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#### **SAFE HARBOR**



Certain statements in this presentation concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements. Important factors that could cause actual results to differ materially from our expectations include, among others, general economic and business conditions in India, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian biotechnology and pharmaceuticals industries, changes in political conditions in India, and changes in the foreign exchange control regulations in India. Neither our company, nor our directors, nor any of their respective affiliates have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition. Statements on strategy or on direction of policy should not be construed as events which require prior notification to India's regulatory authorities. Such events will crystallize only once full regulatory steps have been taken in India.



## **INTRODUCTION**

## **PRODUCTS AND SERVICES**

## **RE-CALIBRATING INDUSTRY**

## **STRATEGY AND R&D PIPELINE**



## INTRODUCTION

**PRODUCTS AND SERVICES** 

**RE-CALIBRATING INDUSTRY** 

STRATEGY AND R&D PIPELINE



Biocon is an emerging, global Bio-pharmaceutical enterprise that is focused on developing affordable products and services for patients, partners and healthcare systems across the world.

#### Biocon is committed to:

- Reducing therapy costs of chronic diseases. (Diabetes, cancer and immune-mediated diseases).
- Research and marketing partnerships that provide global access.
- Leveraging the India cost advantage to deliver high value, licensable R&D assets.

## **SNAPSHOT**









Revenue	USD 512 mn
Net profit	USD 62 mn
Market capitalisation	USD 1.3 bn
Incorporation	1978
Initial public offering	2004 (Listed on BSE & NSE, India)
Patent Portfolio	182 patents granted
Headquarters	Bangalore, India
Global reach	~ 75 countries
Human Resource	4500 employees
	(10% PhDs)

#### **BUSINESS STRUCTURE**







#### **UNIQUE BIO-PHARMA BUSINESS MODEL**



#### **Products + Research Services**

Global scale USFDAcompliant biomanufacturing of Statins, Immunosuppressants, Insulins, MAbs. Therapeutic areas:
Diabetes; Oncology;
Immune-mediated
diseases.

Focus on biosimilars: Insulins, MAbs.

Self-financed, riskbalanced R&D pipeline; spend at 8% of sales.

Research alliances
with global
companies: Mylan;
Amylin; BMS.

Growing presence in emerging markets through alliances in LATAM, MENA, ASIA & CIS.

- Asia's largest Insulin manufacturer.
- Among the world's largest producers of Statins and Immuno-suppressants.
- 2 novel drugs in late-stage clinical trials: Oral Insulin; Anti-CD6 MAb.



### **INTRODUCTION**

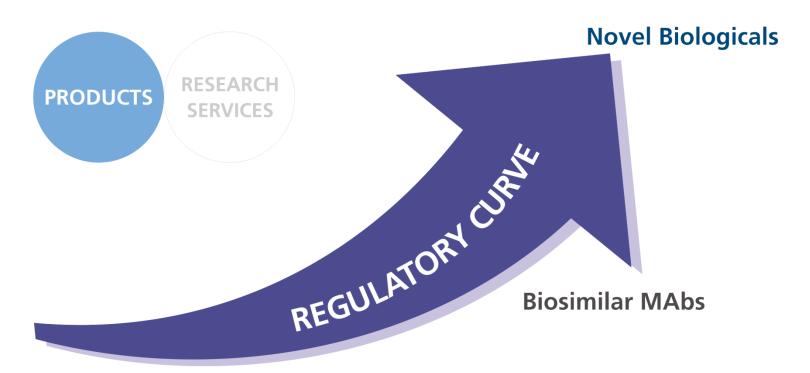
## **PRODUCTS AND SERVICES**

**RE-CALIBRATING INDUSTRY** 

STRATEGY AND R&D PIPELINE

#### **BALANCED PORTFOLIO: PRODUCTS**





Generic APIs
Statins
Immunosuppressants

Biosimilar Proteins Insulin Insulin Analogues

#### **BALANCED PORTFOLIO: END-TO-END SERVICES**





**GLOBAL CLIENT BASE** 

Syngene

**Pre-Clinical Discovery Services** 

Clinigene

**Clinical Research Services** 

Estimated cost savings of 50-60% for clinical trials done in India\*

Global R&D outsourcing reached 21% of total spend in 2009 (<1% in 1997)

**36%** Revenue CAGR in last 5 years

\* Source: PharmaBiz, visiongain 2006



**INTRODUCTION** 

**PRODUCTS AND SERVICES** 

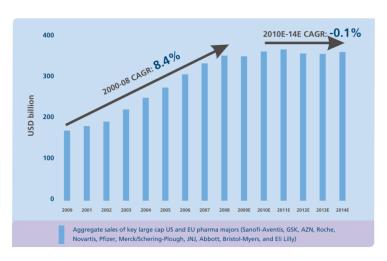
## **RE-CALIBRATING INDUSTRY**

STRATEGY AND R&D PIPELINE

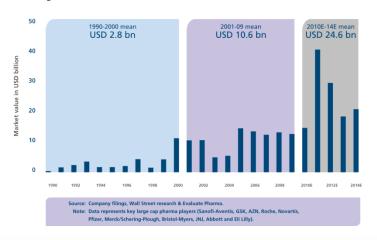
#### **CHALLENGING TIMES AHEAD**



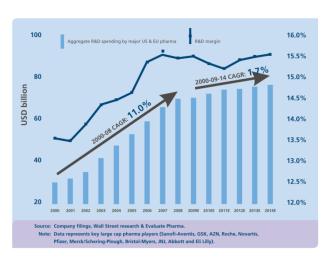
#### **Stagnating Sales**



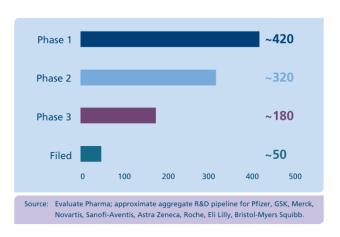
#### **Unprecedented Patent Cliff**



#### **Declining Research ROI**

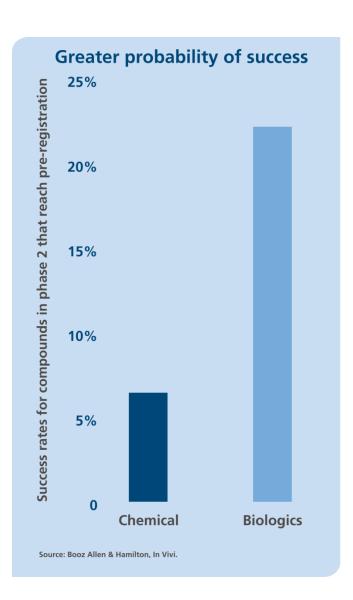


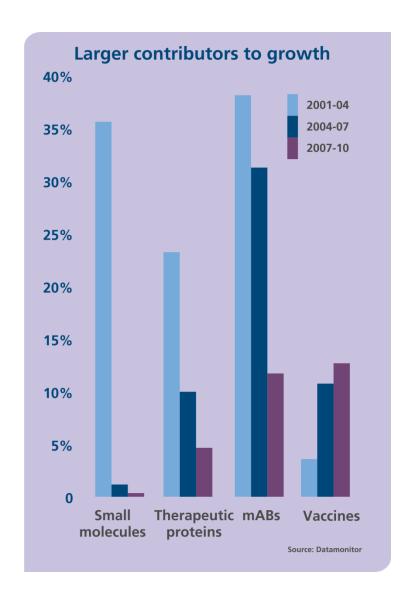
#### **Shrinking Late-stage R&D Assets**



#### **BIOLOGICS EXPECTED TO RESTORE GROWTH**

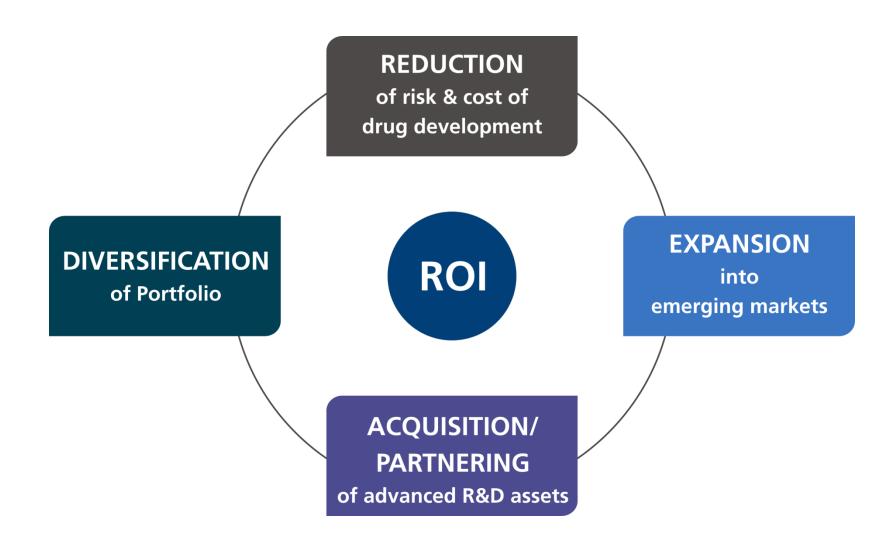






#### THE BIO-PHARMA INDUSTRY IS RE-CALIBRATING







### **INTRODUCTION**

### **PRODUCTS AND SERVICES**

## **RE-CALIBRATING INDUSTRY**

## STRATEGY AND R&D PIPELINE

## **GROWTH STRATEGY ALIGNING WITH EMERGING TRENDS**



**REDUCTION** 

of risk & cost of drug development

Leveraging India Advantage -Research Services

**EXPANSION** 

into merging markets

Biosimilar Insulins & MAbs

DIVERSIFICATION of Portfolio



Expanding in
India &
Emerging Markets

Partnering & Licensing R&D programs

ACQUISITION/
PARTNERING
of advanced R&D assets

## **GLOBAL ALLIANCES:** PARTNERED RESEARCH, CO-DEVELOPMENT



**BIOSIMILARS** Mylan **Oncology, Auto-Immune Diseases NOVEL PEPTIDE Amylin Diabetes BIO BETTER MAbs Vaccinex** Oncology **IMMUNOCONJUGATED MAbs IATRICa** Oncology SUPPLY OF NOVEL API **Optimer** 

First-in-class anti-infective (C.difficile)

## **HIGH POTENTIAL PRODUCT PIPELINE**



Product	Areas	Names	Discovery	Preclinical	Phase I	Phase II	Phase III	Market
	Diabetes	Oral Insulin						
	Oncology/ Inflammation /auto immune Oncology	Anti-CD6  Targeted Immunoconjugates						
	Oncology	Anti-CD20						
	Diabetes	Peptide Hybrid						
	Oncology	Anti-EGFR						
	Oncology/ Immunology	Biosimilar MAbs						
Biosimilars	Diabetes	Insulin & Analogues - Lispro, Aspart						
Diodillilard	Diabetes	rH Insulin, Glargine						
	Oncology	GCSF, EPO						

## 2 novel drugs in late stage clinical trials

In development
In market

Oral Insulin: Potentially addressing 300 million diabetes patients worldwide

Anti-CD6: Initiated Phase 3 Human clinical trial for Psoriasis which affects 3% of global population

#### **LEAD PROGRAM: ORAL INSULIN IN-105**



## **Conjugated peptide**

Lower immunogenicity and mitogenicity.

Comparable safety and good clearance profile.

Metabolically equivalent.

## **Established oral delivery**



Stable tablet formulation.

Four phase 1 studies completed.

A phase 2 study shows IN-105 absorption is proportional to dose administered.

#### **Monotherapy**

Combination therapy with metformin, sulfonylurea, PPAR agonists, DPP4i, etc

Pre-meal insulin in combination with basal insulins

# Currently undergoing Phase 3 trials in India as an add-on therapy to metformin

6-month double-blind placebo-controlled trials in type 2 diabetes patients who are poorly controlled on metformin and primary endpoint as HbA1c control.

To initiate Phase 1 studies under US IND shortly

#### **Anti-CD6 MAb: T1h**



#### Target: CD6

is a type I cell membrane glycoprotein belonging to the scavenger receptor cysteine-rich (SRCR) superfamily group B.

## CD6 is predominantly expressed by T cells & a B cell subset.

#### CD6 binds ALCAM

(activated leukocyte cell adhesion molecule) which is expressed on

- Activated T cells, B cells & Monocytes.
- Skin fibroblasts, keratinocytes & rheumatoid arthritis synovium.

## Phase 3 clinical trials for Psoriasis has been initiated.

Planned

Phase 2/3 double blind trial in RA. Phase 1/2 double blind trial in MS.

#### 0.4mg/kg once every 4 weeks



Day 1

Day 29

#### 0.8 mg/kg once every 4 weeks





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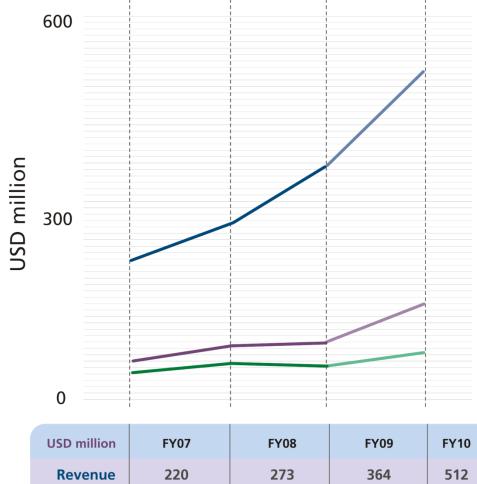
### **PRODUCTS AND SERVICES**

## **RE-CALIBRATING INDUSTRY**

STRATEGY AND R&D PIPELINE

## **REVENUE, PROFIT**



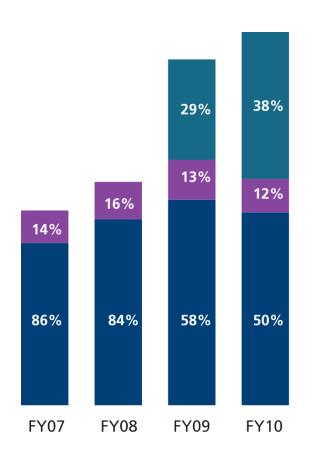


FY10	
Revenue growth	44%
EBITDA margin	21%
Net margin	12%

USD million	FY07	FY08	FY09	FY10
Revenue	220	273	364	512
EBITDA	63	83	84	108
Net profit	44	56	52	62

### **REVENUE MIX: GROUP**





**USD** million

	FY07	FY08	FY09	FY10
Biopharma Products	190	229	211	258
Research Services	30	44	49	60
Axicorp	-	-	104	194
Grand Total	220	273	364	512

#### **TAKEAWAYS**





Global-scale USFDA-compliant bio-manufacturing



Strong Biosimilars portfolio: Insulins, MAbs



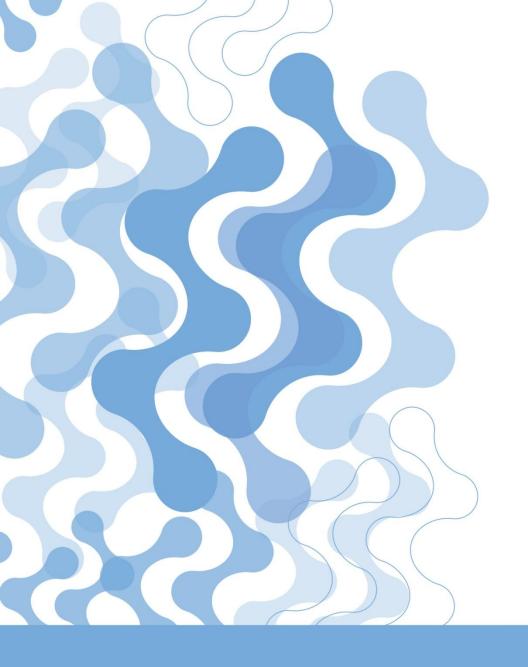
High potential research pipeline through global partnerships



Self-funded research and manufacturing provides greater financial leverage



**Expand global footprint through marketing** alliances





Thank You