



## **Investor Presentation**

January 2011

## Safe Harbor



Certain statements in this presentation concerning our future growth prospects are forwardlooking 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.



Biocon is an emerging global biopharmaceutical enterprise with products and research services that span the entire drug value chain:

> pre-clinical discovery to clinical development through to commercialization.

## Snapshot



Incorporation Initial public offering Patent portfolio Headquarters Global reach Workforce Market capitalisation

### FY10 Earnings

Revenue Net profit

### 9-mo FY11 Earnings

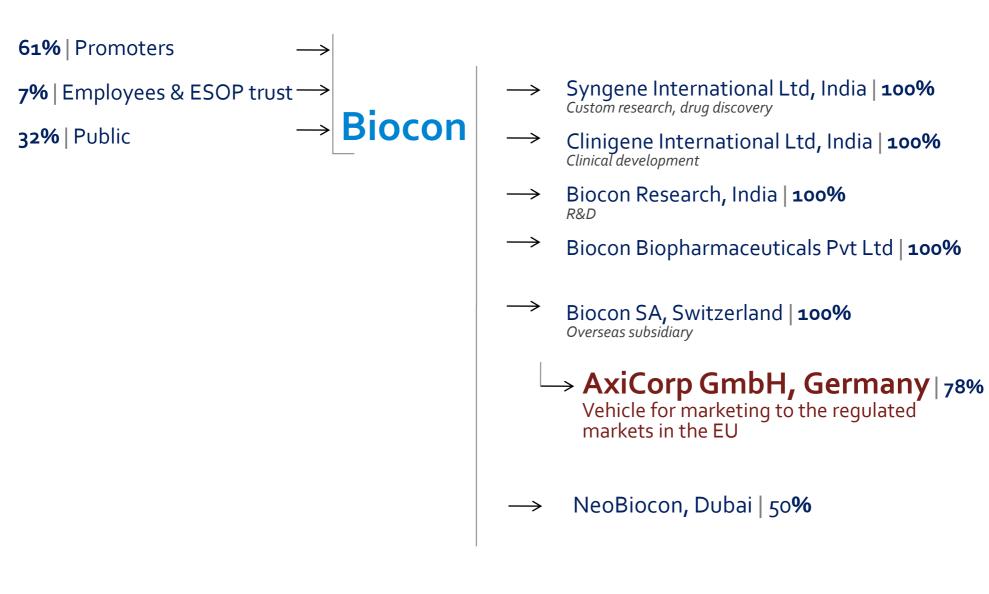
Revenue Net profit 1978 2004 (BSE &NSE (India) 182 patents granted Bangalore, India ~ 75 countries 5300+ employees (10% PhDs) ~INR 7500+ crore | USD 1.6 bn

INR 2405 crore | USD 512 mn INR 293 crore | USD 62 mn

INR 2,097 crore | USD 456 mn INR 267 crore | USD 58 mn

## Business structure, holdings





## Unique bio-pharma business model



## **Products + Research Services**

Global scale USFDA-compliant bio-manufacturing of statins, immuno-suppressants, insulins, MAbs. Therapeutic areas: Diabetes; Oncology; Immune-mediated diseases.

Focus on biosimilars: Insulins, MAbs. Self-financed risk-balanced R&D pipeline; spend at approx 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.

## Capabilities – manufacturing



## Biocon

### **Active ingredients**

- → Classic fermentation
- → Microbial fermentation\*
- -> Mammalian fermentation
- → Synthetic chemistry

### Aseptic – fill & finish

→ Cartridges, Vials (Lyophilized), PFS

- \* Asia's largest manufacturer of *Pichiα*-based products.
- \* Commercialized the world's first *Pichia*-derived r-human insulin.

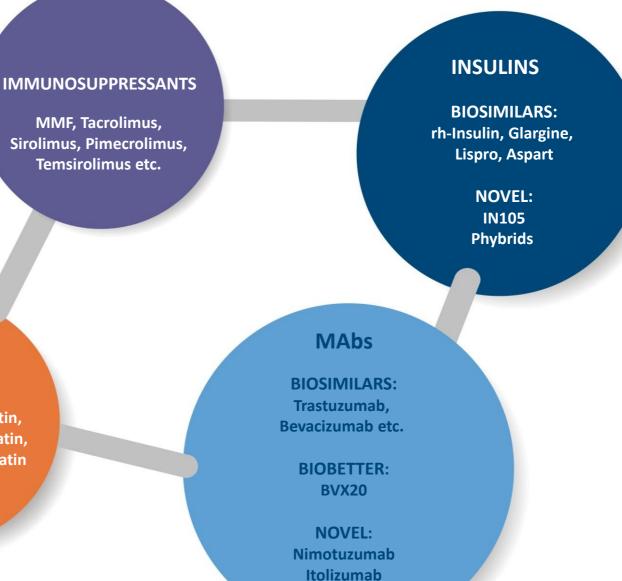
Asia's largest insulin plant.

The first plant of its kind in India for recombinant therapeutic proteins.

US FDA and EU GMP approved.

## Product Pipeline - A Portfolio Approach



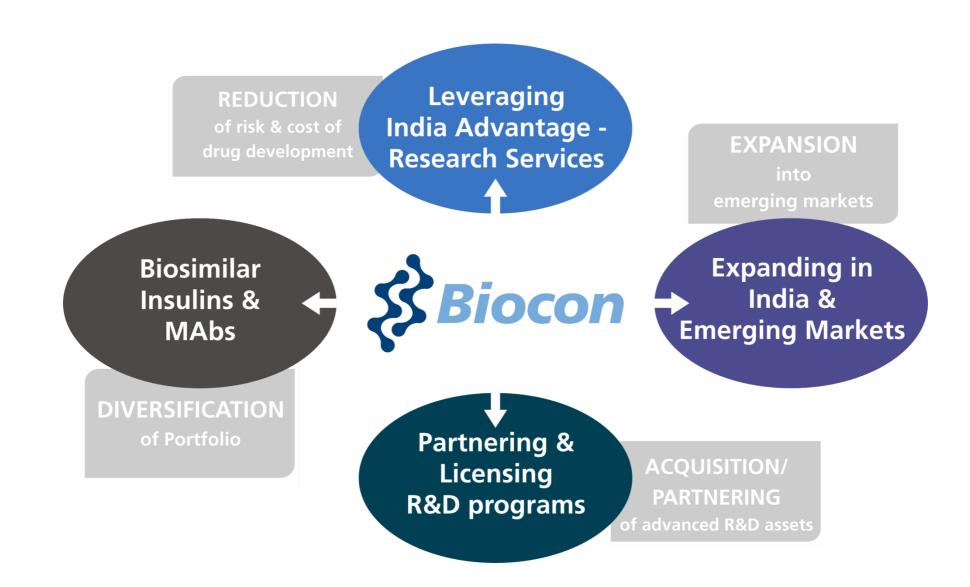


**Conjugated MAbs** 

#### **STATINS**

Lovastatin, Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, Fluvastatin etc.

## Our growth strategy aligns with emerging trends



## Emerging markets offer great potential



### Rising GDP | Improving health care access | Stronger regulation



Biocon is an early mover into many of these markets....



• Current EM ~\$1.5 billion

Biosimilar Insulins

- 5 year CAGR 15%
- EM estimated to be a \$5 billion Insulins market by 2020
- Emerging Markets account for 70% of world's Diabetic Population
- Lower regulatory barriers offer faster market entry

Biosimilar mAbs

- Current market size estimated at \$1.5 billion
- Estimated to be a \$2.6 billion market by 2016

• 50% of European prescriptions, 75% of US prescriptions

Generics

- Generics growth outlook robust over next 6 years (\$185 bn patent cliff)
- 3-year CAGR (2007-10) at 11%. Global Pharma at 5.5% CAGR
- APAC accounts for 16% of \$124 bn generics mkt with fastest growth

## India focus - Branded Formulations business



## **Brand folio**



INSUGEN<sup>®</sup> | BLISTO<sup>™</sup> | PIODART<sup>®</sup> | TriGPM<sup>™</sup>-1/2 GMAB<sup>™</sup> Plus | ZUKER-MF<sup>™</sup> | BASALOG<sup>™</sup> GABIL<sup>™</sup> | OLISAT<sup>™</sup> | METADOZE-IPR<sup>®</sup>

BIOMAb EGFR® | Abraxane® ERYPROsafe™ | NUFILsafe™



ERYPRO<sup>™</sup> | CYCLOPHIL ME<sup>™</sup> | TACROGRAF<sup>™</sup> RENODAPT<sup>™</sup> | RAPACAN<sup>™</sup> | CeRACaL<sup>™</sup> BIOSAVE | NARITA<sup>+</sup>



STATIX® | TELMISAT™ | ZIGPRIL® THINRIN™ | ZARGO® | CLASPRIN® CLOTIDE™ | DYNALIX® | ACTIBLOK™ - IPR MYOKINASE™ | BESTOR® | BRADIA™

**36** key brands across four therapeutic segments Launched two divisions Q2 FY11 – Immunotherapy and Comprehensive Care

Field force – 900



## High Potential Novel Pipeline

Product	Areas	Names	Discovery	Preclinical	Phase I	Phase II	Phase III	Market
	Diabetes	IN105 (Oral Insulin)					*	
	Oncology / Auto immune	Itolizumab (Anti CD6 mAb)					*	,
Novel Molecules	Oncology	Nimotuzumab (Anti EGFR mAb)						
	Oncology	BVX 20 (Anti CD20 mAb						
	Diabetes	Hybrid Peptide						
	Oncology	Fusion mAbs (Tumour Vaccines)						

\* Proof of Concept Phase III trials

## The India Advantage - Research Services



## Syngene

## Preclinical, drug R&D

Chemistry services

- → Synthetic chemistry
- → Medicinal chemistry
- → Process R&D
- → Polymer chemistry
- → Analytical R&D
- → Custom manufacturing

Biology, biologics services

- → Early biology
- $\rightarrow$  Preclinical
- → Biologics/custom manufacturing

Pharmaceutical services

- → Formulation development
- Regulatory consulting and support

Long term contract with Bristol-Myers Squibb. Ongoing collaborations with 60 companies worldwide. Collaborations with 7 of global big pharma's top 10.

## The India Advantage - Research Services



## Clinigene

- → Clinical trials management
- → Clinical development
- → Central lab
- → Clinical data management
- → Bio-analytical research lab
- $\rightarrow$  Human pharmacology unit
- → Regulatory services

Conducted studies involving up to 1500 subjects.

Vast experience in oncology, diabetes, osteoporosis segments.

- 100% approval from regulators with clinical trial applications.
- Fixed fee, time + material contracts and full-time equivalent agreements.

## **Clinical Research**

India's first CAP, NABL accredited clinical research labs.

ISO 15189:2003 accredited for quality and competence.

## Research Services: Aligning With Global Trends



### **Dynamic and Favorable Macro Environment for Research Services**

Externalization a key driver as Pharma & Biotech R&D is reinventing itself

Move from component to integrated programs

**Chemistry to Biologics** 

**FTE to Preferred Supplier to Strategic Development Partner** 

**Cost/time productivity arbitrage to innovation and value addition** 

**Expanding Biologics pipelines within Big Pharma far exceeding internal capacity** 

**BIOLOGICS:** Constitute >25% of drug pipelines. In-licensing from small Biotechs accounts for 35% of Biologics in development.



### Syngene / Clinigene well placed to address these opportunities

Integrated Platform offering end-to-end solutions for NCE & NBE

Increasing focus on long term strategic partnerships vs. transaction based model

**Development capabilities for biologics include scale-up & bioanalytics** 

Flexible service models including FTE/FFS, Co-development and Risk Sharing

Strong infrastructure in early clinical development and translational medicine

Clinical experience in novel Biologics supported by Phase I unit

BBRC: A new paradigm in externalized R&D pioneered by BMS at Syngene. A dedicated, integrated R&D hub pursuing pipeline development with 450 researchers.



DISEASE	PRODUCTS	CATEGORY	PARTNER
DIABETES	INSULIN + ANALOGS	BIOSIMILAR	PFIZER
DIABETES	PHYBRIDS	NOVEL	AMYLIN
ONCOLOGY & IMMUNE DISORDERS	MAbs	BIOSIMILAR	MYLAN
ONCOLOGY & IMMUNE DISORDERS	ITOLIZUMAB BVX 20 Cancer Vaccines	NOVEL NOVEL NOVEL	CIM VACCINEX IATRICa

## **Global partnerships for Biosimilars**





## Insulin and Insulin analogs

# **Monoclonal anti-bodies**

## **Biosimilars partnership - Pfizer**



### Insulin and Insulin analogs



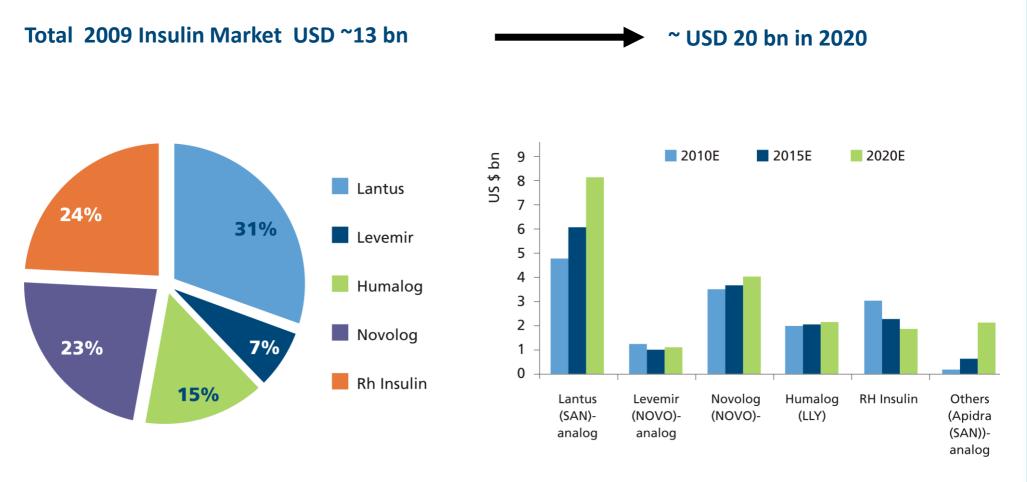
## Combines Biocon's research and manufacturing capabilities with Pfizer's global marketing prowess

Global agreement for the commercialization of Biocon's biosimilar versions of Insulin and Insulin Analog products: Recombinant Human Insulin, Glargine, Aspart, and Lispro. Pfizer will have exclusive rights, with some exceptions, to commercialize these products globally. Biocon will be responsible for clinical development, manufacture, supply, and regulatory approvals.

# Upfront from Pfizer USD 200 mn → Development, regulatory milestone payments 150 USD mn → Payments linked to global sales

## Total Insulin Market 2009





### Growth forecast of ~6% per annum\*

\*Factoring the advent of Biosimilar Insulins



## Biocon's insulin business in India



Biocon's ranking in the ndian Market:	The 2007-2010 CAGR figures for unit sales of Insulin 40 IU:	Biocon's market share by volume:
<b>‡20</b> in the OAD market	Market: <b>10.6%</b>	rh-Insulin: <b>10.8%</b>
<b>43</b> in the rh-Insulin market	Biocon: <b>12.7%</b>	Glargine: <b>13.2%</b>
<b>#2</b> in the Glargine market	NN: <b>9.3%</b>	
re : IMS HEALTH – HAS+SSA DATA– SEPT-MAT 10	Biocon ha both OAD and insuli	os space



### Monoclonal Antibodies (MAb)



### Combines Biocon's R&D and manufacturing of novel biologics/bio-generics with Mylan's regulatory and commercialization capabilities in the US and Europe

Exclusive collaboration for development and commercialization of complex biogenerics and biosimilars, MAbs in particular. Mylan and Biocon to share development and capital costs.

- Mylan will have exclusive commercialization rights in the regulated markets; profits to be shared.
- Biocon and Mylan to have co-exclusive commercialization rights in other markets.

## Global alliances – Amylin







Oncology





Immunoconjugated MAbs



Supply of novel API

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

Novel peptide Diabetes

Exclusive arrangement to jointly develop, commercialize, and manufacture a novel peptide therapeutic in diabetes segment. Co-development with shared costs of development. Commercialization territorial rights clearly marked out for each partner.

## Global alliances – Vaccinex





Diabetes



### **Bio-better MAbs**

Oncology

Combines Vaccinex's MAb discovery strengths with Biocon's expertise in clinical research and biologics manufacturing. To identify promising antibody candidates and move them rapidly into clinical development.

Discovery and co-development of anti-body products.



Immunoconjugated MAbs Oncology



Supply of novel API

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

### First molecule – BVX20

Non-Hodgkin's Lymphoma (NHL) is the most common cancer of the lymphoid organs. BVX-20 is a novel humanized Monoclonal Antibody that binds to CD20, a protein located on both normal and malignant B-cells. After binding, BVX -20 kills B-cells by recruiting the body's own immune system.

## Global alliances – IATRICa





Novel peptide Diabetes



Bio-better MAbs





Supply of novel API First-in-class anti-infective (C-difficile)

### Immunoconjugated MAbs

Oncology

Invested in IATRICa in 2008, a US-based start-up Biotech firm.

To co-develop novel, anti-cancer molecules based on a proprietary immuno-conjugation technology licensed from Johns Hopkins University, USA. Bio-hybrid molecules for targeted immunotherapy are considered to be the next generation drugs. The first molecule: Conjugated-Trastuzumab for Breast Cancer.

## Global alliances – Optimer Pharmaceuticals







Immunoconjugated MAbs

Oncology



### Supply of novel API

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

A long-term supply agreement for the commercial manufacturing of the API Fidaxomicin, Optimer's lead product candidate for the treatment of Clostridium difficile infection (CDI).

For the past five years, Biocon has been an important partner in optimer's Fidaxomicin development program and will continue this relationship with the manufacture and supply of this product once approved. Optimer expects to submit an NDA in the second half of the year.



## 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.

4 phase 1 studies completed.

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

6-month double-blind placebo controlled trials in Type 2 diabetics poorly controlled on metformin and primary endpoint as HbA1c control.

## Phase 1 studies for Type I Diabetics under US IND ongoing



### Monotherapy.

Combination therapy with metformin, sulfonylurea, PPAR agonists, DPP4i. Pre-meal insulin in combination with basal insulins.



Efficacy	<ul> <li>•HbA1c drop up to 0.8% from baseline observed in drug arm</li> <li>• Greater than expected placebo effect observed</li> <li>• Significant drug effect in several subsets</li> <li>• Statistically significant reduction in PPG throughout trial</li> <li>• Frequent SMBG likely to have influenced placebo effect</li> </ul>
Safety	<ul> <li>Excellent overall safety profile</li> <li>No clinically relevant hypoglycemia observed</li> <li>Data indicates drug is not immunogenic</li> <li>Data indicates drug is weight neutral</li> </ul>
Studies	<ul> <li>Further studies under US IND on Type I Diabetes ongoing</li> <li>Further studies to be conducted post partnering</li> </ul>

## Anti-CD6 MAb : T1h



### Target CD6

is a type 1 cell membrance 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 trial for Psoriasis ongoing.



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

### o.4mg/kg once in 4 weeks



### o.8mg/kg once in 4 weeks







**EMERGING MARKETS** 

**BIOSIMILAR INSULINS: PFIZER** 

**BIOSIMILAR mAbs: EMERGING MARKETS** 

LICENSING OF NOVEL PROGRAMS: IN105, Itolizumab

**RESEARCH SERVICES:** 

Syngene & Clinigene

STATINS, IMMUNO-SUPPRESSANTS, PROSTS: APIs & ANDA Dossiers



## Revenue, profit



INR crore / USD mn	F	Y07	F	Yo8	F	Yo9	FY10	)
Revenue	990	220	1090	273	1673	364	2405	512
EBITDA	287	63	335	83	388	84	509	1
Net profit*	200	44	225	56	240	52	293	62

	Q3 FY11	INR Crore/ USD mn 9-mo FY11
Revenue	738 164	<b>2097</b> 456
<b>EBITDA</b> EBITDA Margin	<b>178   4</b> 0 24%	<b>471</b> 102 23%
<b>Net Profit</b> Net margin	<b>101</b> 22 14%	<b>267</b> 58 13%
EPS Rs 5.2	2/share	Rs 13.7 /share

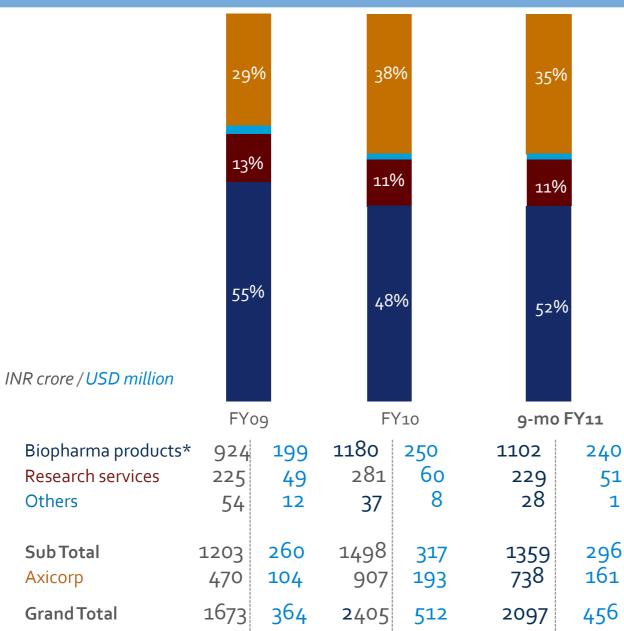
FY07-10: Avg.exch.rate in that fiscal 9-mo FY11: USD 1 = INR 45.90 \* Net profit is pre-exceptionals in table 1 No exceptional items in Q3FY11 and 9-mo FY11.

## Revenue mix: group

Others

Axicorp





FY09 and FY10: Avg.exch.rate in that fiscal 9-mo FY11: USD 1 = 45.90 INR \*Biopharma includes Licensing Income

1

