



# Zydus' Biologics Program



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**Sanjeev Kumar, Ph.D.**  
**Senior Vice President – Biologics**  
**Zydus Cadila**  
**Ahmedabad, Gujarat, India**

# Contents

- **Zydus – A Snapshot**

- Zydus vision and aspirations for Biologics
- Zydus biologics development program and key R&D and Manufacturing capabilities
- Zydus – An ideal company for partnership on novel biologics therapeutics

# Fully integrated pharma player with global footprints

**~60 years**

Operational experience

**\$ 1 bn +**

Global Revenues

**~7% of sales**

Annual R&D Spend

**20+ mfg. sites**

Manufacturing Strength

**~23% CAGR**

Growth in Sales and Net Worth (FY '06 – FY '11)

**300+ products**

Registered annually for US, EU, Japan and emerging mkts.

**15,000+ employees**

Across the globe, with >1050 for R&D

**>25% CAGR**

In Net Profits (FY '06 – FY '12)

**7 NCE programmes**

In pipeline, at various stages of clinical trials

**Among top 5**

Pharmaceutical Companies in India

**19 brands**

Among top 300 brands in India

**19 Biologics**

17 Biosimilars and 2 Novel Biologics; Phage Display

**10<sup>th</sup> largest**

Generic co. In US in terms of prescriptions

**\$ 3 bn +**

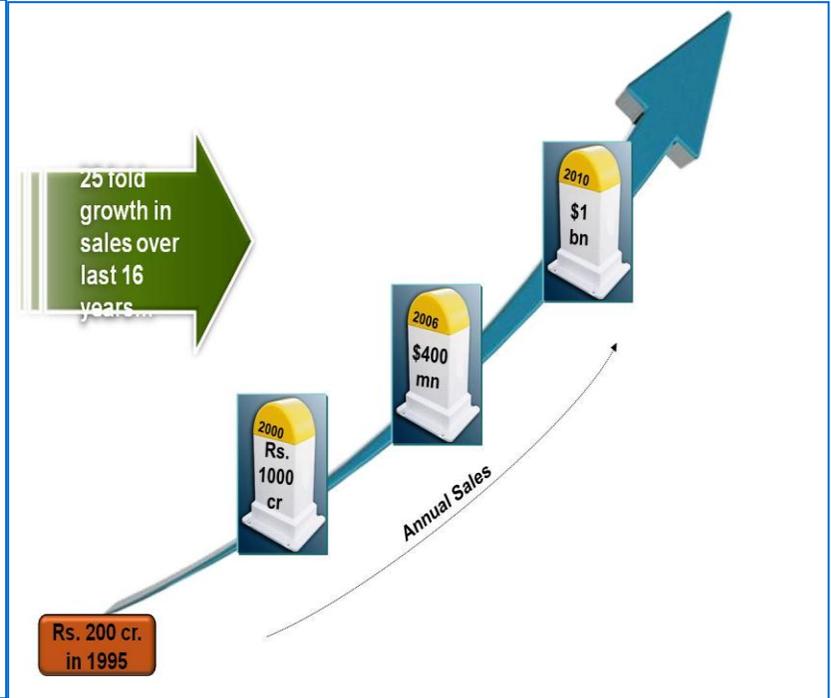
Market Cap

**800+ patents**

Filed globally

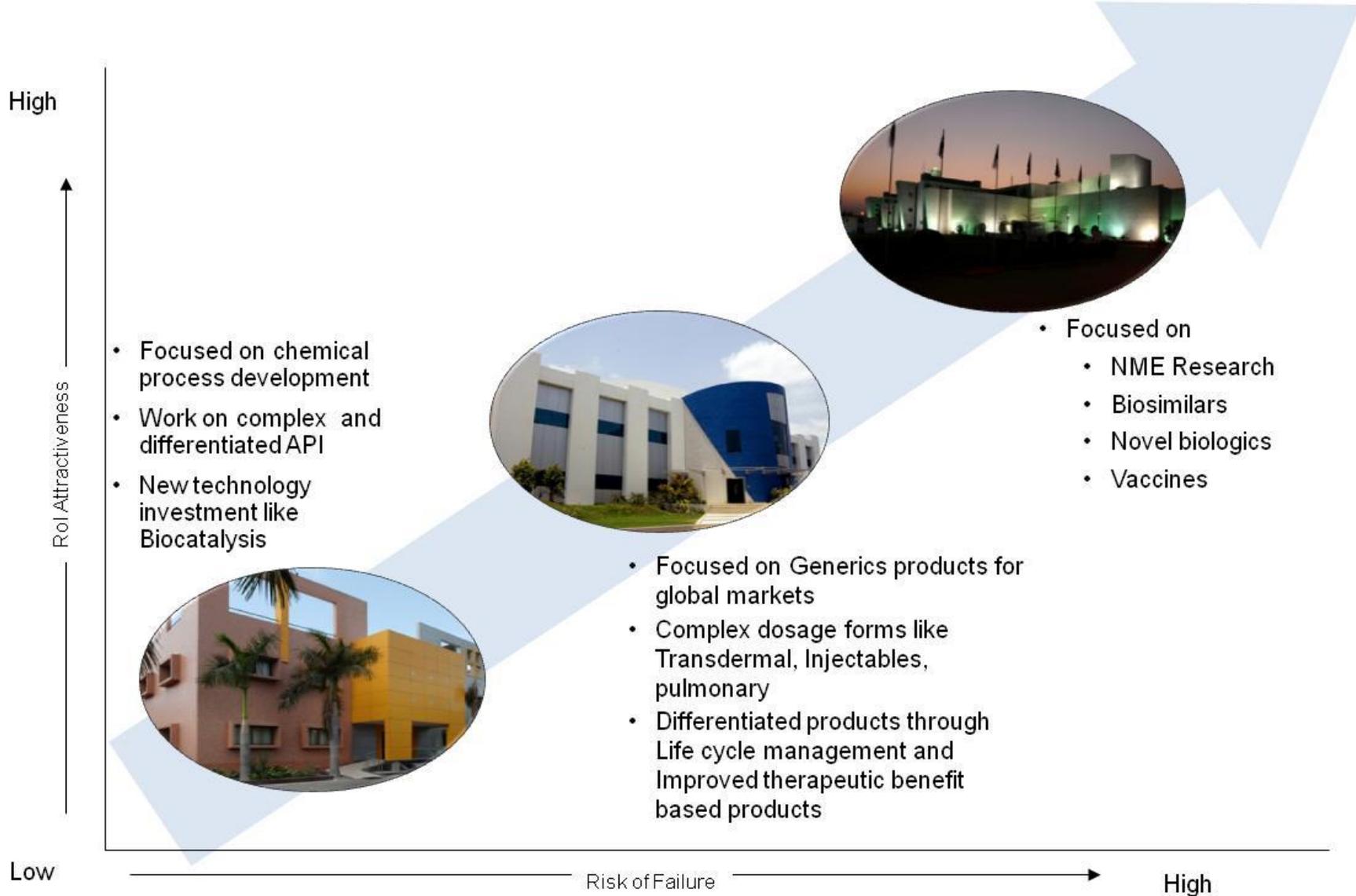
# Vision Statement

**Zydus shall be a leading global healthcare provider with a robust product pipeline; Stepping beyond the billion, we shall achieve sales of over \$3 bn by 2015 and be a research-based pharmaceutical company by 2020...**



**A company culture that prides itself on honoring commitments**

# Zyklus has diversified its R&D investments spread across three key areas



**Unique risk-reward profile evenly spread across various business opportunities**

# Zydu Research Centre (ZRC) – Biologics and NCE - Discovery and Development from Concept to First-in-man trials

(Discovery, Pre-clinical development and Clinical Phase I unit on the same campus )



Chemistry



Pilot Plant



Dog House



Small Animal House



Biologics and NCE – Discovery and Development



Primate Research Center



Clinical



Clinical Pathology Lab

# NCE research pipeline at Zydus Research Centre

**Aspirations : Add more NCEs in pipeline to drive towards becoming a research based pharma co. by 2020**

Key strengths	NCE Pipeline										
<ul style="list-style-type: none"> <li>State-of-the art research facility</li> <li>Capability of target identification to pre-clinical research / early clinical development</li> <li>400+ scientists dedicated for NME research</li> </ul>	Project	Target	Indication	Drug Discovery	Lead optimi-saiton	Pre-clinical Develop-ment	IND	Phase I	Phase II	Phase III	NDA
	ZYH1	PPAR- $\alpha,\gamma$	Dyslipidemia	▶							
	ZYH7	PPAR- $\alpha$	Dyslipidemia	▶							
	ZYD1	GLP-1 Agonist	Diabetes, Obesity	▶							
	ZYOG1	Oral GLP-1 Agonist	Diabetes, Obesity	▶							
	ZYGK1	Glocokinase Activator	Diabetes	▶							
	ZYPH 0907	Oral PTH	Osteoporosis	▶							
	ZYG19	GPR 119 Agonist	Diabetes	▶							

# Zybus Biologics : focused on Therapeutic proteins and Mab's

**Aspirations :**  
 Drive substantial business by 2015 through...

- Marketing in India and emerging markets
- Licensing / co-development for advanced markets

**Strengths to be leveraged**

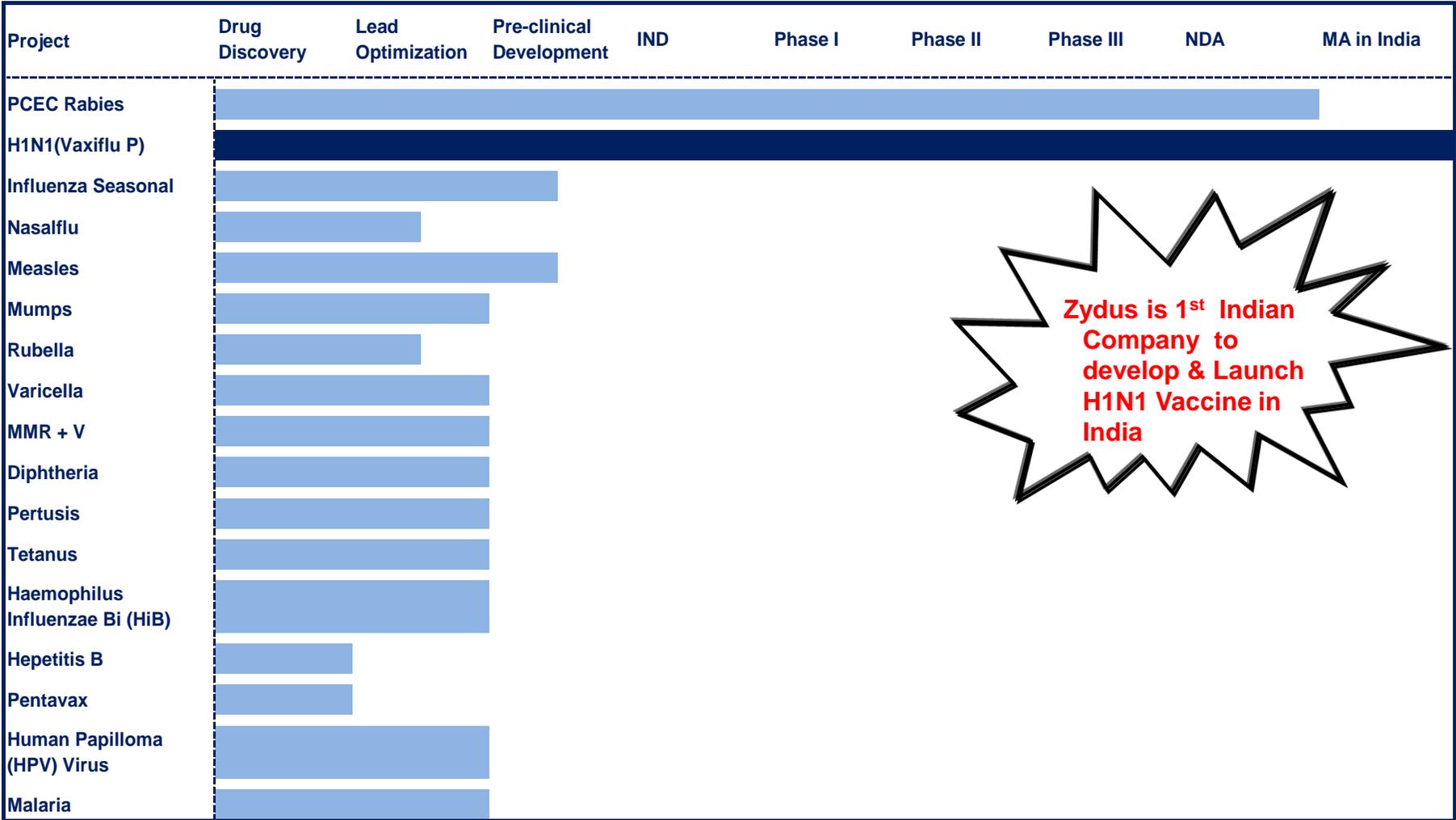
- Dedicated facility for product development and mfg.
- 170+ experienced scientists
- Strong pipeline: 17 biosimilars and 2 novel products
- Strong IP position either through own patent or non-infringing processes



Sr no	Product	Indication	Cloning	Process Dev.	Toxicology	Regulatory permission	Clinical Dev.	Indian Market Authorization
1	IFN- $\alpha$ - 2b	Infectious diseases	<b>LAUNCHED (in India)</b>					
2	PEG-IFN	Infectious diseases						
3	PTH	Osteoporosis						
4	G-CSF	Oncology						
5	PEG GCSF	Oncology						
6	EPO	Oncology/Nephrology						
7	ZRC-3165	Oncology/Nephrology	Progress bar					
8	ZRC-3110	Inflammation	Progress bar					
9	IFN $\beta$ 1b	Multiple sclerosis	Progress bar					
10	ZRC-3160	Inflammation/Oncology	Progress bar					
11	ZRC-3114	Oncology	Progress bar					
12	ZRC-3113	Oncology	Progress bar					
13	ZRC-3197	Inflammation	Progress bar					
14	ZRC-3189	Thrombolytic drug	Progress bar					
15	ZRC-3109	Fertility	Progress bar					
16	ZRC-3209	Fertility	Progress bar					
17	ZRC-3210	Fertility	Progress bar					
18	PEG EPO	Oncology/Nephrology	Progress bar					
19	Rabies Mabs Cctl	AntiRabies	Progress bar					

\* Estimated brand sales

# Vaccine Product Pipeline

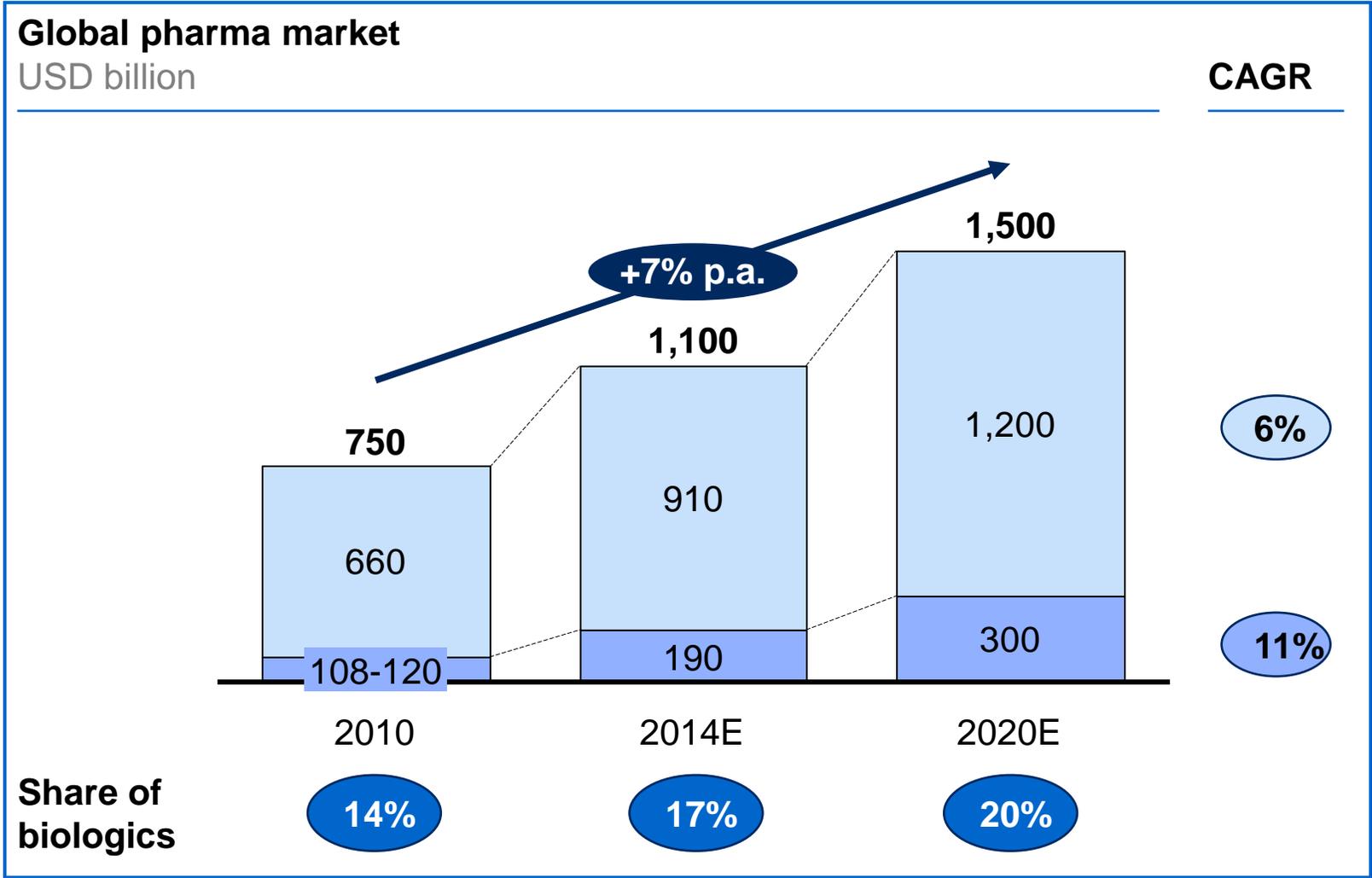


**Zydus is 1<sup>st</sup> Indian Company to develop & Launch H1N1 Vaccine in India**

# Contents

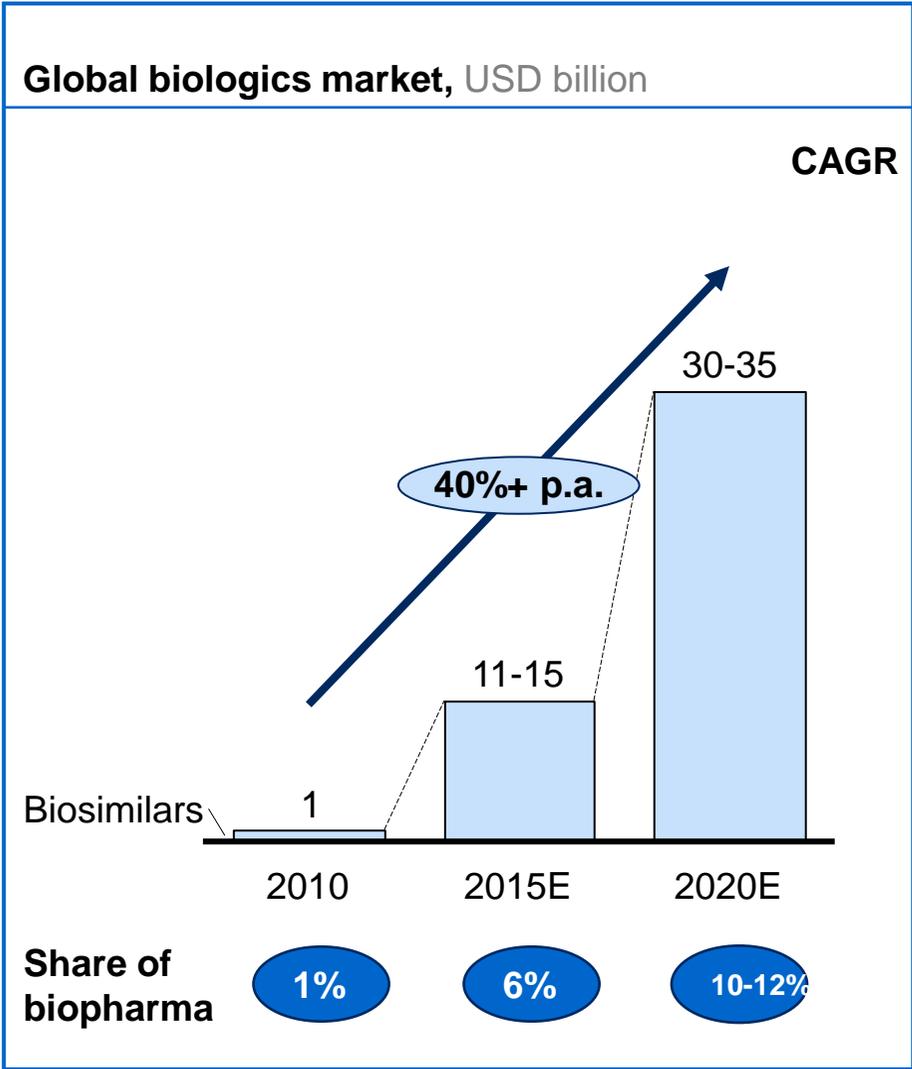
- ZyduS – A Snapshot
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# The growth of the biologics segment will outpace the chemical segment from 2010 to 2020



# Within the large molecules segment, biosimilars are likely to become USD 30-35 billion by 2020

- Key driving forces for biosimilars growth**
- 1 Opening of biosimilar regulatory pathway in US
  - 2 Significant payor pressure in US & EU
  - 3 Relatively lower price erosion of biosimilars expected compared to small molecule generics
  - 4 High entry barriers to limit cogestion
  - 5 Significant emerging market opportunity



1 Bernstein estimates global biosimilars market of USD 10-12 billion in 2015 for early expiry products (EPO, hGH, Interferon alfa and beta, Neulasta, Enbrel)

# Zydus has taken a two phased approach to participate in the Biologics Market

**Phase1 – Learn all aspects of developing biologics by first doing biosimilars**

**Phase 2 – Having learnt biosimilars, get into Novel Biologics**

## Zydus has long term commitment to biosimilars



Our vision for biosimilars is to enhance patient value through **high quality, yet cost effective products**, thereby creating sizeable business in **developed as well as emerging markets** through **strategic commercialization partners**.

We have built a wide portfolio of products developed by an **in-house** R&D program, resulting in one of the **best bio-similarity** in the industry, cost competitive biological manufacturing; a strong regulatory strategy and **non-infringing** processes and our own patents allowing **freedom-to-operate**. We believe that this has led to products with new **benchmarks** in comparability, safety, purity and efficacy.



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# Key Themes of Zydus' Investment in the Biologics Space

## Research

- Ongoing investments in biologics R&D from last 10 years
- Fully integrated & proven **In-house** capabilities from clone development to manufacturing
- Total **19 products** under development; **6** product approved and **1** under market authorization and **4** more to enter clinical trials this year

## Development

- Developed industrial process for fermentation, purification, formulation, Development process in-line with the upcoming manufacturing facility
- **Non-infringing/ patent protected** vectors, processes and product formulations
- Toxicological evaluation conducted for lead products

## Manufacturing

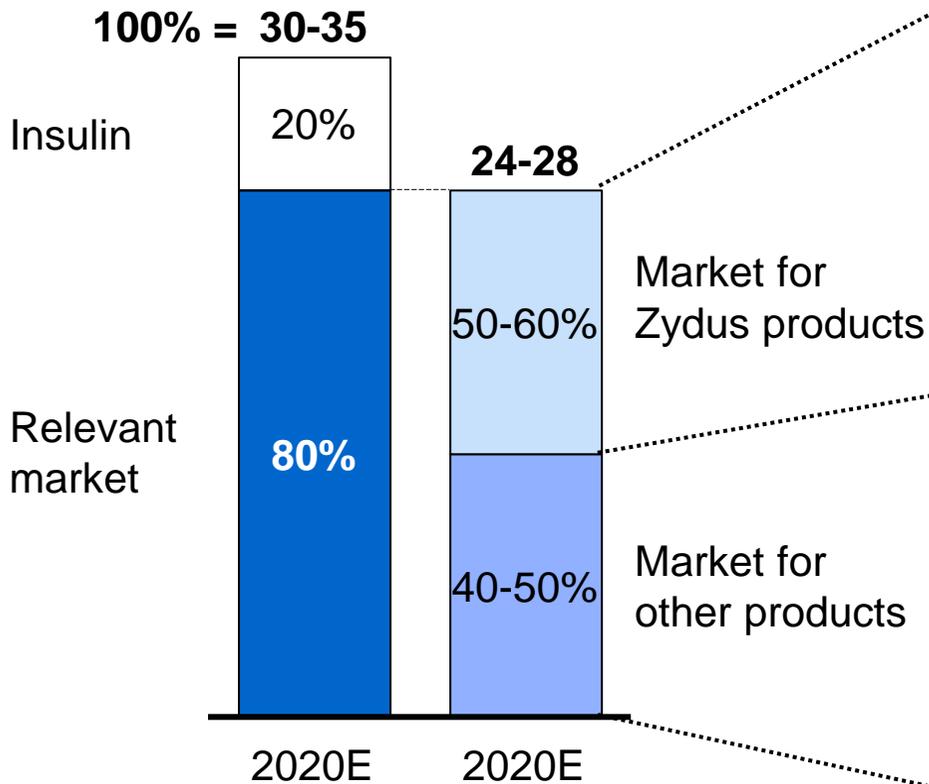
- State of the art biological manufacturing facilities in Ahmedabad
- Fully compliant to regulatory requirements of India, and other markets like US & EU
- One of the most **cost competitive** manufacturing facility to build and operate
- Best-in-class **process yields** providing most competitive Cost of Goods

## Capabilities

- More than **170 FTE's** dedicated to biologics product development and manufacturing
- Supported by **long-term** investments in infrastructure and skill-sets

# Today Zydus has one of the widest portfolios in the industry participating in 50-60% of the total biosimilars market

Global biosimilars market, USD billion



### Key molecules already in Zydus portfolio

- Avastin
- Herceptin
- Aranesp
- Humira
- Rituxan
- Enbrel

### Molecules not in Zydus portfolio due to late patent expiry or redundancy

- Avonex/Rebif
- Lucentis
- Omalizumab
- Actemra
- Eptacog alfa

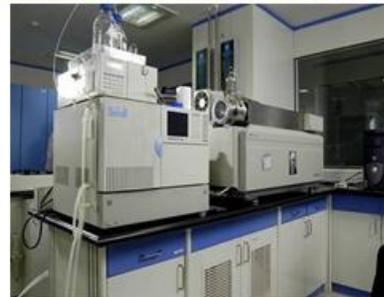
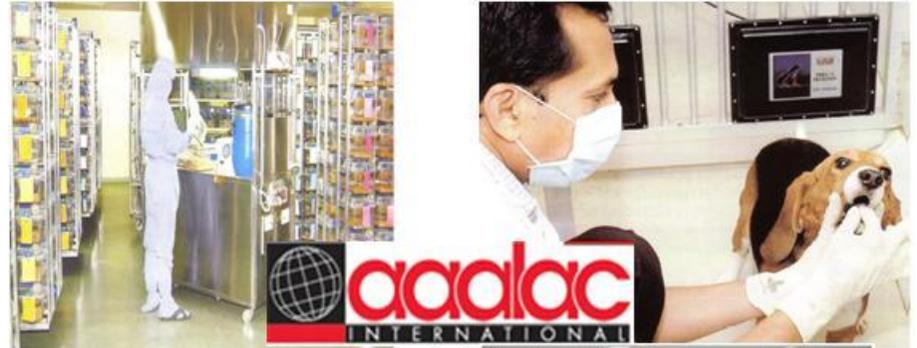
# Biologics Pipeline status

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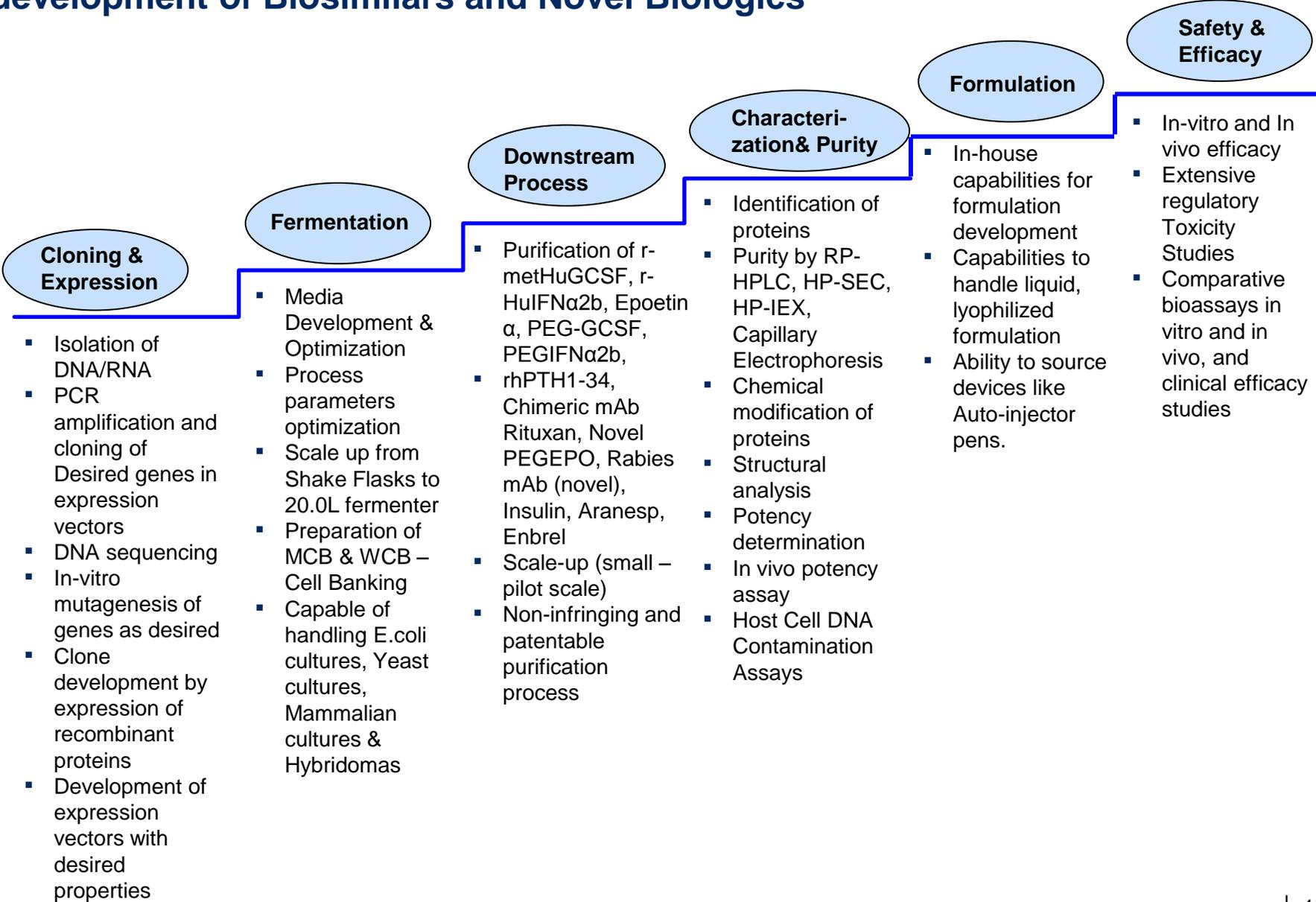
# Zydus has full set of R&D infrastructure, Capabilities and team on one site for Biologics development

## R&D facility

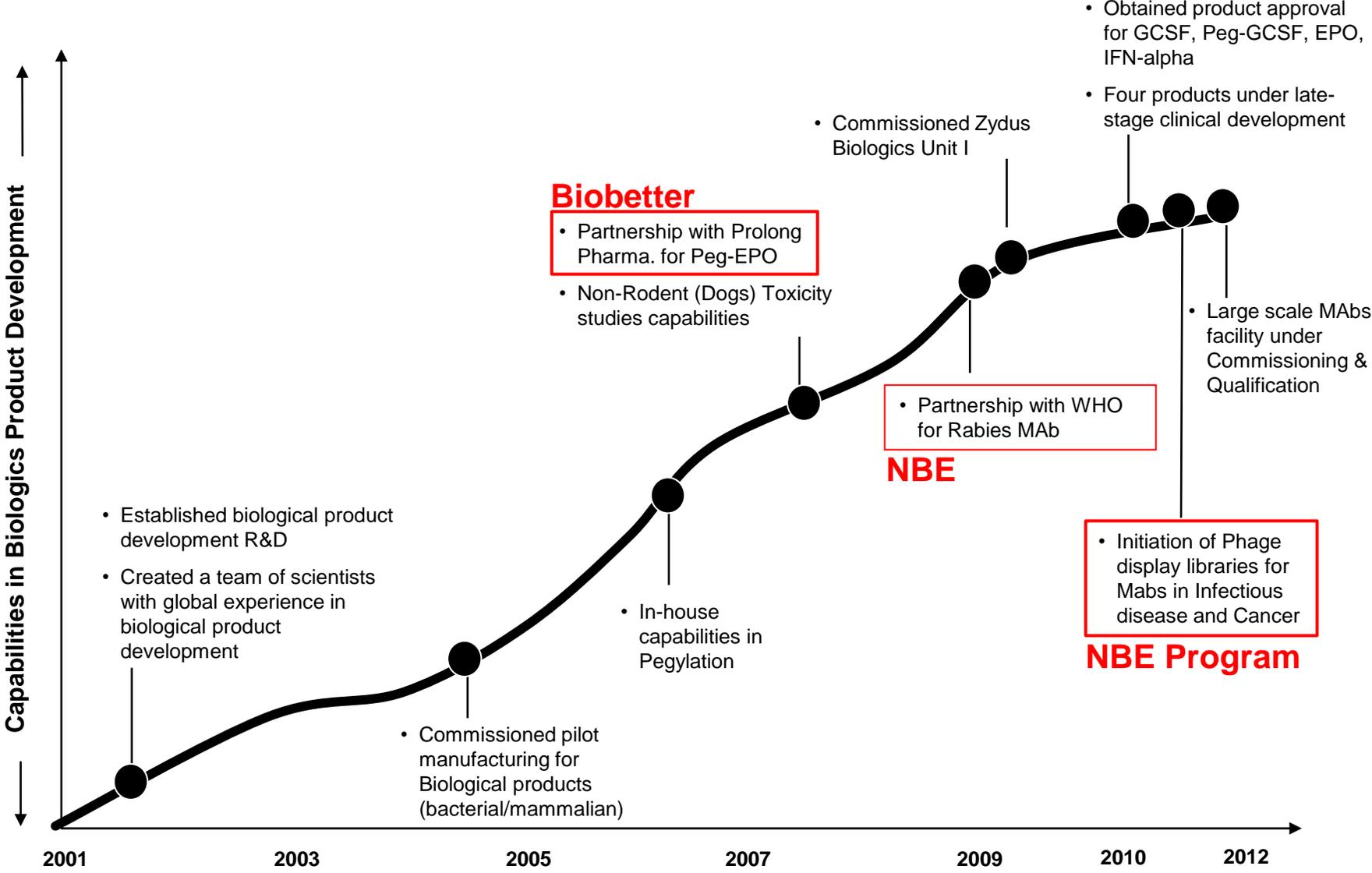
- 400+ Scientists
- GLP-compliant facility
- Completed pre-clinical efficacy and toxicology studies for several NCEs and multiple biosimilars
- Multiple INDs filed with DCGI and US FDA successfully. Capability to conduct all global toxicology studies for biosimilars
- Facilities for 15,000 small animals, 300 beagle dogs, & primate facility
- Small Scale Fermentation (20L to 200L), Purification, complete physicochemical characterization, potency assays



# Zydu's integrated in-house capabilities in product development allow rapid development of Biosimilars and Novel Biologics

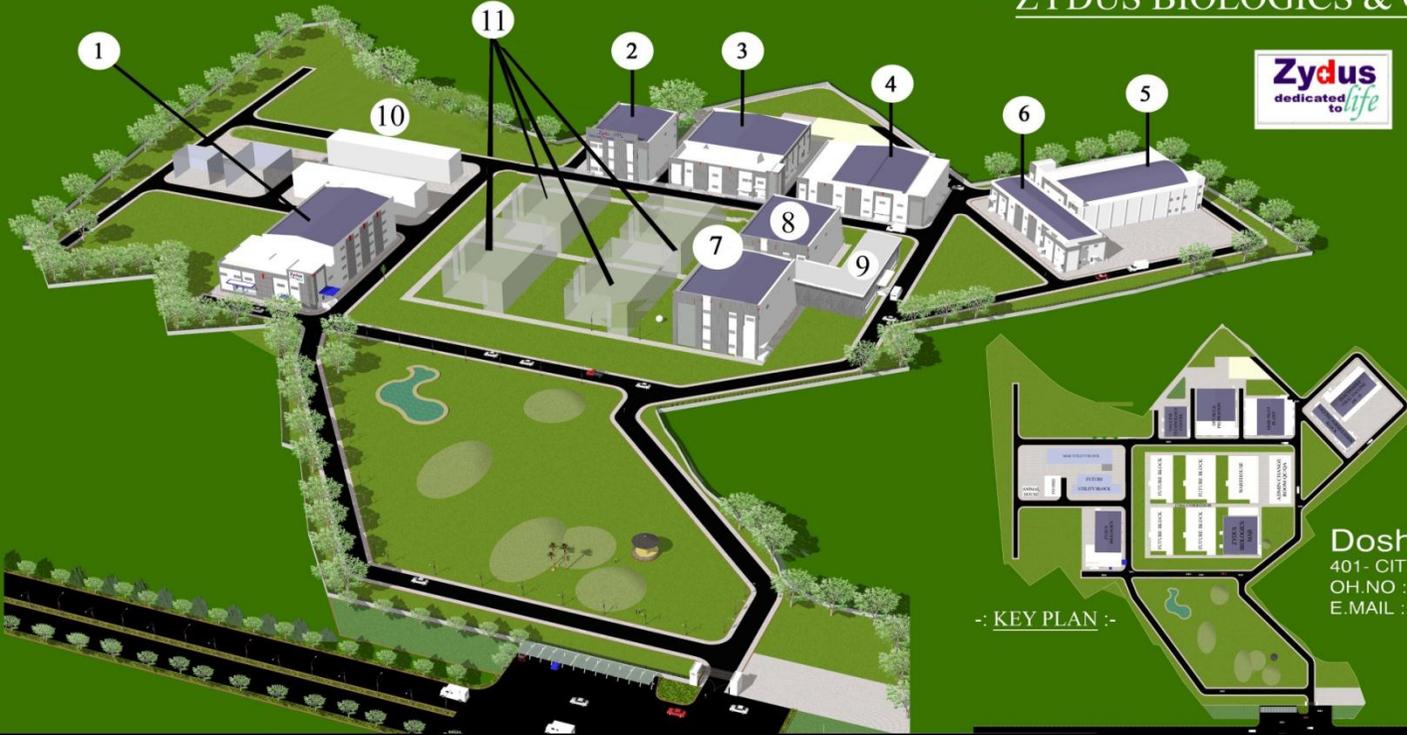


# The journey towards **Phase 2** has started...two INDs filed with DCGL...phage display program for monoclonal antibodies initiated



# ZyduS biologicals manufacturing park: Biologics & Vaccine manufacturing facilities

## \*\* ZYDUS BIOLOGICS & COMPLEX VIEW \*\*



- LEGEND :-**
- 01. ZYDUS BIOLOGICS
  - 02. ZYDUS VACCINE TECHNOLOGY CENTRE
  - 03. ZYDUS DPT BULK PREPRATION
  - 04. ZYDUS MMR PILOT PLANT
  - 05. ZYDUS INACTIVE VIRAL VACCINE DS - II
  - 06. ZYDUS VACCINE FORMULATION BLOCK
  - 07. ZYDUS BIOLOGICS MAB
  - 08. WARE HOUSE
  - 09. ADM BLOCK
  - 10. MAB UTILITY BLOCK



-: KEY PLAN :-

PROJECT CONSULTANT



**Doshi Consultants (P) Ltd.**  
 401- CITY CENTRE 570 M.G ROAD, INDORE-1 (M.P) INDIA.  
 OH.NO : + 91-731--25441457, 2545290 FAX : 2538443  
 E.MAIL : doshicon@sancharnet.in  
 doshicon@hotmail.com



01. ZYDUS BIOLOGICS



02. ZYDUS VACCINE TECHNOLOGY CENTRE



03. ZYDUS DPT BULK PREPRATION



04. ZYDUS MMR PILOT PLANT



05. ZYDUS INACTIVATED VIRAL VACCINE DS - II



06. ZYDUS VACCINE FORMULATION BLOCK



07. ZYDUS BIOLOGICS MAB

# 1 DS Manufacturing facility for recombinant therapeutics at Ahmedabad

## Key Features

- The facility was constructed and commissioned in a record time (11 months).
- Total land area of Zydus Biologics Unit I - 15000 m<sup>2</sup>; Total production area ~2500 m<sup>2</sup>.
- Designed to be a cGMP compliant multi-product facility
- Process validations completed and commercial production ongoing for manufacturing of G-CSF, PEGG-CSF, IFN alpha 2b, PEG IFN alpha 2b, and EPO.
- Trial batches of rPTH<sup>1-34</sup> are in progress.

## Zydus Biologics Unit I



## 2 DS Manufacturing facility for monoclonal antibodies at Ahmedabad

### Zydus Biologics Unit II

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#### Key Features

- The ground breaking of Unit II was done in April 2011. Commissioning ongoing. First Mab engineering batch in May 2013.
- Total land area of Zydus Biologics Unit II ~12000 m<sup>2</sup>; Total production area in a 7-level production building ~6900 m<sup>2</sup>.
- The state-of-art multiproduct facility is designed to be fully cGMP compliant.
- Largely dedicated to the production of monoclonal antibodies
- Two independent production streams, having 10 KL and 1 KL bioreactors



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# Zydus Cadila: Partnership Philosophy

## Alliance Creation & Management

- 1 Shared strategic intent with partners
- 2 Clear decision-making processes
- 3 Organizational architecture for ALLIANCE MANAGEMENT
- 4 Commitment to performance, driven by strong working culture & processes, performance measures/policies
- 5 Ethical business processes across various business functions

# Proven Track Record of Successful Partnerships

Deal Type	Company	Details
Joint Ventures	 Bayer Schering Pharma	50:50 JV for marketing product for Indian market focusing on women's healthcare, diagnostic imaging, cardiovascular diseases, anti-diabetic treatments, and oncology
		Contract manufacturing & marketing of injectable oncology products
		Contract manufacturing of APIs
		Development & Marketing agreement JV for new drug delivery system (NDDS) for an approved anti-cancer product for the global markets
Product in licensing for Indian market		In licensing agreement for Novolizer (MDPI) for respiratory segment
		In licensing agreement for 2 brands (Buscopan (anti spasmodic) and Dulcolax (laxative)) for marketing in India- # 1 brands in their molecule category
Product out licensing for E.M.	 <b>Abbott</b> A Promise for Life	Licensing and supply agreement for a portfolio of pharmaceutical products that Abbott will commercialize in 15 emerging markets, to further accelerate its emerging markets growth
Co-Development	 <b>Prolong Pharmaceuticals™</b>	Prolong brings the pegylation IP and Zydus brings the EPO and product development expertise to co-develop a 3 <sup>rd</sup> generation EPO, PEGEPO.
Worldwide Development	 <b>WHO</b>	WHO brought in the anti-Rabies hybridomas through US/EU academia and Zydus brought the product development expertise for a worldwide development of an anti-Rabies Mabs cocktail.

**Thank You**