

**2016-17**  
Annual Report

# ***STRATEGIC BLUEPRINT FOR THE NEXT DECADE***

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We have come a long way in a short time. 16 years ago, we were a USD 31 mn company focussed on the Indian pharma market. Today, we are a USD 1.4 bn global pharma organisation with over 13,000 employees in 50 countries, deriving 70% of our revenues from international markets.

Our objective is to earn 30% of our revenues from specialty and innovative products by 2025. Our innovation programme, that we began investing over a decade ago, has begun to deliver results with new molecules, currently in different stages of development, in the three focus areas of oncology, respiratory and dermatology. In parallel, we are growing in size and reach, expanding our manufacturing footprint and providing differentiated products to customers globally.

Over the following pages, you will know that our confidence in our ability to deliver on our strategic objectives is well-founded. We will tell you about our generics pipeline, which is a rich mix of mass-market, niche, and complex products. You will read about BEAT®, our breakthrough technological platform to develop novel, more efficacious drugs for patients battling breast

cancer and multiple myeloma, and how those drugs are making steady progress in the lab and the clinic. You will see how our scientists are using incremental innovation to devise specialty products that can bring relief to patients with near-debilitating allergies. They are also working on developing convenient and economical solutions to improve the quality of life of patients living with chronic respiratory diseases.

We will lay out our plans to accelerate growth and profitability in various parts of the business without departing from our sharp focus on the chosen therapy areas of oncology, respiratory and dermatology. At the same time, we are conscious of the many hurdles in our path and are gearing up to surmount them.

We hope that you will continue to support us in this exciting journey.



# GLENMARK AT A GLANCE

We are a leading research-driven, global and integrated pharmaceutical organisation committed to making a difference in patients' lives. Since our entry into the pharmaceutical industry in 1977, we have emerged as a leading player in the discovery of novel molecules, both NCEs (New Chemical Entity) and NBEs (New Biological

Entity), and differentiated generic formulations.

We have several molecules in various stages of pre-clinical and clinical development and are primarily focussed in the areas of oncology, respiratory and dermatology. We have improved the lives of millions of patients by offering

safe and affordable medications for nearly 40 years.

Strategic research and development form the basis of all our offerings and we have more than 13,000 employees from 60 nationalities dedicated to the goal of enriching lives across the globe.



## One of the Top 75

Pharma and Biotech  
companies in the world<sup>1</sup>



## Ranks 10<sup>th</sup> among companies

based out of emerging  
markets<sup>1</sup>



Members of Glenmark's R&D team in Switzerland

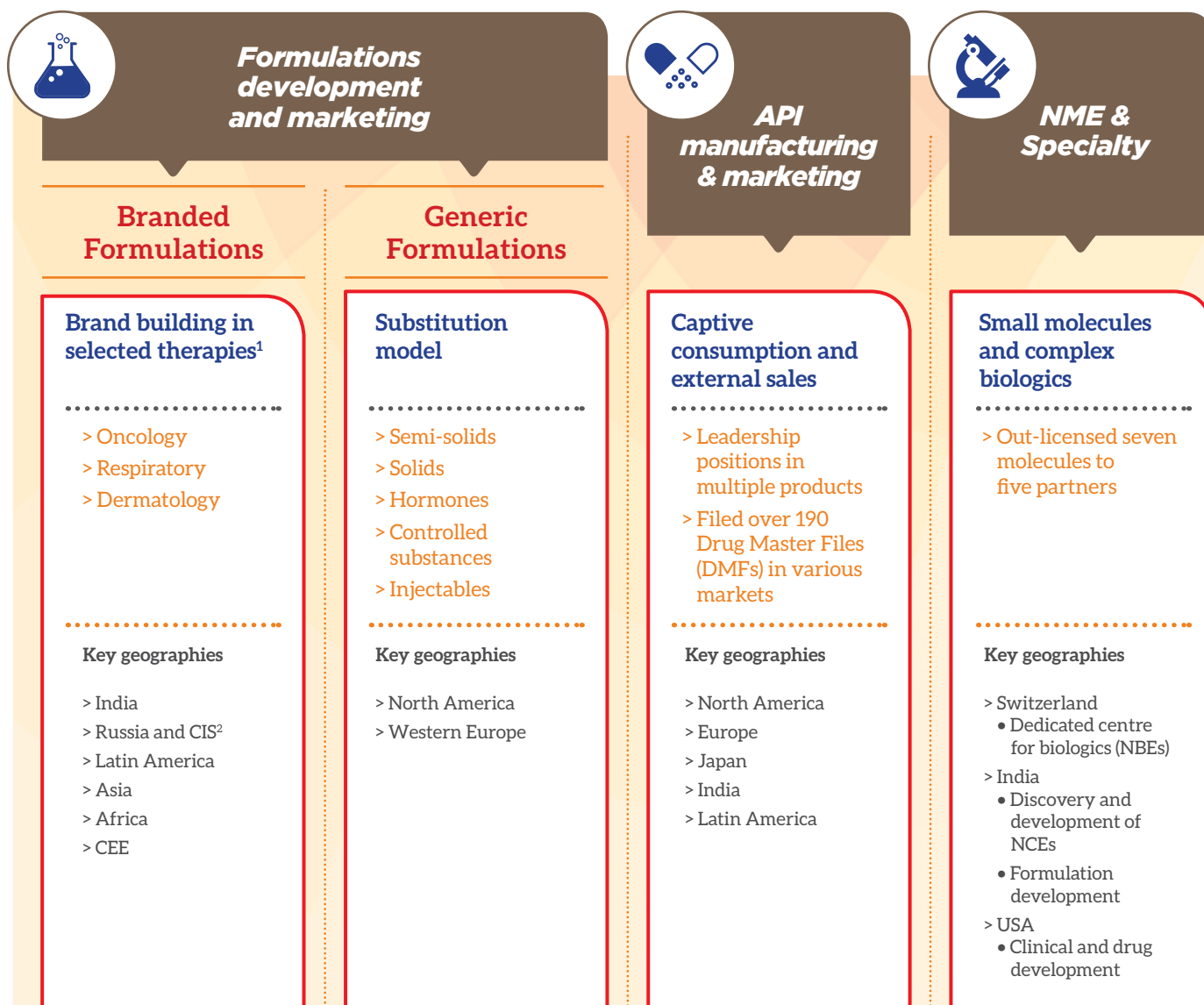
1. Source: Scrip 100 - 2017 Rankings

## Glenmark's business divisions

Our business is primarily structured into Branded and Generic Formulations, Active Pharmaceutical Ingredients (APIs), and Novel Molecular Entities (NME) & Specialty Products.



Glenmark's manufacturing facility at Goa, India



1. Additional therapies in some markets like cardio-metabolic in India and CNS in Central and Eastern Europe (CEE)

2. Commonwealth of Independent States

# EVOLUTION OF GLENMARK

We are at the threshold of an exciting phase - one that holds great promise. In a short span of 17 years, not only have we evolved into a successful global branded generics organisation; but have also built a reputation of being an innovation driven organisation in a space

dominated by global pharmaceutical giants. Over the years, we expanded our manufacturing footprint to 16 facilities across the world and augmented our international operations to build a strong overseas presence. We onboarded the best talent who shared our vision of taking

Glenmark to new heights of success.

Over the next decade, we expect to unlock many new opportunities that will help us transform into a leading innovative global pharmaceutical company.

## Evolved into a successful global organisation over the last 17 years



Consolidated turnover: USD 31 mn

Consolidated turnover: **USD 1.4 bn**



Our revenue base is now strategically diversified. Our business has multiple growth drivers, which will give us a competitive advantage in the years ahead

## Manufacturing footprint

2 Formulations facilities

> 16 facilities across Formulations and API in 4 continents

> GMP-grade biologics plant in Switzerland

> 7 FDA-approved manufacturing facilities

State-of-the-art manufacturing facilities across the US, India, Switzerland, Argentina and Czech

### Formulation Facility

- > Goa
- > Indore
- > Baddi
- > Aurangabad
- > Nalagarh
- > Nashik

- > Sikkim
- > Monroe, USA
- > Argentina
- > Czech Republic

### API Facility

- > Ankleshwar

- > Dahej
- > Aurangabad
- > Kurkumbh
- > Mohol

### Biologics Facility

- > Neuchatel, Switzerland

## International operations

About 8% of total turnover

More than 70% of total turnover

Presence across the US, Europe, Russia, Brazil etc.



### FY 17 revenue breakup of our global operations

- |               |              |
|---------------|--------------|
| > USA - 40%   | > ROW - 11%  |
| > India - 26% | > Latam - 6% |
| > Europe - 8% | > API - 9%   |

## Innovation

### Initiation of NME research

- > 7 outlicensing deals signed with Eli Lilly, Merck, Sanofi, Teijin Pharma and Forest Labs
- > USD 200+ mn of cash through outlicensing
- > 9 novel products in pipeline focussed in the therapeutic areas of oncology, respiratory and dermatology

### End-to-end capabilities spanning from engineering to clinical development and commercialisation



120+ scientists researching new chemical entities based in India



120 scientists researching new biological entities based in Switzerland



A facility in the US supporting clinical development

9

core assets under investigation

3

core therapeutic areas – oncology, respiratory and dermatology

6

assets in clinical trials

## Novel Molecular Entities



**GBR 1302**  
(breast cancer  
gastric cancer)



**GBR 1342**  
(multiple  
myeloma)



**GBR 1372**  
(colorectal cancer)



**GBR 8383**  
(multiple  
cancers)



**GBR 830**  
(atopic dermatitis)



**GRC 39815**  
(COPD, IPF)

## 3 Specialty Products



**GSP 301**  
(allergic  
rhinitis)



**GSP 304**  
(COPD)



**GBR 310**  
(asthma, CIU)

Note: Non core assets include GRC 17536, GBR 900 and GBR 500. These three molecules and GRC 27864 are candidates for out-licensing.

## Employees

Less than 1,000

More than 13,000



A strong team of over 13,000 employees from 60 nationalities are committed to enriching lives across the world

YEAR 2000

YEAR 2017

Note: Revenues for FY2000 and FY2017. FX Rate: USD 1 = ₹ 67

# CHAIRMAN'S MESSAGE



**Glenn Saldanha,**  
Chairman & MD

” —

At its core, our strategic blueprint for the next decade diversifies risk and envisages the systematic unlocking of high-growth and profitable new revenue streams across the pharmaceutical value chain with a view to delivering on goals in a riskier and more uncertain world

## **Dear Shareholders,**

These are testing times for the global drug industry. In advanced markets, prices are under pressure from greater competition, a rapidly consolidating group of buyers/ channels with more bargaining heft, and governments keen to cap spiralling healthcare costs. Regulators from these markets have also stepped up their scrutiny of manufacturing units supplying into their markets, and drug inspectors are taking a tough stand on even relatively minor deviations.

As countries move towards regulatory harmonisation, drug control administrations in emerging markets are raising the bar for approvals. A case in point is the Indian government's attempt to take a sizeable number of fixed dose combinations off the market citing irrationality; though not entirely successful, it is a sign of things to come.

Drug pricing is a recurring theme across markets and product segments. Then, governments across the world are on a drive to push local manufacturing and job creation. Success, therefore, also depends on being able to skilfully navigate myriad business and political landscapes and invest judiciously.

Glenmark continued to deftly manoeuvre through these challenges and delivered strong growth in FY 16-17. Our consolidated revenues in the 12 months ended 31 March 2017 rose from 20.08% to ₹ 91,856.81 mn (USD 1,371.62 mn). Our net profit for FY17 was ₹ 9,159.21 mn (USD 136.77 mn).

During the year under review, our India Formulation business recorded a stellar



performance, growing at 9.22%. This is despite one of our largest products being brought under price control and the regulatory uncertainty around certain fixed dose combinations.

In the US, our largest market, our business grew by 52.90% benefitting significantly from the increasing number of approvals. The standout launch during the year was that of the first and only generic of Merck's cholesterol drug ZETIA® with 180-day

In emerging markets, while the Russia business rebounded strongly, we stopped selling in Venezuela from the third quarter of FY17. We also took a write-down on the cash that is presently lying in our Venezuela subsidiary.

The Active Pharmaceutical Ingredients division performed very well on account of new launches with exclusivity periods and strong domestic sales.

With this blueprint as our guide, we are prepared to transition from being a generics-driven organisation to one that has an optimal mix of generics, specialty and research-driven innovative products. We will do this by remaining tightly focussed on three key therapy areas: oncology, respiratory and dermatology. In these three fast-growing therapies characterised by substantial gaps in treatment options, the combined force of our product development/ manufacturing skills and our marketing expertise - built over decades and across geographies - will yield definitive results not just for investors but also for patients in need.

The building blocks are already in place. Generics continues to be the engine of growth. Our products are now available in nearly all major geographies. While India is our primary production base, we have a manufacturing presence across four continents.

In emerging markets, we have built a strong branded generics portfolio with a loyal prescriber base. In the US and western European markets where commoditisation of generics is a real danger, we have created a pipeline of complex, niche and difficult-to-make generics such as cytotoxic injectables, and respiratory inhalers, through a combination of internal development and licensing to stave off competition and protect prices. We continue to exploit first-to-file opportunities in the US for blockbusters such as generic ZETIA®, launched in December 2016. We expect to file 20-25 ANDAs each year over the next



**GBR 310 has the potential to be the first biosimilar of XOLAIR®. This product is of special interest to us as it is indicated for disease conditions in two of our three focus therapy areas i.e respiratory and dermatology**

exclusivity, in partnership with Endo International. Besides the launch of generic ZETIA®, the base business also recorded strong growth. The US generics market continues to be challenging with greater price erosion, consolidation of the supply chain and increasing number of competitors.

The Europe business, on a constant currency basis, performed well. However, in the UK, our largest market in Europe, business was impacted by the devaluation of the pound sterling. This adversely affected the Company's overall performance in this region.

In the year ahead, we are confident of growing both revenues and profits with improved performance in the base business and new product launches in multiple markets.

Our confidence stems from a meticulously crafted strategic blueprint for the next decade. At its core, this strategy diversifies risk and envisages the systematic unlocking of high-growth and profitable new revenue streams across the entirety of the pharmaceutical value chain. It has been devised with a view to delivering on goals in a riskier, more uncertain world.

# CHAIRMAN'S MESSAGE (CONTD.)

five years and launch between 10 and 20 products annually.

While remaining positive on the generics opportunity, we also anticipated the so-called 'new normal' in the global generics business and planned our investments in differentiated and innovative products.

Our pipeline of specialty products, to be rolled out over the next three

is of special interest to us as it is indicated for disease conditions in two of the three therapy areas that are of critical importance to the organisation, i.e., respiratory and dermatology. GBR 310 has the potential to be the first biosimilar of XOLAIR® on market and a Phase I study has already been initiated. We expect to file for marketing approval in CY 20.

Over a decade ago, we began a novel R&D effort in the face of skepticism.

These are bi-specific antibodies (bsAbs) that can work on not one but two targets in the body implicated in cancer and are thus potentially more effective than available therapies.

Key among these is GBR 1302, a potential first-in-class treatment for HER2+ breast and gastric cancers that is currently in Phase I trials. In preclinical studies, it showed faster and more complete killing of tumor cells compared to existing first-and-second-line treatments. GBR 1342 for multiple myeloma and GBR 1372 for colorectal cancer are some of the other exciting bsAbs based on the BEAT® platform that are being prepared for clinical development.

Among monoclonal antibodies, we have GBR 830, a potential best-in-class OX40 antagonist that is currently in Phase II trials in the US and Canada for moderate-to-severe atopic dermatitis. It is also the first OX40 antagonist globally to successfully complete Phase I studies. We are exploring the development of GBR 830 in other autoimmune diseases, as well.

The innovative R&D business has the ability to greatly boost our revenues and profits while also paving the way for Glenmark to take its place in the global club of pharma innovators.

Barring unforeseen circumstances, we are well-positioned to deliver on our strategy such that by 2025, specialty and innovative products will comprise 30% of our revenues. Over



**In the three chosen therapy areas, the combined force of our product development, manufacturing skills and also our marketing expertise will yield definitive results not just for investors but also for patients in need**

to four years, is expected to act as a defence against generics price erosion and increase in competition, and boost profitable growth. GSP 301, a novel fixed dose combination of two drugs in a nasal spray format for seasonal allergic rhinitis is our first branded, specialty product to clear Phase III, the final phase of clinical trials. We will seek USFDA approval for it in Calendar Year (CY) 18. Besides GSP 301, we are also excited about GBR 310, a biosimilar of the allergic asthma and Chronic Idiopathic Urticaria drug XOLAIR®. This product

It is a matter of pride for us that those efforts, continued in spite of reversals and relatively limited financial resources, are yielding results. Scientists at our biologics laboratory in Neuchatel, Switzerland have developed a proprietary, cutting-edge technological platform called BEAT® (Bispecific Engagement by Antibodies based on the T-cell receptor). This platform, which has been successfully developed by surmounting substantial hurdles of scale-up and purification, allows us to make a new range of targeted therapy in cancer treatment.