

# Strategic Blueprint for the Next Decade

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

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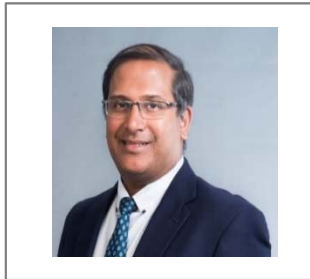
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# Glenmark Team

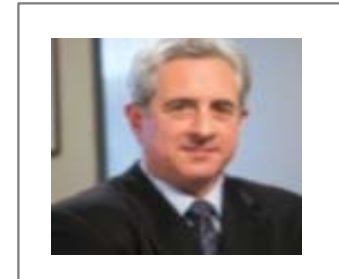
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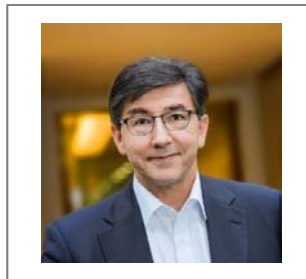
**Glenn Saldanha**  
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Chief Medical Officer



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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



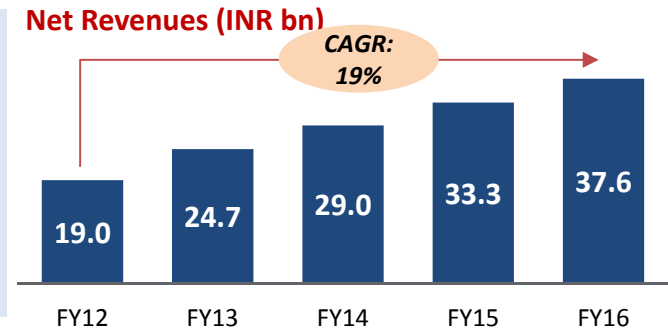
	Year 2000	Year 2016
Wealth Creation	Revenue: <b>US\$ 31 mn</b> Market Cap.: <b>US\$ 40 mn</b>	Revenue: <b>US\$ 1.2 bn</b> Market Cap: <b>US\$ 3.9 bn</b>
Manufacturing Footprint	2 formulations facilities	<b>17</b> facilities across 4 continents; 7 approved by USFDA
International Operations	~ <b>8%</b>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

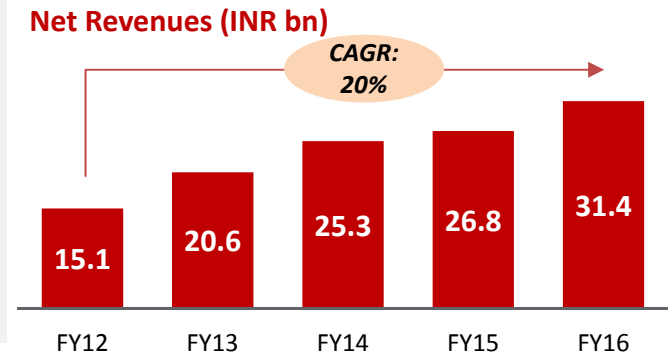
## Branded Formulations

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



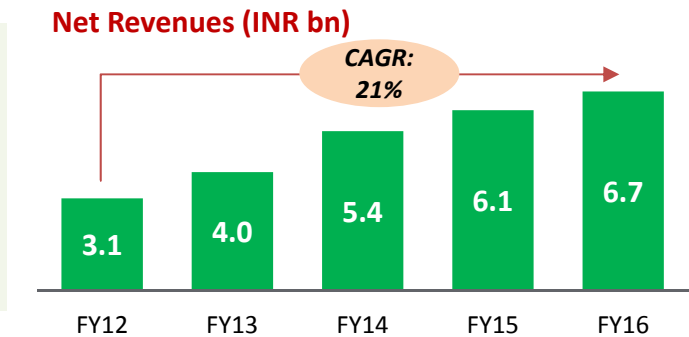
## Generic Formulations

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



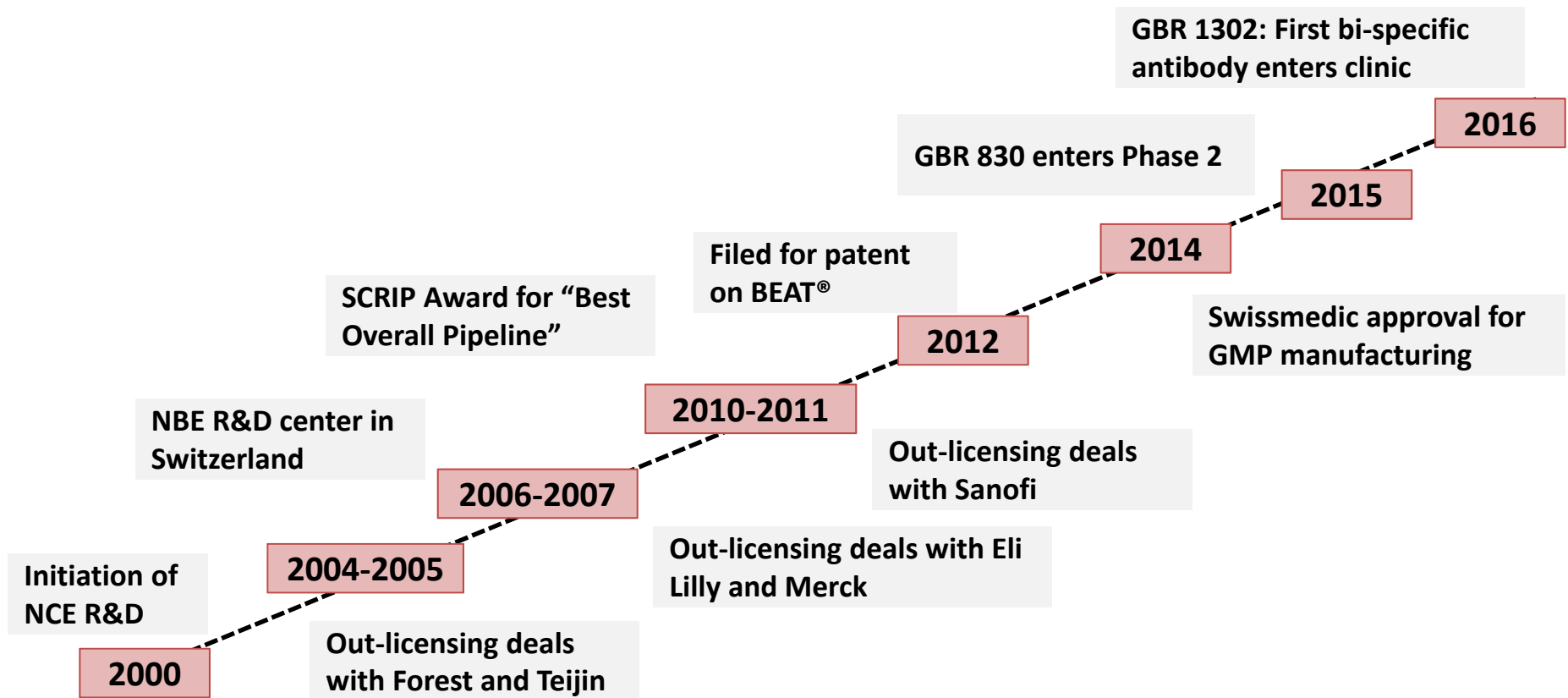
## API

- **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

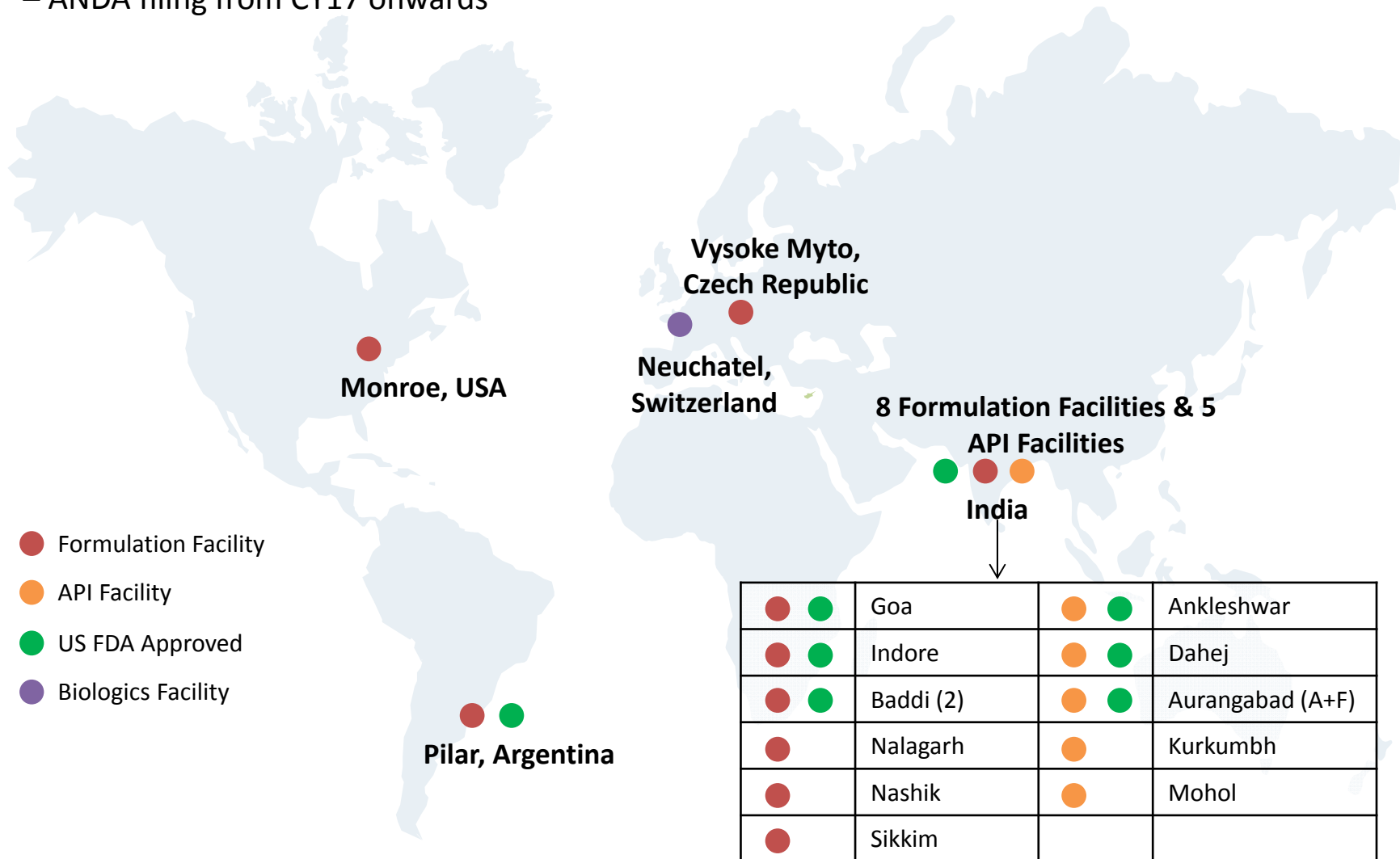


Seven out-licensing deals since 2004, with cumulative revenues of US\$ 200+ mn



# 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

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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

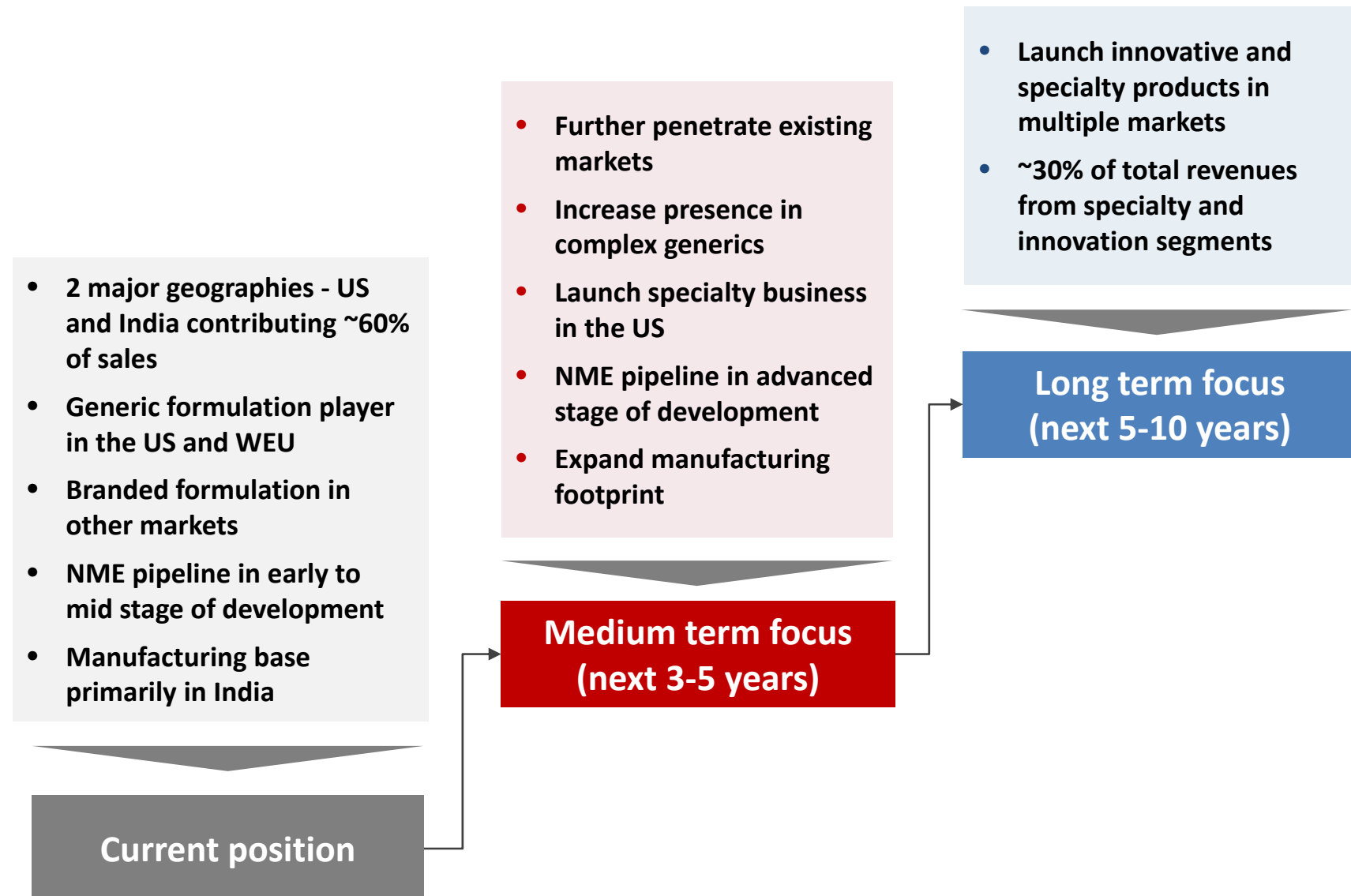
### Industry Challenges

- 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

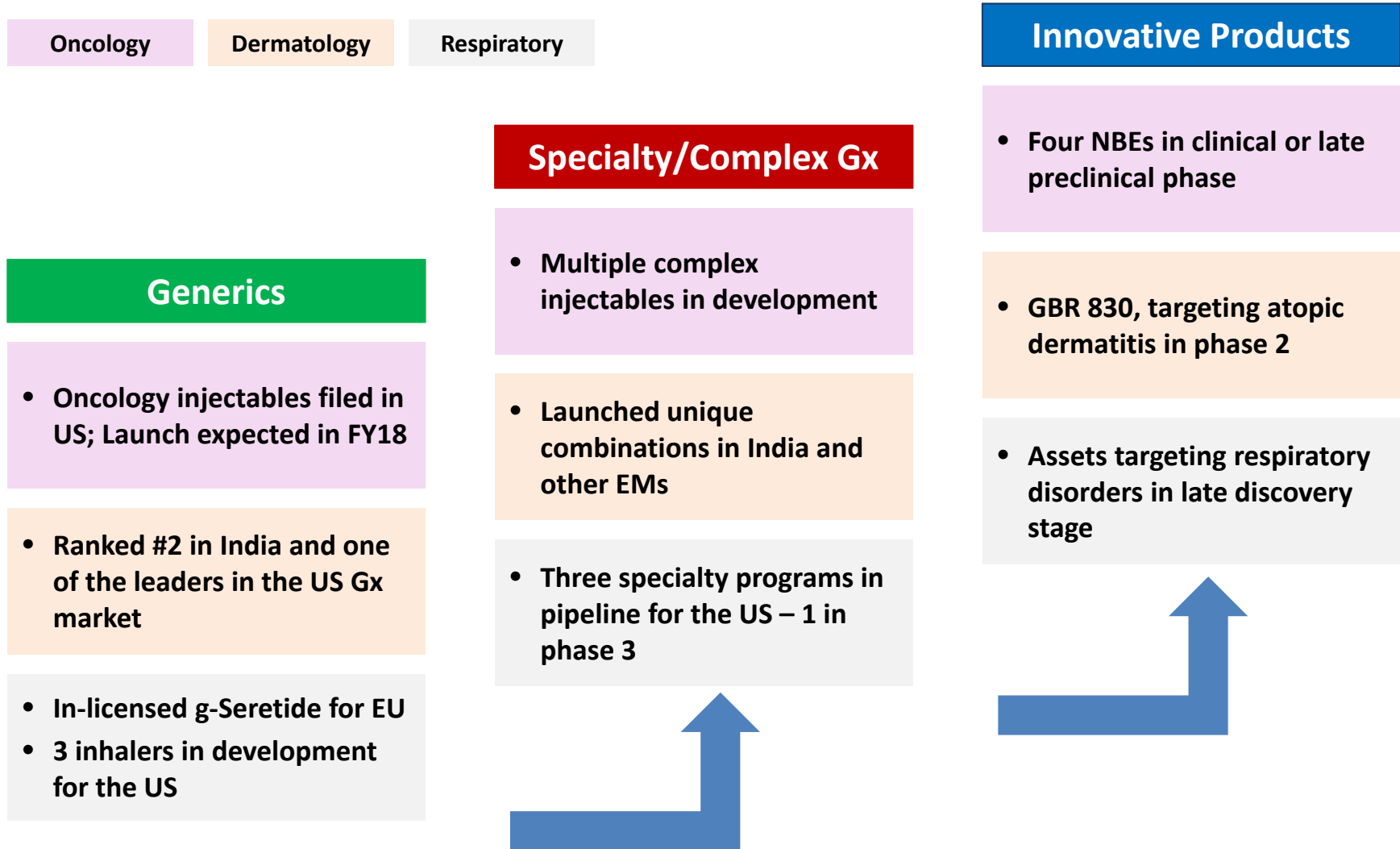
### Strategic Elements

- 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

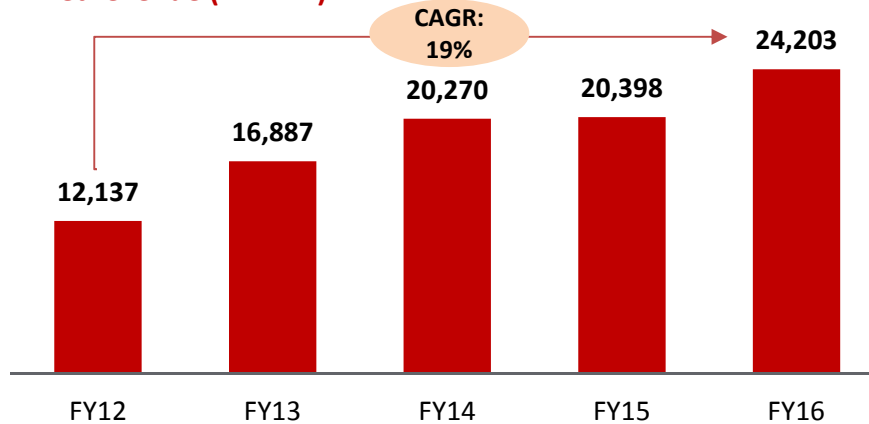
Summary

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

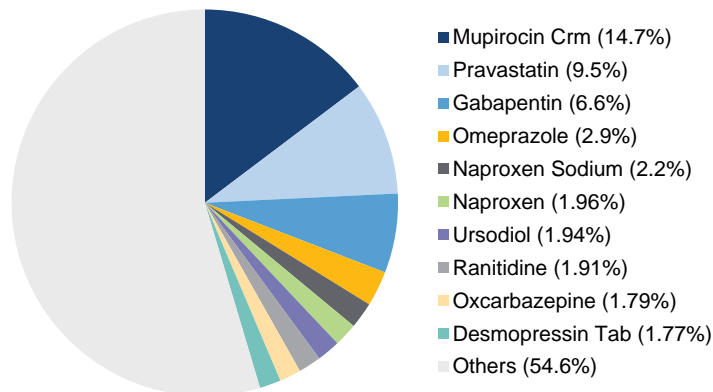


## Revenues doubled in the last 5 years

Net revenue (INR mn)



## Well diversified Portfolio



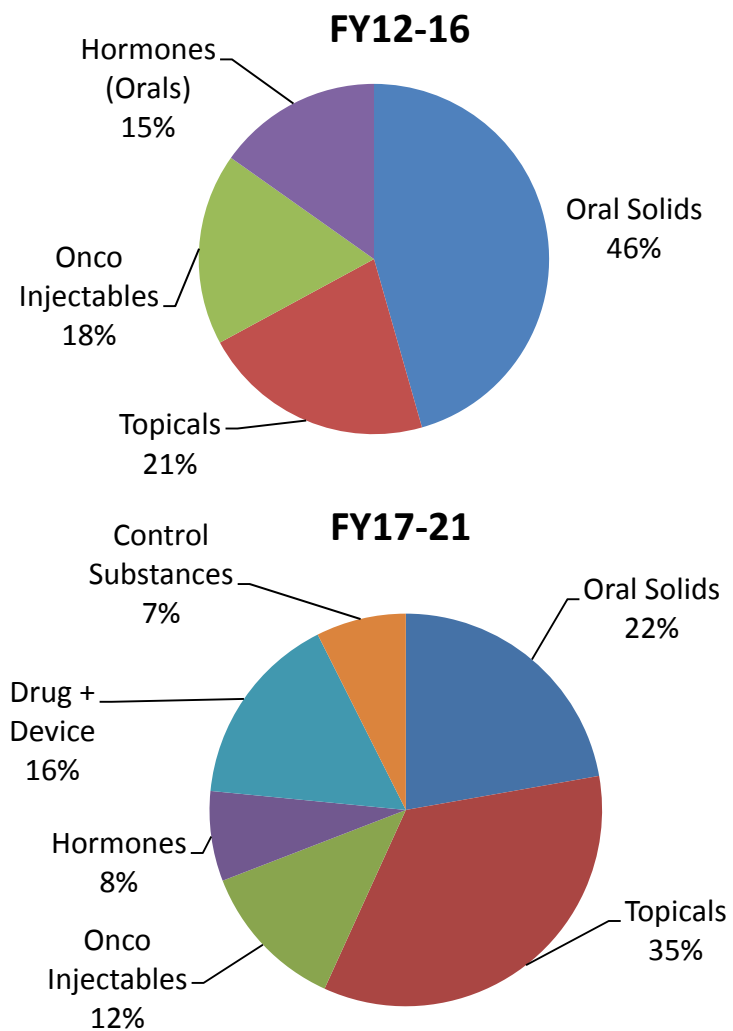
Source: IMS NSP MAT Oct 2016 for the US market

## 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)

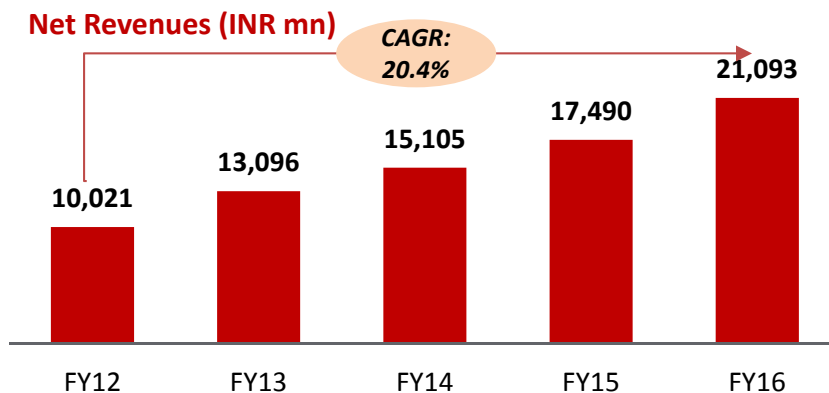


- Optimal combination of internal R&D and strategic development partnerships
- Targeting multiple new dosage forms to differentiate against competition
  - Launch of inhalers in the next 3-4 years
  - Working on 2 additional new dosage forms, with potential launch in CY18 and CY19
- ~15 inlicensing deals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

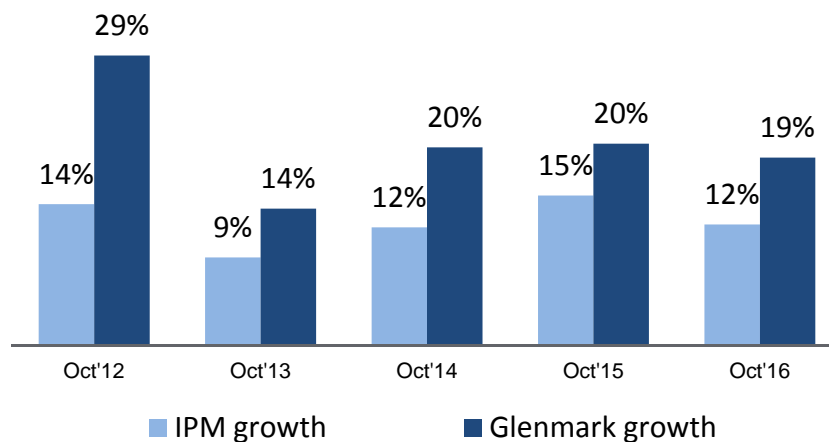


## India business targeting to dominate selected therapies and grow faster than overall market

### Robust growth exhibited in the last five years



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



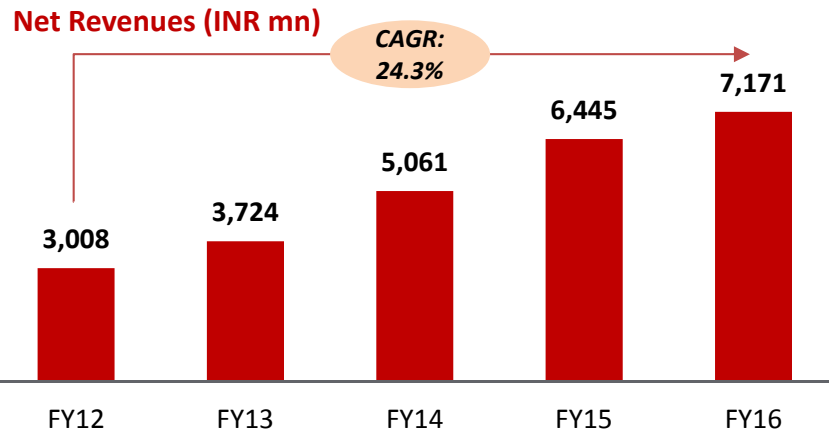
Source: IMS Total Sales Audit MAT Oct'16. IPM: Indian Pharmaceuticals Market

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

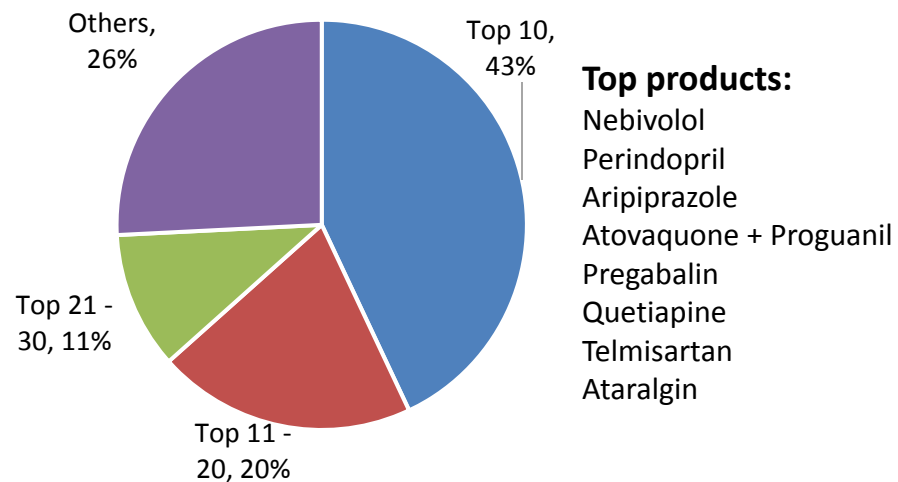
- Strengthen presence in large and fast growing therapies
  - Dermatology, Cardiac, Anti-Diabetic, Respiratory and Oncology
- Continue to build strong brands– 8 brands amongst top -300 in the IPM
- Leverage recently launched products such as Tenepliptin and Digihaler
- Introduce innovative products in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

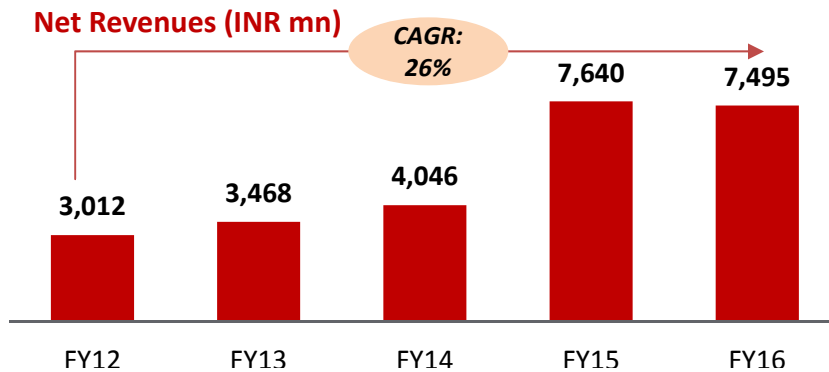


### Key Growth Drivers in the next 4-5 years

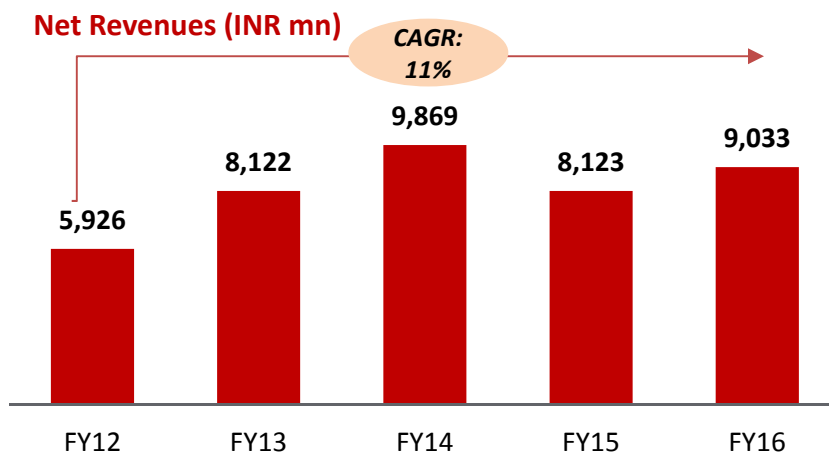
- Leverage existing infrastructure and maximize value from existing markets – UK, DE, CEE
- Selectively enter 1-2 markets primarily in the tender segment e.g. Entered Spain in FY16
- Focus on products, technologies with limited competitive intensity
- Looking to launch complex generic products in the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