

December 19, 2016

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

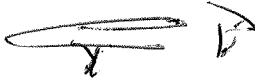
**Sub: Glenmark announces its 'Strategic Blueprint for the Next Decade'**

Dear Sir,

We are enclosing herewith the press release and presentation on 'Strategic Blueprint for the Next Decade' to be presented today at Press Meet 2016 for your information and record.

Thanking you.

Yours faithfully,  
For **Glenmark Pharmaceuticals Ltd.**



**Cherylann Pinto**  
Director – Corporate Affairs

Tel: 4018 9999

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

**Encl: as above**

Press Release

For Immediate Release

## Glenmark Unveils its Strategic Blueprint for Transition into an Innovation-Led Global Pharmaceutical Organization in the Next Decade

- Leverages Company's industry-leading capabilities to expand discovery and development of Glenmark's robust generics and innovative portfolio
- Focuses resources on growth catalysts
  - Focus on innovative new molecular entities (NME)
  - Filing as many as nine new drug application (NDA)/biologic license application (BLAs) in the next 10 years
  - Targeting 30 percent of total revenues from specialty and innovation segments over the next decade

**Mumbai, India December 19, 2016:** Glenmark Pharmaceuticals Ltd. (GPL), a global research-driven, integrated pharmaceutical company headquartered at Mumbai, today announced its **"Strategic Blueprint to Transition into an Innovation-led Global Pharmaceutical Organization over the next decade"**. The Blueprint conveys the Company's greater business alignment expanding generics to prioritizing research and development efforts in three key therapeutic areas: oncology, respiratory and dermatology. The innovative oncology pipeline, with candidates targeting multiple tumors, is the top priority with the greater promise to deliver novel, first-in-class molecules and help Glenmark evolve into a fully commercialized, innovation-led pharmaceutical company.

"Since 2000, it has been the primary objective of Glenmark to facilitate the Company's evolution from a generics organization to a fully integrated, globally commercialized pharmaceutical company with innovative products," stated Glenn Saldanha, Chairman & Managing Director. "Over the last 16 years, we have created significant shareholder value and this has been possible because of our continuous investments in R&D. As we prepare for the next wave of growth, we have built strong capabilities that uniquely positions us to differentiate our product offerings primarily in our core therapy areas and will invest across the value chain from generics to new molecular entities in our effort to build a truly global pharmaceutical organization. "

Glenmark is an early leader at the point of convergence of generic and innovative pharmaceutical R&D. With end-to-end capabilities from R&D to full-scale manufacturing, both in small molecules & novel biologics. The Company enjoys an enviable market position of self-reliance, strong IP leadership and a global footprint for rapid market penetration. These intellectual assets are already producing results for the Company with a specialty and New Molecular Entity (NME) pipeline consisting of nine assets in the three core areas, four of which are in clinical or late pre-clinical development. The company expects to launch its specialty business in the U.S. with its first FDA NDA approval in respiratory within 3 – 5 years.

The strategic blueprint also outlines aggressive plans to increase Glenmark's presence worldwide by strengthening focus on complex generics including injectables, expanding its manufacturing footprint (growing from two formulation facilities to 17). Currently, the Company has more than 110 Abbreviated New Drug Application (ANDAs) approved and an additional 135 products in regulatory review or in development in the US. Based on the power of the pipeline, Glenmark expects to file 20-25 ANDAs and launch 20 generic products annually in the US. Its business in emerging markets is also well positioned for continuous and sustained growth over a long period in time

"Building from our enviably strong foundation has given us operational and financial flexibility that allows us to execute on our ambitious plans, we expect the next wave of our growth to be as impressive as our first," added Saldanha. "

Click [here](#) for full Strategic Blueprint presentation.

***About Glenmark Pharmaceuticals Ltd.:***

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2016). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain]. The company has a significant presence in the branded generics markets across emerging economies including India. GPL along with its subsidiaries operate 17 manufacturing facilities across four countries and has five R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries including the US, EU, South America and India.

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# Strategic Blueprint for the Next Decade

**19<sup>th</sup> December, 2016**

## Disclaimer

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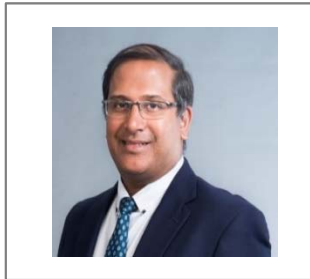
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## Glenmark Team

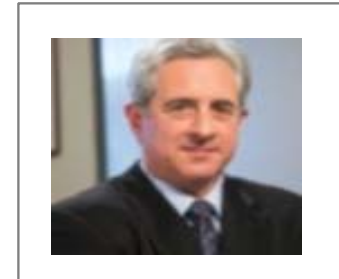
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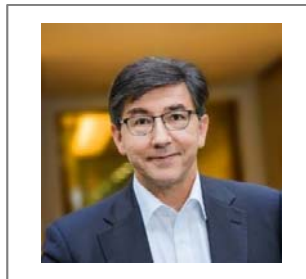
**Glenn Saldanha**  
Chairman & MD



**Robert Matsuk**  
President  
North America + API



**Dr. Fred Grossman**  
President  
Chief Medical Officer



**Dr. Kurt Stoeckli**  
President  
Chief Scientific Officer



**P Ganesh**  
President  
Chief Finance Officer

# Agenda

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**Journey over the last 15 years**

**Strategic Roadmap**

**Global Generics Business**

**Research and Development**

**Summary**

# Agenda

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## Journey over the last 15 years

Strategic Roadmap

Global Generics Business

Research and Development

Summary



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



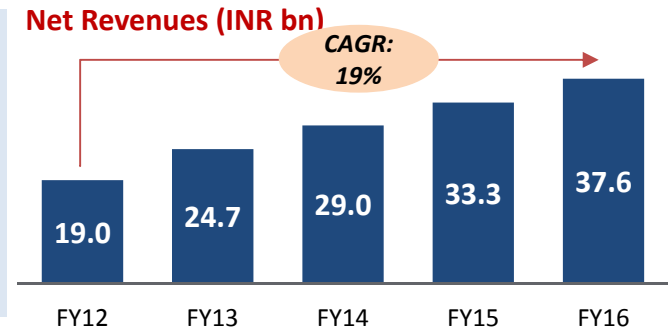
	Year 2000	Year 2016
Wealth Creation	Revenue: <b>US\$ 31 mn</b> Market Cap.: <b>US\$ 40 mn</b>	Revenue: <b>US\$ 1.2 bn</b> Market Cap: <b>US\$ 3.9 bn</b>
Manufacturing Footprint	2 formulations facilities	<b>17</b> facilities across 4 continents; 7 approved by USFDA
International Operations	~ <b>8%</b> of total revenues	<b>&gt;70%</b> of total revenues Present in US, EU, RCIS, LATAM etc.
Innovation	Initiation of NME research	<b>Novel molecules</b> in pipeline Focused on <b>Oncology, Dermatology and Respiratory</b>
Employees	<b>&lt;1,000</b> : Primarily in India	<b>&gt;12,000</b> : Spread over 50 countries

Note: Revenues for FY2000 and FY2016. Market Capitalization is as of 31<sup>st</sup> March 2000 and 16<sup>th</sup> Dec 2016. FX Rate: US\$1 = INR 67

# Robust growth exhibited across business segments

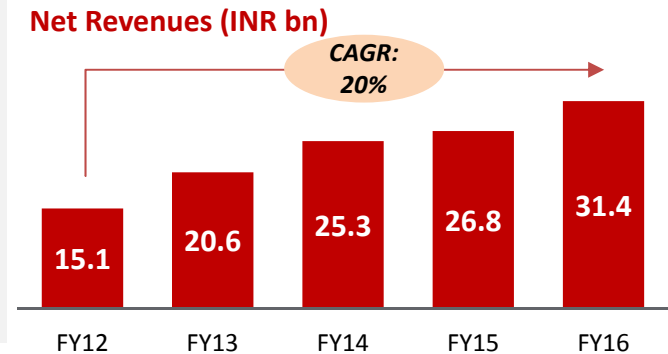
## Branded Formulations

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



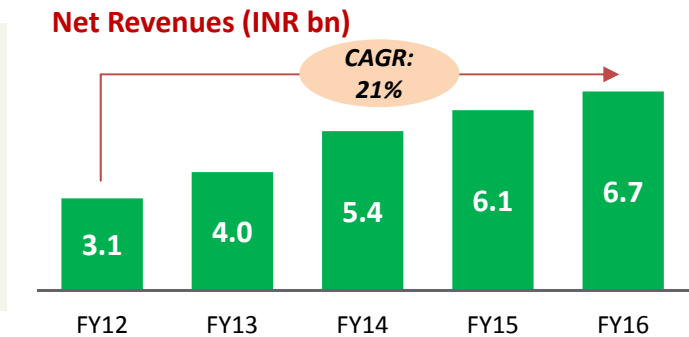
## Generic Formulations

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



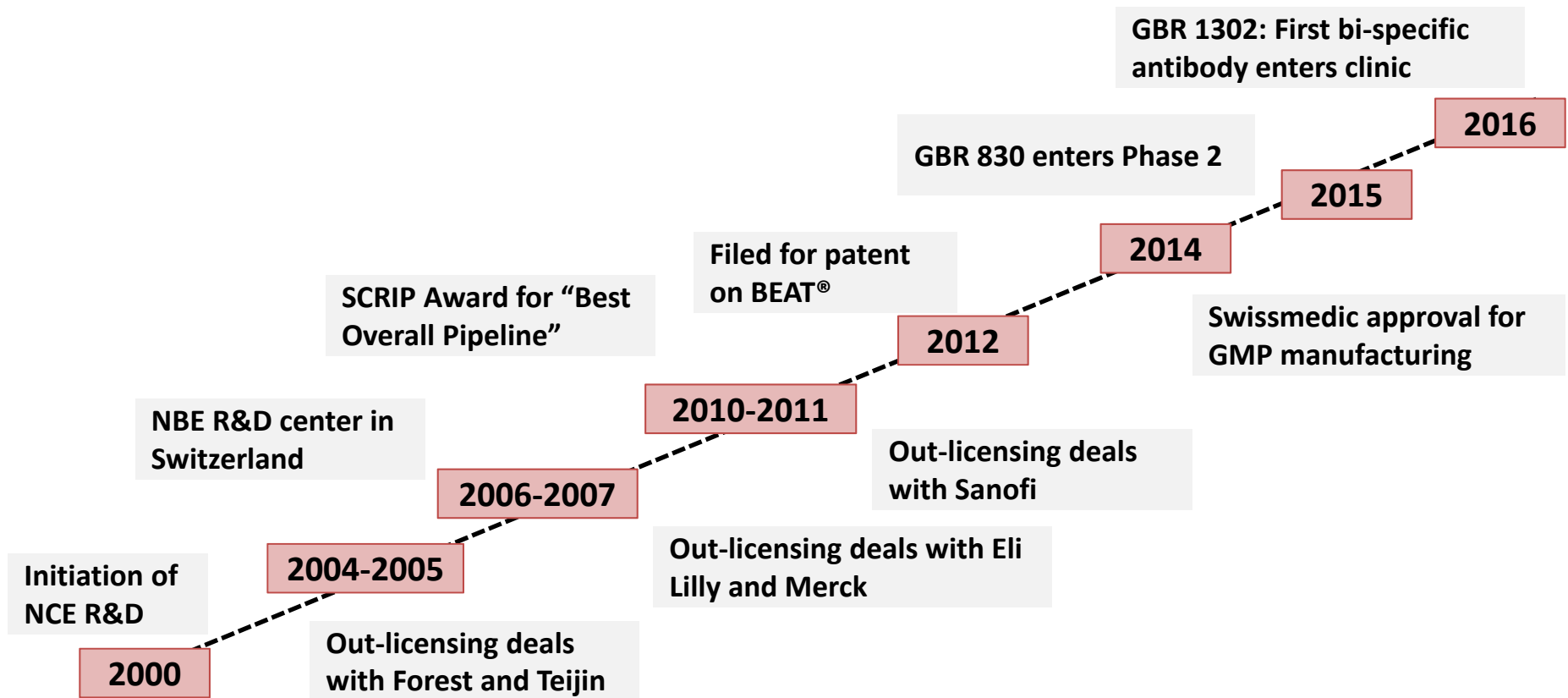
## API

- **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

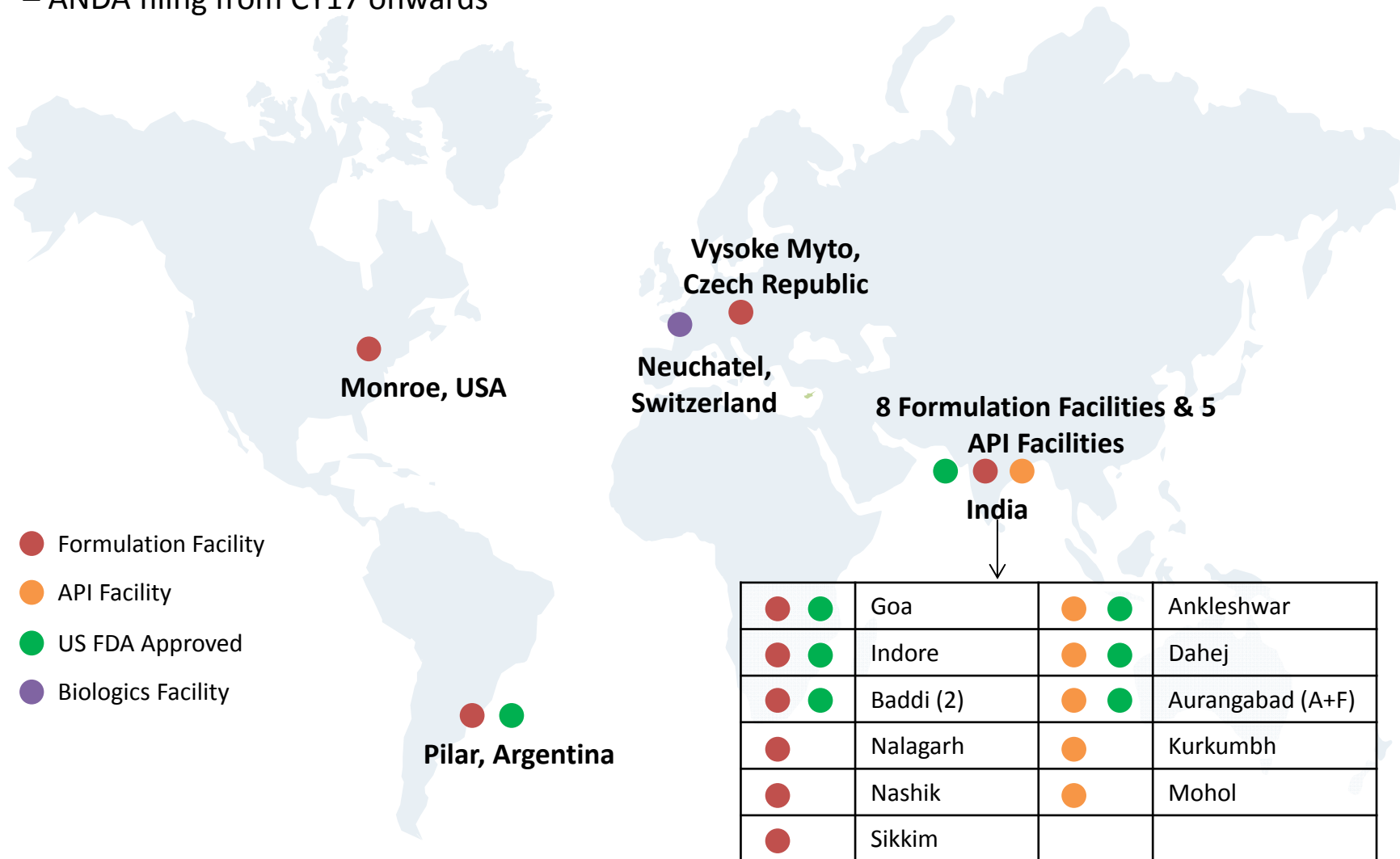
## Initiated novel R&D in 2000 with a vision to bring innovative molecules to market



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



# Agenda

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Journey over the last 15 years

**Strategic Roadmap**

Global Generics Business

Research and Development

Summary

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

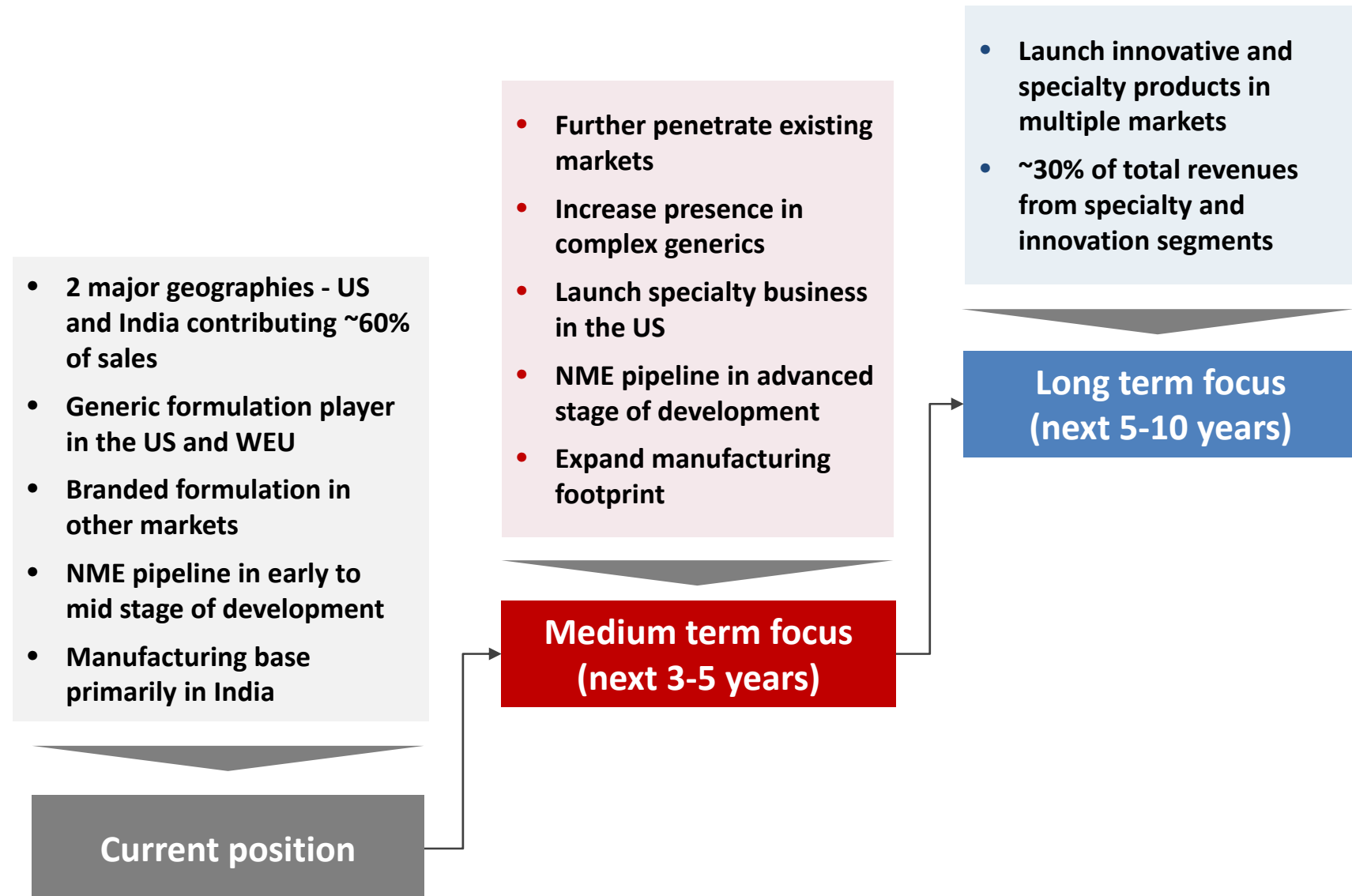
### Industry Challenges

- 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

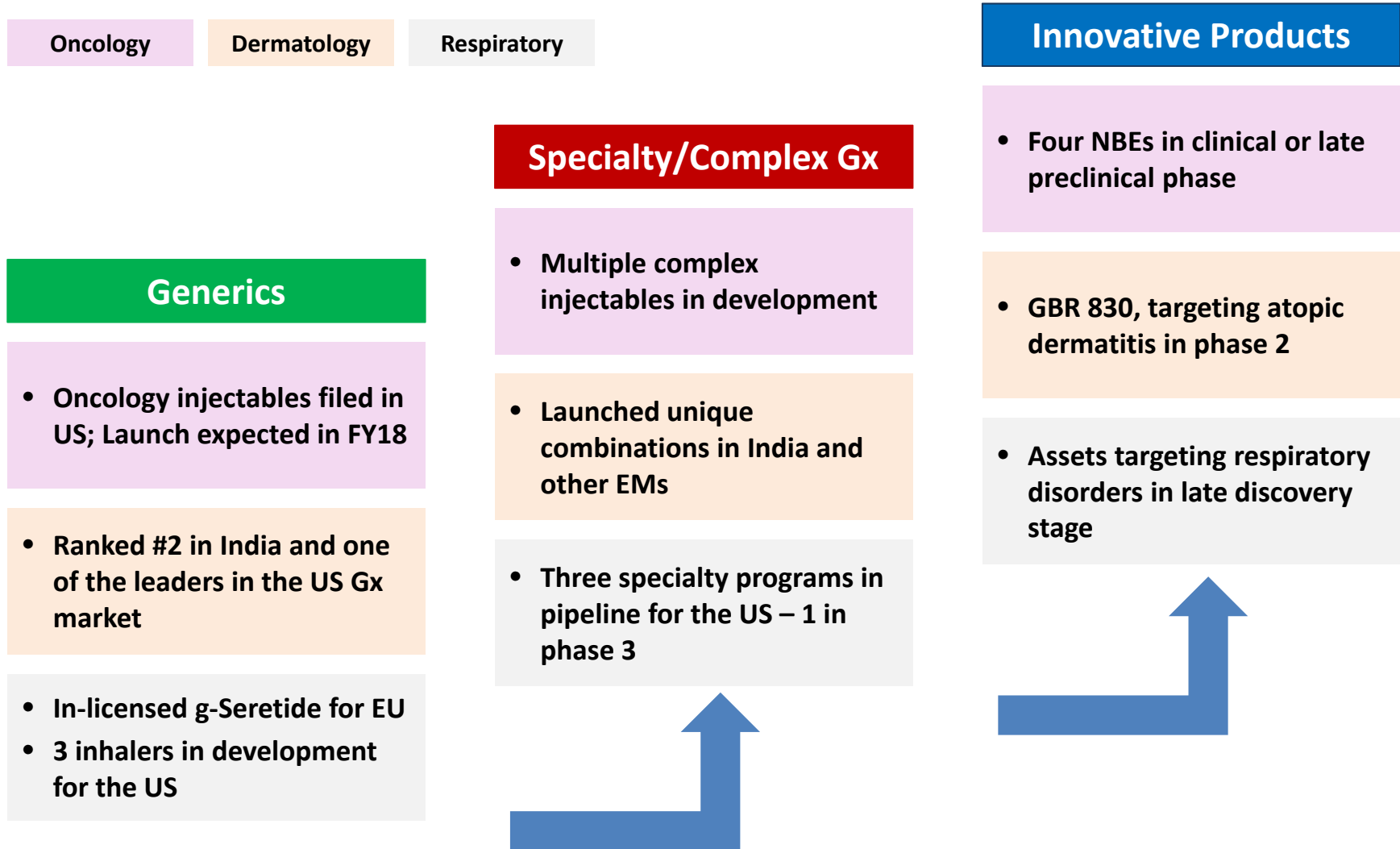
### Strategic Elements

- 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



# Focusing across the value chain in core therapy areas





# Agenda

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Journey over the last 15 years

Strategic Roadmap

**Global Generics Business**

Research and Development

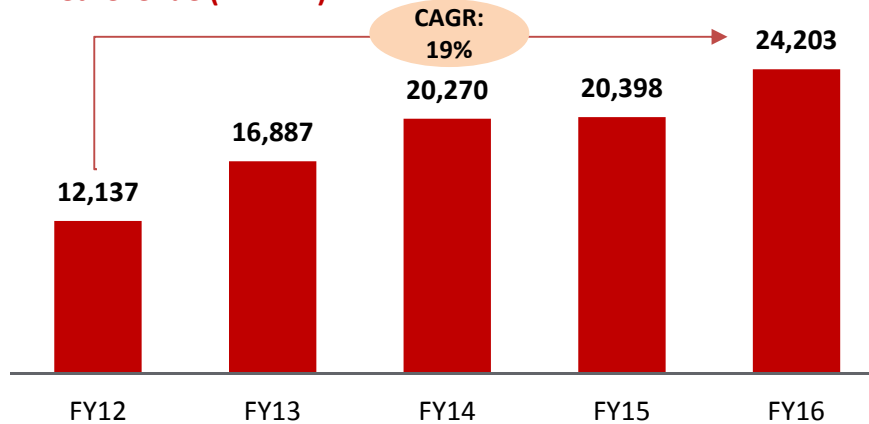
Summary

# Launch of niche, complex generics and specialty products to drive US Business

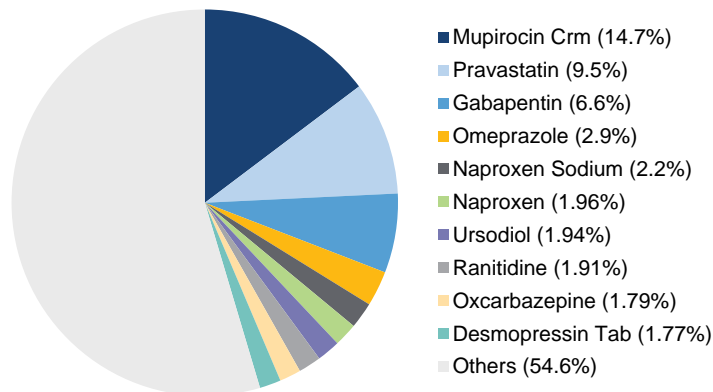


## Revenues doubled in the last 5 years

Net revenue (INR mn)



## Well diversified Portfolio



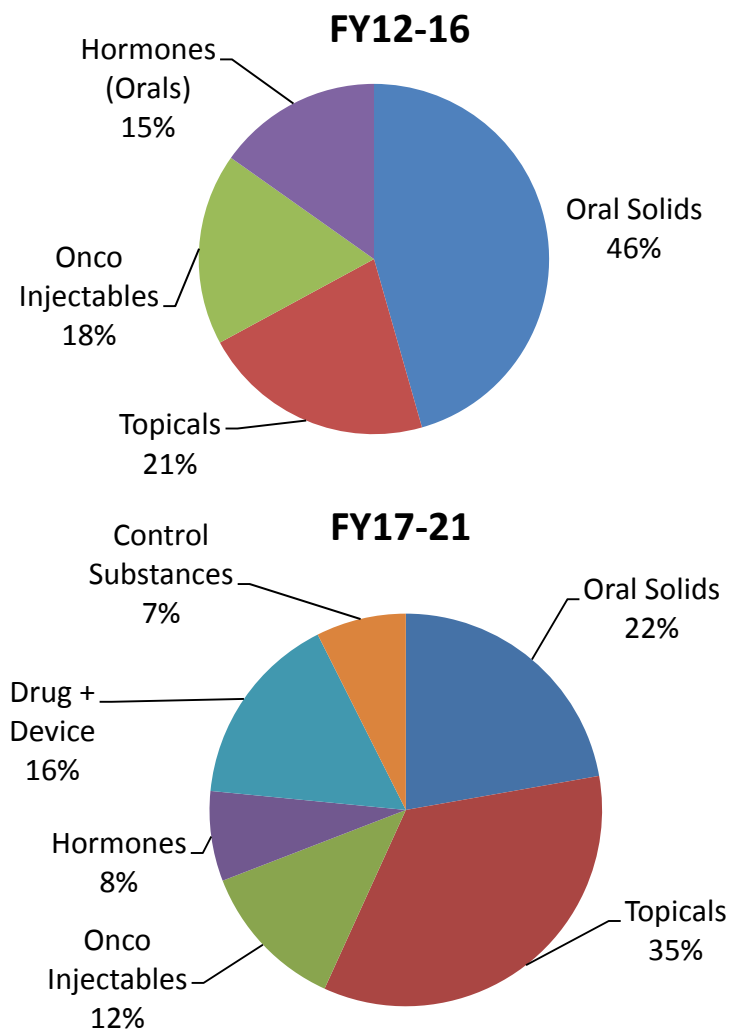
Source: IMS NSP MAT Oct 2016 for the US market

## Key Growth Drivers in the next 4-5 years

- Sole FTF gZetia launched on 12<sup>th</sup> December
- Large product portfolio: 110+ ANDAs approved, 60+ under approval and 75+ in development
  - Top 10 products account for ~45% of sales and Top 20 account for ~60%
- Targeting to file 20-25 ANDAs and launch ~20 products annually
- Leverage expertise in the dermatology segment – 15+ ANDAs pending for approval and 20+ products in development
- Enhance quality of pipeline through addition of complex generics and niche technologies
- Launch of specialty respiratory products in the next 3-4 years

## Internal capabilities and external partnerships to drive high quality pipeline

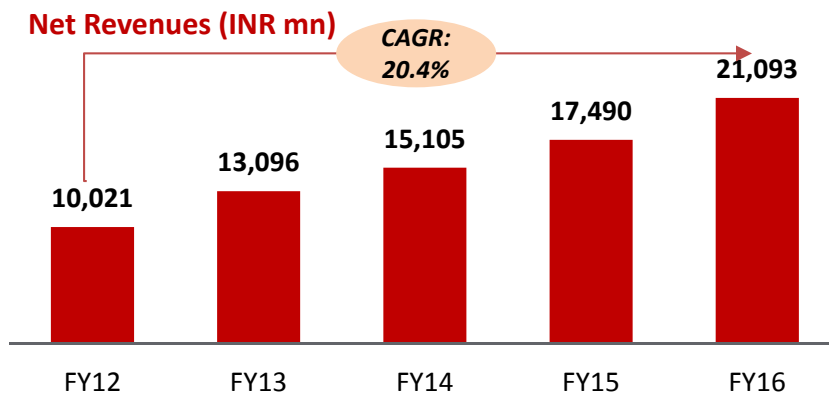
### Distribution of ANDAs filed (Count)



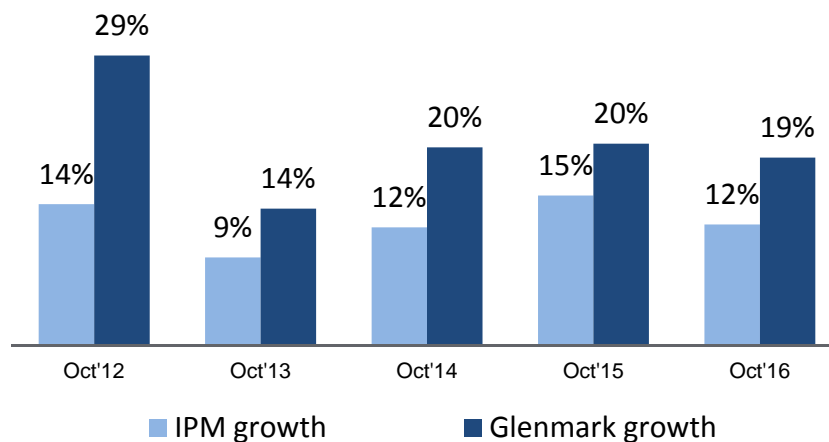
- Optimal combination of internal R&D and strategic development partnerships
- Targeting multiple new dosage forms to differentiate against competition
  - Launch of inhalers in the next 3-4 years
  - Working on 2 additional new dosage forms, with potential launch in CY18 and CY19
- ~15 inlicensing deals either signed or in advance discussion stage
  - Focus on signing global deals: Expected to launch products from CY17 onwards
  - Total market size of deals signed or under discussions is US\$ ~12 bn
  - Agreements already executed include products such as g-Abraxane, g-Nuvaring and g-Suboxone

## India business targeting to dominate selected therapies and grow faster than overall market

### Robust growth exhibited in the last five years



### Consistently growing at >1.5x of IPM growth



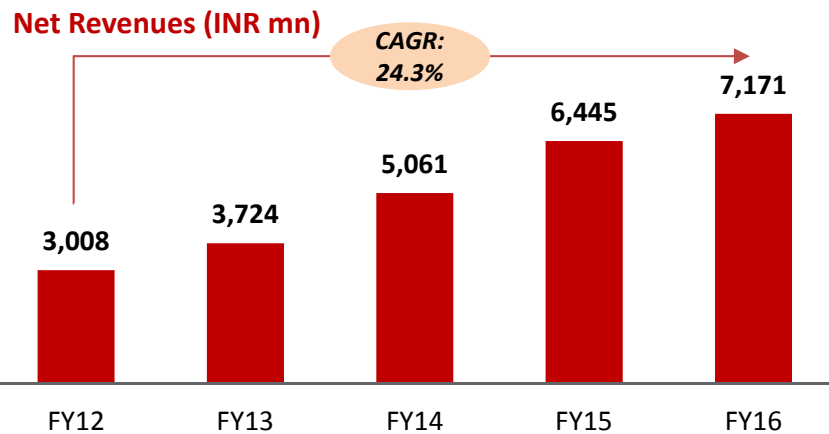
Source: IMS Total Sales Audit MAT Oct'16. IPM: Indian Pharmaceuticals Market

### Key Growth Drivers in the next 4-5 years

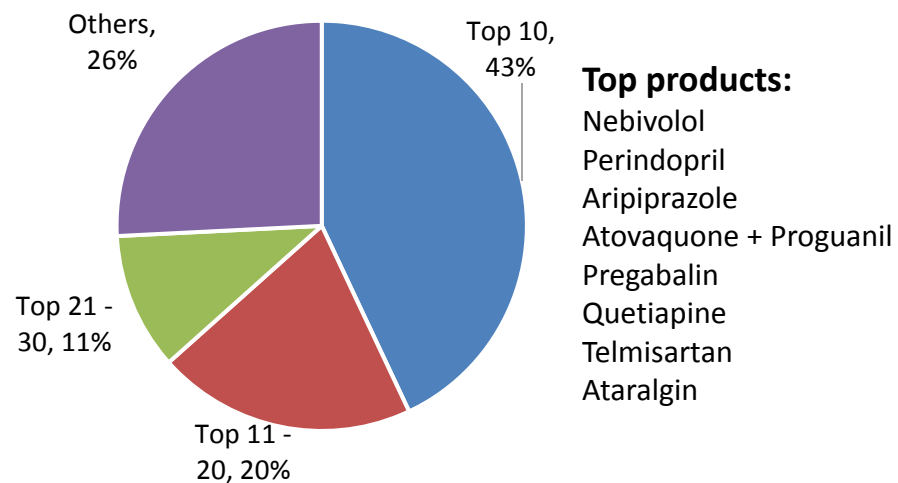
- Strengthen presence in large and fast growing therapies
  - Dermatology, Cardiac, Anti-Diabetic, Respiratory and Oncology
- Continue to build strong brands– 8 brands amongst top -300 in the IPM
- Leverage recently launched products such as Teneligliptin and Digihaler
- Introduce innovative products in core therapy areas – Internal development and Inlicensing
- Grow OTC business through focus on existing brands like Vwash and Candid Powder and new launches

## Niche, complex generics to drive growth in Europe

### Strong growth exhibited in the last five years



### Wide portfolio of products

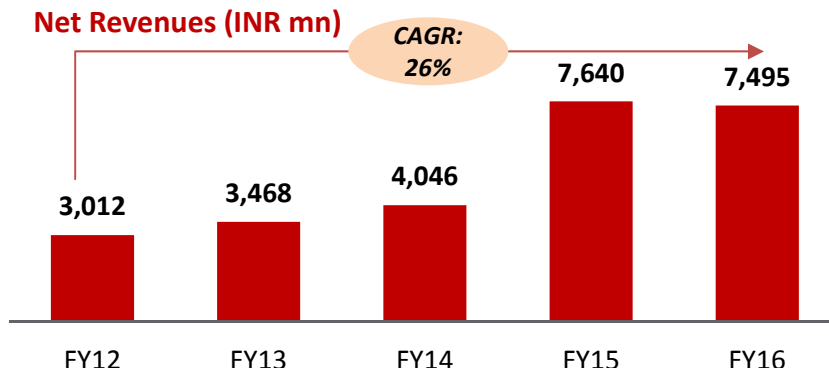


### Key Growth Drivers in the next 4-5 years

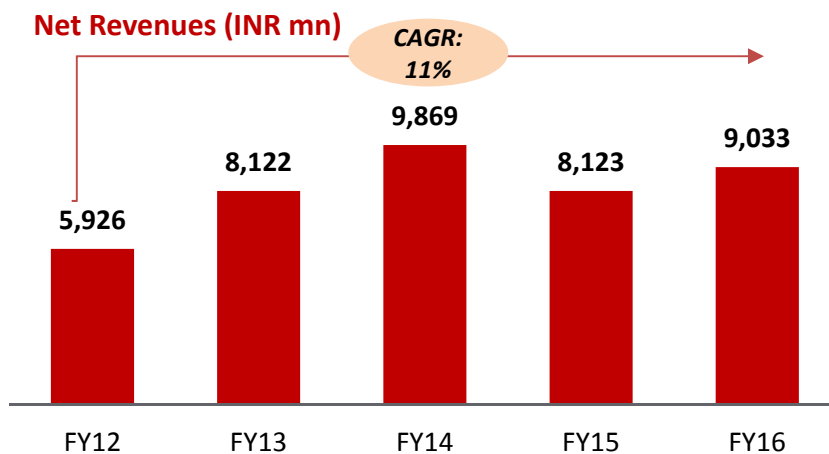
- Leverage existing infrastructure and maximize value from existing markets – UK, DE, CEE
- Selectively enter 1-2 markets primarily in the tender segment e.g. Entered Spain in FY16
- Focus on products, technologies with limited competitive intensity
- Looking to launch complex generic products in the near future
  - e.g. In-licensed gSeretide (DPI) for 15 countries with market size of US\$ ~700 mn
  - Expected to launch in FY18
- Continue to leverage in-licensing efforts to strengthen the portfolio in addition to internal development efforts

## LATAM and RoW growth to be driven by large markets and focus on core therapies

### LATAM



### RoW (Russia, Asia, Africa and CIS)



### Key Growth Drivers in the next 4-5 years

#### • LATAM

- Leverage presence in large markets such as Brazil, Mexico and Argentina
- Strengthen presence in core therapy areas – Dermatology, Respiratory and Oncology
- Business to turn profitable from FY18 onwards

#### • Rest of World (RoW)

- Key markets in the region include Russia, Malaysia, Philippines, Kenya and South Africa
- Limit front end presence to existing markets (~ 900 field force) and use partnerships in other markets
- Strengthen presence in select therapies and launch differentiated products

# Agenda

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Journey over the last 15 years

Strategic Roadmap

Global Generics Business

**Research and Development**

Summary

## 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

#### 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 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

#### 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)

**Novel and Specialty pipeline to focus on Oncology, Immunology (Dermatology) and Respiratory**



## 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	██████████	██████████			
Dermatology	GBR 830	OX40 Antagonist	Atopic Dermatitis	██████████	██████████	██████████		
Respiratory	GRC 388XX	Undisclosed	COPD, IPF	██████████	██████████			
Respiratory	GSP 301	Steroid + AH	Allergic Rhinitis	██████████	██████████	██████████	██████████	
Respiratory	GSP 304	LAMA	COPD	██████████	██████████	██████████		
Respiratory	GBR 310	Biosimilar	Asthma, CIU	██████████	██████████			
Pain	GRC 27864	mPGES-1	Chronic Pain	██████████	██████████	██████████		

Note: Non core assets such as GRC 17536, GRB 900, GBR 500 deprioritized for any further investment. These 3 and GRC 27864 are candidates for outlicensing

## Oncology: Significant unmet medical needs across indications being pursued

### GBR 1302

#### Breast\* and Gastric Cancer

- Resistant metastatic breast cancer (mBC)
  - Primary resistance to trastuzumab ~60-70%<sup>1-5</sup>
  - ~70% of patients acquired resistance to trastuzumab within 1 year of treatment<sup>1-5</sup>
- Lack of adequate treatment options for HER2 equivocal mBC
- Gastric Cancer
  - 2<sup>nd</sup> leading cause of cancer-related mortality worldwide. Only 2 targeted therapies – trastuzumab and ramucirumab

### GBR 1342

#### Multiple Myeloma

- New treatments have improved the survival rate but MM still not curable
- Current treatment regimes not effective in aggressive cases of MM
- Substantial challenge to manage toxicity due to aged patient population

### GBR 1372

#### Colorectal Cancer

- 3<sup>rd</sup> most common cancer with stage IV incidence rate of ~20%
- ~60% of patients progress to 2L and over 30% progress to 3L treatment options
- Lack of efficacious & safe treatment options, esp. RAS mutant and refractory patients
- Cetuximab and panitumumab approved only in KRAS WT

Note: \*Resistant metastatic breast cancer, HER 2 equivocal metastatic Breast Cancer

1. Wong AL, et al. *Int J Breast Cancer*. 2012;2012:415170; 2. Arribas J, et al. *Cancer Res*. 2011;71(5):1515-1519; 3. Spector NL, et al. *J Clin Oncol*. 2009;27(34):5838-5847; 4. Pohlmann PR, et al. *Clin Cancer Res*. 2009;15(24):7479-7491; 5. Vu T, et al. *Front Oncol*. 2012;2:62

## Respiratory: Presence across the disease and device spectrum

- 3 Specialty and 3 Generic assets in development
- NCE program is in late discovery phase
- Targeting to launch specialty products in the US in next 3-4 years along with generics

### Disease Segments

**Asthma**

**COPD**

**Allergic Rhinitis**

### Device Platforms

**MDI**

**DPI**

**Injectable**

**Nebuliser**

**Nasal Sprays**



Note: Images are for representation purpose only

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



Therapy Area	Molecule	Status	Filing Timelines (NDA/BLA)				
			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					✓

Note: Above timelines are based on currently planned studies. They may change based upon data, regulatory agencies feedback etc.

# Agenda

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Journey over the last 15 years

Strategic Roadmap

Global Generics Business

Research and Development

**Summary**

## 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

- Enhanced presence in existing markets
- Portfolio of complex generics products
- 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**