

# Management Discussion and Analysis for the Fourth quarter of the Financial Year 2009-10 Ended 31st March 2010

# **Revenue Figures - Consolidated**

[Rs. in millions]

	T					
	Q4 FY 2009-10			FY 2009-10		
	2009-10	2008-09	Growth %	2009-10	2008-09	Growth %
	2007.10					
Speciality Business						
India	2,184.03	1,616.85	35%	7,528.62	6,141.94	23%
Semi Regulated Markets [SRM]	1,369.71	422.87	224%	3,863.67	2,355.00	64%
Latin America	345.86	268.76	29%	1,360.90	1,579.89	-14%
Europe	459.01	383.55	20%	1,362.75	995.91	37%
Total Speciality Business	4,358.61	2,692.03	62%	14,115.94	11,072.74	27%
Out-Licensing Revenue				232.40	-	
Total Speciality Business	4,358.61	2,692.03	62%	14,348.34	11,072.74	30%
Generics Business						
US	1,852.30	1,563.60	18%	7,230.45	7,337.73	-1%
Europe	97.81	74.09	32%	299.38	146.94	104%
Latin America	80.21	76.00	6%	343.02	400.48	-14%
API	702.55	505.12	39%	2,627.28	1,972.28	33%
Total Generics Business	2,732.86	2,218.81	23%	10,500.12	9,857.43	7%
Consolidated Revenue	7,091.47	4,910.84	44%	24,848.46	20,930.17	19%

 $<sup>^{\</sup>rm 1}$  Average conversion rate in FY 2009-10 considered is Rs. 47.74 / USD 1.00  $^{\rm 2}$  Average conversion rate in FY 2008-09 considered is Rs. 46.47 / USD 1.00

USD figures are only indicative



# Review of Operations for the Fourth Quarter of the Financial Year 2009-10

For the Fourth Quarter of FY'2010, Glenmark's consolidated revenue was at Rs. 7,091.47 Mn [USD 152.81 Mn] as against Rs. 4,910.84 Mn [USD 95.60 Mn], an increase of 44%. Revenue from the generics business was at Rs. 2,732.86 Mn (USD 59.11 Mn), as against Rs. 2,218.81 Mn (USD 42.94 Mn), a growth of 23%. The Speciality formulation business revenue was at Rs. 4,358.61 Mn (USD 93.70 Mn) as against Rs. 2,692.03 Mn (USD 52.66 Mn) for the corresponding quarter of the previous year, registering a growth of 62%.

For the financial year 2009-10, Glenmark's consolidated revenue increased to Rs. 24,848.46 Mn [USD 520.44 Mn] as against Rs. 20,930.17 Mn [USD 450.40 Mn], a growth of 19%. Revenue from the generics business was at Rs. 10,500.12 Mn (USD 219.92 Mn), as against Rs. 9,857.43 Mn (USD 212.12 Mn), registering growth of 7%. The Speciality formulation business registered revenue of Rs. 14,348.34 Mn (USD 300.52 Mn) as against Rs. 11,072.74 Mn (USD 238.28 Mn), registering growth of 30%.

# **Specialty Business:**

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

# **India**

Sales for the formulation business in India increased to Rs. 2,184.03 Mn [USD 47.03 Mn] for the Fourth Quarter of this financial year as compared to Rs. 1,616.85 Mn [USD 31.95 Mn] in the previous corresponding quarter, recording a growth of 35%

According to the latest ORG-IMS data it was reported that the company registered value growth of 21.7 % vis-à-vis that of the industry 17.7% [ORG: Apr'09 – Mar'10]



For the fourth quarter, all Glenmark brands that are in the top 300 i.e. Ascoril, Candid B, Telma, & Telma H improved their rankings substantially and registered strong growth rates. The India formulations business launched seven products during the quarter.

During the quarter, there was an increase in market share in two important therapy segments as compared to the previous quarter (ORG Mar MAT'10 vs. Dec MAT'09) - Cardiology market share was at 2.0 % as compared to 1.9% and Dermatology market share was at 8.0% as compared to 7.9%

The most significant product launch during the quarter was Prasugrel (Aplet), which was launched for the first time in India. It is a revolutionary new anti-platelet drug for the management of Acute Coronary Syndrome with PCI (Percutaneous Coronary Intervention). It is indicated specifically for patients who have undergone an angioplasty procedure to open up a blocked heart artery after experiencing a heart attack.

The other important product launches were Ascoril-LS for paediatric, Xaria was launched to strengthen our respiratory portfolio, Triglow in the Melasma therapy segment, and ERLEVA for lung cancer management

#### Africa, Asia and CIS Region

For the Fourth Quarter of the financial year, revenue from Africa, Asia and CIS region was Rs. 1,369.71 Mn [USD 29.29 Mn] as against Rs. 422.87 Mn [USD 7.88 Mn] for the previous corresponding quarter, recording an increase of 224%. The strong growth is partly on account of low sales during the corresponding quarter of the previous year.

In the region, Glenmark filed 25 product dossiers during the quarter and received 16 product approvals. For the entire year, Glenmark filed 113 product dossiers and received 90 product approvals



#### Russia/CIS Region

The secondary sale for the Russian Subsidiary has shown good growth in the fourth quarter. According to Pharmexpert data, on a MAT basis, the company is growing at a rate of 50% and the market share has consistently improved rankings in the market to the current rank of 75 in March 2010. The company has consolidated its position in the dermatology segment and is the fastest growing company in the segment. All the power brands of the company continue to show a healthy growth.

In the other CIS markets, Ukraine, Kazakhstan and Uzbekistan are continuing to show positive trend in secondary sales. We have appointed top national distributors in all these three countries which will ensure wider and faster availability of all our products.

### **Africa/Middle East**

The Africa and Middle East business recorded good secondary sales growth in the quarter. The focus on prescription led growth resulted in the 9 power brands recording strong performance in the region. The markets of Kenya, South Africa, Nigeria, Sudan and Yemen saw an increase in sales for the quarter. A specialty force to focus on Dermatology and Gynaecology was launched in Nigeria which increased Glenmark's focus on its core therapies. South Africa launched a number of cosmeceutical preparations under the umbrella brand of "Synacare" which compliments its existing strong dermatology franchise. A new division "Acme" launched in Nigeria to focus on dermatology and Gynaecology. A number of in-licensing agreements were made in Egypt and South Africa for the launch of differentiated products.

# **Asia**

The Asia region continued to perform well with renewed focus on marketing activities which were the main drivers for the increase in secondary sales. The strategy of power brands has led to these key brands driving growth for the Asia region. The Philippines subsidiary strengthened its position to the 45<sup>th</sup> rank as compared to 52<sup>nd</sup> rank in the last



quarter. Vietnam also registered good growth due to the introduction of cardiovascular range of products

#### **Latin America**

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 345.86 Mn [USD 7.49 Mn] for the Fourth Quarter of 2009-10 as against Rs. 268.76 Mn [USD 4.96 Mn] a growth of 29%.

In the region, Glenmark filed 18 product dossiers during the quarter and received 19 product approvals. For the entire year, Glenmark filed 65 product dossiers and received 51 product approvals

The Brazilian subsidiary continued to consolidate its presence in the country and the growth in the region reflects the impact of the restructuring of operations in Brazil which were carried out over the last few quarters. We now anticipate sequential growth from in this region in FY 2010-11 and beyond.

During the quarter, the company generated its first sales in Venezuela and the Mexican operations expanded to include important drugstore chains into the distribution channel.

#### Europe

Glenmark Europe's operations registered Fourth Quarter revenue of Rs. 459.01 Mn [USD 9.83 Mn] as compared to Rs. 383.55 Mn [USD 7.87 Mn] for the previous corresponding quarter, an increase of 20%.

During the quarter, Glenmark successfully launched. 'Losartan' in the Czech Republic and Slovakia to strengthen its cardiology portfolio. The Romania subsidiary also launched "Clopidogrel", which belongs to a group of anti-aggregants, to strengthen its cardiology 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.

# **Oglemilast (GRC 3886):**

Glenmark's lead PDE4 inhibitor molecule, Oglemilast (GRC 3886) did not meet the primary endpoint in its Phase IIb study on Asthma patients. Forest and Glenmark would discuss further course of action regarding Oglemilast.

#### **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 outlicense 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. 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 calendar 2010.

#### **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.

# **Generics Business:**

#### **USA Formulations**

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations of Rs. 1,852.30 Mn (USD 40.09 Mn) for the fourth quarter of FY'10 against revenue of Rs. 1,563.60 Mn (USD 30.01 Mn), an increase of 18% over the corresponding quarter of the previous year.

Revenues for the full financial year 2009-10 were Rs. 7,230.45 Mn (USD 151.44 Mn) against revenue of Rs. 7,337.73 Mn (USD 157.90 Mn) in the previous year, reflecting a marginal decline of 1%.

During the fourth quarter, the Company received final approval for four ANDA applications. The ANDA's approved were Calcipotriene ointment, Moexipril HCl tablets, Moexipril HCl + HCTZ tablets and Ropinirole tablets. Glenmark has accomplished successful launch of the three oral solid formulations in the U.S. market. Glenmark also received tentative approval from the U.S. FDA for Trandolapril + Verapmail extended-release tablets.



The Company received a total of 16 ANDA approvals by the U.S. FDA in financial year 2009-10 of which 6 were tentative approvals. In the previous financial year, Glenmark had received 11 ANDA approvals.

During the financial year, 13 ANDAs were filed with the USFDA by Glenmark, as well as a number of applications submitted through partnerships for which Glenmark is entitled to exclusive U.S. marketing rights upon approval.

Glenmark's current marketing portfolio consists of 53 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 Company will realize new business potential resulting from the settlement of patent actions regarding Fluocinonide, the generic version of Medicis' Vanos® cream, and Ciclopirox Olamine, the generic version of Medicis' Loprox® gel. Under the terms of the Settlement Agreement, Glenmark will be able to market and distribute its generic version of Vanos® cream under license from Medicis no later than December 2013, or earlier in certain circumstances. In addition, Glenmark will have a license to launch a generic version of Loprox® gel 0.77%, as supplied by Medicis.

During the quarter, the company announced that New Drug Applications (NDA's) were previously submitted for Oxycodone Hydrochloride Capsules, and Liquid Solution by their partner Lehigh Valley Technologies (LVT) to the USFDA. The FDA in a letter to the company indicated it has completed the filing review and begun reviewing the application for Oxycodone Hydrochloride. Total sales for Oxycodone Hydrochloride Capsules and Liquid Solution in the twelve month period ending December 2009 were USD 16 million as reported by IMS Health and Glenmark has the exclusive right to market and distribute the product in the US.



The summary of Glenmark's ANDA filings with Para-IVs with sole exclusivity is shown below:

	Brand			Litigation	
Product	Name	Plaintiff	Sales	Status	Approval Status
		Schering			Tentative Approval
Ezetimibe	Zetia	Plough	US\$ 1.4Bn	Case Settled	Received
		Abbott/			Final approval received
Trandolapril +		Sanofi-		Trials set for	for one of the 4 dosage
Verapamil	Tarka	Aventis	US\$ 58Mn	Aug 2, 2010	strengths
Fluticasone					
Lotion	Cutivat			Case to be	
0.005%	е	Nycomed	US\$ 45Mn	scheduled	Awaited
Atovaquone +	Malaro	Glaxo-			
Proguanil Hcl	ne	Smithkline	US\$ 58 Mn	Case Settled	Awaited

<sup>\*</sup>Sales are IMS for FY ending March 2010

Patent actions concerning Atovaquone and Proguanil Hydrochloride 250mg/100mg tablets, the generic version of GSK's Malarone® tablets

Under the terms of the Settlement Agreement, Glenmark will be able to market and distribute its generic version of Malarone® tablets under license from GSK in the third quarter of 2011, or earlier in certain circumstances. In addition, Glenmark will launch an authorized generic version of Malarone® pediatric tablets 62.5mg/25mg supplied by GSK.

Patent actions involving Glenmark's challenge to Merck's patent covering ZETIA ® (ezetimibe).

Under the Settlement Agreement, Glenmark will be able to launch their product on December 12, 2016 or earlier under certain circumstances, ahead of the April 25, 2017 expiration of Merck's patent exclusivity for ZETIA®.



#### **EU Formulations**

The European business continued to grow through a mix of product sales and outlicensing. During the quarter the business launched two more products in the UK (one developed in-house and the other in-licensed), which brings the total number of launched products in the UK to six products. The UK business expanded its coverage of the market by adding several new important accounts across the wholesale and retail channels.

In parallel, our out-licensing business successfully signed two more deals for licensing and supply of products in various EU markets. In this quarter, we also shipped out products for two new launches in three additional EU markets.

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

Overall, the EU formulation business posted revenue of Rs. 97.81 Mn (USD 2.10 Mn) for the quarter against revenue of Rs. 74.09 Mn (USD 1.55 Mn), an increase of 32%, over the corresponding quarter of the previous year. Revenues for the full year of FY10 were Rs. 299.38 Mn (USD 6.27 Mn) against revenue of Rs. 146.94 Mn (USD 3.16 Mn), an increase of over 100% over the previous year.

# **Oncology**

During the quarter, the oncology business based out of Argentina launched six new products. Glenmark's revenue from the Argentina operations were Rs. 80.21 Mn [USD 1.74 Mn] in the fourth quarter of 2009-10 as against Rs. 76.00 Mn [USD 1.43 Mn] for the fourth quarter of the previous year, an increase of 6%.

For the full year of FY10 revenues were Rs. 343.02 Mn [USD 7.18 Mn] as against Rs. 400.48 Mn [USD 8.62 Mn] for the previous year, a decline of 14%.



#### **Active Pharmaceutical Ingredients [API]**

The API business continued to strengthen its presence in regulated markets by launching three new products during the year viz. Perindopril, Lercanidipine and Topiramate. During the year, Glenmark also registered its first sale of API to Russia.

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 702.55 Mn [USD 15.18 Mn] for Q4 FY10 against Rs. 505.12 Mn [USD 9.95 Mn] for Q4 of the previous year, recording an increase of 39%. For the full year of FY10 revenues were Rs. 2,627.28 Mn [USD 55.03 Mn] against Rs. 1,972.28 Mn [USD 42.44 Mn] for the previous year, recording an increase of 33%.

#### Disclaimer

"Glenmark Generics Limited ("Company") a subsidiary of Glenmark Pharmaceuticals limited is proposing, subject to market conditions and other considerations, a public issue of its equity shares and has filed a Draft Red Herring Prospectus with SEBI. The Draft Red Herring Prospectus is available on the website of SEBI at www.sebi.gov.in and the respective websites of the BRLMs at www.enam.com and www.kmcc.co.in.

Investors should note that investment in equity shares involves a high degree of risk and for details relating to the same, see the section titled "Risk Factors" of the aforementioned Draft Red Herring Prospectus."

#### Disclaimer

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