

# Strategic Blueprint for the Next Decade

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

## Disclaimer

---

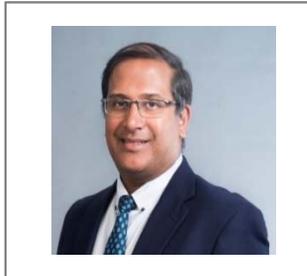
These materials have been prepared by Glenmark Pharmaceuticals (“Glenmark” or the “Company”) solely for informational purposes, and are strictly confidential and may not be taken away, reproduced or redistributed to any other person. By attending this presentation, participants agree not to remove this document from the conference room where such documents are provided without express written consent from the Company. Participants agree further not to photograph, copy or otherwise reproduce these materials at any point of time during the presentation or while in your possession. By attending this presentation, you are agreeing to be bound by the foregoing restrictions. Any failure to comply with these restrictions may result in a violation of applicable laws and commencement of legal proceedings against you

It is not the Company’s intention to provide, and you may not rely on these materials as providing, a complete or comprehensive analysis of the Company’s financial position or prospects. The information contained in these materials has not been independently verified and is subject to verification, completion and change without notice. The information contained in these materials is current as of the date hereof and is subject to change without notice, and its accuracy is not guaranteed. The Company is not under any obligation to update or keep current the information contained in these materials subsequent to the date hereof. Accordingly, no representation or warranty, express or implied, is made or given by or on behalf of the Company, or any of its directors and affiliates or any other person, as to, and no reliance should be placed for any purposes whatsoever on, the fairness, accuracy, completeness or correctness of, or any errors or omissions in, the information contained in these materials. Neither the Company, its directors, officers or employees nor any other person accept any liability whatsoever for any loss howsoever arising from any use of these materials or their contents or otherwise arising in connection therewith

These materials contain historical information of the Company which should not be regarded as an indication of future performance or results. These materials may also contain forward-looking statements that are, by their nature, subject to significant risks and uncertainties. These forward-looking statements reflect the Company’s current views with respect to future events and are not a guarantee of future performance or results. Actual results, performance or achievements of the Company may differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Company’s present and future business strategies and the environment in which the Company will operate in the future, and must be read together with such assumptions. Predictions, projections or forecasts of the economy or economic trends of the markets are not necessarily indicative of the future or likely performance of the Company, and the forecast financial performance of the Company is not guaranteed. No reliance should be placed on these forward-looking statements, if any.

## Glenmark Team

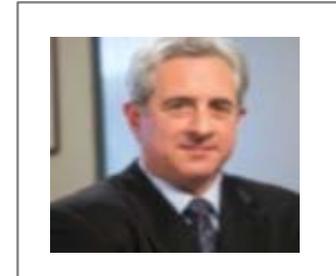
---



**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

---

**Journey over the last 15 years**

**Strategic Roadmap**

**Global Generics Business**

**Research and Development**

**Summary**

# Agenda

---

## 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



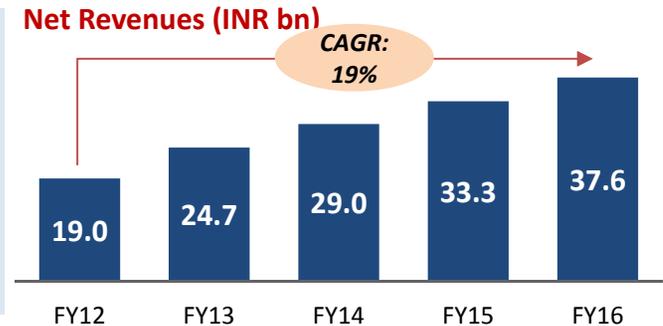
	Year 2000	Year 2016
Wealth Creation	Revenue: <b>US\$ 31 mn</b> Market Cap.: <b>US\$ 40 mn</b>	Revenue: <b>US\$ 1.2 bn</b> Market Cap: <b>US\$ 3.9 bn</b>
Manufacturing Footprint	2 formulations facilities	<b>17</b> facilities across 4 continents; 7 approved by USFDA
International Operations	~ <b>8%</b> 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</b> and <b>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

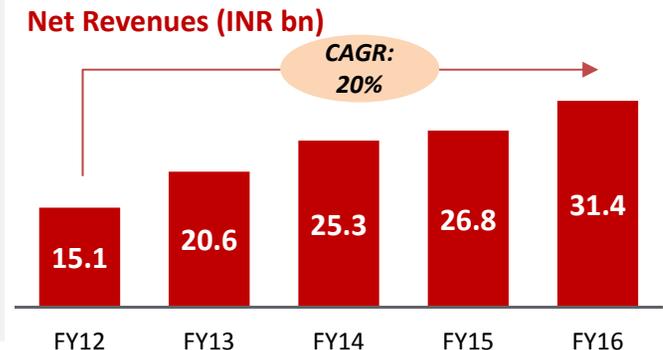
## Branded Formulations

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



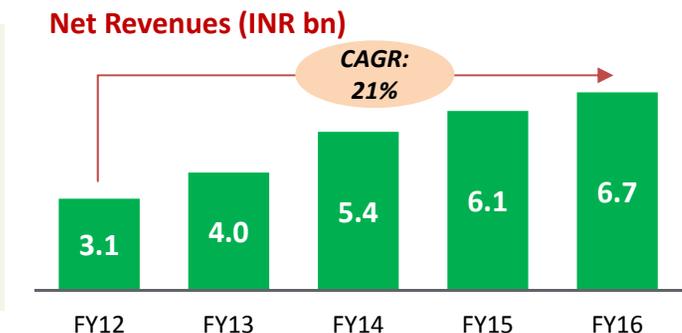
## Generic Formulations

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



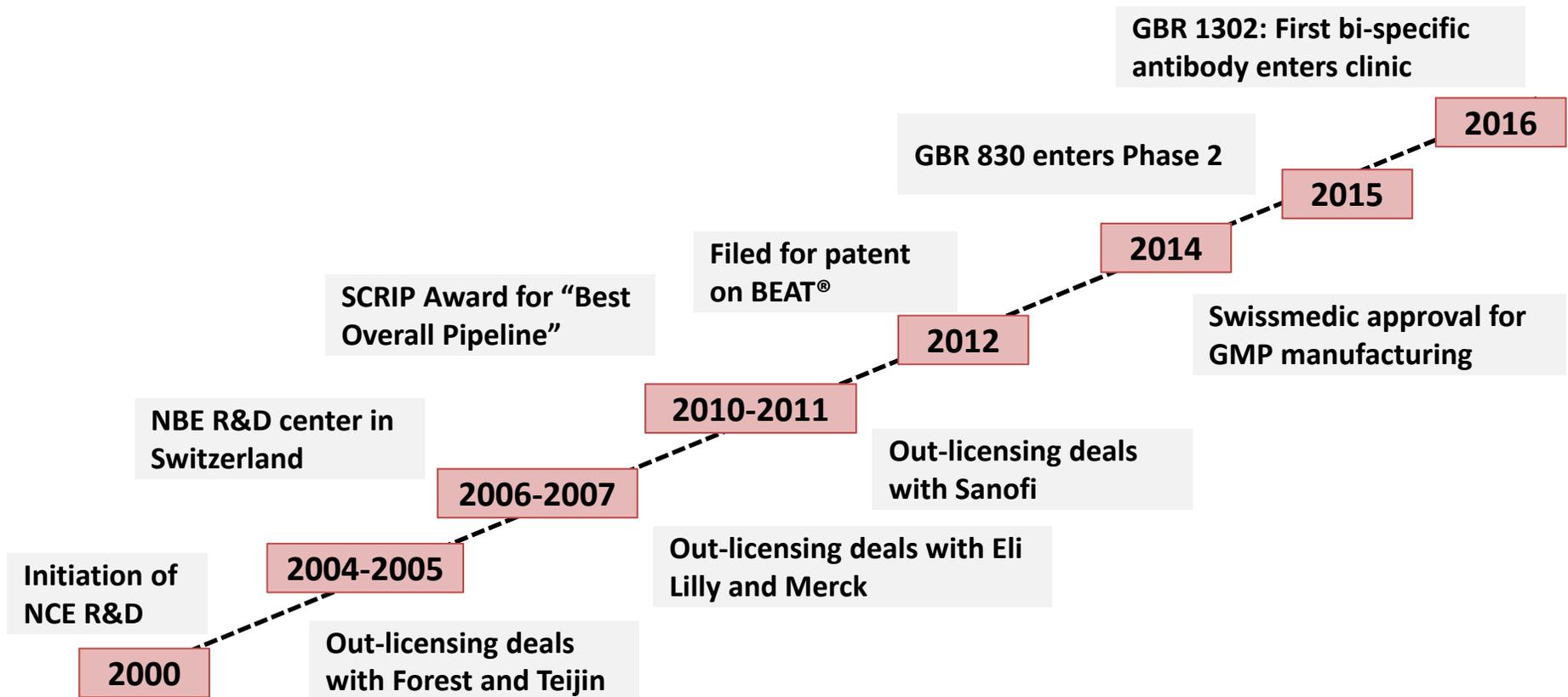
## API

- **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

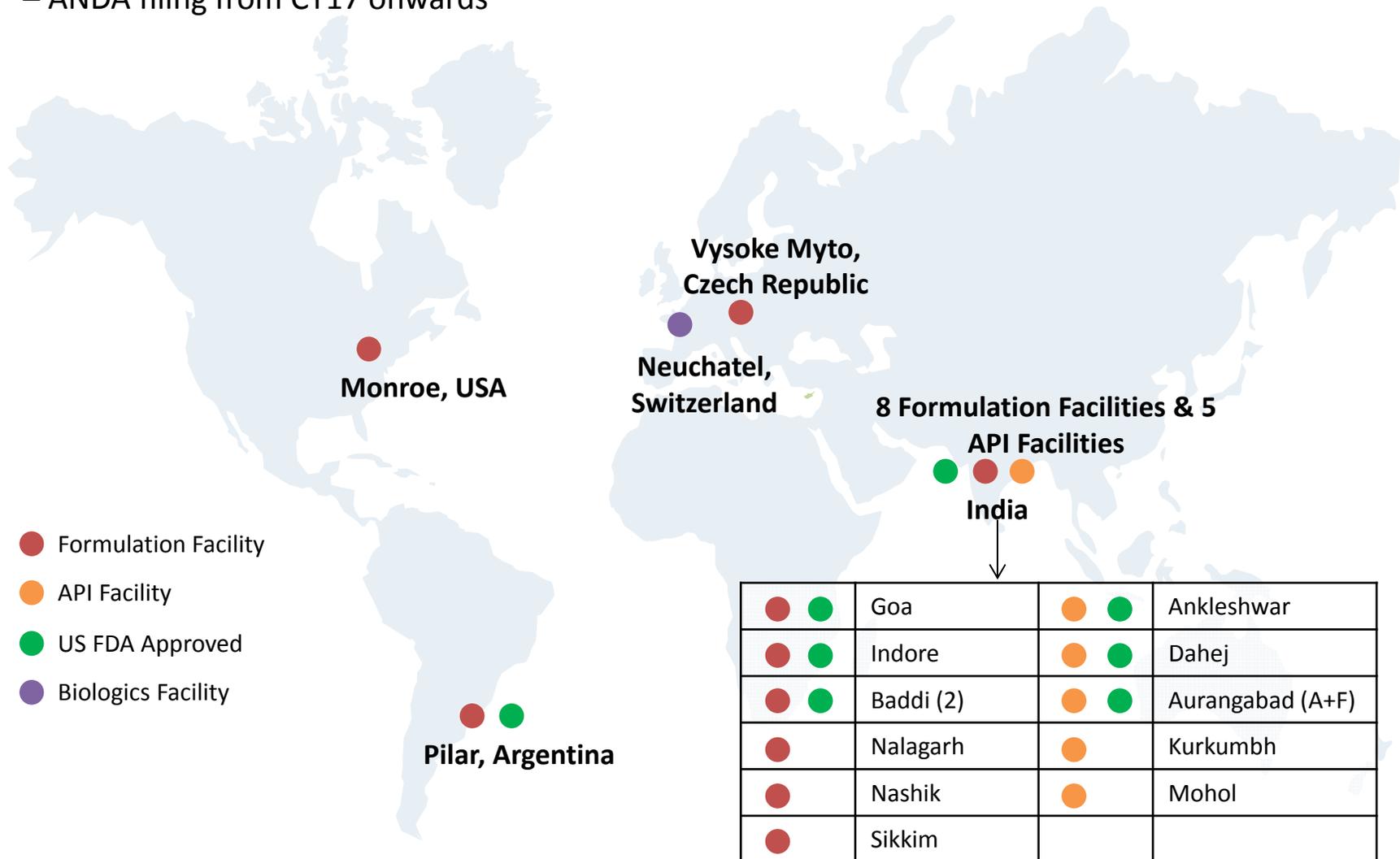
## Initiated novel R&D in 2000 with a vision to bring innovative molecules to market



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

---

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

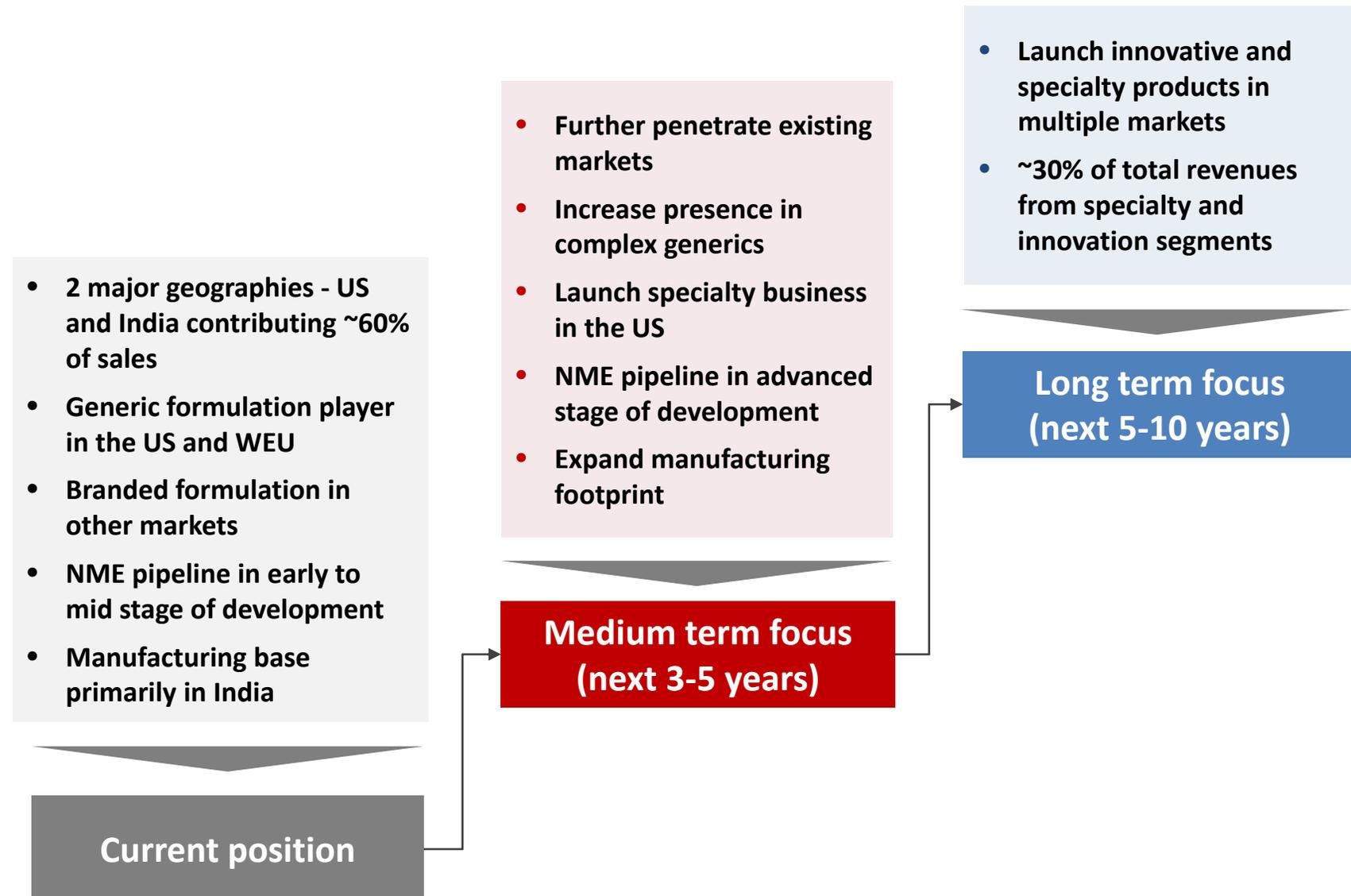
### Industry Challenges

- 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

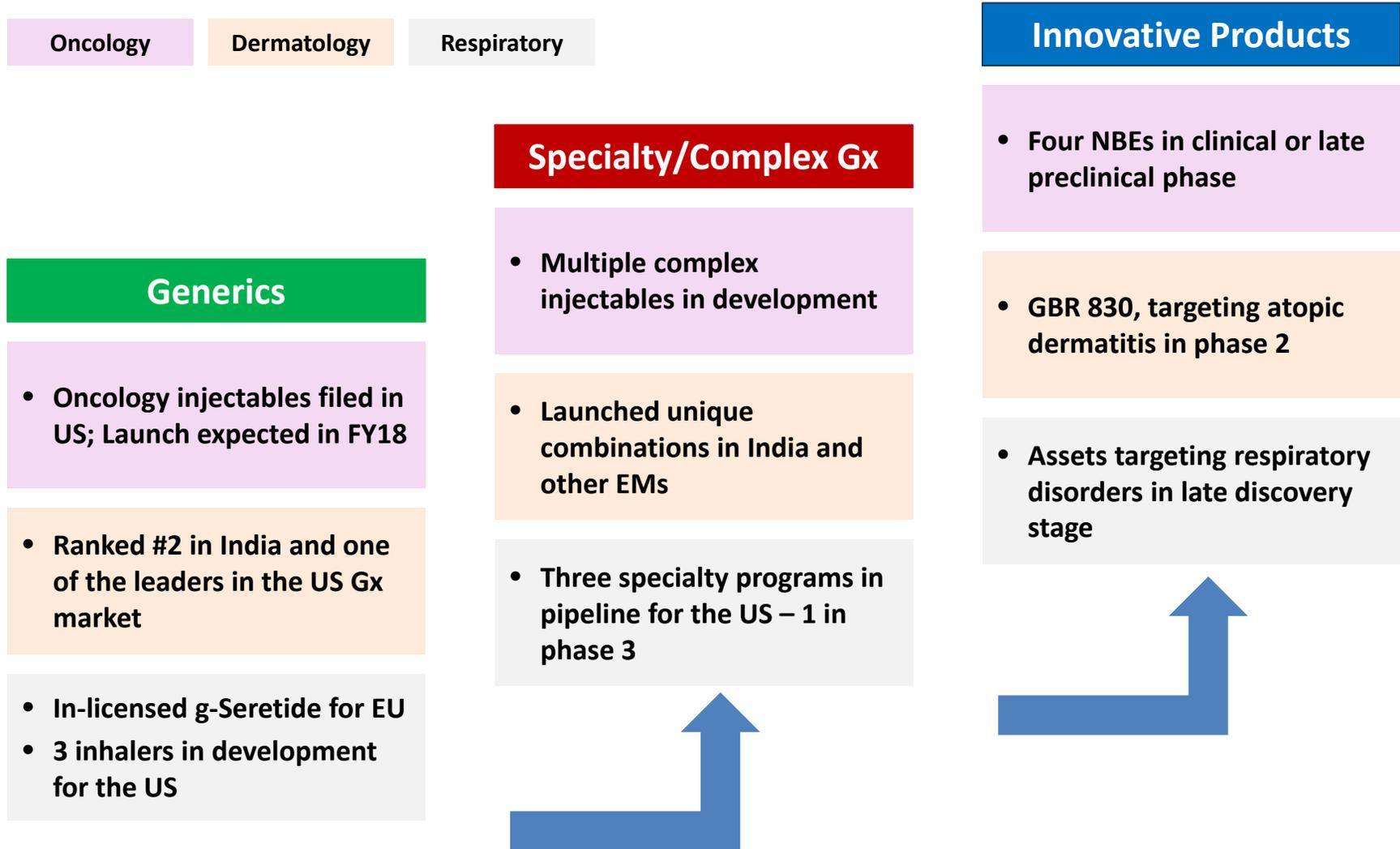
### Strategic Elements

- 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

---

Journey over the last 15 years

Strategic Roadmap

**Global Generics Business**

Research and Development

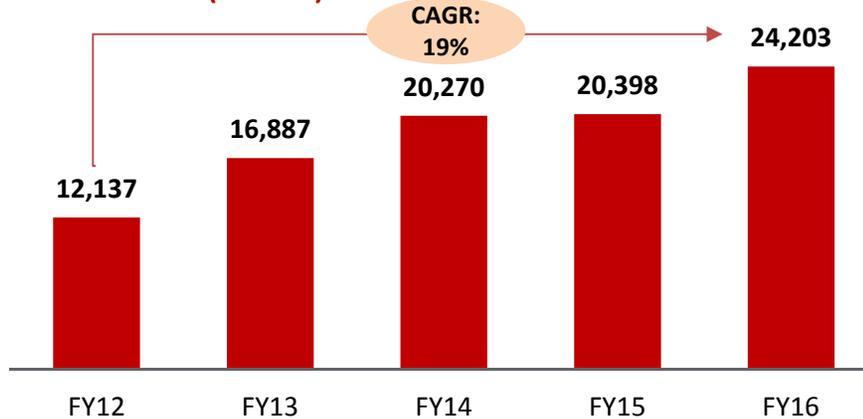
Summary

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

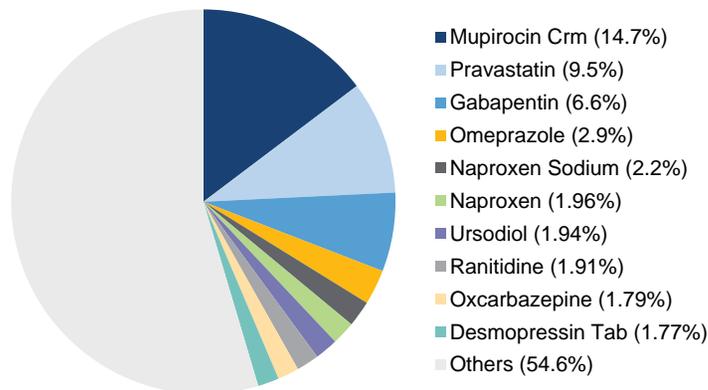


## Revenues doubled in the last 5 years

Net revenue (INR mn)



## Well diversified Portfolio



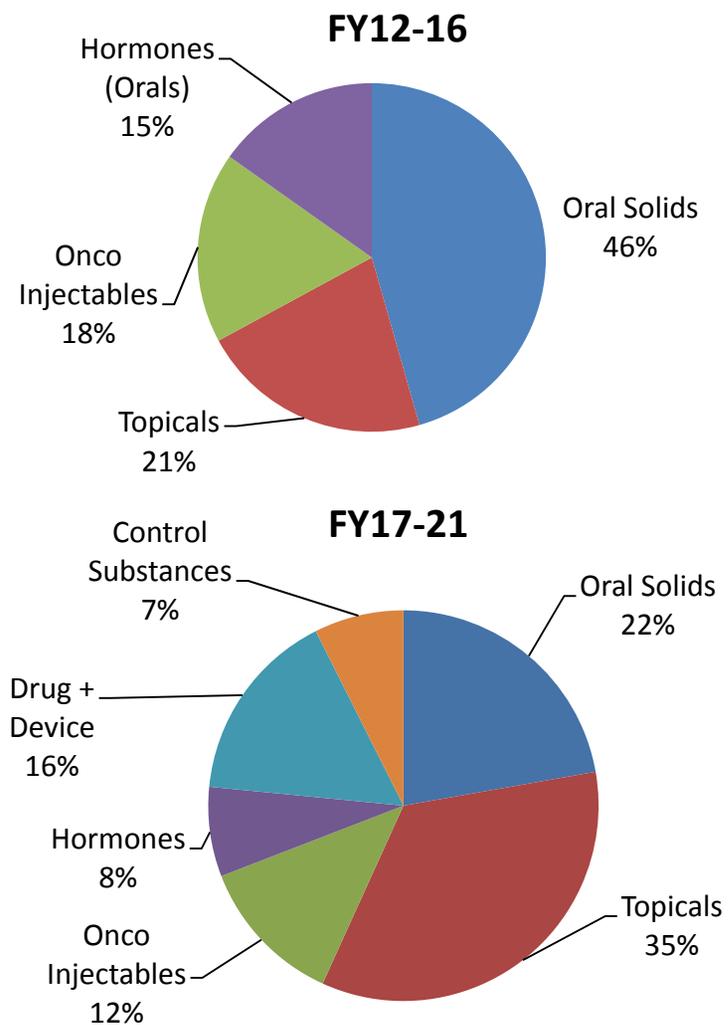
Source: IMS NSP MAT Oct 2016 for the US market

## 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)

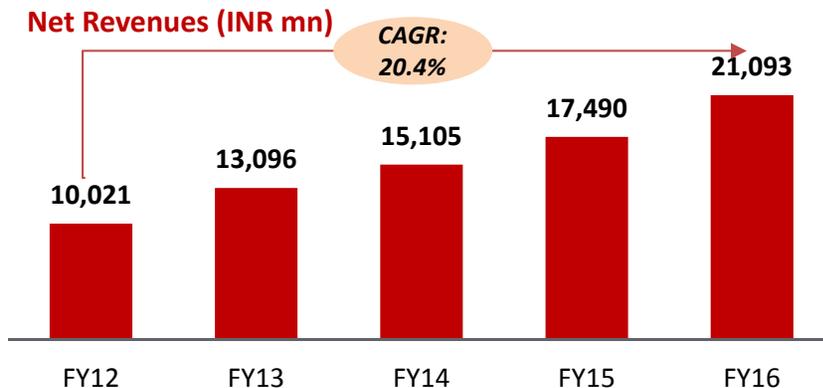


- Optimal combination of internal R&D and strategic development partnerships
- Targeting multiple new dosage forms to differentiate against competition
  - Launch of inhalers in the next 3-4 years
  - Working on 2 additional new dosage forms, with potential launch in CY18 and CY19
- ~15 inlicensing deals 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

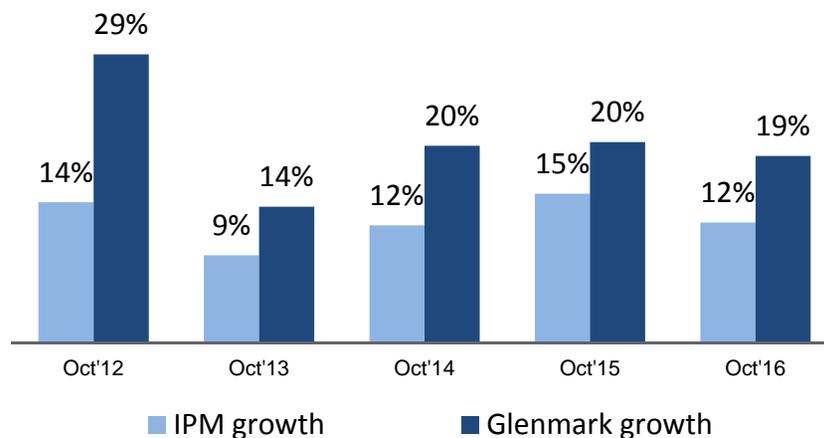
# India business targeting to dominate selected therapies and grow faster than overall market



## Robust growth exhibited in the last five years



## Consistently growing at >1.5x of IPM growth



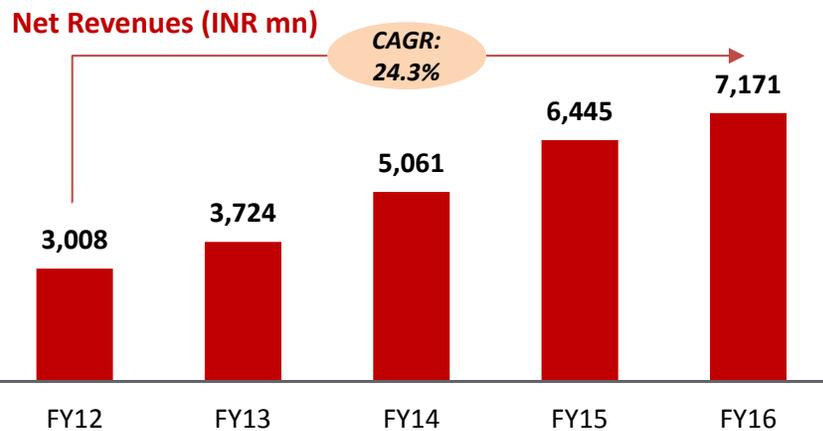
Source: IMS Total Sales Audit MAT Oct'16. IPM: Indian Pharmaceuticals Market

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

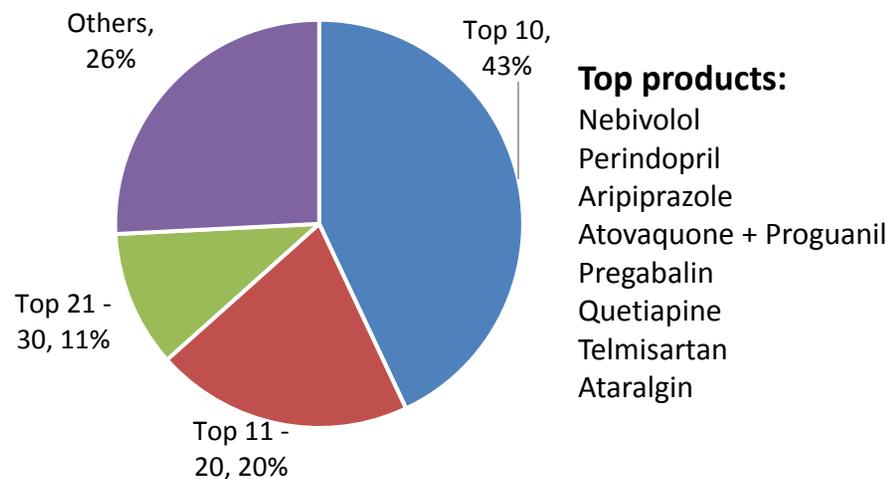
- Strengthen presence in large and fast growing therapies
  - Dermatology, Cardiac, Anti-Diabetic, Respiratory and Oncology
- Continue to build strong brands– 8 brands amongst top -300 in the IPM
- Leverage recently launched products such as Tenzelgipitin and Digihaler
- Introduce innovative products 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

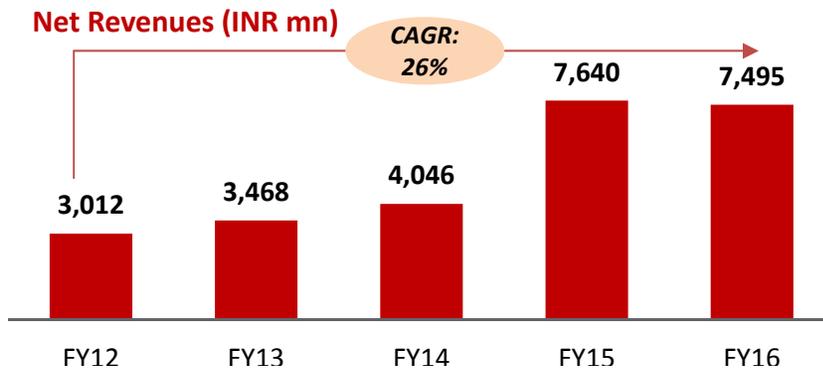


### Key Growth Drivers in the next 4-5 years

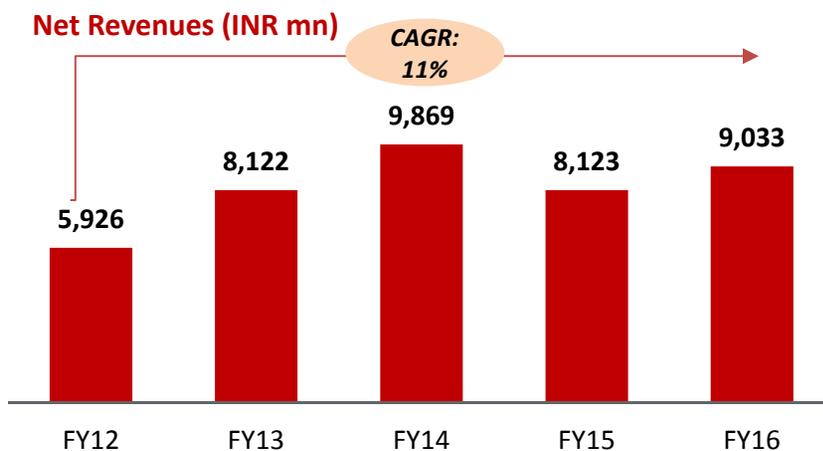
- Leverage existing infrastructure and maximize value from existing markets – UK, DE, CEE
- Selectively enter 1-2 markets primarily in the tender segment e.g. Entered Spain in FY16
- Focus on products, technologies with limited competitive intensity
- Looking to launch complex generic products in the 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

---

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

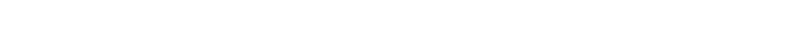
- Team of 350+ involved in R&D on NCEs
- Target selection to clinical development
- Key TAs: Respiratory, inflammatory disorders
- Evaluation of Novel SM immunomodulators in Immuno-Oncology

#### 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

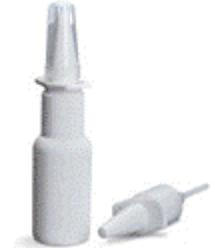
**MDI**

**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

---

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**