

# **Glenmark Pharmaceuticals Ltd.**

37th Annual J.P. Morgan Healthcare Conference  
January 2019

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# Glenmark is a research oriented, integrated global pharmaceutical company



Annual revenue of ~\$1.5 bn in FY19E with CAGR of ~12% over last 5 years

Commercial infrastructure in the US, India, Europe, Russia and other emerging markets

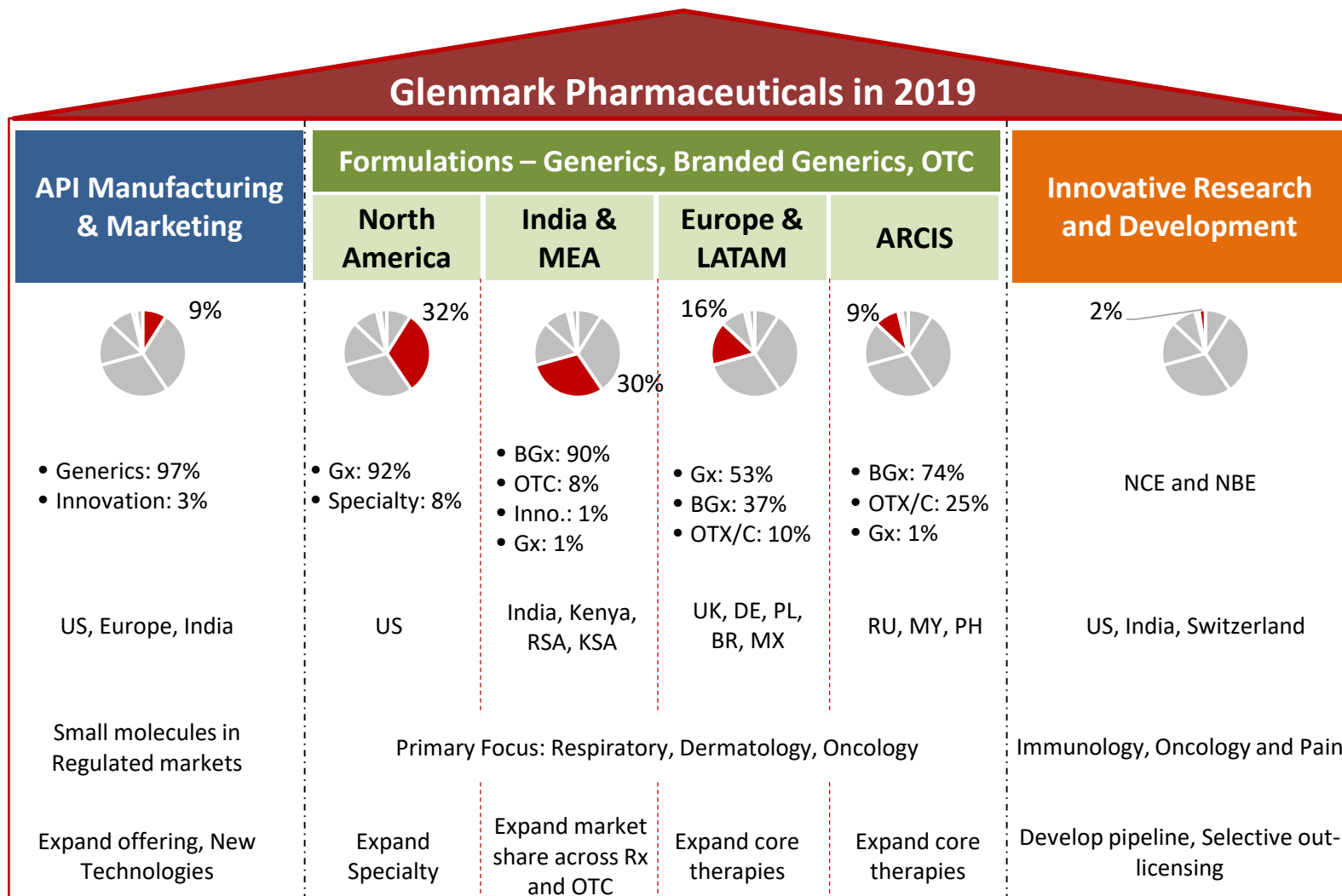
EBITDA pre-R&D expenses at ~30% in FY19E

Global manufacturing footprint with 16 facilities and capability to manufacture small molecules and biologics

Consolidated R&D expense: 12-13% of revenue

Balanced portfolio of NCEs and NBEs with 9 assets in the pipeline

# Business overview



Note: Revenue numbers are based on estimated sales in FY1920; Also includes other income of 1.5%

MEA – Middle East and Africa, LATAM – Latin America, ARCIS – Asia, Russia and other Commonwealth of Independent States



# Business overview

## Glenmark Pharmaceuticals in 2019

	API Manufacturing & Marketing	Formulations – Generics, Branded Generics, OTC				Innovative Research and Development
		North America	India & MEA	Europe & LATAM	ARCIS	
<b>Contribution to Glenmark</b>	<p>9%</p>	<p>32%</p>	<p>30%</p>	<p>16%</p>	<p>9%</p>	<p>2%</p>
<b>Business Mix</b>	<ul style="list-style-type: none"> <li>Generics: 97%</li> <li>Innovation: 3%</li> </ul>	<ul style="list-style-type: none"> <li>Gx: 92%</li> <li>Specialty: 8%</li> </ul>	<ul style="list-style-type: none"> <li>BGx: 90%</li> <li>OTC: 8%</li> <li>Inno.: 1%</li> <li>Gx: 1%</li> </ul>	<ul style="list-style-type: none"> <li>Gx: 53%</li> <li>BGx: 37%</li> <li>OTX/C: 10%</li> </ul>	<ul style="list-style-type: none"> <li>BGx: 74%</li> <li>OTX/C: 25%</li> <li>Gx: 1%</li> </ul>	NCE and NBE
<b>Key Geographies</b>	US, Europe, India	US	India, Kenya, RSA, KSA	UK, DE, PL, BR, MX	RU, MY, PH	US, India, Switzerland
<b>Current Focus</b>	Small molecules in Regulated markets	Primary Focus: Respiratory, Dermatology, Oncology				Immunology, Oncology and Pain
<b>Key Strategy</b>	Expand offering, New Technologies	Expand Specialty	Expand market share across Rx and OTC	Expand core therapies	Expand core therapies	Develop pipeline, Selective out-licensing

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## API Business

### Business Today

- **\$200+ mn\* revenue with EBITDA margin of >30%**
- One of the leading players in products such as Amiodarone, Lercanidipine, Atovaquone, Aprepitant and Perindopril
- Filed ~200 DMFs across key markets with 7-8 US DMF filings annually
- 4 dedicated API manufacturing facilities of which 3 approved by US FDA
- Recently transferred to a wholly-owned subsidiary – Glenmark Life Sciences Ltd., to enhance strategic focus and add new capabilities

### Strategic Priorities

Target revenue growth of 15+% and maintain profitability at current levels

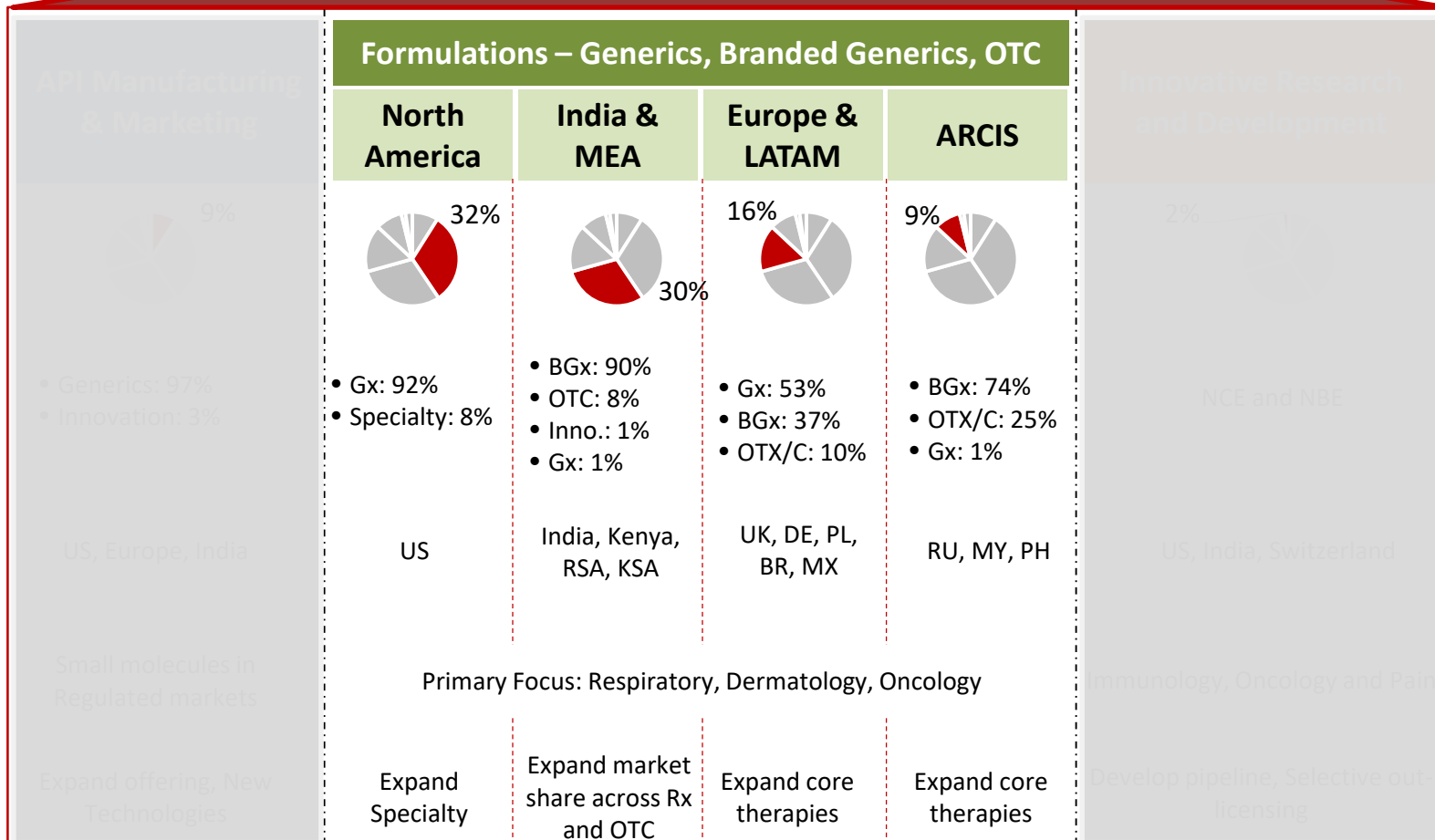
Expand presence in the US and EU, and penetrate other large markets such as China and Japan

Build additional capabilities and manufacturing infrastructure

Leverage India advantage to accelerate business growth

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## Formulation business – key growth drivers

### Focus on select Rx therapeutic areas

- Primary areas – Dermatology, Respiratory, Oncology across all markets
- Secondary areas – Cardio-metabolic, CNS in select markets

### Build strong partnerships



### Launch global brands

- Preparing to launch Ryaltris™\* across key markets globally
- Recently launched Nebzmart across India, LATAM, ARCIS markets
- Other specialty pipeline products under development

### Strengthen commercial infrastructure

- Increase presence in large markets of MEA and Asia
- Expand field-force in selected markets such as the US, India and LATAM

\*Ryaltris is an investigation product that has not yet been approved for marketing by the U.S. Food and Drug Administration (FDA) or any other regulatory authority. The trade name, Ryaltris has been conditionally accepted as the brand name for GSP 301 Nasal Spray.



## North America

### Business Today

- **~\$480 mn revenue** with 5-year **CAGR of 10%**
- Ranked 15<sup>th</sup>\* in terms of total prescriptions filled by generic companies
- 145 ANDAs approved, 50+ pending approval and 50+ in development
- One of the leading companies in the generic dermatology segment
- Key products launched in the last 12 months include Gx Welchol<sup>®</sup>, Gx Vagifem<sup>®</sup>, Gx Protopic<sup>®</sup>
- Entered branded dermatology segment through acquisition of brands from Exeltis
- Strong pipeline of generics in development:
  - Respiratory: Gx Advair<sup>®</sup>, Gx Flovent<sup>®</sup>
  - Dermatology: 10+ products with cumulative market size of \$700+ mn
  - 5 large, complex OSDs targeting \$1.3 bn market

### Strategic Priorities

Will enter specialty respiratory market with launch of Ryaltris<sup>TM</sup>

Launch 2 additional branded dermatology products in 12-18 months

Introduce new dosage forms such as foams, respules and inhalers

Ramp-up operations from US plant based in Monroe, NC

## India and MEA

### Business Today

- **Revenue of ~\$450 mn with 5-year CAGR of 13%**
- Has consistently grown faster than the overall market
- 8 brands among the top 300 Brands in the Indian Pharmaceutical Market
- Launched multiple first-in-market products across core therapy areas – Nourkrin<sup>®</sup>, Aprezo<sup>®</sup>, Digihaler<sup>®</sup>, Akynzeo<sup>®</sup>
- Established OTC business in India with ~\$30 mn revenue growing in excess of 25% - Key brands include Vwash<sup>®</sup>, Candid<sup>®</sup> Powder and Scalpe<sup>®</sup>
- Key markets in Middle East and Africa include South Africa, Kenya, Saudi Arabia

### Strategic Priorities

Launch innovative products through strategic partnerships

Establish leadership in key therapy areas – Dermatology, Respiratory, Cardiac, Anti-diabetic

Expand OTC business by creating powerful brands

Establish local partnerships and manufacturing capabilities in select MEA markets

## Europe and LATAM

### Business Today

- **Revenue of ~\$235 mn** with 5-year **CAGR of 13%**
- Key markets include the UK, Germany, Poland, Brazil and Mexico
- Strong product portfolio developed through in-house R&D and in-licensing partnerships
- Portfolio consists of unique combination of branded generic, generics and OTC products
- Received first regulatory approval for substitutable generic of Seretide® Accuhaler across Nordic countries
- Launched differentiated products like Levolukast® and Nebzmart® in LATAM markets

### Strategic Priorities

Expand presence in respiratory segment; e.g. Gx Seretide® DPI, Tiotropium DPI, Ryaltris™

Expand into OTC / OTX business in Europe

Focus on products, technologies with limited competitive intensity

Expand presence in LATAM through new product launches and partnerships

## ARCIS

### Business Today

- **Revenue of ~\$130 mn** showing robust growth
- Ranks 7<sup>th</sup> in the dermatology market and 4<sup>th</sup> in the expectorant market in Russia
- Strengthened presence in core therapy areas – Key products include Ascoril<sup>®</sup>, Candid<sup>®</sup>
- Continue to bring differentiated products to the market – recent launch of Nourkrin<sup>®</sup> Hair formula
- Large OTC presence in Russia further strengthened through increased market penetration
- Key markets in Asia include Malaysia and the Philippines
- Partnerships in large markets such as Indonesia, Australia, China, Thailand

### Strategic Priorities

Life-cycle management for products such as Momate Rhino Advance<sup>®</sup> and OfloMil<sup>®</sup>

Expand presence in respiratory and derma through launches like Nebzmart<sup>®</sup> and Nourkrin<sup>®</sup>

Further expansion in dermatology through new technology products

Expand business in large markets such as China, Japan, Australia

# Looking to build powerful brands through global launches – Ryaltris™



- Fixed dose nasal spray combination of mometasone furoate and olopatadine hydrochloride
- First global specialty brand of Glenmark
- NDA filed with the US FDA and accepted for review – PDUFA date of March 21, 2019
- Filings initiated in key ex-US markets starting FY19
- Continue to pursue tie-ups in markets with no commercial footprint
  - Signed exclusive out-licensing agreement with Seqirus for Australia and New Zealand markets

Expected launch in H1 CY19 in the US

Potential peak sales of ~\$180-200 mn across all markets

May explore additional opportunity through Rx to OTC switch

## Looking to build powerful brands through global launches – GBR 310 and GSP 304



- GBR 310 is proposed biosimilar of Xolair® (omalizumab)
- Xolair® sales of ~\$1.7 bn in the US, and ~\$0.9 bn in ex-US markets in CY17
- Phase 1 study completed – PK/PD, safety and immunogenicity profiles comparable with RLD
- Target to file/initiate Phase 3 study in the US in FY20

Potential to become one of the first biosimilars of Xolair® in the US

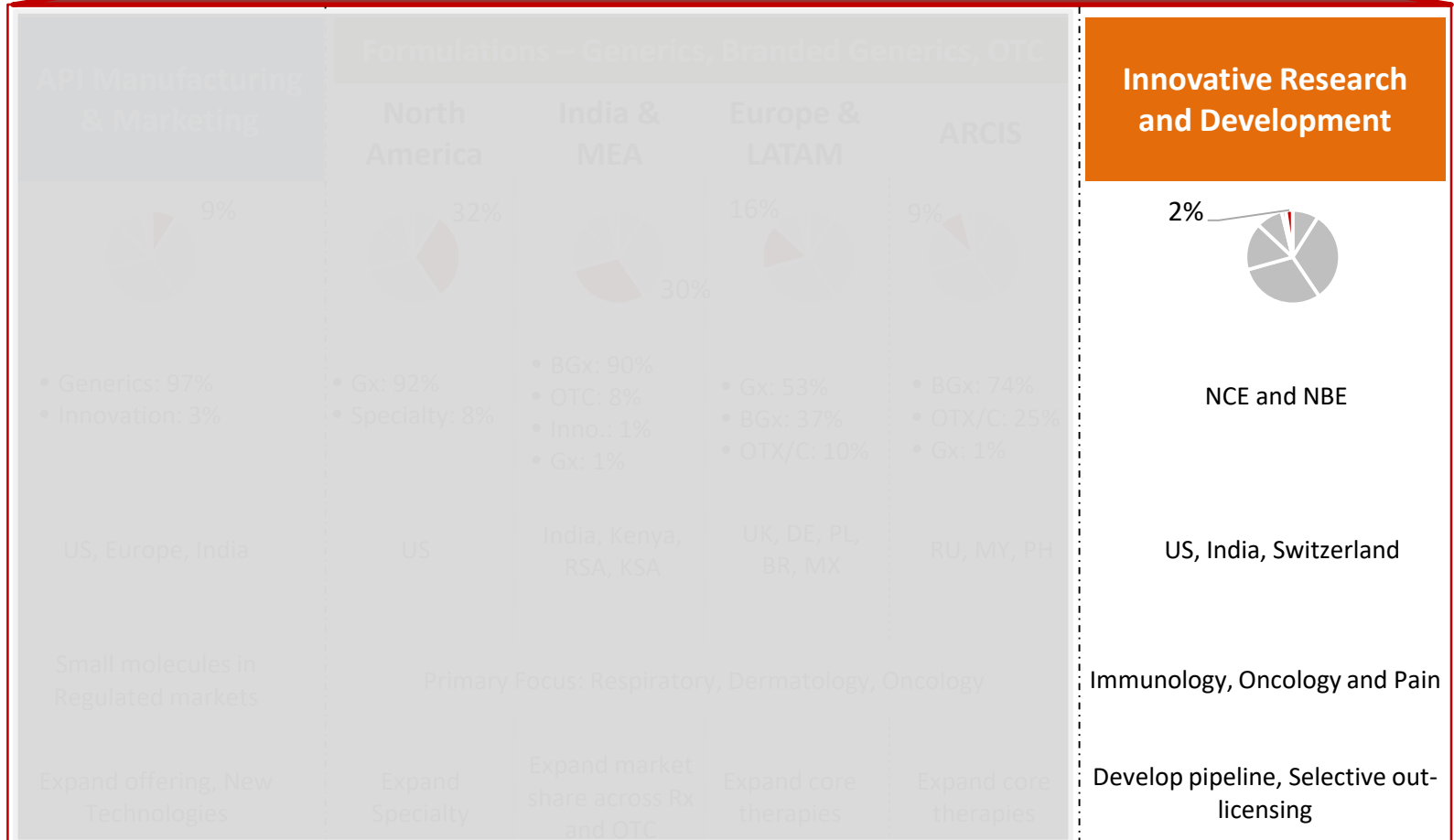
Actively pursuing partnering opportunities

- GSP 304 is nebulized formulation of tiotropium
- Currently in Phase 2 development in patients with mild to moderate COPD
- Development plan for ex-US markets under progress

Significant commercial opportunity expected across markets

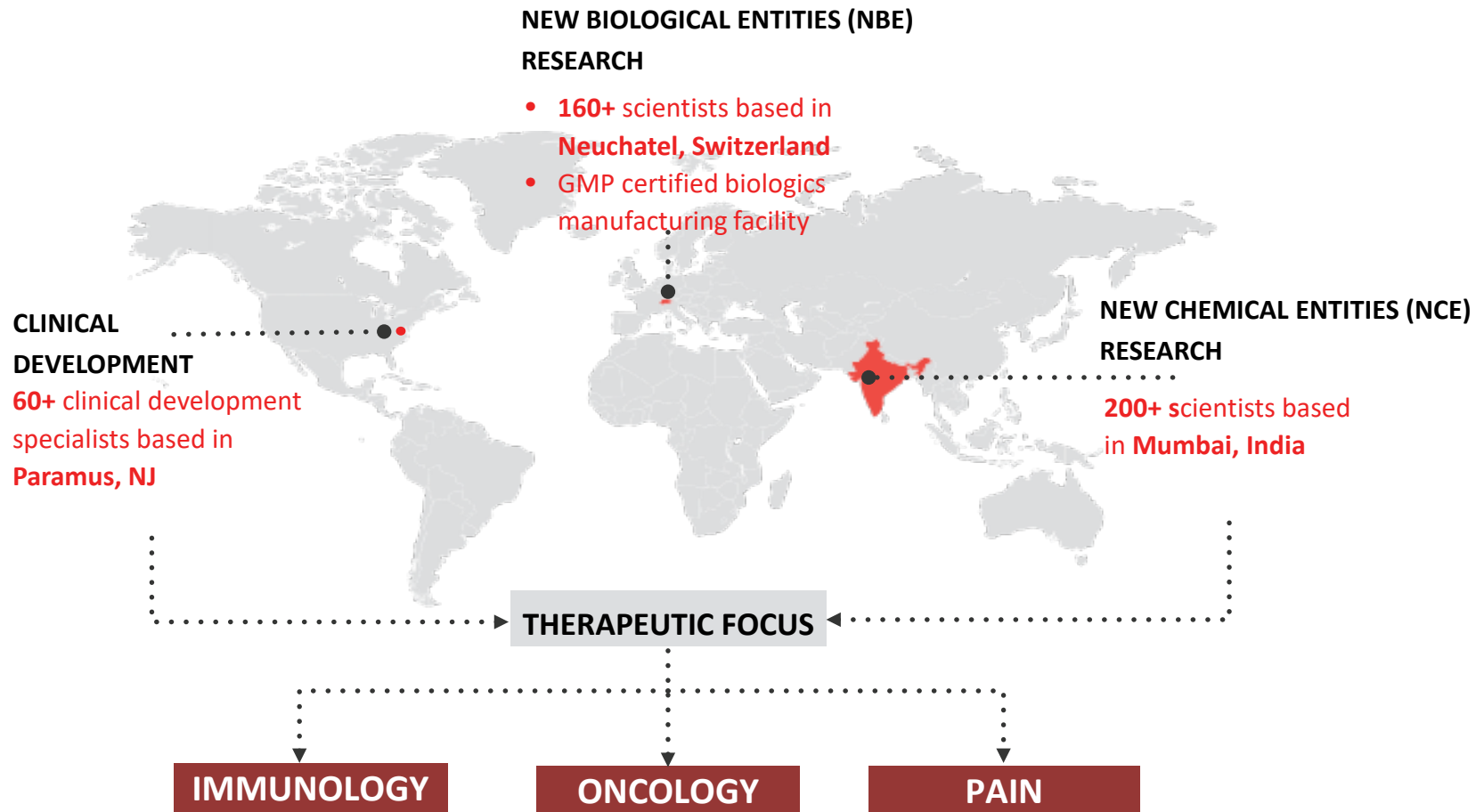
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# Glenmark is one of the leading innovative R&D-focused companies from the emerging markets



**Global innovative R&D infrastructure spread across the US, Switzerland and India**



## Innovative research pipeline

Therapy	Molecule	MoA/Class	Potential Indication	Pre Clinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Approval
Immunology	GBR 830	OX40 Antagonist	- Atopic Dermatitis						
			- Systemic Lupus Erythematosus (SLE) - Ulcerative Colitis (UC)						
	GRC 39815	RORyt Inhibitor	- COPD						
Oncology	GBR 1302	HER2 X CD3	- Breast Cancer - Gastric Cancer						
	GBR 1342	CD38 X CD3	- Multiple Myeloma - Solid Tumors						
	GBR 1372	EGFR X CD3	- Colorectal Cancer						
	TBD	MAP4K1 Inhibitor	- TBD						
Pain	GRC 27864	mPGES-1 Inhibitor	- Osteoarthritic Pain						
	GRC 17536	TRPA1 Antagonist	- Diabetic Peripheral Neuropathic Pain						

## Innovative research pipeline - Summary

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5 clinical and 4 pre-clinical assets currently in development

2 clinical assets currently in Phase 2b, and one asset likely to enter Phase 2b in FY20

3 immuno-oncology bispecific antibodies from the BEAT<sup>®</sup> platform

All clinical assets developed in-house, no financial commitment to any 3<sup>rd</sup> party

Balanced portfolio consisting of NCEs and NBEs

*Note: For further information on the research pipeline, please refer to the detailed Innovative R&D update presentation on [www.glenmarkpharma.com](http://www.glenmarkpharma.com)*

## Strong focus on corporate social responsibility (CSR)

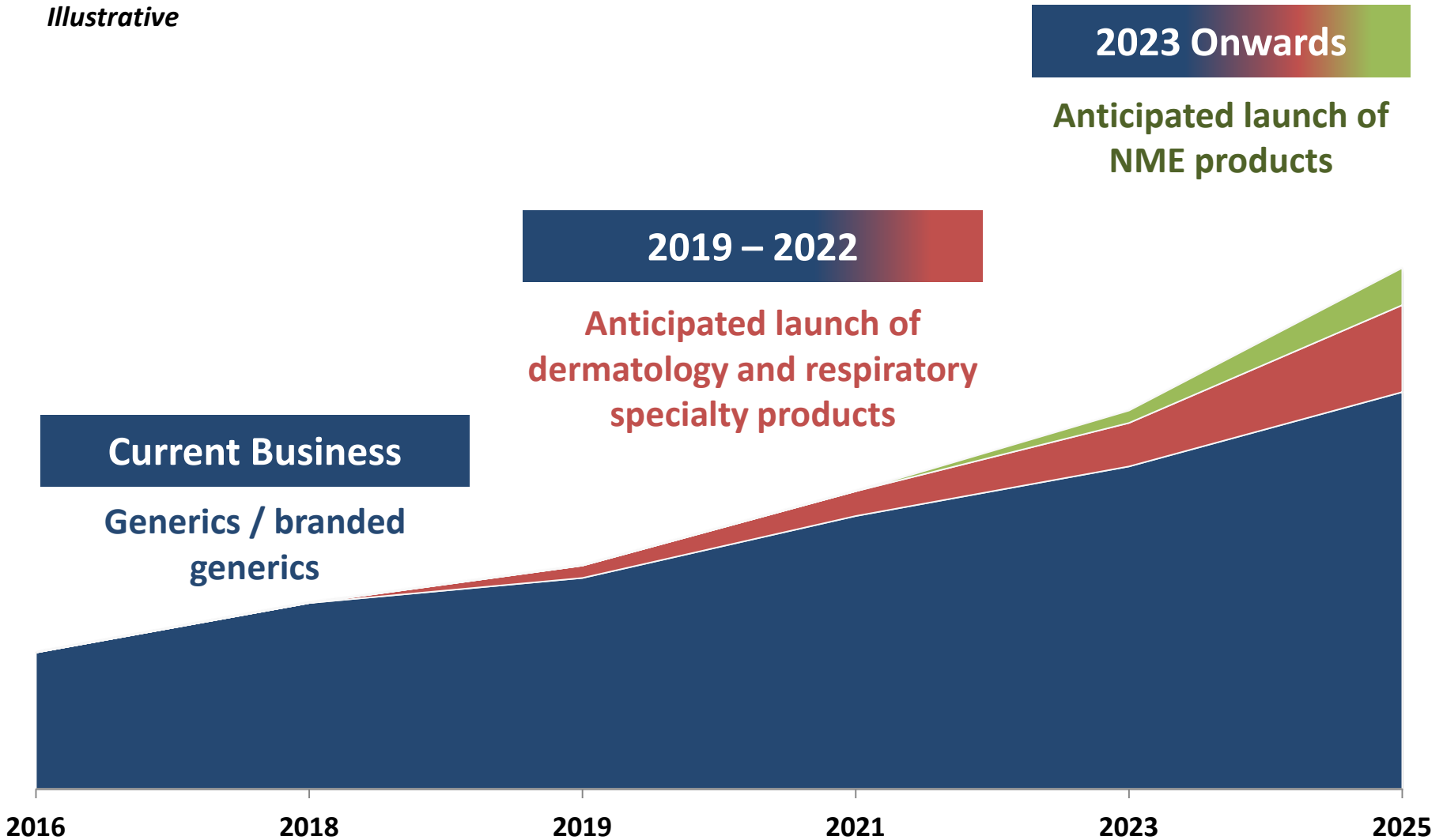
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- Glenmark listed in the Dow Jones Sustainability Emerging Markets Index 2018
  - One among the two pharmaceutical companies to be listed in the DJSI Emerging Markets Index
- Impact of CSR initiatives
  - 8,70,000+ lives touched through child health interventions
    - 1,80,000+ children reached out through nutrition, immunization and sanitation interventions
  - 2,450+ swimmers trained under Glenmark Aquatic Foundation
  - 18,000 differently abled lives improved
  - 5,400+ employees volunteered over 27,000 hours of community service
- 9 manufacturing plants are OHSAS 18001 certified

# Projected revenue roadmap going forward – Moving up the value chain



*Illustrative*



## Financial objectives

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- Target consolidated revenue growth of 12-15% over the next 3-5 years
- R&D expense to continue at 12-13% of revenue
- Continue to focus on margin expansion
- Ensure that business is free cash flow generating
- Net debt to EBITDA ratio to progressively reduce going forward
- Continue to focus on out-licensing of NME assets

## Summary

### Glenmark Today

- Further scaling up the branded generic business globally
- Initiating launch of specialty dermatology and respiratory products in the US
- Advancing Innovation pipeline forward
- Building additional capabilities to enter new segments in API
- Continuing partnership approach to in-license innovative molecules

### Glenmark in 2025

- Global pharmaceutical business across generics, branded generics and OTC
- Specialty business to ramp-up across all key markets globally
- Potential launch of innovative products in markets with existing commercial footprint
- Further expansion of API business through increased penetration and new capabilities



**glenmark**

A new way for a new world