Glenmark
A new way for a new world

Glenmark Pharmaceuticals Limited

J P Morgan Healthcare Conference

January, 2015

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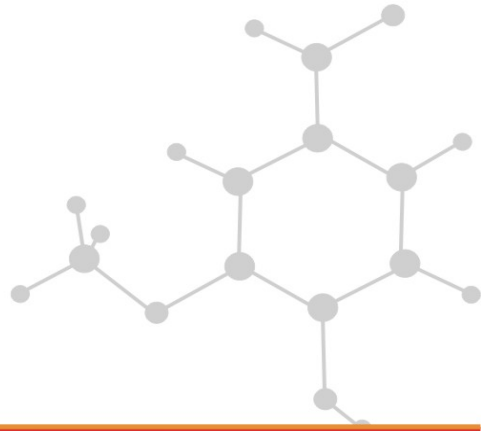
GLENMARK : TRACK RECORD

BUSINESS OVERVIEW

LOOKING AHEAD



Glenmark : The Evolution

Year 2000

- Consolidated Turnover - Rs 1380 Mn ($ 31.62 Mn)
- 2 Formulations Manufacturing Facilities
- Sales from International operations – 8%
- Initiation into NCE research

Year 2014

Research Driven

- 7 NCEs + NBEs in Clinics
- USD 217 Mn of cash received from NCE/NBE out-licensing deals
- Seven out-licensing deals since 2004

Global

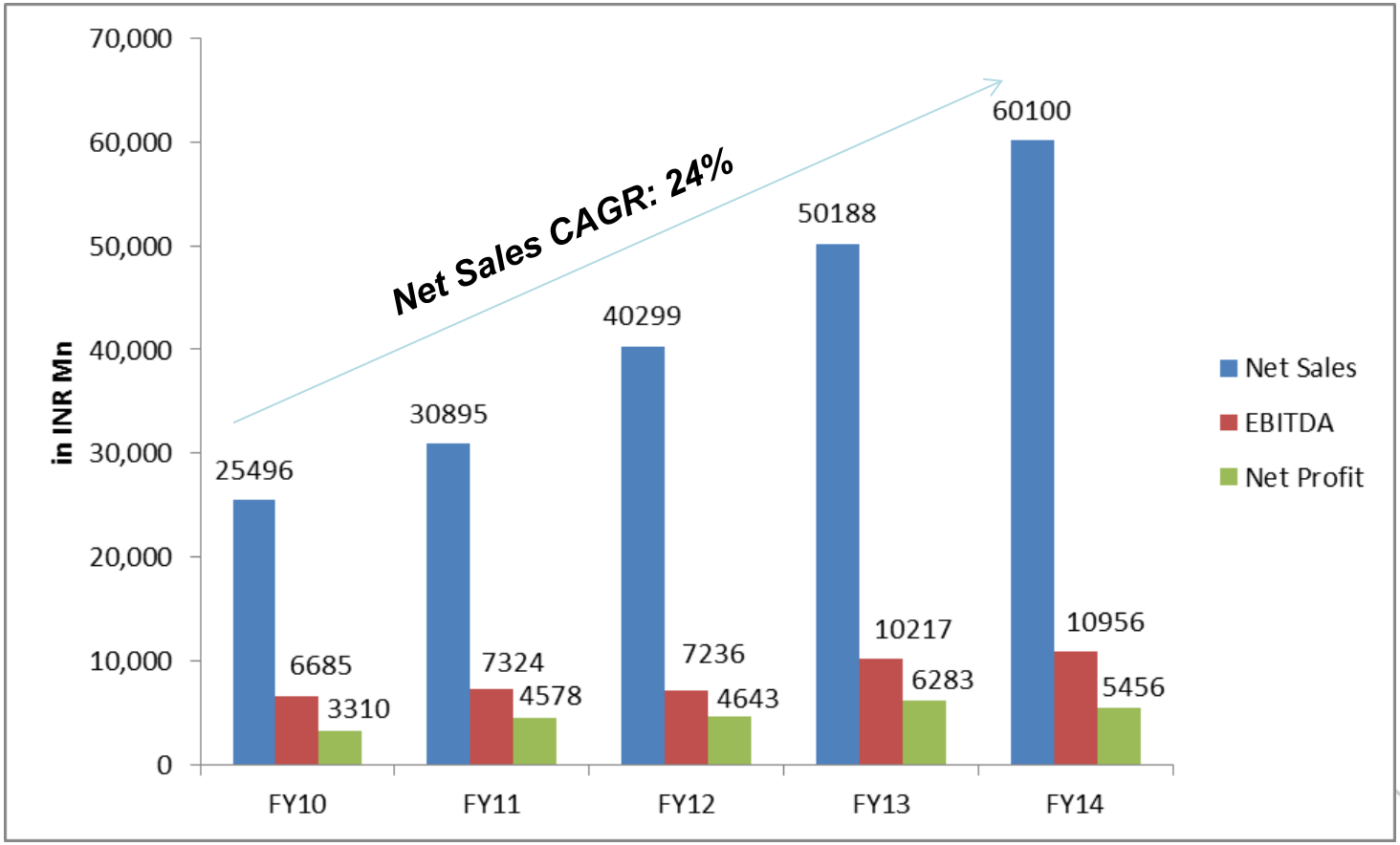
- Consolidated Turnover – INR 60069.35 Mn (USD 995 Mn)
- Global Operations with more than 20 subsidiaries and over 11, 000 employees
- 14 manufacturing facilities in 4 countries
- Front-end in key markets worldwide

Integrated

- 3 API plants
- 11 Finished dosage plants
- 6 Research facilities

A track record of Wealth Creation

Market Capitalization (in USD)	2000	2014
	~ USD 40 Mn	~ USD 3.5 Bn



***FY14 Net profit is calculated after deducting exceptional item of INR 217.5 crores on account of TARKA litigation which closed in Q4 FY14. Excluding TARKA exceptional item*

Agenda

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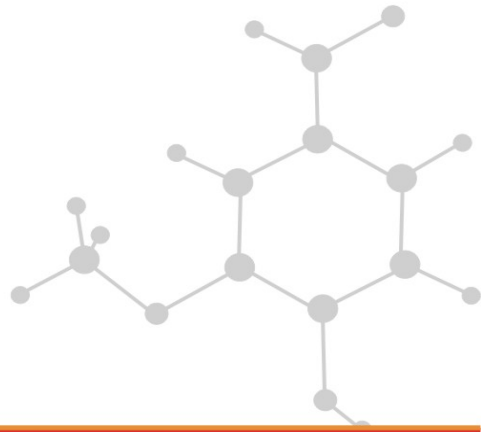

Glenmark Value Proposition

Glenmark Generics moving down the value chain in to Pure Generics & API space

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Glenmark Pharma moving up the value chain with Discovery research

Big pharma moving down the value chain by entering the Branded Generics & Pure Generics space

API Manufacturing → Pure Generics Business → Branded Generics business → Propriety Branded Business

PHARMACEUTICAL VALUE CHAIN

Key Requisites
Low cost; low margins
Forging IP challenges
"Push" for products
Efficient distribution

Key Requisites
Innovation Brand Building
"Pull" for products
Marketing front end

Business

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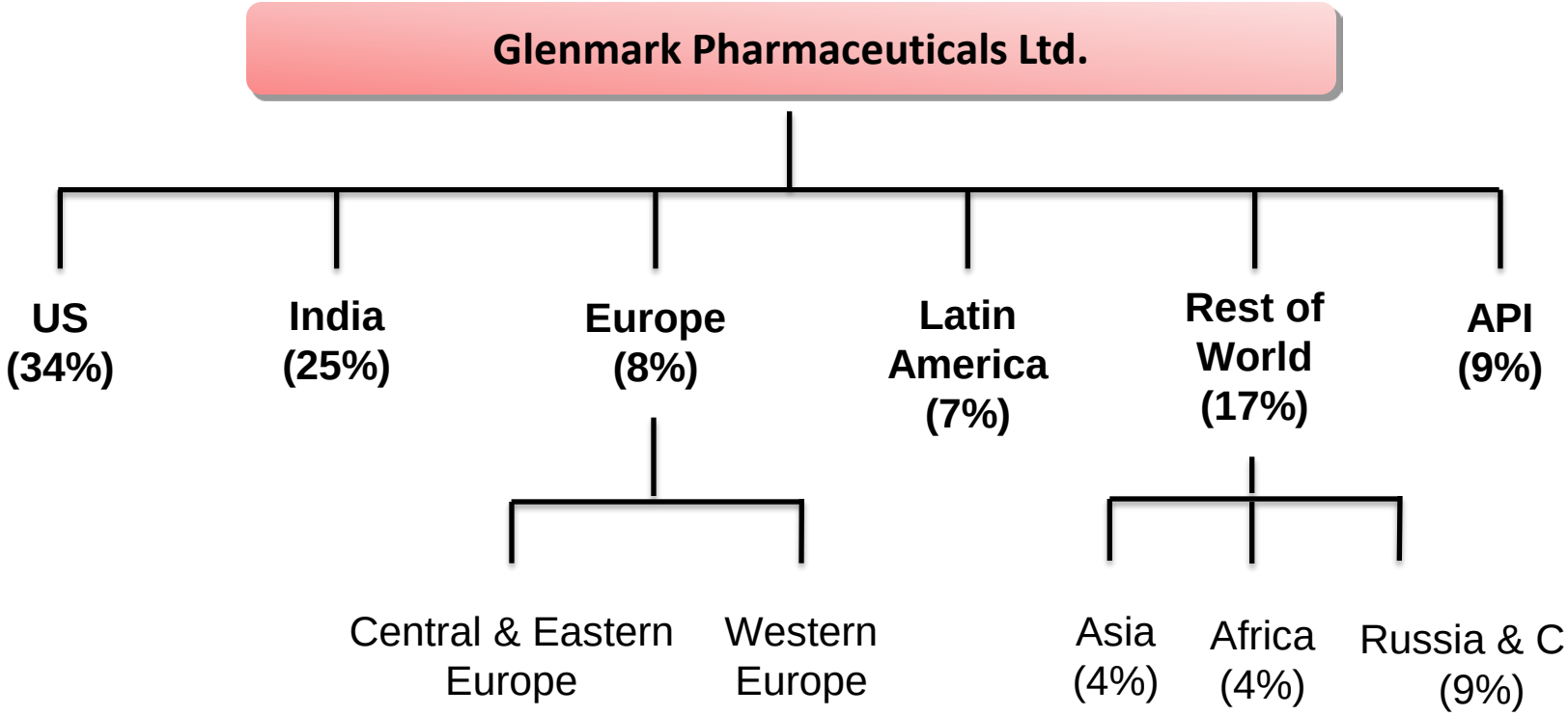
	Novel Research & Development	Specialty Business	Generics Business

FOCUS	• Focus on New Drug Development
	  • NCE
	  • NBE
		• Specialty/ Proprietary Business
		• Focus on branded products market
			• Pure Generics Business
			• Focus on marketing of APIs and generic formulations

Business Structure



- Key markets: US, Europe, India, Russia, Brazil, Latin America
- Focus: To build expertise around focus therapeutic areas across all operating regions viz. Dermatology, Respiratory and Oncology
  - 1-2 additional therapeutic areas in each region

(%) – as a percentage to overall turnover of FY Q1 2015

ANDA Filings

Niche / Focus Area	Pending Approval	Authorized to Distribute	Total Filings	Market Size ($ Mn)
Immediate Release	31	47	78	25391.80
Hormones	14	11	25	2461.70
Modified Release	4	9	13	1763.10
Dermatology	10	23	33	2131.30
Complex Injectables	5	0	5	1284.84
Immunosuppressant	2	0	2	901.13
Controlled Substances	0	4	4	197.30
Oncology – Injectables	8	0	8	2919.18
Total	74	94	168	37050.35
Para IV filings	39	0	39	15988.40

Source Data: IMS Health September 2014

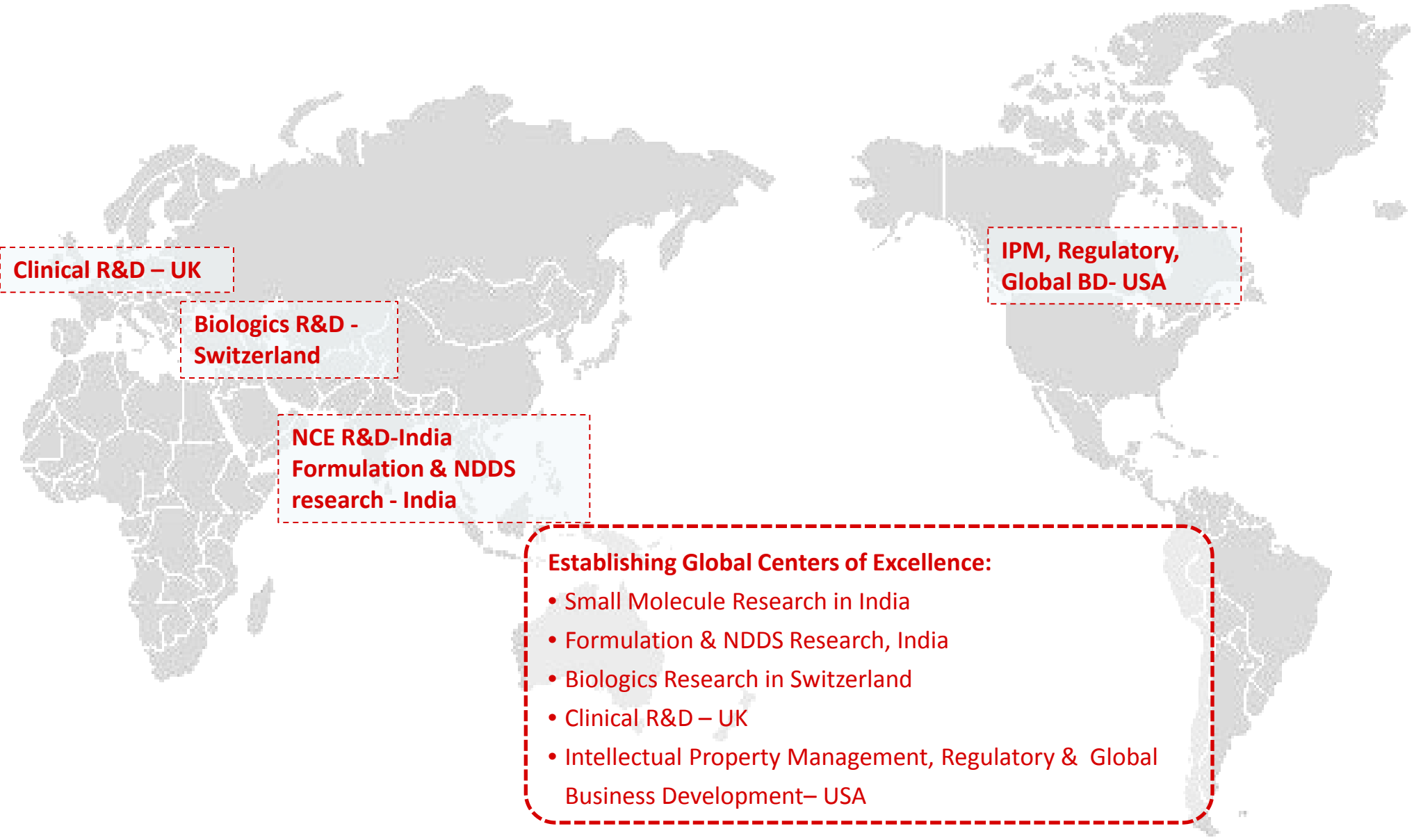
Pipeline as on December 2014

Generics : FTF Opportunities

- Sole FTF opportunity for all products
- The below mentioned Para IV litigations settled except Azelaic Acid Gel

Product	Brand name	Plaintiff	Sales* (MAT Jun 2014)	Likely Launch date
Ezetimibe	Zetia	Schering Plough	USD 1.86 Bn	Dec 2016
Azelaic Acid Gel 15 %	Finacea	Intendis/Bayer	USD 111 Mn	
Hydrocortisone Butyrate Cream	Locoid Lipocream	Triax and Astellas	USD 37 Mn	Launched Dec 2013

Novel R&D: Infrastructure and capabilities



Establishing Global Centers of Excellence:

- Small Molecule Research in India
- Formulation & NDDS Research, India
- Biologics Research in Switzerland
- Clinical R&D – UK
- Intellectual Property Management, Regulatory & Global Business Development– USA

Novel R & D: Out-licensing deals

GBR - 500: Sanofi-Aventis 2011

- First novel biologics outlicensing deal for Glenmark
- Upfront payment of USD 50 Mn; Received USD 5 Mn in May 2014 Total deal size – USD 613 Mn

mPGES-1 Inhibitors Forest Labs 2012

- Received USD 15 Mn payment from Forest labs on an option agreement.
- Forest has the first right to refusal after Phase I completion

GRC 15300: Sanofi-Aventis 2010

- Received USD 25 million in upfront and milestone payments for development & commercialization rights of a first in class TRPV3 antagonist
- Phase II trial did not meet the Primary endpoint in May 2014

GRC 6211: Eli Lilly 2007

- Eli Lilly acquired the rights to a portfolio of TRPV1 antagonist molecules
- Received an upfront fee of USD 45 Mn
- Development of the lead compound GRC 6211 has been stalled

Melogliptin: Merck KGaA 2006

- A deal worth USD 250 Mn in October 2006. Received total payments of USD 31 Mn
- Due to a reduced R&D focus on Diabetes, Merck returned the molecule to Glenmark in April 2008
- Melogliptin completed Phase II b trials and is ready to enter Phase III

Oglemilast: Forest Labs 2004

- A deal worth USD 190 Mn on Oglemilast US Rights
- Received $35Mn as upfront and milestone payments

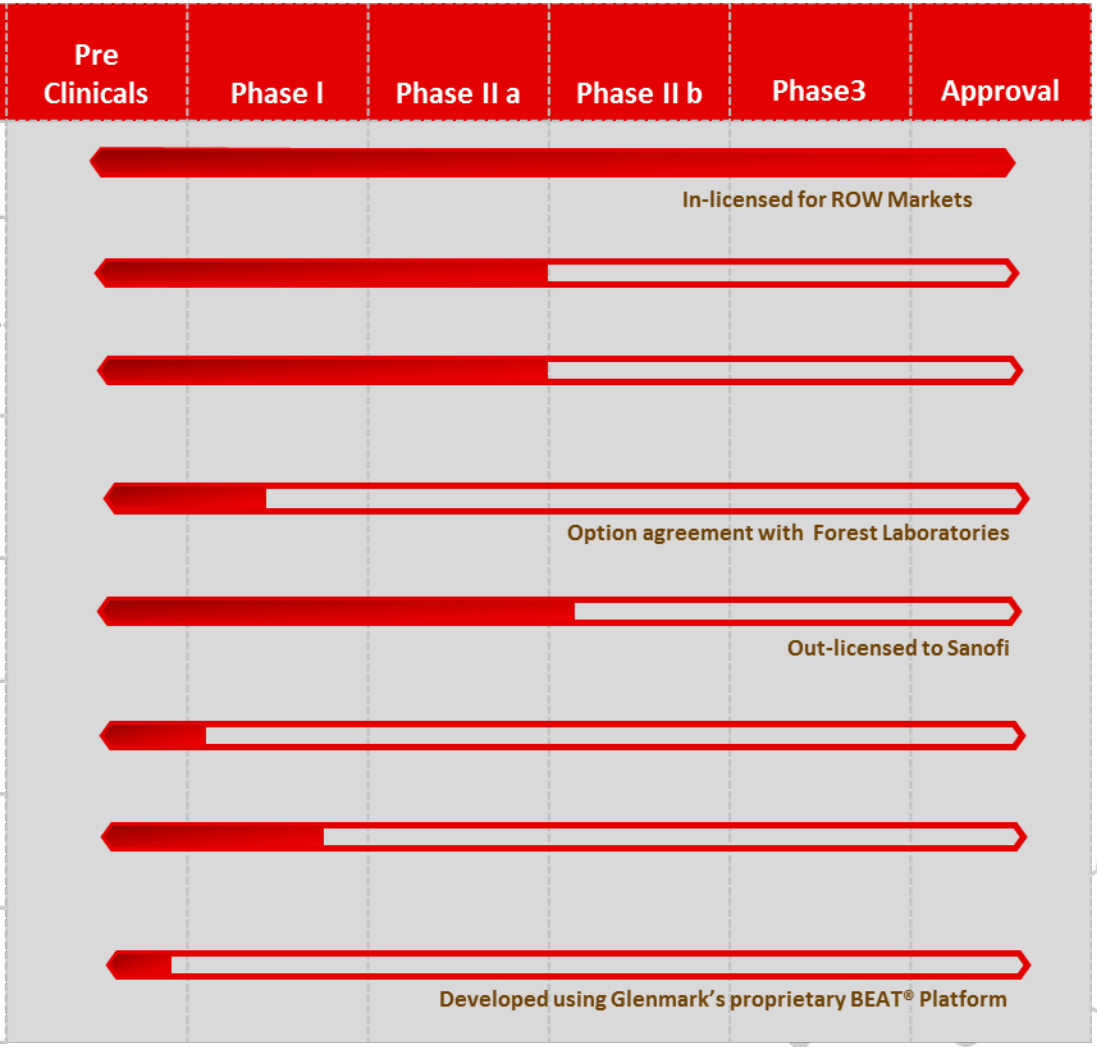
Oglemilast: Teijin Pharma 2005

- A USD 53 Mn deal for Oglemilast Japan rights
- Teijin Pharma paid an up-front payment of USD 6 Mn

GPL has completed seven out-licensing deals since 2004, with a cumulative payment of USD 217 Mn received in terms of upfront and milestone payments

Novel R&D: Pipeline

	Compound	Primary Indications	Target
NCE	Crofelemer	HIV related Diarrhea	CFTR Inhibitor
NCE	GRC 17536	Neuropathic Pain	TRPA1 Inhibitor
NCE	GRC 17536	Respiratory disorders	TRPA1 Inhibitor
NCE	GRC 27864	Chronic Inflammatory conditions including Pain	mPGES-1 Inhibitor
NBE	Vatelizumab (mAb)	Multiple Sclerosis	VLA - 2 Antagonist
NBE	GBR 900*	Chronic Pain	TrkA Antagonist
NBE	GBR 830 (mAb)	Autoimmune Disorders	OX 40 Antagonist
NBE	GBR 1302 (bispecific Ab)	Breast Cancer & Ovarian Cancer	HER2xCD3



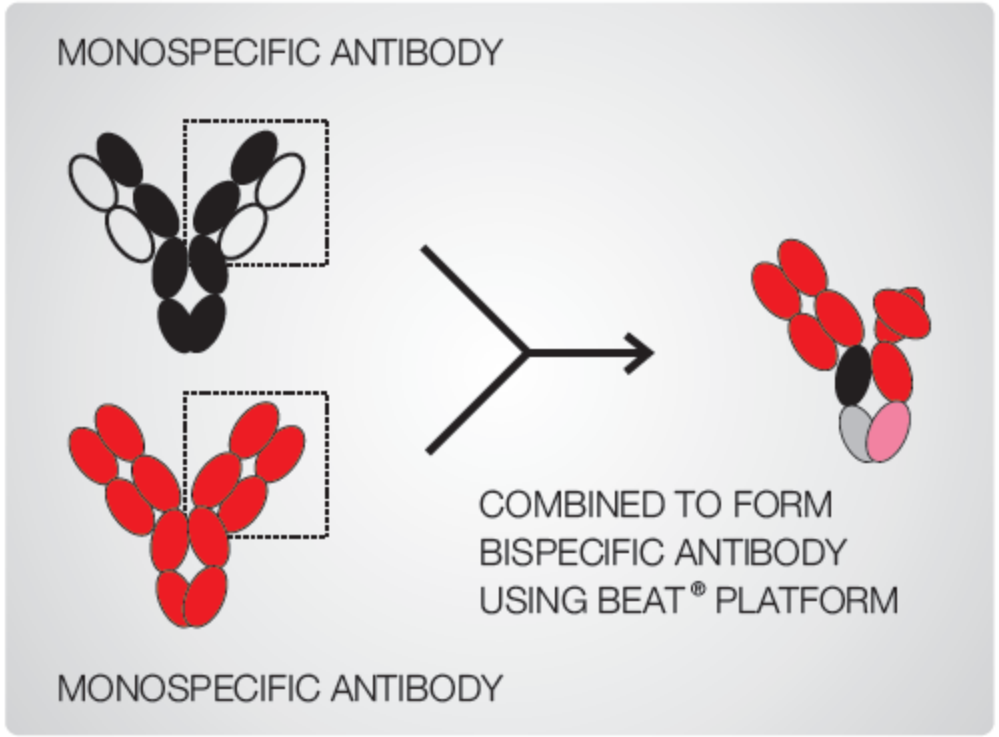
GBR 900 is a monoclonal antibody inlicensed from Lay Line Genomics, Italy. With this, Glenmark has the exclusive target license to commercialize monoclonal antibodies against TrkA receptor for pain

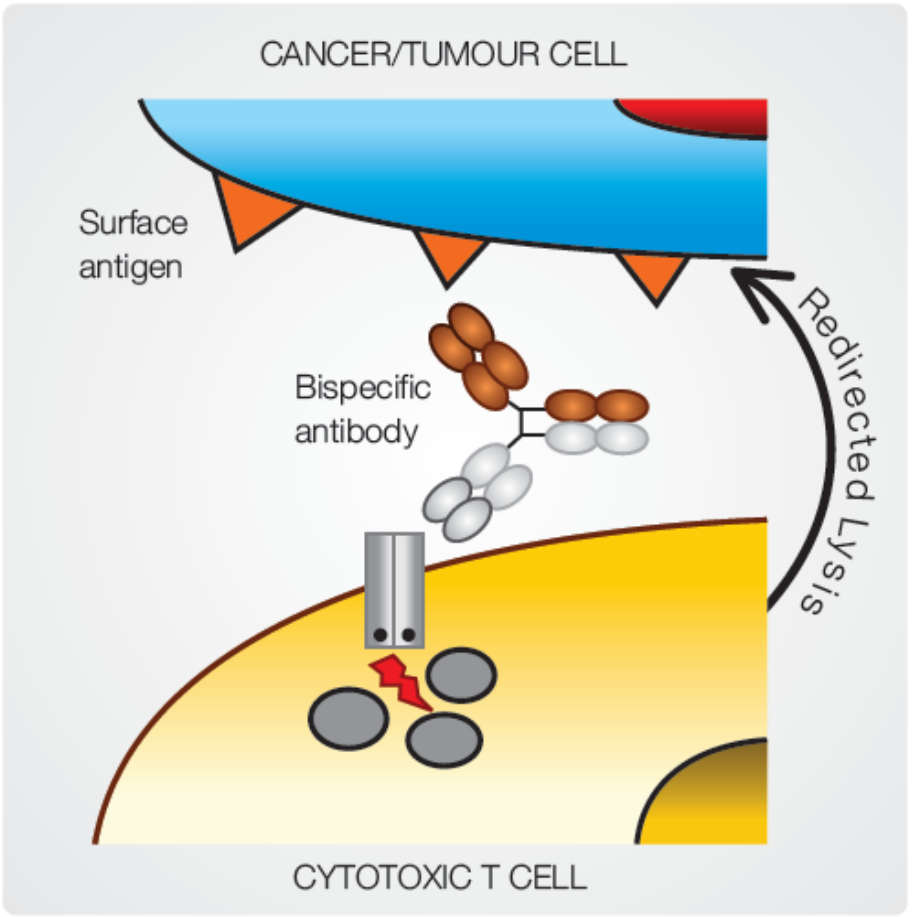
*Updated as on December 2014

Molecules in pipeline are either licensed or are licensable

Novel R&D: Glenmark's proprietary BEAT® Platform

BEAT® (Bispecific Engagement by Antibodies based on the T-cell receptor) is a proprietary, best-in-class, bi-specific antibody platform technology developed by Glenmark.





Glenmark's BEAT® Technology: production like standard antibody

Antibody engineering platform

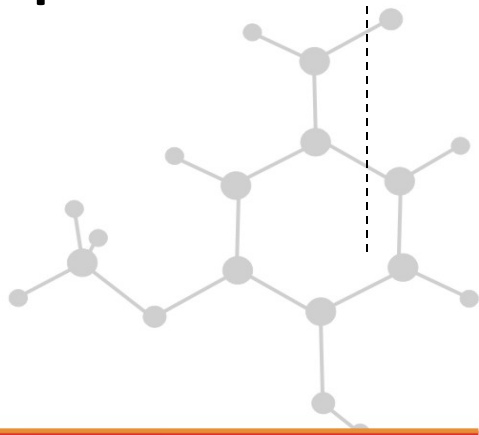
- Plug and play system
- Effector functions, half-life preserved
- Low mispairing of binders

Cell line development and cell banking

- CHO cell line
- MCB, WCB
- high expression levels

Manufacturing

- High yield
- Utilization of standard methods and equipment



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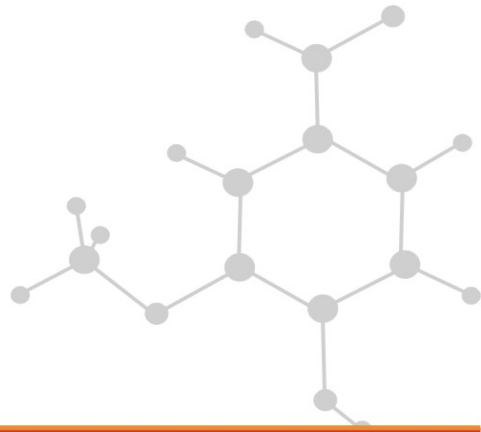

Looking ahead

Innovation

- Initiate clinical development of at least one NME each year
- New target areas to be preferable first-in-class globally
- Focus areas for research will remain inflammation, pain and oncology
    - NBE research will remain focused on monoclonal antibodies (mAb)
- Leverage Glenmark's proprietary BEAT® technology to develop further mAb clinical candidates
    - Glenmark's bispecific antibody technology has a unique format; very good assembly and purification; intellectual property
- Continue with out-licensing model
- Simultaneously build capabilities to do late stage development work

Looking ahead

Generics/Specialty business

Continue our efforts to transition to a proprietary/innovative business

- US, India, Europe, Russia and Brazil to remain focus markets
- US Generics will continue to focus on niche/limited competition products
    - Majority of products pending or to be filed with US FDA fall in this category
- The objective for the India business is to ensure higher than industry growth and gain market share
- Currency devaluation impacting emerging markets
- Build a differentiated product pipeline centred around three therapeutic areas i.e. Dermatology, Respiratory and Oncology
- The objective for the API business will be continuously increase sales from developed markets

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Thank You

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