

January 10, 2017

The Dy. General Manager
Dept. of Corporate Affairs
The Bombay Stock Exchange Ltd,
Phiroze Jeejeebhoy Towers
Dalal Street
Mumbai: 400001

Dear Sir,

Kindly find enclosed herewith the presentation that will be made at the J. P. Morgan Healthcare Conference, San Francisco, USA, the same will also be made available on our website.

The above is for your information and record.

Thanking you.

Yours faithfully,

For Glenmark Pharmaceuticals Ltd.

Rajesh V. Desai Executive Director

Tel: 4018 9999

Fax No: 4018 9986 (Legal & Secretarial Dept.)

Encl: as above



### J P Morgan Healthcare Conference

**Glenmark Corporate Overview** 

January, 2017



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Journey over the last 15 years

**Strategic Roadmap** 

**Growth Drivers** 

**Research and Development** 



### Journey over the last 15 years

**Strategic Roadmap** 

**Growth Drivers** 

**Research and Development** 

# **Evolved into a successful global organization over the last 15 years**



	Year 2000		Year 2016
Wealth Creation	Revenue: US\$ 31 mn Market Cap.: US\$ 40 mn	<b>=</b>	Revenue: US\$ 1.2 bn  Market Cap: US\$ 3.8 bn
Manufacturing Footprint	2 formulations facilities	$\Rightarrow$	17 facilities across 4 continents; 7 approved by USFDA
International Operations	~8% of total revenues	<b></b>	>70% of total revenues Present in US, EU, RCIS, LATAM etc.
Innovation	Initiation of NME research	$\Rightarrow$	Novel molecules in pipeline Focused on Oncology, Dermatology and Respiratory
Employees	<1,000: Primarily in India	<b></b>	> <b>12,000</b> : Spread over 50 countries

## Current business is spread across API, Branded and Generic Formulations



### **Formulations Development and Marketing**

**Branded Formulations** 

API Manufacturing & Marketing

NME & Specialty

Brand Building in Selected Therapies

**Substitution Model** 

**Generics Formulations** 

**Captive Consumption** and External Sales

Biologics and Small Molecules

### **Key geographies**

- India
- Russia & CIS
- Latin America
- Asia
- Africa
- CEE

### **Key geographies**

- North America
- Western Europe

### **Key geographies**

- North America
- Europe
- Japan
- India
- Latin America

### **Key facilities**

- Switzerland
  - Dedicated center for biologics
- India
  - R&D center for NCEs
  - Development hub for specialty

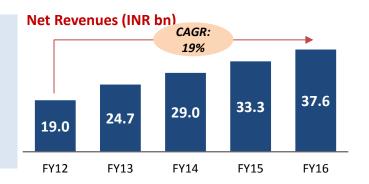
**Revenue generating segments** 

Investing for the future

### Robust growth exhibited across business segments

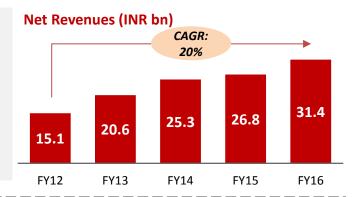
Branded Formulations

- CAGR of 19% over last five years
- Focused on brand building in select TAs
- Strong field force of 5,500+ globally



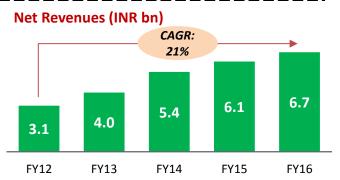
Generic Formulations

- CAGR of 20% over last five years
- Growth driven by niche products and selected large scale opportunities
- Leading Gx derma player in the US



**API** 

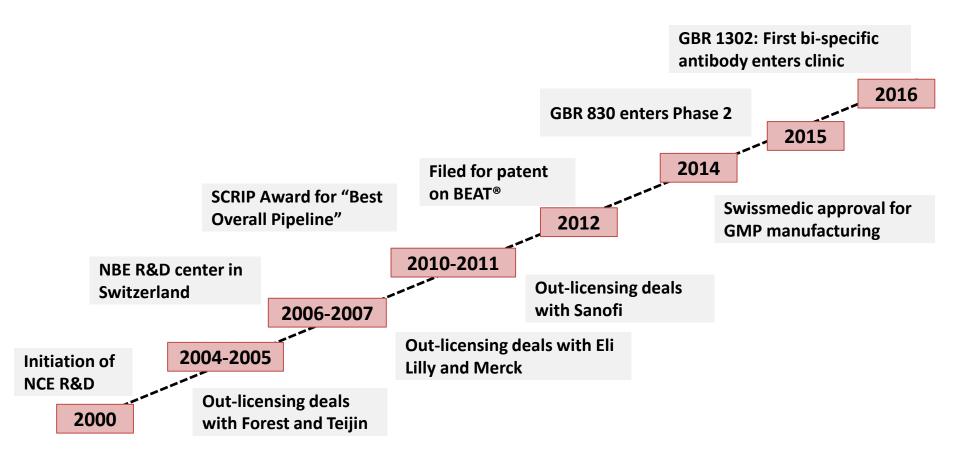
- CAGR of 21% over last five years
- Leadership position in multiple products
- Filed ~200 DMFs in various markets



Note: Net revenues in Generics Formulations chart include US, WEU and CEE

## Initiated novel R&D in 2000 with a vision to bring innovative molecules to market



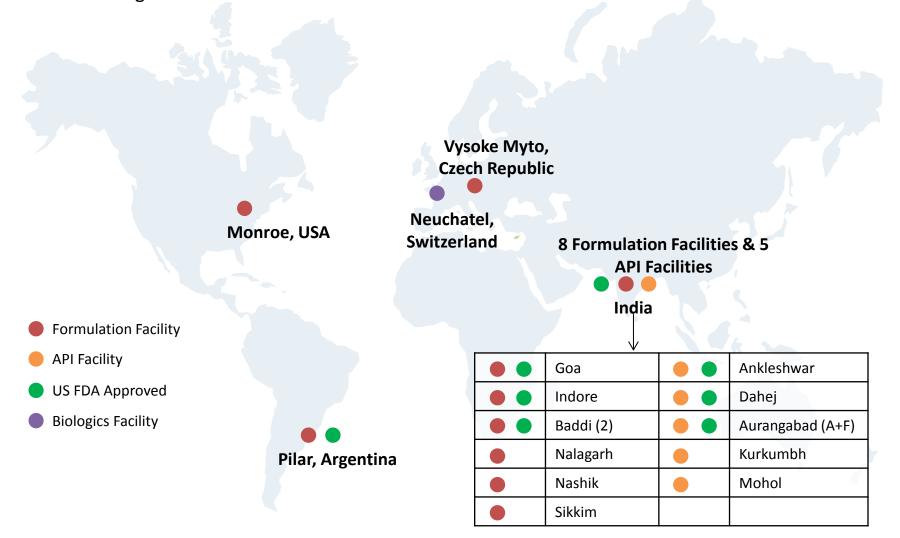


Seven out-licensing deals since 2004, with cumulative revenues of US\$ 200+ mn

# Manufacturing network spread over 4 continents; 7 facilities approved by the USFDA



Commissioned US manufacturing site in 2016 and obtained DEA license for controlled substances – ANDA filing from CY17 onwards





Journey over the last 15 years

### **Strategic Roadmap**

**Growth Drivers** 

**Research and Development** 

## Strategic elements to overcome the key challenges faced by the Pharmaceuticals Industry



### **Industry Challenges**

- Decline in small molecule generics opportunities in the US
- Increase in competitive landscape due to entry of new players
- Consolidation of competitors and customer base in the US and EU
- Pricing pressure in developed markets driven by need to manage healthcare budget
- Push towards local manufacturing of generics in key emerging markets

### **Strategic Elements**

- Focus on 3 core therapy areas –
   Oncology, Dermatology and Respiratory
- Continue to grow generics business through differentiated products and launch specialty and innovative products
- Enhance development efforts on niche generics and complex technologies such as semi solids and Hormones
- Enter new dosage forms with low competitive intensity e.g. Inhalers
- Advance NME pipeline and continue to look for partnering opportunities

## Roadmap to evolve into a innovative research led firm and launch proprietary products



- 2 major geographies US and India contributing ~60% of sales
- Generic formulation player in the US and WEU
- Branded formulation in other markets
- NME pipeline in early to mid stage of development
- Manufacturing base primarily in India

- US, India, Europe and API to contribute >80% of sales
- Increase presence in complex generics
- Launch specialty business in the US
- NME pipeline in advanced stage of development
- Expand manufacturing footprint

Medium term focus (next 3-5 years)

- Launch innovative and specialty products in multiple markets
- ~30% of total revenues from specialty and innovation segments

Long term focus (next 5-10 years)

**Current position** 

### Focusing across the value chain in core therapy areas

Oncology

Dermatology

Respiratory

### **Generics**

- Oncology injectables in EMs
- 9 oncology injectables filed in US; Launch from FY18 onwards
- Ranked #2 in India
- One of the leaders in the US Gx market – Launched 30+ products
- Launched inhalers in EMs
- In-licensed g-Seretide for EU
- 3 inhalers in development for US

### **Specialty/Complex Gx**

- Licensed g-Abraxane; FY19 filing
- Internally developing other complex injectables
- Launched unique combinations in India, EMs
- Assets in development for the US
- 3 Specialty programs in pipeline for US – 1 in P3
- Unique combinations and devices in India, other EMs

### **Innovative Products**

- Focused on bispecific and multivalent antibodies
- Four programs in clinical or late preclinical phase
- GBR 830, targeting atopic dermatitis, in phase 2
- Other autoimmune disorders under evaluation
- Assets targeting respiratory disorders in late discovery stage
- Disease Areas: COPD, IPF





Journey over the last 15 years

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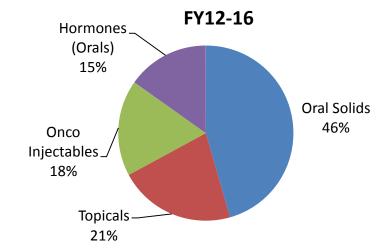
## Niche, complex generics and specialty products to drive growth in the US business

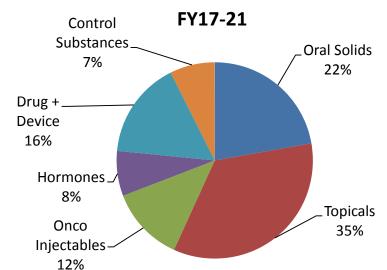


#### Key growth drivers in the next 4-5 years

- Sole FTF gZetia launched in December 2016
- Large portfolio: 110+ ANDAs approved, 60+ under approval and 75+ in development
- File ~20 ANDAs and launch 10-20 products annually
- Leverage expertise in dermatology segment
  - 15+ ANDAs under approval and 20+ in development
- Multiple new dosage forms in development
  - Launch of inhalers in the next 3-4 years
  - 2 additional new dosage forms, with potential launch in CY18 and CY19
- ~15 deals signed or in advance discussions to inlicense complex generics; market size of US\$ ~12 bn
- Launch specialty respiratory products in the next 3-4 years

### **Distribution of ANDAs filed (Count)**





## Focus on differentiated products and select therapies to drive growth in other businesses



### India

- Strengthen presence in large and fast growing therapies: Dermatology, Cardiac, Anti-Diabetic, Respiratory and Oncology
- Continue to build strong brands 8 brands amongst Top -300 in the IPM
- Grow OTC business through focus on existing brands and new launches

### Europe

- Leverage presence in existing markets such as UK, DE, CEE
- Selectively enter 1-2 markets primarily in the tender segment e.g. Entered Spain in FY16
- Launch products with limited competitive intensity e.g. In-licensed gSeretide (DPI) for 15 countries with market size of US\$ ~700

### Rest of World

- Strengthen presence in large markets such as Russia, Brazil and Mexico
- Limit front end presence to existing markets and use partnerships in others
- Build strong brands in core therapy areas Dermatology, Respiratory and Oncology

### **Global API**

- Leadership position in products such as Amiodarone, Lercanidipine, Adapalene etc.
- Primarily target players focused on US and Europe and strengthen presence in new markets such as Japan
- Focus on differentiated products and cost competitiveness



Journey over the last 15 years

**Strategic Roadmap** 

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**Research and Development** 

### **R&D** capabilities across the value chain

### End to End R&D capability – New Chemical Entities, Novel Biologics, Generic APIs and Formulations

#### **Generic API**

- Supports both internal and external market demand
- ~200 DMFs filed across key markets: US, Europe, Japan etc.
- Ability to develop and scale up molecules with complex chemistry

#### **Novel Chemical Entities**

- Team of 350+ involved in R&D on NCEs
- Target selection to clinical development
- Key TAs: Respiratory, inflammatory disorders
- Evaluation of Novel SM immunomodulators in Immuno-Oncology

### **Generic and Specialty Formulations**

- Primarily based out of India
- Dosage forms Solids, Semi solids, Inhalers, oral liquids, parenteral etc.
- Focus on Novel Drug Delivery Systems (NDDS)

### **Novel Biologics**

- Team of 110+ involved in NBE R&D
- Monoclonal antibodies to bispecific and multivalent antibodies
- Proprietary technology Platform: BEAT®
- Key TAs: Oncology and Immunology (Derma)

### **Overall NME and Specialty pipeline**

Therapy	Molecule	MoA/Class	Indication	Pre Clinical	Phase 1	Phase 2	Phase 3	Approval
Oncology	GBR 1302	HER2 X CD3	Breast Cancer Gastric Cancer					
Oncology	GBR 1342	CD38 X CD3	Multiple Myeloma					
Oncology	GBR 1372	EGFR X CD3	Colorectal Cancer					
Oncology	GBR 8383	OX40R Agonist	Multiple Cancers	<b>—</b>				
Dermatology	GBR 830	OX40 Antagonist	Atopic Dermatitis	<b>——</b>				
Respiratory	GRC 388XX	Undisclosed	COPD, IPF					
Respiratory	GSP 301	Steroid + AH	Allergic Rhinitis	<b>——</b>				
Respiratory	GSP 304	LAMA	COPD	<b>——</b>				
Respiratory	GBR 310	Biosimilar	Asthma, CIU					<b></b>
Pain	GRC 27864	mPGES-1	Chronic Pain					

## Update on clinical studies for lead NME assets in core therapies



#### **GBR 830**

### Atopic Dermatitis

- Phase 1 SAD study completed successfully in healthy volunteers
  - Safe and well tolerated in 34 healthy adults vs. 18 on placebo
  - No clinically significant findings in lab test results, vital signs, ECG, cytokines
  - Dose proportional PK profile with  $t_{1/2}$  between 10 and 15 days
- PoC study ongoing in USA and Canada in adults with moderate-to-severe AD
  - Primary endpoints include safety, tolerability & biological response in skin biopsies
  - Expect to complete by Q3 CY17

### **GBR 1302**

# Breast and Gastric Cancer

- Phase 1 part 1 dose escalation study currently underway in HER2+ subjects
  - 4 patient cohorts completed in Germany. To open US sites in CY17 (US IND opened in Q4 CY16)
  - Primary endpoints include MTD and Safety
- Part 2 expansion study to be conducted at MTD determined in Part 1
  - Patient population: HER2+ resistant mBC, HER2 equivocal mBC and other HER2+ metastatic tumors including GI
- Phase 1 completion targeted for Q2 CY19 (monotherapy)
- Additional studies including combinations planned within the CDP lifecycle

# Expected to file 9 NDA/BLA in the next decade across NME and Specialty portfolio



Therapy Area	Molecule	Status	Filing Timelines (NDA/BLA)					
тистару тиса			2019	2020	2021	2022	2023 and Beyond	
Respiratory	GSP 301	Phase 3	✓					
	GSP 304	Phase 2	✓					
	GBR 310	Pre Clinical		✓				
	GRC 388XX	Pre Clinical					✓	
Dermatology	GBR 830	Phase 2				✓		
Oncology	GBR 1302	Phase 1				✓		
	GBR 1342	Pre Clinical					✓	
	GBR 1372	Pre Clinical					✓	
	GBR 8383	Pre Clinical					✓	



Journey over the last 15 years

**Strategic Roadmap** 

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### Financial outlook for the next 4-5 years

### **Growth and Profitability**

- Revenues to grow at a CAGR of 15-20% over the next 5 years
- India, US, EU and API to contribute >80% to the overall revenues
- Operating margin to be at 22-23% from FY18 onwards. Higher margin in FY17 on account of g-Zetia launch
- R&D expense, net of outlicensing income, to be ~11% of revenues
- Corporate tax rate to be ~25% going forward

### Investments and Financial Status

- Capital expenditure of INR 600-700 cr. on fixed assets annually
- Annual spend on Intangible assets to be INR 200 cr. on account of inlicensing of complex generics
- Net Debt to EBITDA ratio to progressively go down from hereon
  - Mar'17 net debt to be lower than Mar'16 levels
- Net Working capital to be ~110 days (of sales)
- ROCE to be 18-20% over the next 4-5 years

### **Summary**

### Glenmark in 2016

- 2 major geographies -US and India
- Revenue stream consisting of purely generics portfolio
- US, EU business based on substitution model
- NME pipeline in early to mid stages
- Manufacturing base primarily in India
- Profitability margin at ~20%

### Glenmark in 2020

- US, India, Europe and API to contribute >80% of sales
- Increased presence in complex generics
- Launch of specialty business in the US
- NME pipeline in advanced stage of development
- Global manufacturing footprint
- Profitability margin at ~23%

### Glenmark in 2025

- Launch of innovative products
- Specialty business ramp up in the US
- Specialty and Innovative segments to be the main growth drivers
- Increased presence in complex generics space
- ~30% of total revenues from specialty and innovation segments
- Profitability margin at ~25%



### **Thank You**