



Zydus' Biologics Program



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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

10th largest

Generic co. In US in terms of prescriptions

\$ 3 bn +

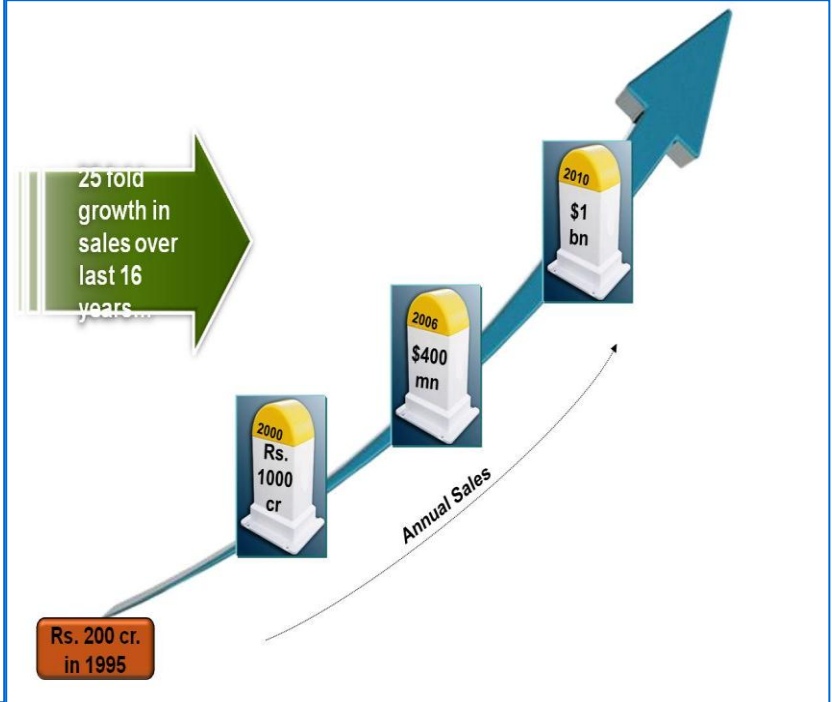
Market Cap

800+ patents

Filed globally

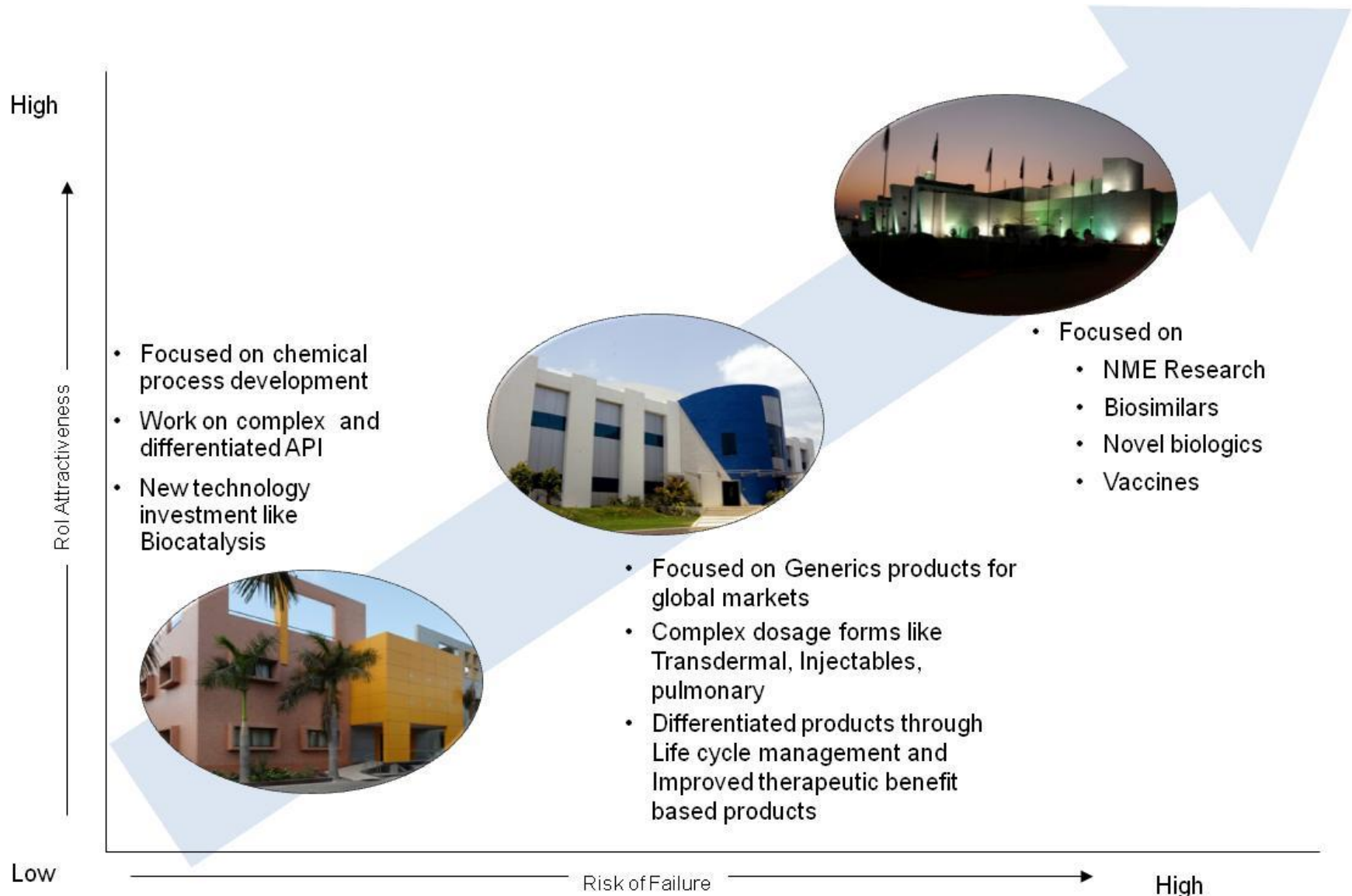
Vision Statement

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

Zyklus 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">State-of-the art research facilityCapability of target identification to pre-clinical research / early clinical development400+ scientists dedicated for NME research	Project	Target	Indication	Drug Discovery	Lead optimi-saiton	Pre-clinical Develop-ment	IND	Phase I	Phase II	Phase III	NDA
	ZYH1	PPAR- α,γ	Dyslipidemia								
	ZYH7	PPAR- α	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								

Zyklus 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

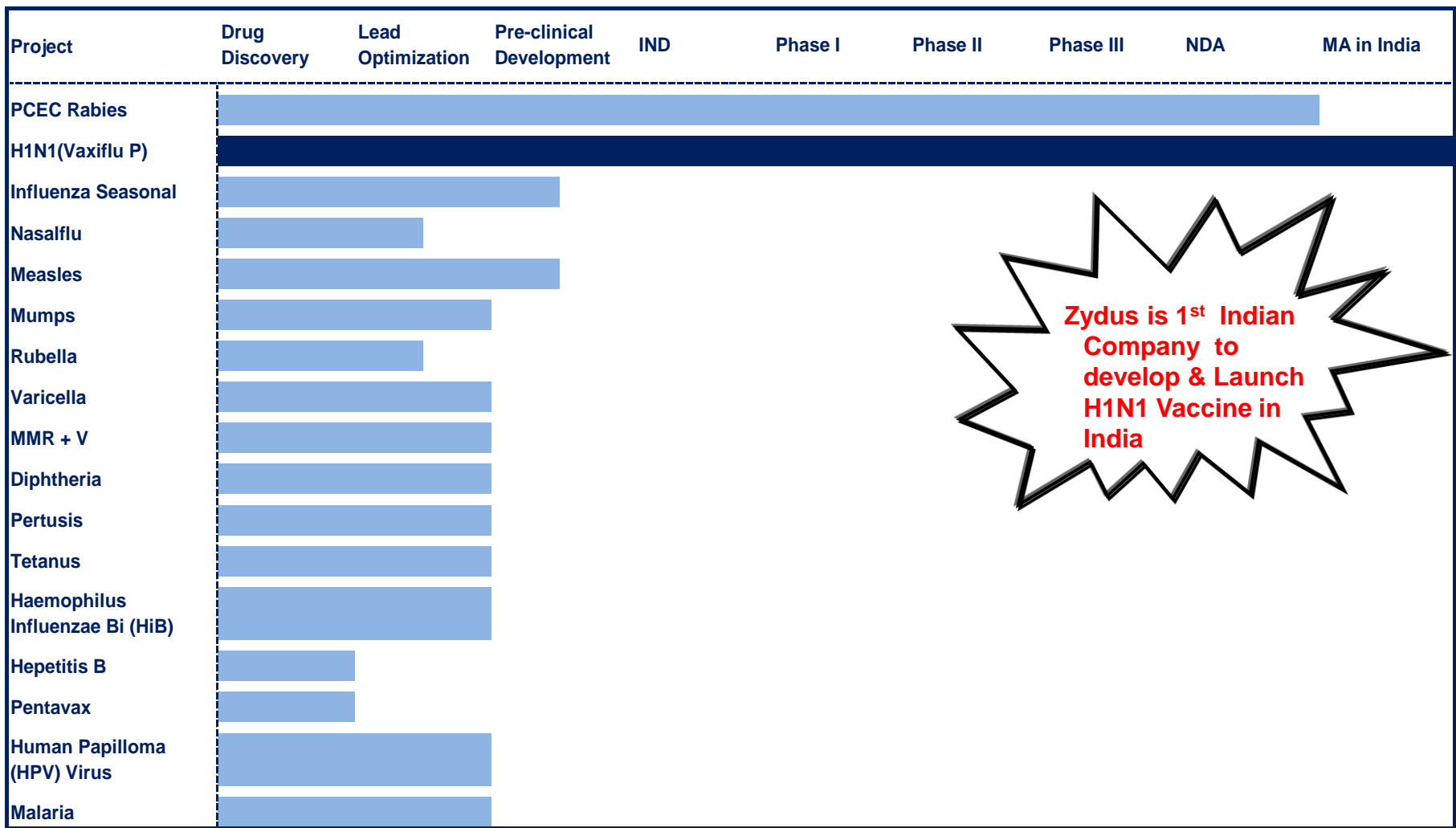
- Dedicated facility for product development and mfg.
- 170+ experienced scientists
- Strong pipeline: 17 biosimilars and 2 novel products
- Strong IP position either through own patent or non-infringing processes



Sr no	Product	Indication	Cloning	Process Dev.	Toxicology	Regulatory permission	Clinical Dev.	Indian Market Authorization
1	IFN-α- 2b	Infectious diseases	LAUNCHED (in India)					
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						
8	ZRC-3110	Inflammation						
9	IFN β 1b	Multiple sclerosis						
10	ZRC-3160	Inflammation/Oncology						
11	ZRC-3114	Oncology						
12	ZRC-3113	Oncology						
13	ZRC-3197	Inflammation						
14	ZRC-3189	Thrombolytic drug						
15	ZRC-3109	Fertility						
16	ZRC-3209	Fertility						
17	ZRC-3210	Fertility						
18	PEG EPO	Oncology/Nephrology						
19	Rabies Mabs Cktl	AntiRabies						

* Estimated brand sales

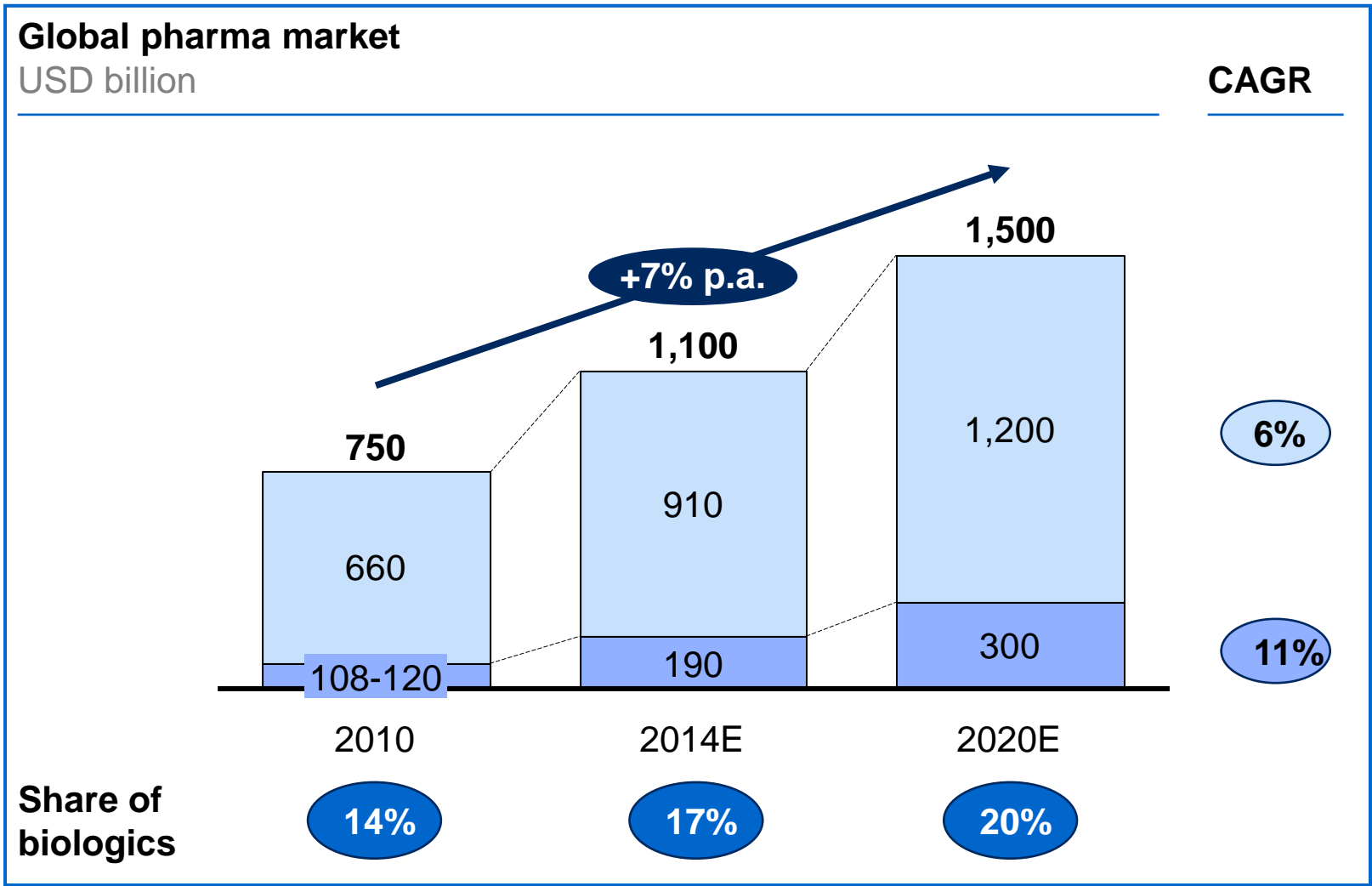
Vaccine Product Pipeline



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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

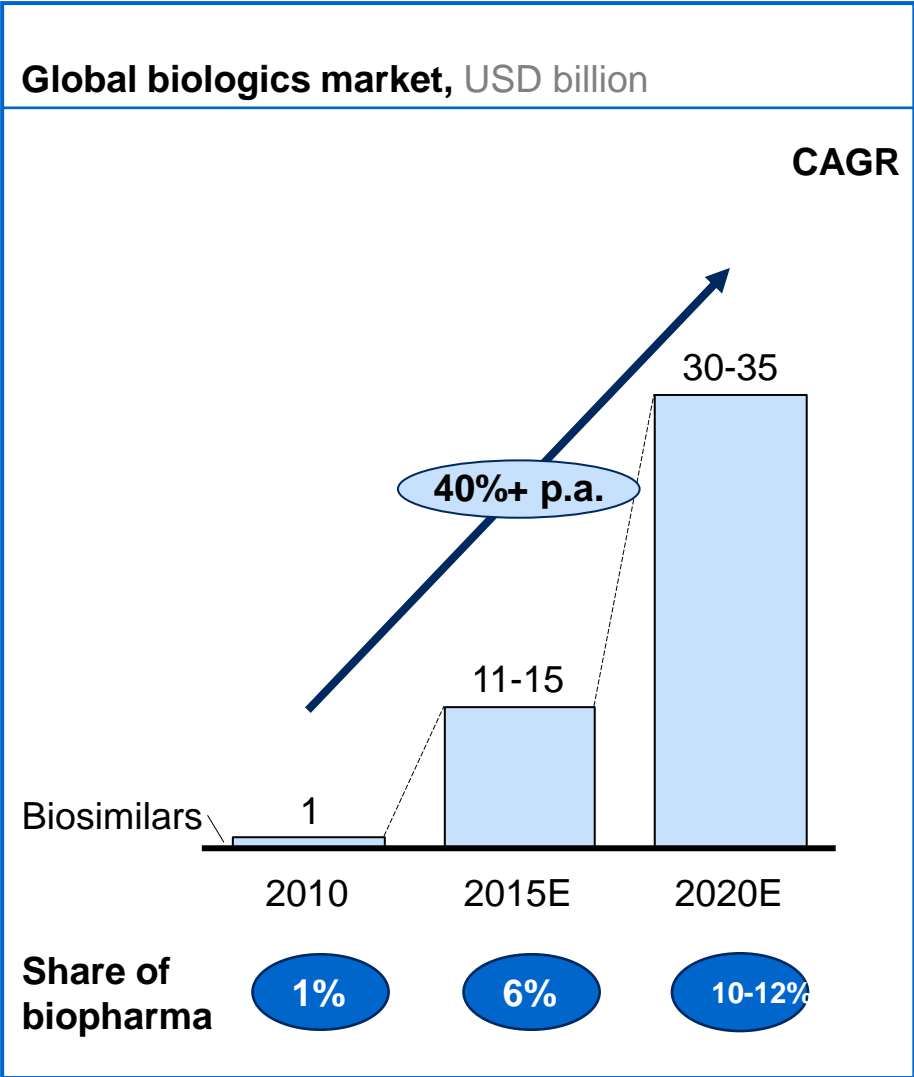
Opening of biosimilar regulatory pathway in US
- 2

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

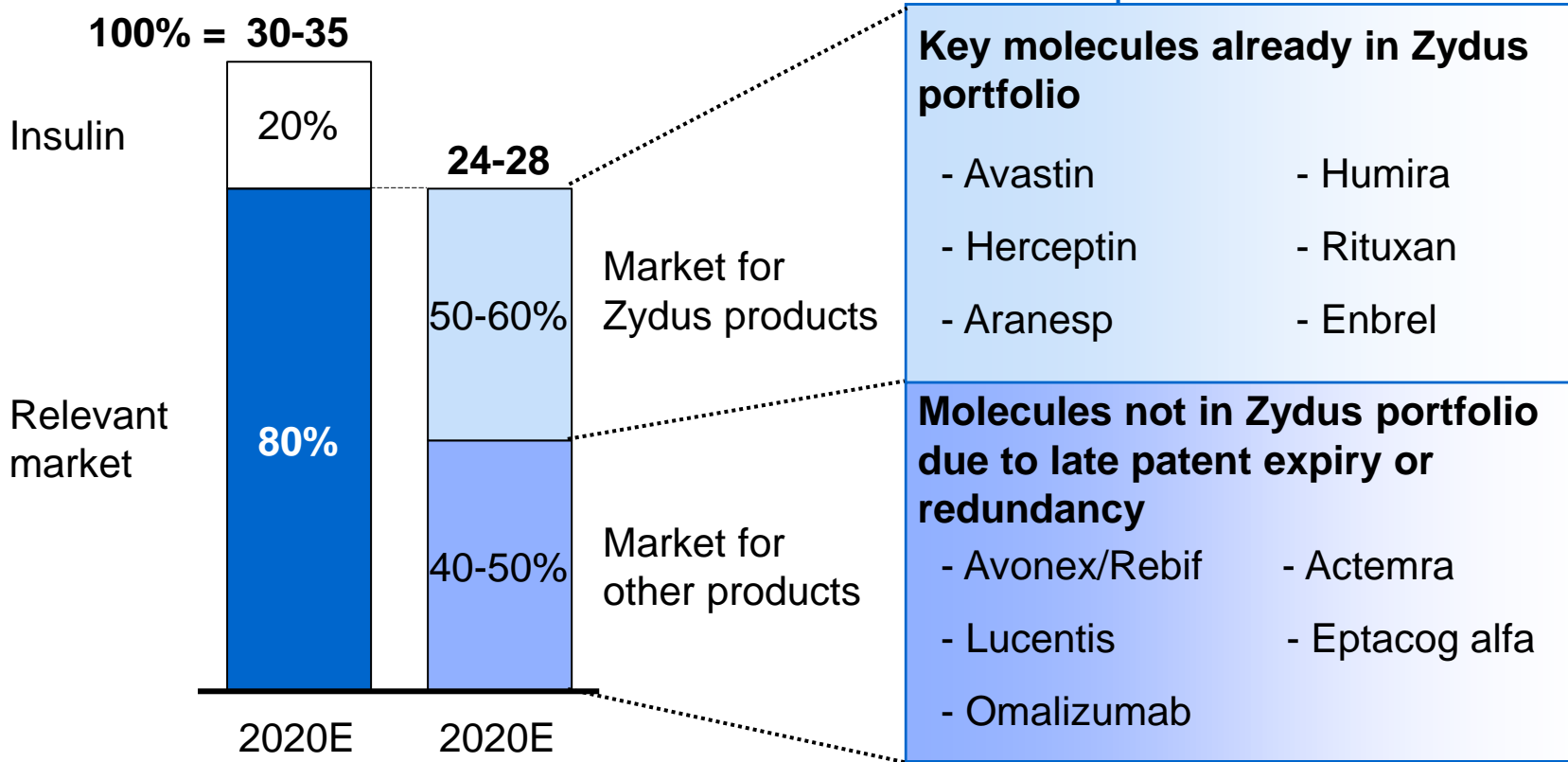
- State of the art biological manufacturing facilities in Ahmedabad
- Fully compliant to regulatory requirements of India, and other markets like US & EU
- One of the most **cost competitive** manufacturing facility to build and operate
- Best-in-class **process yields** providing most competitive Cost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



Biologics Pipeline status

Sr no	Product	Indication	Cloning	Process Dev.	Toxic ology	Regulatory permission	Clinical Dev.	Indian Market Authorization
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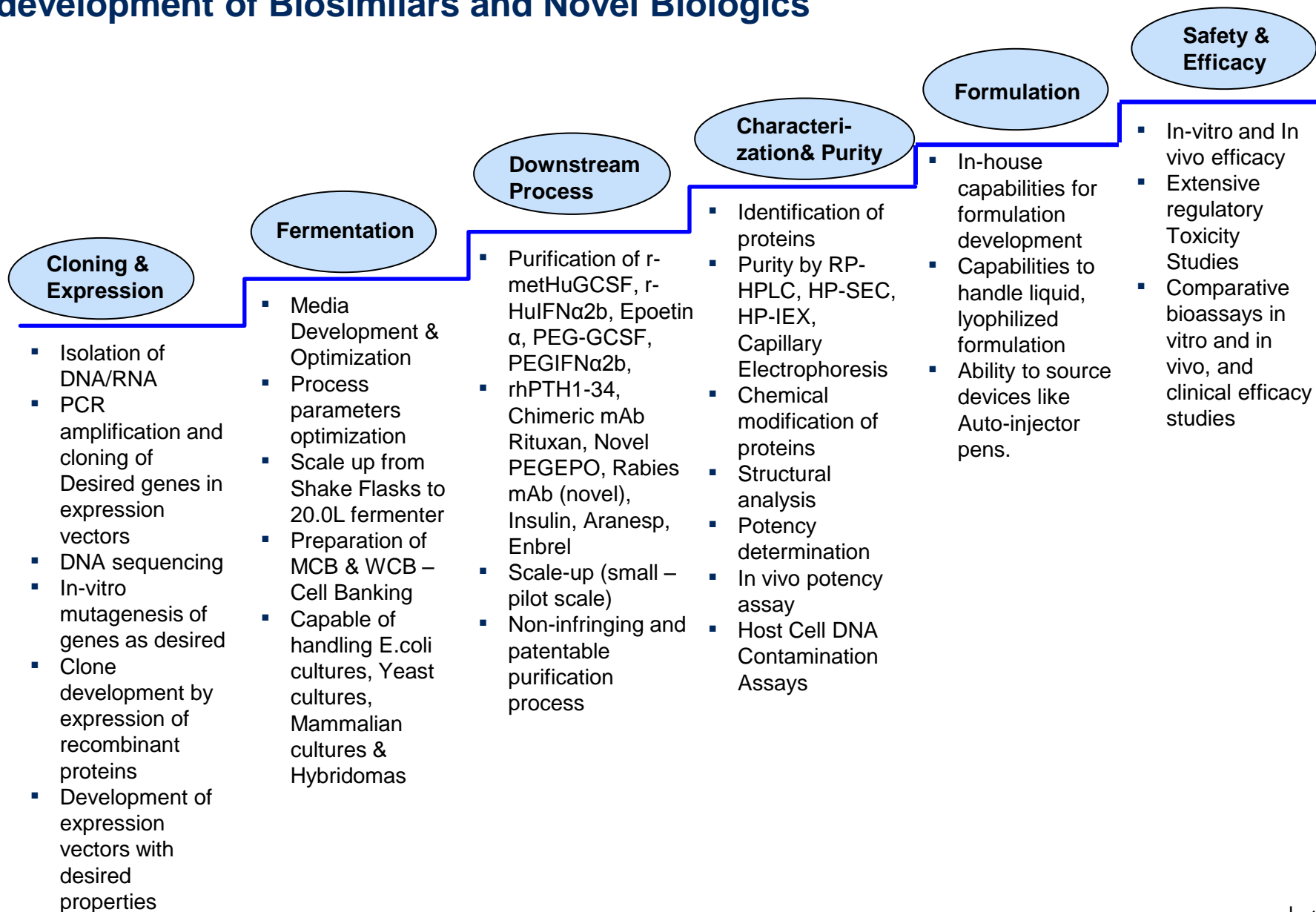
Zyklus has full set of R&D infrastructure, Capabilities and team on one site for Biologics development

R&D facility

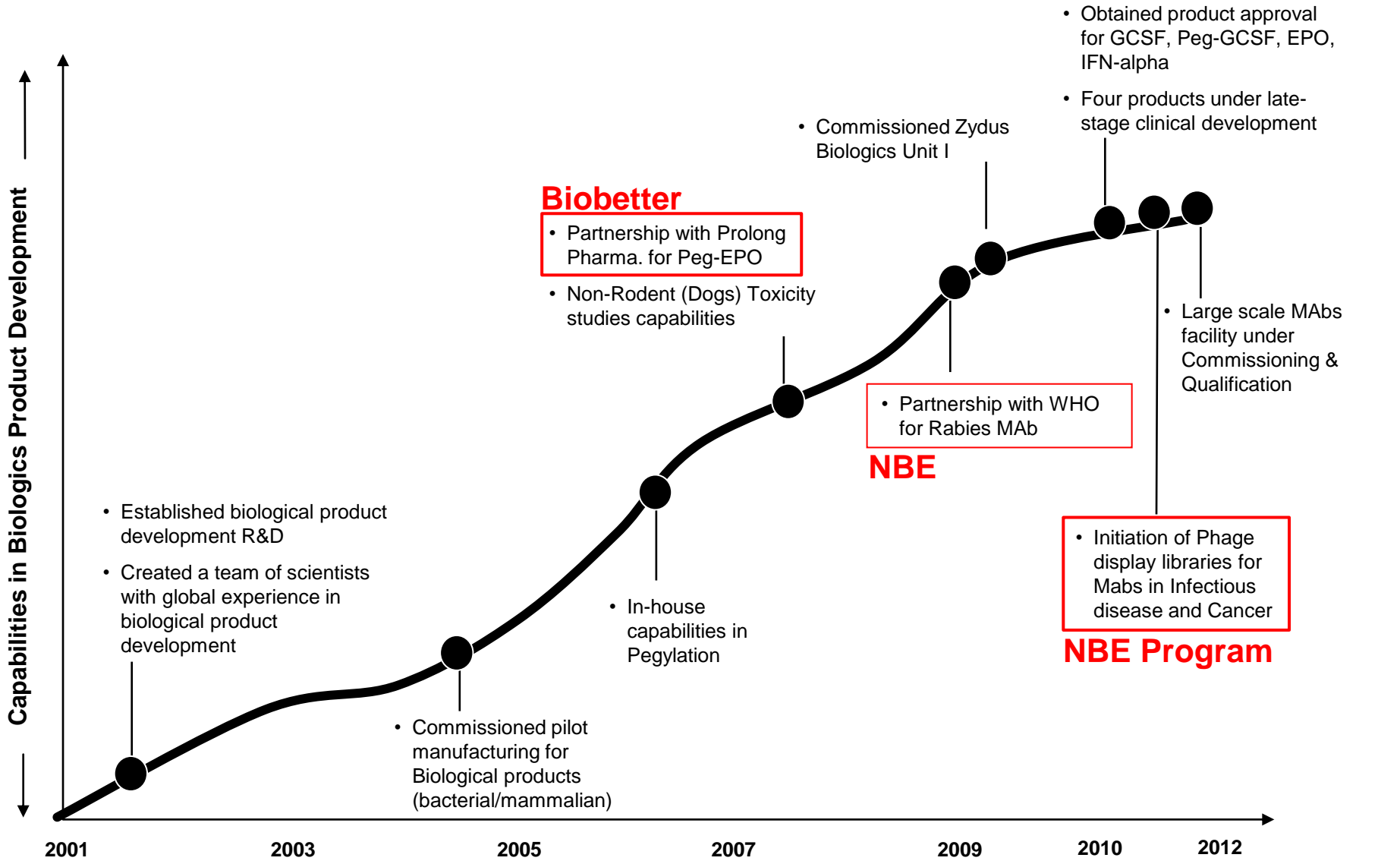
- 400+ Scientists
- GLP-compliant facility
- Completed pre-clinical efficacy and toxicology studies for several NCEs and multiple biosimilars
- Multiple INDs filed with DCGI and US FDA successfully. Capability to conduct all global toxicology studies for biosimilars
- Facilities for 15,000 small animals,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



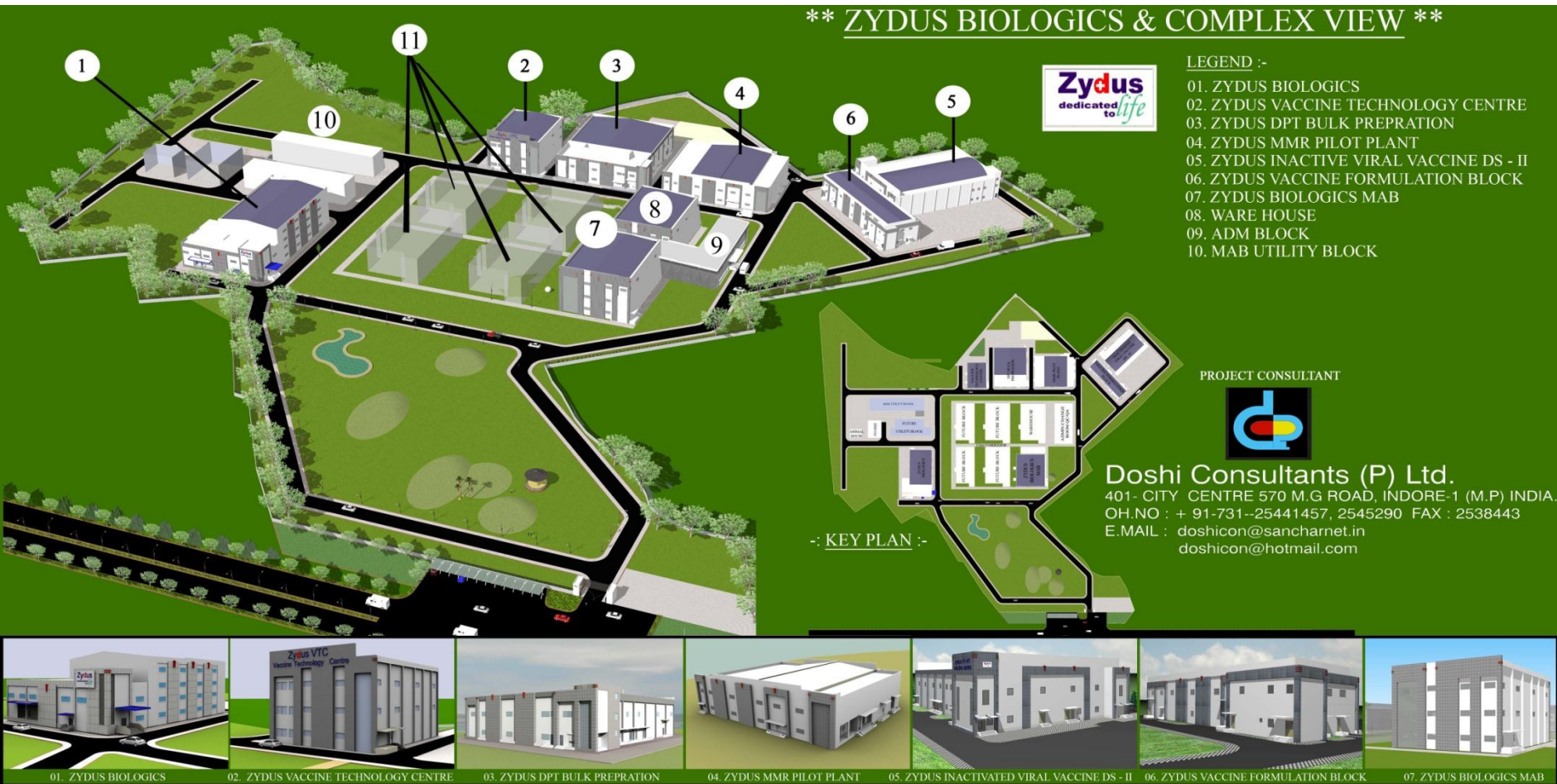
Zydu's integrated in-house capabilities in product development allow rapid development of Biosimilars and Novel Biologics



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



ZyduS biologicals manufacturing park: Biologics & Vaccine manufacturing facilities



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 m²; Total production area ~2500 m².
- 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 rPTH¹⁻³⁴ are in progress.

Zydus Biologics Unit I



2 DS Manufacturing facility for monoclonal antibodies at Ahmedabad

Zyduz Biologics Unit II

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 Zyduz Biologics Unit II ~12000 m²; Total production area in a 7-level production building ~6900 m².
- 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.	 Abbott 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		Prolong brings the pegylation IP and Zydus brings the EPO and product development expertise to co-develop a 3 rd generation EPO, PEGEPO.
Worldwide Development	 WHO	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