Annual Report 2009-10

A New Way for A New World

Glenmark
Pharmaceuticals Ltd

Safe Harbour Statement

This report has been prepared by Glenmark Pharmaceuticals Ltd. The information, statements and analysis made in this report describing company's objectives, projections and estimates are forward looking statements and progressive within the meaning of applicable security laws and Regulations. Forward-looking statements may include words or phrases such as "believes", "expects", "anticipates", "intends", "plans", "foresees", or other words or phrases of similar import Similarly, statements that describe objectives, plans or goals both for itself and for any of its business components also are forward-looking statements. All such forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those contemplated. The analysis contained herein is based on numerous assumptions. Actual result may vary from those expressed or implied depending upon economic conditions, government polices and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this report. This report should not be regarded by recipients as a substitute for the exercise of their own judgment.

Operations in over 80 countries

Near 7000 employees globally

5 Research facilities

7 New molecules in clinics

13 Manufacturing facilities
in 4 countries

Leading the way
to a New World

A New Way for
A New World

Glenmark Research Facility
Mahape, Navi Mumbai, India

Contents

From the CEO's Desk 2

Key Financials 5

Highlights & Objectives 6

Innovation 8

Management Discussion & Analysis 14

- Industry Outlook 14
- Glenmark : The Way Ahead 16
- Business Unit Performance 18
- Global Human Resource Development 25
- Corporate Social Responsibility 26

Risk Management 28

Corporate Information 29

Financial Statements 30

From the CEO's Desk

"Treading through tough times, we have turned around and emerged much stronger. With our fundamentals robust and vision set, we are bound to stretch the horizons of excellence in research and business in the coming years"

Mr. Glenn Saldanha
Managing Director & CEO

Dear Friends,

In the last one year, we have seen a radical shift in the global pharmaceutical industry, perennially altering the landscape that we operate in.

On one hand, we have seen many large pharmaceutical players shed their orthodox thinking and come up with out of the box strategies to bolster their presence in the branded generics markets. The strategies include significant investments in India and other emerging markets because of which we have seen some big ticket acquisitions by global pharma majors as they try to get a slice of India's fast growing pharmaceutical market. Simultaneously, there has been a significant slowdown in innovative R&D investment by these pharma majors. Nearly all of them have cut their innovative R&D budgets sharply and also downsized their manpower.

At the same time, Indian companies that have been operating in developed and emerging markets hit a roadblock. While the US FDA slowed down its ANDA approval process impacting new launches, emerging markets lost much of their shine as they were still reeling from the aftershocks of the severe depression that derailed many of these economies.

We began the financial year on an unsteady note against this backdrop of tumultuous change in the industry and an ongoing global recession. The preceding year was one of the toughest Glenmark had ever faced – almost all our businesses were impacted severely in FY* 09. Our drug discovery R&D lost out on potential revenues as global pharma was wary of acquiring any molecules that were under development. In addition, as sales slumped across markets, we were hit badly as our fixed overheads continued to be high due to significant investments we had made into fixed assets just before the crisis emerged.

At the start of this year, the clouds of uncertainty still loomed large over both the short-term and long-term horizon. We were confronted with several challenges and it seemed like we were veering towards a situation that would take us at least two financial years to get back on the growth track.

However, we beat the odds and managed a transformation in less than a year and the numbers at the end of the financial year speak for themselves. While sales for the entire year grew by 18 %, the net profit for the company increased by 71 % to Rs. 3,310.32 Mn.

Glenmark's transformation was not in the least bit serendipitous. It was the result of a carefully crafted and efficiently implemented strategy that helped us recover quickly and also laid the foundation for sustained growth in the near future.

The key aspect of our strategy was to improve our cash flow position. We focused on cost optimization across operating markets and receivables were given utmost priority. On the ground, we targeted improving the working capital cycle that deteriorated in the previous financial year due to the recession and through our sustained efforts in FY 10, we managed to reduce net working capital. At the same time, we deferred all capital expenditure and executed only those projects in which market demand was imminent. Our acquisition plans were also put on hold temporarily.

> The key aspect of our strategy was to improve our cash flow position

Simultaneously, we worked on improving our income by increasing sales across markets. We took a multi-pronged approach towards this – first, by concentrating on 'power brands' across geographies and second, by consistently introducing new products in every market we operate in. The new product introductions were in line with our strategy to be dominant in certain therapeutic categories across operating markets.

The other key long-term aspect of this strategy was the decision of continuing with healthy investments in R&D. We believe innovation R&D has a bright future at Glenmark and our conscious effort to maintain R&D as a priority in our business plans is beginning to yield fruit once again. The recent deal with Sanofi-Aventis, where we out-licensed our first-in-class molecule for neuropathic pain - GRC 15300, is a major achievement on this front, as Glenmark is arguably the first company globally that has managed to progress a TRPV3 molecule to clinical trials. It is for this reason that the

> The deal with Sanofi-Aventis for GRC 15300 reaffirms our commitment to cutting-edge work in the area of drug discovery

fourth largest pharma company in the world, Sanofi-Aventis, has decided to invest in our molecule. This reaffirms our commitment to cutting-edge work in the area of drug discovery.

On the specialty side, the India business continued to remain our shining jewel registering strong growth at 19 %. The Rest of World markets, particularly Russia and CIS, rebounded extremely fast to post a stunning growth of 64 %. We have also seen a significant increase in operating margins from these businesses and their contribution has increased sharply. Even though the Central Eastern Europe (CEE) business registered good growth, we expect much more from this region. While CEE has recovered quickly and

** Fiscal Year ending March 31st*

managed to cut losses sharply – we still need to grow at a much faster pace to turn cash-positive in this current financial year. Business from the Latin American division, which shrank in the last financial year, will remain a challenge in this year as we need to put in place a sustainable growth model in this region. However, as the long term outlook for Latin America remains positive, and given its market size, Glenmark is determined to succeed in this region.

On the generics front, the slowing down of ANDA approvals by the US FDA impacted the growth of the US generics business this year in a big way. While we have continued filing ANDAs with the same vigor, we also remain optimistic about our US generics strategy. We clearly have built a pipeline which will generate consistent sales growth in future. Most importantly, the kind of therapeutic segments that we are venturing into will not only generate good sales numbers, but will also provide higher operating margins. Glenmark boasts of being the only Indian company that has captured a share of two such niche therapies, dermatology and hormone therapy. We have been aggressively filing ANDAs in these two, amongst the other key niche segment. The other strategy for our US generics business is our Para IV strategy where we have presently four opportunities where Glenmark is the sole 'first-to-file' applicant.

The Europe generics business registered its first sale during the financial year. This business will grow manifold in subsequent years, with entry into new markets like Germany and Netherlands planned this year. The API division grew by 37 % and is now a sizeable business. It has done a phenomenal job of transitioning itself from focusing on semi-regulated markets, to high value regulated markets. The division is already making a mark for itself, with all the top ten generic players doing business with us.

During the financial year, we concluded a Qualified Institutional Placement (QIP) and successfully raised Rs. 4,135.56 Mn, which helped bring our debt down. Our improved cash flows not only managed to reduce the overall debt, but most importantly provided the cash to fund our expansion programs. The resultant Debt: Equity ratio stands at 0.8: 1 at the end of FY 10 and we will be able to bring this down further.

As the cash flow position in the organization improved, we decided to put on hold indefinitely our plan to list the generics subsidiary Glenmark Generics Limited (GGL). The objective of this listing was two-fold: To unlock value for the parent shareholder i.e. Glenmark Pharmaceuticals Limited (GPL) and reduce collective debt of the organization. The announcement of the IPO did not provide any visibility to value creation for the parent company's shareholders and with the overall debt falling down sharply, the listing of the subsidiary was not serving any objective. Thus we decided to postpone the IPO indefinitely.

With all these efforts we have not only recovered from the global recession but have also put in place structures that will lead to sustainable growth in future. Having now built a strong foundation in the last year, we intend to accelerate the implementation of our growth plans.

We have not only recovered from the global recession but have also put in place structures which will lead to sustainable growth in future

In the next five years, we plan to move GPL up the value chain from a branded generics player to a differentiated innovator, while moving GGL down the value chain into pure generics and API space. Our efforts shall be directed towards the development of leadership in three key therapeutic segments of dermatology, respiratory and oncology, across the markets of GPL and GGL.

GPL's growth shall be fuelled by both expansion of the branded generics portfolio, as well as enrichment of the novel drug pipe line through in-licensing, mergers & acquisitions of late stage new molecular entities (NMEs) and focused development of our own NME portfolio. The transition shall be marked by key novel product launches, most imminent being Crofelemer- an in-licensed NCE, which is slated for launch in FY 12.

Our efforts shall be directed towards the development of leadership in dermatology, respiratory and oncology, across the markets of GPL and GGL

GGL will continue to focus on developing its strengths in niche therapeutic areas, while expanding its reach further into new regulated markets.

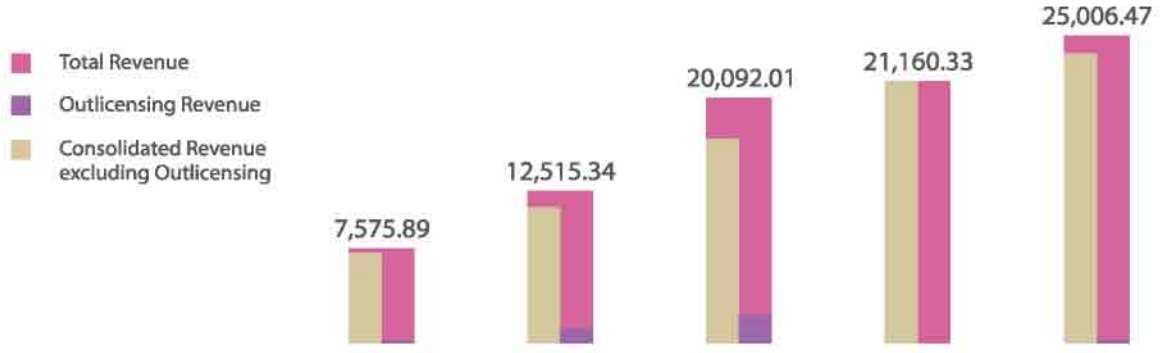
We are all set to venture forth with the new-found wisdom that only comes from overcoming adversity. We continue to be innovative in our thinking and are confident that our strategies will continue to create immense value for each and every stakeholder of our organization. I take this opportunity to thank each of you, our shareholders, for your confidence in Glenmark and look forward to your continued support.

Yours sincerely,

Glenn Saldanha
CEO & MD

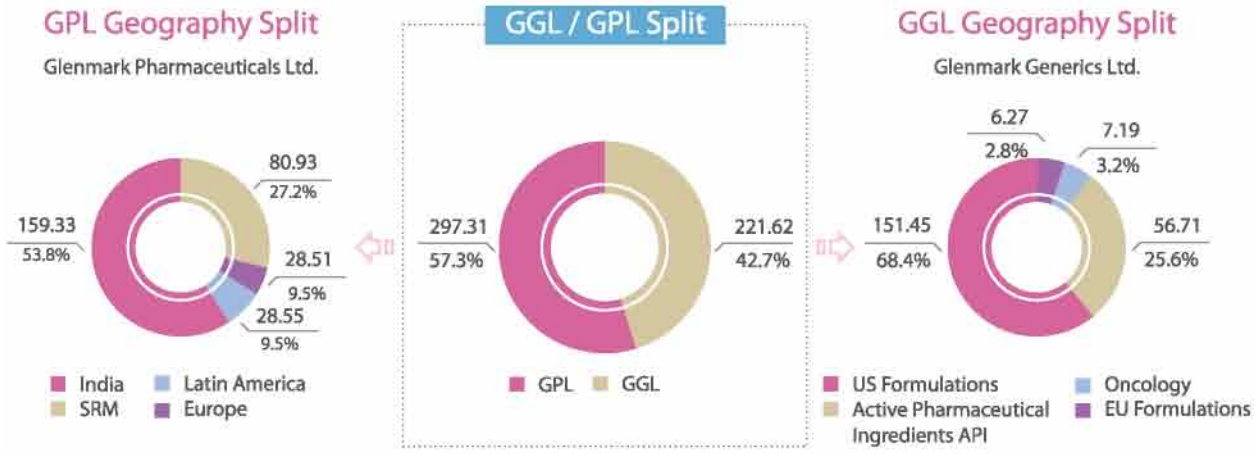
Key Financials

Revenue Trends



	FY 06	FY 07	FY 08	FY 09	FY 10
Consolidated Revenue excluding Outlicensing	7,310.26	11,120.22	17,689.28	21,160.33	24,774.07
Outlicensing Revenue	265.63	1,395.12	2,402.73	-	232.40
Total Revenue	7,575.89	12,515.34	20,092.01	21,160.33	25,006.47

(All values in Rs. Mn)



(All values in USD Mn)

	FY 06		FY 07		FY 08		FY 09		FY 10	
	Rs Mn	USD Mn	Rs Mn	USD Mn	Rs Mn	USD Mn	Rs Mn	USD Mn	Rs Mn	USD Mn
Turnover	7,575.89	171.09	12,515.34	283.54	20,092.01	498.81	21,160.33	455.35	25,006.47	523.81
Other Income	128.20	2.90	156.99	3.56	458.20	11.38	1,740.12	37.44	489.64	10.26
PBDIT	1,500.26	33.88	4,419.85	100.13	8,463.46	210.12	6,289.95	146.97	6,685.29	140.04
Interest	147.20	3.32	384.08	8.70	631.68	15.68	1,404.77	30.23	1,640.21	34.36
Depreciation	232.34	5.25	422.59	9.57	716.80	17.80	1,026.83	22.09	1,206.10	25.26
PBT	1,120.72	25.31	3,613.18	81.86	7,114.98	176.64	2,688.81	57.86	3,838.98	80.41
Tax	240.96	5.44	512.58	11.61	793.87	19.71	754.08	16.23	528.66	11.07
PAT	879.76	19.87	3,100.60	70.25	6,321.11	156.93	1,934.73	41.63	3,310.32	69.34

Average conversion rate for FY 10 of Rs. 47.74 / USD 1.00
for FY 09 of Rs. 46.47 / USD 1.00

Highlights & Objectives

Highlights

For the financial year 2009-10, Glenmark's consolidated revenue increased to Rs. 25,006.47 Mn (USD 523.81 Mn) from Rs. 21,160.33 Mn (USD 455.35 Mn) in the previous year, registering a growth of 18 %. Revenue from the generics business was at Rs. 10,580.37 Mn (USD 221.62 Mn) as against Rs. 9,857.43 Mn (USD 212.13 Mn) the previous year, registering a growth of 7 %. The specialty formulations business grew by 26% to take the revenue to Rs. 14,193.70 Mn (USD 297.31 Mn) from Rs. 11,302.90 Mn (USD 243.23 Mn) registered the previous year. The Consolidated Net Profit for the financial year was at Rs.3,310.32 Mn (USD 69.34 Mn) as compared to Rs. 1,934.73 Mn (USD 41.63 Mn) for the previous financial year, an increase of 71 %

Glenmark Pharmaceuticals Limited

Research and Development

- Signed an out-licensing agreement with Sanofi-Aventis for its molecule for neuropathic pain, GRC 15300 in the month of May, 2010. The company received an upfront fee of USD 20 Mn for development and commercialization rights of the 'first-in-class' TRPV3 antagonist, with a cumulative milestone payment potential of USD 325 Mn over the course of development
- Out-licensed a specialty topical pharmaceutical product to Medicis Pharmaceutical Corporation for North American markets
- Completed the dose selection stage of Phase III trials for Crofelemer, the in-licensed anti-diarrheal molecule from Napo Pharmaceuticals USA. The potential 'first-in-class' anti-secretory molecule also progressed to final stage of Phase III trials in the US
- Initiated US Phase I trials on GBR 500, the first monoclonal antibody (mAb) from Glenmark and arguably from India, to enter the clinical trial phase

Formulations Business

- Filed 250 product Stock Keeping Units (SKUs) across various geographies, with 110 of them in top 10 focus markets
- Launched 10 'first-to-market' products in the Indian market. Amongst the most significant launches was Aplet (Prasugrel)
- Completed the construction of a new plant for inhaler manufacturing at Baddi (India) to enhance focus on its respiratory portfolio
- Initiated revenue generation with new product launches in Mexico, UAE, Egypt and Venezuela
- Completed the acquisition of the Nalagarh manufacturing facility in Baddi

Glenmark Generics Limited

- Glenmark Generics Inc. (GGI) USA filed 13 Abbreviated New Drug Applications (ANDAs) and received 16 ANDA approvals by the United States Food and Drug Administration (US FDA)
- GGI received the US FDA approval for Glenmark's and India's first hormone product for the US market from its dedicated hormone facility in Goa, India
- GGI entered into an exclusive licensing agreement with Par Pharmaceuticals, USA to market Ezetimibe tablets, and with Taro Pharmaceuticals, USA for a branded product in May 2010
- GGI settled its patent litigations in relation to Fluocinonide cream and Ciclopirox Olamine Gel with Medicis Pharmaceutical Corporation
- GGI also settled its patent litigations in relation to Atovaquone and Proguanil tablets with Glaxo SmithKline LLC in April 2010 and for Ezetimibe tablets with Merck & Co., Inc. in May 2010
- Glenmark Generics Europe Limited (GGEL) submitted 5 new product dossiers, equivalent to 34 Marketing Authorization Applications (MAAs) and received approvals for 4 product dossiers, resulting in 31 Marketing Authorization Approvals (MAs). GGEL also established its local presence in the UK with the launch of 6 products
- Glenmark Generics Argentina (GGSA) commissioned a new oncology injectables facility at Pilar, Argentina
- GGL commissioned a new plant for oral solid dosage (OSD) formulations at Indore SEZ, India
- The formulations plant at Goa, India, successfully completed audits by UK-MHRA, EMEA and USFDA
- Initiated the project for a new Active Pharmaceutical Ingredient (API) manufacturing facility at Dahej SEZ, India