



GEARED FOR THE NEXT  
LEVEL OF **GROWTH.**

GLENMARK ANNUAL REPORT | 2013-14



## GEARED FOR THE NEXT LEVEL OF **GROWTH**.

Glenmark stands in a position of strength. We are now a US\$ 1 billion pharmaceutical company with a global presence. With its fast growing portfolio of products and a significant focus on innovation, Glenmark is poised to make greater strides. To take this big leap, we have made strategic decisions in key areas that will drive faster growth and create better outcomes for all our stakeholders around the world. Some of these key strategies are:



Innovation is one of the main pillars of our business. We take pride in the fact that we are recognized as an organization that is built around innovation. While innovation of new products is an important focus, we also continuously strive to integrate innovation across every function to optimize our resources, our portfolio, our systems and our profitability



In our pursuit of creating 'A New Way for a New World', we have established presence in over 80 countries from Asia to Latin America



With our topline reaching one billion dollar milestone, our revenue base is now strategically diversified. Our business now not only has the breadth but also has multiple growth drivers where we would leverage our investments in the years ahead



Our Research & Development efforts have always focused on innovative and highly effective drugs that fulfill unmet patient needs. This continues to remain central to our strategy and fundamental to our future success



We believe that creating intellectual capital is not enough to succeed. It is equally important to enable it with the right mix of systems and processes to realize its true potential. We are augmenting our processes and systems to support our growing businesses



We have a robust pipeline of 3 NCE and 3 NBE molecules in clinical trials or ready to enter clinical trials. This is another validation of the work that we are doing on the innovation front and once again puts us at the fore-front of cutting edge pharmaceutical companies



'Enriching lives' is a key element of Glenmark's philosophy. We believe that we should be the catalyst for change in urban and rural India by supporting the community through targeted initiatives



Our people are our biggest assets and core differentiator. Our people and their potential to contribute to the success of our company will be the key drivers in our high growth agenda



What sets Glenmark apart is the passion for achievement. Glenmark aims to raise the bar for quality and competence at every possible opportunity



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## Chairman's Letter



**Glenn Saldanha**  
Chairman & MD

“We are now poised for greater heights. We have a robust pipeline of products across all markets, a strong innovative engine, a well spread & diversified manufacturing setup, a truly global team and robust systems & processes to help us scale the next peak.”

### Dear Shareholder,

Your organization has achieved yet another milestone, with revenue crossing ₹ 6,000 crore (INR 60,000 Mn) during the year under review. For the third year in a row, we have grown revenue by over 20% on an ever expanding base business. Further, you will be pleased to know that we now rank among the Top-80 pharmaceutical companies in the world<sup>(1)</sup>. All this has been possible because of your unstinting support and commitment to the organization.

Glenmark's business has been built keeping long term and sustainable growth in mind. Over the years we have built a strong foundation and with our current size and scale we stand in a position of strength. We have a solid base, and we are

geared to handle the next level of growth over the next few years. We are now poised for greater heights. We have a robust pipeline of products across all markets, a strong innovative engine, a well spread & diversified manufacturing setup, a truly global team and robust systems & processes to help us scale the next peak.

However during the year under review, it has not been easy going. In terms of the global regulatory environment, the year under review continued to be fraught with challenges. Ever increasing competition, delayed product approvals across geographies and increasing regulatory scrutiny contributed in making the operating environment extremely gruelling.

1. SCRIIP 100 Rankings

Globally, government pressure on pharmaceuticals companies has been increasing and a number of companies are ending up paying huge fines for non-compliance. On the other hand, the USFDA has become increasingly vigilant and stricter in terms of compliance. In addition, regulatory delays have impacted the pharmaceutical industry in Russia and Brazil. We will need to wait and watch how this year pans out in terms of approvals in these markets.

We have also seen a spate of acquisitions being done by pharmaceutical companies based in the US and valuations for businesses are at an all-time high. The generic market in the US is getting more and more competitive because of the channel consolidation. This will put pressure on the generic business in the long run and especially during this year, when they go about completing their acquisition. The number of generic companies in the US is also increasing every year and the opportunities are getting fewer and fewer.

Therefore at this point in time, all the main focus markets continue to be riddled with challenges i.e. India, US, Russia and Brazil. And these markets put together account for nearly 75% of overall company's revenue.

### **Business overview: A year of strong growth**

But despite the odds in the marketplace, during the year under review we have reported yet another year of strong growth fuelled by good performances across our markets like the US, India, Europe, and the API business.

Our revenue base is now strategically diversified and hence our business not only has the breadth but we also have multiple growth drivers where we would leverage our investments in the years ahead. Being a research led pharmaceutical company; we have transitioned from developing only generic medicines to a range of specialty products in niche segments apart from having our own pipeline of several innovative molecules.



**The focus is to build the organization on our unique R&D capabilities rather than build it on the basis of cost differential model. We are clearly among the leading companies in emerging markets in terms of R&D investments and presently 10% of our sales is invested in R&D development.**



In the year under review, Glenmark has entered into new niche and high entry barrier segments like Immunosuppressants and Complex Injectables categories in the US. Both are very exciting areas and present fairly large opportunities for the company. Glenmark has also put up manufacturing assets in both these areas by setting up a new Immunosuppressants as well as Complex Injectables facilities in Indore (Central India). Our focus in niche segments including dermatology, hormones, controlled substances and modified release products have helped Glenmark ensure a sustainable market opportunity and continued profitability in the US market.

Similarly, we have built a pretty robust pipeline for our India and other Emerging Markets businesses. During the year under review, the India business grew by 15%, ROW business grew by 16%, Europe region grew by 36% and the Latin America region grew by 17%. We continue to file differentiated products in these markets and the focus is to build these businesses in therapeutic areas viz. Dermatology, Respiratory and Oncology. An example in this regard is the launch of generic Seretide, an inhaler product, in Mexico, Venezuela and Philippines. The R&D in vitro equivalence for generic Seretide; as well as the chemistry, manufacturing and control (CMC) development were extremely challenging and hence it's a great testimony of our cutting edge R&D capabilities in these focus therapeutic areas.

During the year under review, we have seen robust growth from the European business and we feel this will continue during this year also. Further with the regulatory changes now implemented in Russia, this business should also bounce back as we have received new product approvals which can drive growth for this subsidiary. In the Latam region, we are hopeful of a good showing of the Mexico and the Venezuela unit due to new product introductions while the Brazil subsidiary continues to be impacted due to approval delays. The India business will continue to record good growth despite the slowdown in the industry while in the US, your organization is dependent on new product approvals for growth and that at the moment is getting significantly delayed.

On the manufacturing side, in an era of increasing scrutiny, Glenmark's manufacturing facilities have successfully cleared several audits from authorities like the US-FDA, MHRA-UK and others. As an organization, we will continue to take steps to improve our quality systems and processes to ensure compliance at all times. We have now a well spread manufacturing base with facilities in India, Brazil, Argentina and the Czech Republic. We are looking to expand our manufacturing footprint to the US also which will happen anytime during this year. With this new facility, we have spread our manufacturing base and made it truly global in every sense.

We are also looking at a host of other measures which will support our next level of growth. One such initiative is our Project Disha (Direction) – which aims to ramp up our IT infrastructure to support a growing global organization like ours and ensure better control. As we build a robust, scalable and secure IT infrastructure; Quality and Regulatory compliance will be given foremost priority in the process. We are also looking at strengthening our clinical development capabilities globally.

Your organization continues to invest in the community and we now run 8 large

projects impacting over 600,000 people. The focus area for the organization remains in the area of child health and we will keep on increasing our investments in the area of corporate social responsibility.

### **R&D – A key driver for the future**

Glenmark has always believed that innovation is the only way to transform into a truly global pharmaceutical company. We have aggressively invested in innovation R&D for the past 14 years and have created a promising pipeline of first-in-class molecules addressing unmet medical needs in areas of pain and inflammation. These molecules have the potential to alter treatment pathways in the targeted therapeutic areas and transform the lives of millions of patients worldwide. Our innovation pipeline now is unique and unparalleled for any company across any emerging market.

Today, apart from the small molecule (NCE) innovation work, we are especially excited with the novel biologics program as we have several first-in-class monoclonal antibodies in clinical development. We recently inaugurated a new Antibody Manufacturing Facility in La Chaux-de-Fonds, Switzerland which gives us end-to-end capabilities for the development of novel, state-of-the-art monoclonal antibodies including bi-specific antibodies.

In its short existence of just about 10 years, Glenmark's Swiss biologics research centre has filed several patents on novel biologic entities. GBR 900 is the first anti-TrkA monoclonal antibody to enter clinical development. We also have GBR 830, an OX-40 antagonist, a first-in-class molecule globally which has shown great promise to emerge as a valuable therapeutic option to treat patients suffering from autoimmune diseases.

Besides, our mPGES-1 discovery program has also moved forward to human trials, which reaffirms our position globally in the development of novel pain therapies. Our out-licensed program, GBR 500 has

also progressed ahead. Our partner Sanofi has now announced a phase II study in multiple sclerosis which will be conducted during this financial year. Your organization will continue to remain committed to this business and out-licensing our first-in-class molecules to big pharma will continue to be a core element of our strategy.

**“We have realized early on, that the only way for sustained profitable growth in the US is focus on complex and niche generics where R&D investment is high and also very challenging. These products are not only tough to develop but the filing for these products are also expensive as compared to general immediate release products.”**

Our commitment to research and development is evident from our high investments in R&D over the years. You would know by now, that R&D is the backbone of your organization. And the focus is to build the organization on our unique R&D capabilities rather than build it on the basis of cost differential model. We are clearly among the leading companies in emerging markets in terms of R&D investments and presently 10% of our sales is invested in R&D development. A bulk of our R&D spends - apart from innovation research - will go towards developing products for the US market which has become very competitive because of the increasing number of players; especially from India. We have realized early on, that the only way for sustained profitable growth in the US is focus on complex and niche generics where R&D investment is high and also very challenging. These products are not only tough to develop but the filing for these products are also expensive as compared to general immediate release products.

Summing up, I would say that each of our businesses have enough horsepower to grow over the next several years. The US remains a critical growth driver for the organization along with the India and the ROW markets. We continue to invest significant amount of resources in the US in terms of R&D. The India business will also be our mainstay and we will have an India-specific strategy focusing on core therapy areas to help us grow in this market. The ROW markets which are profitable will see increased investments and we will focus to keep the profitability high in these markets. Over the next few years, we feel that the Latam and the Europe business will continue to improve with each year going by. The Europe business now has the right scale and will improve its profitability year on year. The API business which is focused on the regulated markets and is a profitable business for us will see sustained growth and also investments in the next few years. We have put in place all the key facilitators to catalyze the organization's growth over the next few years. The next billion dollar milestone is not too far in the future.

On this note, I would like to thank you for your support and your commitment towards our organization. We continue to power ahead and your support will remain invaluable to us as we take Glenmark to becoming a truly global and innovative pharmaceutical organization.

Yours sincerely,



**Glenn Saldanha**  
Chairman & MD





## Board of Directors



### **Mr. D. R. Mehta**

#### **Non-Executive Director**

Ex Deputy Governor, Reserve Bank of India and Ex Chairman, Securities and Exchange Board of India, he has over 4 decades of rich experience in civil services.



### **Mr. Sridhar Gorthi**

#### **Non-Executive Director**

Presently a partner at Trilegal, he has been involved in legal advisory services to various multinational and domestic corporations on restructuring, debt finance, joint ventures, acquisition/ mergers etc.



### **Mr. J. F. Ribeiro**

#### **Non-Executive Director**

A retired Government officer, he has served the country under various assignments like Commissioner of Police, Mumbai and Special Secretary to Government of India, Ministry of Home Affairs.



### **Dr. Brian W. Tempest**

#### **Non-Executive Director**

He has worked in the Pharmaceutical Industry for the last 40 years and managed healthcare businesses across numerous regions. He is a Fellow of the Royal Society of Chemistry and a Fellow of the Royal Society of Medicine.



### **Mr. N. B. Desai**

#### **Non-Executive Director**

Founder of Equitorial Bank PLC, UK, he has rich experience of over four decades in the Financial sector globally, having assumed leadership positions like Chairman, Bank of Baroda Uganda Ltd.



### **Mr. Bernard Munos**

#### **Non-Executive Director**

The Founder, InnoThink Center for Research in Biomedical Innovation served Eli Lilly and Company, USA as Advisor - Corporate Strategy. He has presented his findings at numerous meetings sponsored by academies, foundations, universities in the US and Europe.



### **Mr. Hocine Sidi Said**

#### **Non-Executive Director**

Founder & Director, Bio-nAblar - an investment company, he has over two decades of experience in global pharma industry having been associated with companies like Pfizer and UCB.



### **Mrs. B. E. Saldanha**

#### **Non-Executive Director**

During her 23 year tenure with Glenmark, she was responsible for developing and growing the company's export business.



### **Mrs. Cherylann Pinto**

#### **Director - Corporate Affairs**



### **Mr. Rajesh Desai**

#### **Executive Director**



### **Mr. Glenn Saldanha**

#### **Chairman & Managing Director**



# Key Financials

(All amounts in millions of Indian Rupees, unless otherwise stated)

Consolidated Financial Highlights	2013-14	2012-13	2011-12	2010-11	2009-10
Total Revenue	60,100.37	50,188.27	40,299.04	30,895.88	25,496.10
Earning before Depreciation, Finance cost, and Tax expenses [ EBDIT ]	10,956.21	10,217.63	7,236.24	7,327.89	6,685.29
Depreciation and Amortisation	2,167.95	1,270.09	978.78	946.78	1,206.10
Profit for the year	5,456.03	6,282.90	4,643.07	4,578.33	3,310.32
Equity dividend	200%	200%	200%	40%	40%
Equity Share Capital	271.22	270.85	270.53	270.27	269.84
Reserve and Surplus	29,561.58	27,359.40	23,745.77	20,102.10	23,282.49
Net Worth	29,832.80	27,630.25	24,016.30	20,372.37	23,552.33
Total Debt	32,669.72	27,648.69	22,445.01	21,084.62	18,693.91
Gross Fixed Assets	37,786.47	32,968.40	28,384.24	24,685.23	27,763.12
Net Fixed Assets	30,356.89	27,682.09	24,247.59	21,517.50	23,880.78
Total Assets	86,336.03	71,710.03	58,834.27	50,977.77	43,651.32
Market Capitalisation	153,485.47	125,283.36	83,230.25	76,649.15	71,844.25
Number of Equity shares	271,223,653	270,853,653	270,535,503	270,272,053	269,837,553
Closing market price as on 31 March	565.90	462.55	307.65	283.60	266.25
<b>Key Indicators</b>					
Earning Per Share (₹)	20.01	22.91	17.03	16.78	12.40
Debt : Equity ratio	1.10	1.00	0.93	1.03	0.79
Return on Capital Employed [PAT/Net Worth]	18.29%	22.74%	19.33%	22.47%	14.06%

Note: It must be noted that the financial information for FY 2011 onwards has been prepared under International Financial Reporting Standards (IFRS), where as prior years' financial information have been prepared under Indian Generally Accepted Accounting Principles (I-GAAP); accordingly FY 2011-14 information is not strictly comparable with prior years' information.





# Innovation

For us at Glenmark, innovation is not just a term referring to scientific research and discovery; it's a way of life; it's a means of creating a healthy, happy and ailment-free world. All our actions are guided by innovative thinking and a strong set of values. We practice innovation by finding new ways of doing things – big or small; thereby enabling us enrich lives of people across the globe.

In its pursuit of enriching lives, Glenmark has evolved into a global organization and a leading player in the discovery of new molecules within a short period of time.

**3 Novel Biological Entities and 3 Novel Chemical Entities, most are first-in-class globally**



Today Glenmark's global R&D footprint spans through India, UK and Switzerland, which houses its NCE R&D centre, Biopharmaceutical R&D centre, Clinical R&D centre and 3 Generic R&D centres.

**R&D team of around 800 members across 6 facilities**

**Our vision:  
To emerge as a leading integrated research-based global pharmaceutical company**





## Highlights in R&D

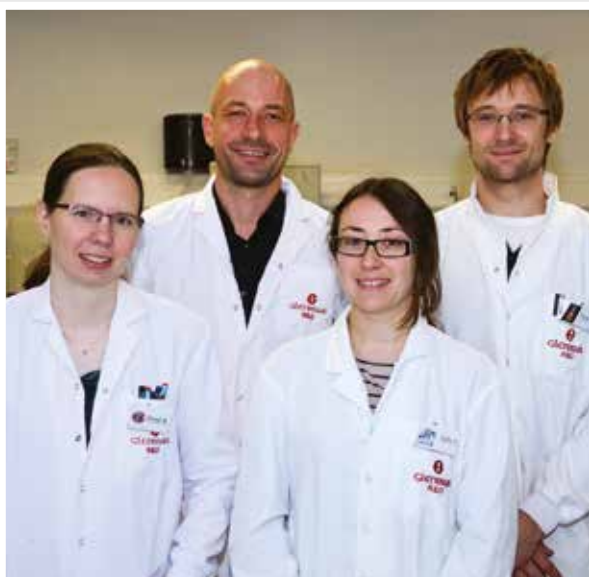
### THREE OF GLENMARK'S NOVEL MOLECULES HAVE ENTERED PHASE I OF CLINICAL DEVELOPMENT

#### mPGES-1 Inhibitors

- **GRC 27864** is a potent, selective, orally bioavailable inhibitor of mPGES-1 - a key enzyme in the pathway responsible for inflammation
- Successfully completed pre-clinical and Phase I enabling studies. Phase I trial (first-in-human) is currently ongoing in UK
- With this announcement, Glenmark has reaffirmed its position globally in the development of novel pain therapies
- Glenmark has entered into an agreement with Forest Laboratories Inc., an international health care leader, on collaboration for the development of novel mPGES-1 inhibitors to treat chronic inflammatory conditions, including pain. The total amount received by Glenmark from Forest Laboratories Inc., towards its novel mPGES-1 inhibitors program is US \$ 15 million



**Glenmark's drug discovery effort is focussed in the therapeutic areas of Inflammation, Pain and Oncology**



#### GBR 900

- **GBR 900** is a first-in-class monoclonal antibody for the treatment of chronic pain targeting TrkA, the receptor of nerve growth factor
- In 2010, Glenmark gained an exclusive worldwide license from Lay Line Genomics S.p.A. (Italy) for anti-TrkA antibodies and their entire intellectual property portfolio in the TrkA field. GBR 900 is the optimized anti-TrkA antibody emerging from this exclusive worldwide license
- Successfully completed the Phase I enabling preclinical development programme and a Phase I clinical trial application has been filed with the MHRA, UK



**Followed strategy of developing and out-licensing its own molecules to large multinationals**



#### GBR 830

- The first anti-OX40 monoclonal antibody - **GBR 830** - was discovered at the Glenmark Biologics Research Centre located in Switzerland
- GBR 830 shows great promise to emerge as a valuable therapeutic option to treat patients suffering from autoimmune diseases. Phase I enabling toxicity studies for GBR 830 have been completed and Glenmark plans to file for a Phase I study in FY 2015

