-80%	473.61	569.45	- 17%
Consolidated Revenue	**10658.56**	**7950.78**	**34 %**	**40206.43**	**29490.70**	**36 %**

Average conversion rate for 12M FY 2011-12 considered is Rs 48.53 / USD 1.00
Average conversion rate in 12M FY 2010-11 considered is Rs. 45.90/ USD 1.00

USD figures are only indicative

Review of Operations for the quarter ended March 31, 2012

For the fourth quarter ended Mar 31, 2012, Glenmark's consolidated revenue was at Rs. 10,658.56 Mn [USD 209.63 Mn] as against Rs. 7950.77 Mn [USD 173.22 Mn], an increase of 34% . Revenue from the generics business was at Rs. 4685.03Mn (USD 92.20 Mn), as against Rs. 3163.02 Mn (USD 68.91 Mn), a growth of 48 %. The Speciality formulation business revenue was at Rs. 5943.75 Mn (USD 116.98 Mn) as against Rs. 4640.29 Mn (USD 101.10 Mn) for the corresponding previous quarter, registering growth of 28% .

For the year ended Mar 31, 2012 Glenmark's consolidated revenue was at Rs. 40,206.43 Mn [USD 831.47 Mn] as against Rs. 29,490.70 Mn [USD 642.50 Mn], an increase of 36 %. Revenue from the generics business was at Rs. 16,405.16 Mn (USD 338.04 Mn), as against Rs. 12,063.10 Mn (USD 262.81 Mn), a growth of 36 %. The Speciality formulation business revenue was at Rs. 23,327.66 Mn (USD 483.66 Mn) as against Rs. 16,858.15 (USD 367.28 Mn) for the corresponding previous period, registering growth of 38 %

Specialty Business:

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

India

Sales for the formulation business in India for the Fourth quarter ended Mar 31, 2012, increased to Rs. 2681.80 Mn [USD 52.55mn] as compared to Rs. 2159.54 Mn [USD 47.05 Mn] in the previous corresponding quarter, recording a growth of 24%

As per ORG IMS MAT Mar 2012 data, Glenmark gained two ranks from 25th to 23rd registering value growth of 22.1% v/s. IPM growth of 14.9%. As per ORG IMS MAT 2012 data, Glenmark market share increased in Dermatalogy from 8.3% to 8.4%, Cardiac from 2.4% to 2.5%, and Respiratory from 1.2% to 2.7%,

Africa, Asia and CIS Region

For the Fourth quarter, revenue from Africa, Asia and CIS region was Rs. 1828.04 Mn [USD 36.15 Mn] as against Rs. 1463.30 Mn [USD 31.88 Mn] for the previous corresponding quarter, recording an increase of 25 %.

Russia/CIS Region

In the beginning of the fourth quarter, two separate business units were created, with the purpose of bringing more focus to the respiratory and dermatology segments. The secondary sales growth for dermatology products is over 50 %. According to Pharmexpert MAT March 2012 data, the rank of the company amongst all other pharma companies in Russia is 59, with value growth of 17.8% (overall pharma market MAT March 2012 growth is 17.4%). In the other CIS markets, Ukraine, Kazakhstan and Uzbekistan are continuing to show positive trend in secondary sales. In Ukraine Glenmark has shown good growth in secondary sales at 83% in Q4 driven primarily by the focus brands.

Africa/Middle East

The Africa & Middle East region recorded secondary sales growth of 43% backed by strong focus on building its power brands. The units of South Africa, Kenya, Tanzania, Egypt and UAE further built on new products launched in the year and achieved highest ever secondary sales performance. Supiroban (Mupirocin) continued its robust secondary growth in South Africa. Flexilor(Lornoxicam) has recorded impressive sales growth in Kenya. UAE entered metabolic disease segment by launching Glimulin(Glimepiride)in Q4. Inspite of political instability, the Middle East & North Africa region recorded good secondary sales growth.

Asia

The Asia region recorded strong secondary sales growth in excess of 30 % The increased secondary offtake is driven by strong demand and continuous focus on power & focus brands in all important markets in the region. Levocetrizine is approved in Malaysia and Philippines in the fourth quarter. In all ten products have been registered in the Asia region during the year and these products will drive growth in FY 2013.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 714.28 Mn [USD 13.92 Mn] for the fourth quarter ended Mar 31, 2012 as against Rs. 500.88 Mn [USD 10.91 Mn] a growth of 43 %

All subsidiaries in the region viz. Brazil, Venezuela, Mexico, Caribbean and Peru continued to record good secondary sales growth. During the quarter, the Brazil subsidiary launched two new products, The Brazilian and the Venezuela subsidiary recorded strong sales growth in the quarter.

Europe

Glenmark Europe's operations revenue for the fourth quarter ended Mar 31, 2012 was at Rs. 719.63 Mn [USD 14.36 Mn] as compared to Rs. 516.57 Mn [USD 11.25 Mn] recording growth of 39 %

During the quarter, the Czech/Slovak unit launched five products during the quarter, the Polish unit launched two products and the Romania unit launched five products

Research & Development

The company has a pipeline of 6 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 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. Both studies are actively recruiting patients in these countries and dosing has been initiated. The Phase IIb studies being carried out will determine the efficacy and safety of the molecule and will also provide dose range finding for Revamilast.

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 plans to file an IND for Revamilast in the US in Q3 FY 13. Glenmark intends to initiate Phase III trials for at least one indication by end of FY 13

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) and awaiting approval in Germany (BfArM). Glenmark plans to file for Phase I/IIa study for respiratory indications in Q2 FY 13.

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. An application will be filed in Q1 FY 2013 to initiate a PoC trial in Ulcerative Colitis in US and other countries.

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 will be initiated in Q1 FY 2012-2013.

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 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 had a successful Pre-IND meeting with the US FDA. Preparation for Phase I submission is currently ongoing.

Crofelemer

Glenmark's in-licensed molecule Crofelemer - for multiple diarrhoeal conditions including HIV associated diarrhoea, acute adult and paediatric diarrhoea – earlier successfully completed Phase 3 clinical testing for HIV associated diarrhoea. The trial was conducted by Salix Pharmaceuticals Inc. in the USA and the PDUFA date issued by the USFDA which was 5th June 2012 has now been extended by the agency to Sep 5, 2012.

The pivotal study in adult acute watery diarrhoea conducted in India and Bangladesh by Glenmark has started recruiting patients. 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.

With respect to Napo's purported termination of the Collaboration Agreement, the Arbitration Panel granted an interim order which prohibits Napo from terminating the Collaboration Agreement or treating the Collaboration Agreement as terminated unless and until the Panel amends the order. The final Arbitration hearing is scheduled for June' 2012.

Generics Business:

USA Formulations

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage fomulations of Rs. 3,434.52 mn (USD 67.55 Mn) for the fourth quarter of FY'12 against revenue of Rs.2242.87 Mn (USD 48.86 Mn), an increase of 53% in Rs. term over the corresponding quarter of the previous year.

Glenmark continued to accelerate it's growth trajectory in the highly regulated US generics market. In the FY 12, Glenmark was granted approval of 14 Abbreviated New Drug Applications (ANDA), comprised of 12 final and 2 tentative approvals. These were mainly in the niche and high entry barrier segments of Dermatology, Oral Contraceptives, Modified Release categories. During the fourth quarter, Glenmark was granted final approval by the U.S. FDA of five ANDAs including Ciclopirox gel, Imiquimod cream, Levonorgestrel/ethinyl estradiol Tablets USP, 0.15/0.03 mg (Marlissa®), Norethindrone/ ethinyl estradiol Tablets (Alyacen 7/7/7®) and Norethindrone/ ethinyl estradiol Tablets (Alyacen 1/35®).

During the fourth quarter, the Company filed three ANDA's with the FDA, increasing the total number of filings to 12 for the fiscal year. Glenmark completed successful launch of 12 products during fiscal year 2012 consisting of a mix of semi-solid preparations, oral-contraceptives, extended release, and immediate release items.

In March 2012, the Company initiated the exclusive launch of Fluticasone Propionate lotion, their generic version of Nycomed's Cutivate® lotion. Under the terms of the Settlement Agreement, Glenmark will market and distribute its Fluticasone propionate lotion under a royalty-bearing license from Nycomed US, for which they are entitled to 180 days exclusivity.

Earlier this year, Glenmark announced that have entered into a settlement and license agreement with Triax Pharmaceuticals, LLC, Astellas Pharma Europe B.V. and Astellas Pharma International B.V. ("Astellas and Triax") to resolve a United States patent infringement suit related to Glenmark's ANDA filing for 0.1% hydrocortisone butyrate cream, Glenmark's generic version of 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 2013. Glenmark believes that it is entitled to 180 days of exclusivity with respect to its hydrocortisone butyrate cream, as the first generic company to file an ANDA for the product.

Glenmark's marketing portfolio through March 31, 2012 consists of 78 generic products authorized for distribution in the U.S. market. The Company currently has 38 applications pending in various stages of the approval process with the US FDA

EU Formulations

The European generics business continued to grow at a fast pace through the steady strategy of Product sales, Licensing revenues and expanding it's presence through Distribution Partners in more European countries.

During Q4, the UK entity continued to add new accounts in UK and also continued product supply in Republic of Ireland through distribution arrangements. Glenmark also launched three products this quarter in UK and two additional products in other European Markets through Out-licensing partners. The Germany business won tenders for two New Products supply of which will start by mid of calendar 2012. Netherlands and Germany Entity continued supplying Products through the existing health insurance contracts. The Out-licensing business successfully signed three new deals for licensing out and supply of products in EU markets. During the quarter Glenmark applied for Marketing Authorization for one product in different European Countries thru a DCP procedure.

Overall, the business posted revenues of Rs 363.86 Mn (USD 7.25 Mn) for the fourth quarter of FY'12 against revenue of Rs 134.44 Mn (USD 2.93 Mn), an increase of 171% in Rs. term over the corresponding quarter of the previous year.

Oncology

During the quarter, the oncology business based out of Argentina filed 11 product dossiers for various countries. Glenmark's revenues from the Argentina operations were Rs. 36.60 Mn [USD 0.72 Mn] in the fourth quarter of 2011-12 as against Rs 167.49 Mn [USD 3.65 Mn] for the fourth quarter of the previous year, a decrease of 78 % in Rs. term.

The new plant facility is now approved by various regulatory authorities and in the process of filing several new product dossiers for future commercial sales.

Active Pharmaceutical Ingredients [API]

During FY 12, the API business launched Telmisartan in Europe and Canada through two global generic players. First sale for the business was registered in the Japan market. The FY 12 witnessed successful inspections from USFDA/ EU agencies. The business continues it's leadership position for Lercanidipine, Topiramate and Amiodarone, combined with launches of new products during the year viz. Atovaquone, Ropinirole, Riluzole and Terbinafine. During the year, two US DMFs were filed.

Revenue from sale of API to regulated and semi-regulated markets globally was Rs 850.05 Mn [USD 16.69 Mn] for Q4 FY12 against Rs. 618.22 Mn [USD 13.47 mn] for Q4 of the previous year, recording an increase of 37 % in Rs. term.

Disclaimer

This document has been prepared by Glenmark Pharmaceuticals Ltd. The information, statements and analysis made in this document describing company's objectives, projections and estimates are forward looking statements and progressive within the meaning of applicable Security Laws and Regulations. The analysis contained herein is based on numerous assumptions. Actual results may vary from those expressed or implied depending upon economic conditions, government policies and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this presentation. This presentation should not be regarded by recipients as a substitute for the exercise of their own judgment.