



**Investor Presentation** February 2013

#### **Safe Harbor**



Certain statements in this release 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, amongst 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 currencies, 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 the company, nor its directors and any of the 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.

## **Agenda**



**Biocon: Aligned With Global Trends** 

## **Growth Segments**

- Small Molecules
- Biosimilars
- Branded Formulations
- Research Services
- Novel Molecules

**Financial Highlights** 





**Biocon: Aligned with Global Trends** 

#### **Biocon: An Introduction**



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

#### **Biocon is committed towards:**

Reducing therapy costs of *chronic diseases*. (diabetes, cancer & auto-immune diseases)

Strategic Research and marketing *partnerships* that provide global access

Leveraging the India advantage to deliver *high value*, *licensable R&D assets* 

#### **YTD FY13 Highlights**



# 9M FY13 Financial Performance

- Group Revenue at ₹ 1,890 Crores (23% YoY growth)
- Growth across all verticals:
  - Biopharma 17%
  - Branded Formulations 35%
  - Research Services 34%
- EBITDA at ₹ 472 Crores (EBITDA Margin: 25%)
- R&D Expense: 11% of Biopharma Revenue

#### Corporate Milestones

- GE Capital proposes Investment to the tune of ₹125 Crores in Syngene
- Commencement of Abbott Nutrition Research & Development Centre
- Inauguration of Biocon Research Centre
- Becomes the only Asian Company to feature in Science magazine's global 'Top 20 Employers' in biotech & pharma.

#### **YTD FY13 Highlights**



# Research & Development Updates

- Mylan expands biosimilar partnership to encompass biosimilar insulin analogs
- Entered into an option agreement with BMS for our novel asset, a prandial oral insulin: IN-105
- Itolizumab: Marketing Approval received from DCGI for plaque Psoriasis in India
- Global Phase III trial initiated for Biosimilar Trastuzumab post the successful completion of its Global Phase I
- Part II of the EU Phase III trial for biosimilar rh-Insulin completed. Part 1 of the trial successfully established the efficacy endpoint with comparable safety & efficacy with innovator products.
- Global Phase I trial for Biosimilar Insulin Glargine successfully completed.

### **Business Structure & Holdings**





#### **BIOPHARMA SUBSIDIARIES**

Biocon Research , India | **100%**R&D- Novel Molecules

Biocon Biopharmaceuticals | **100%**MAbs and Biosimilars

Biocon Sdn. Bhd, Malaysia | **100%** Overseas subsidiary

Biocon SA, Switzerland | **100%** *Overseas subsidiary* 

NeoBiocon, UAE | **50%** *Overseas subsidiary* 

#### **RESEARCH SERVICES**

Syngene International, India | 99% Custom research, drug discovery

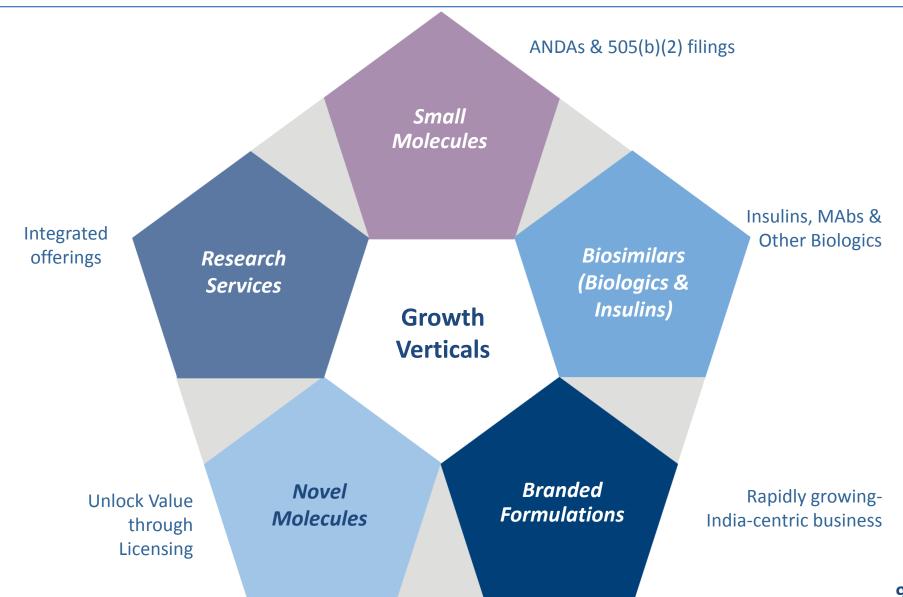


Clinigene International, India | 100% Clinical development

Spanning the entire Value Chain with capabilities ranging from discovery to manufacturing

## **Growth Verticals: Aligned with <u>Shifting Paradigms</u>**







**Growth Segments: Snapshot** 

## **Growth Segment: Small Molecules**





## **APIs** (Generic & Novel)



#### **Formulations**



505(b)(2) & ANDAs

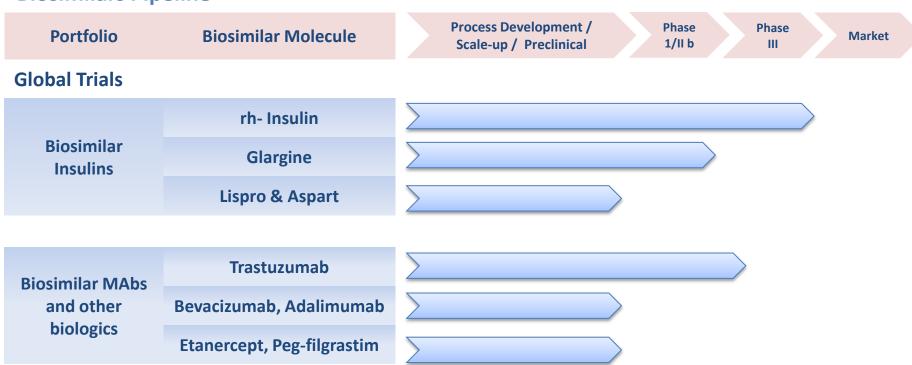
- Product Portfolio which leverage our core fermentation capabilities and have a high degree of complexity
- Early mover in niche products coupled with economies of scale.
- Portfolio based Approach

Current Portfolio	Constituents
Statins	Simvastatin, Atorvastatin, Lovastatin, Rosuvastatin, Fluvastatin & Pravastatin
Immuno suppressants	Tacrolimus, MMF & MPA
Other Biopharma	Orlistat, Fidaxomicin, 50+ other molecules

## **Growth Segment: Biosimilars**



#### **Biosimilars Pipeline**



- Emerging Markets First strategy coupled with a regional partnership commercialization approach
- Biosimilar Insulins Portfolio: Currently being commercialized in Emerging Markets
- Biosimilars MAbs & Other Biologics:
  - Biosimilar Trastuzumab undergoing an ROW focused, India Phase III trial.

## **Growth Segment: Biosimilars**



#### **Biosimilar Insulin & Analogs**

#### Registrations:

rh-Insulin: 40+ countries

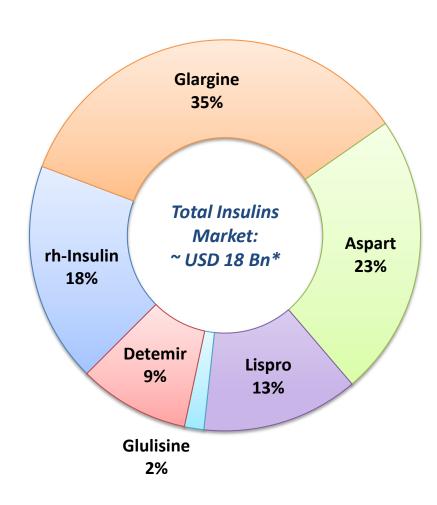
• Glargine: 5+ countries

#### O Biosimilar rh Insulin:

- Part 2 of the EU Phase III trial completed.
- Part 1 of the study establishes the Efficacy end-point (non inferiority to innovator product)
- Immunogenicity & Safety data similar to innovator at 6 month time point.

#### Biosimilar Glargine:

- Global Phase I (PK-PD) study successfully completed
- Established equivalence between our biosimilar insulin glargine and the innovator product



## **Growth Segment: Biosimilars**



#### **Co-Development & Commercialization Collaboration**



Combines Biocon's R&D and manufacturing prowess of biologics with Mylan's regulatory & commercialization capabilities in the US and Europe

	Biosimilar Insulin Analogs	Biosimilar MAbs & other Biologics
Global Market Size of Portfolio*	~ USD 13 Bn	~ USD 34 Bn
Portfolio Constituents	Glargine, Lispro & Aspart	Trastuzumab, Peg-filgrastim, Bevacizumab, Adalimumab, Eternacept
Mylan's <i>Exclusive Commercialization</i> Regions	US, Canada, Europe, Australia & New Zealand	All regulated markets

Structure: Upfront Payment + Cost Sharing + Supplies + Profit Sharing#

Mylan and Biocon to share development and capital costs

#Profit Sharing Arrangement in regions where Mylan has exclusive commercialization rights

Biocon and Mylan have co-exclusive commercialization rights in other markets.

## **Growth Segment: Branded Formulations**





## **Growth Segment: Branded Formulations**



**Affordability Index\*** 

Basalog: 40%

Insugen: 13%

Bestor: 30%

Statix: 25%

Advacan: 45%

Tacrograf: 30%

Evertor: 59%

**BioMAb EGFR: 53%** 

**Picon: 38%** 

Psorid: 28%

INDIA PRODUCT RANKINGS#			
Cardiology			
Clotide	1		
Myokinase	2		
Oncotherapeutics			
BioMAb EGFR	2		
Evertor	2		
Abraxane	3		
Immunotherapy			
Psorid	1		
Picon	2		
Tbis	2		
Nephrology			
Tacrograf	2		
Bioproducts			
Genpirome	2		

## **Growth Segment: Branded Formulations**



## Biocon's Volume Market share\*

100 IU Insulin: 15%

Glargine vials: 72%

#### **Value Growth YoY\***

Fastest growing Insulin company

Biocon: 34%

Sanofi Aventis: 17%

**Novo Nordisk: 10%** 

## Biocon's ranking\*

#4 in overall insulin market

#3 in the 40 IU Insulin market

**#1** in the Glargine vial market

#### INSUPen® ease

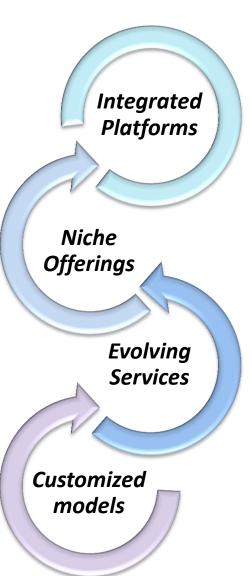
Reusable delivery device based on proprietary German technology, capable of delivering both Insugen<sup>TM</sup> & Basalog<sup>TM</sup> launched in India & Select Emerging Markets



## **Growth Segment: Research Services**



- Integrated Drug Discovery and Development
- Biologics Discovery and Development
- Syngene- Clinigene axis
- Bioanalytical testing of small and large molecules
- Antibody Drug Conjugate (ADC) development
- Unique *In-Vivo* Models- Human tumour tissue Xenograft
- Early and rapid toxicology evaluation (Cardiomyocytes)
- Commercial scale production of NCEs
- High potency (cytotoxic) API manufacturing
- Formulation development
- Dedicated/customized infrastructure
- End-to-end services
- Risk sharing: Milestone based
- Incubation: IP sharing



## **Growth Segment: Research Services**



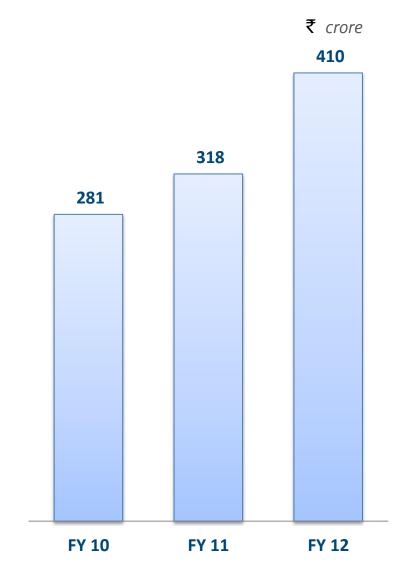
## (gg)

## **GE Capital**

- PE Investment of \$ 25 Mn for a 7.7% stake, valuing Syngene at \$ 325 Mn
- Investment aimed at enhancing
   Syngene's service offerings & fund
   future growth

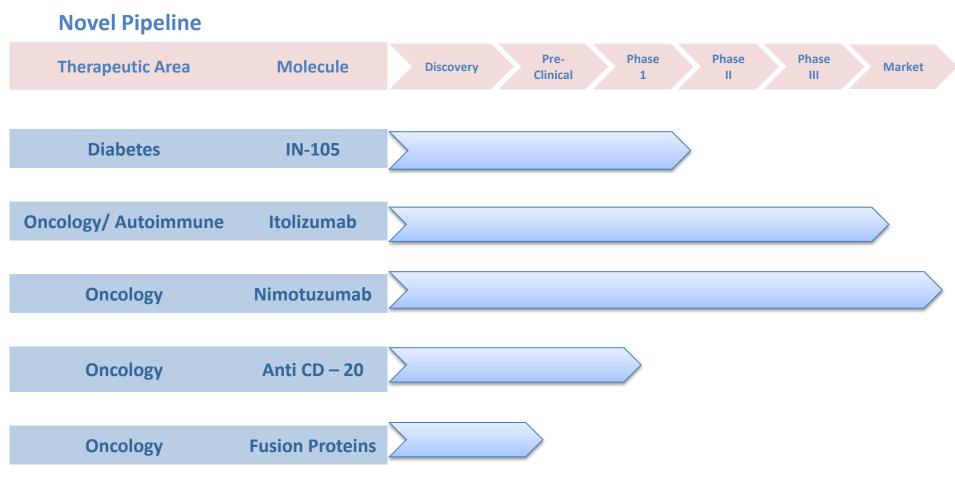


- Dedicated, India-centric nutrition
   R&D Centre
- o Focused on:
  - Maternal & Child Nutrition
  - Diabetes Care



## **Growth Segment: Novel Molecules**





- \* Itolizumab: Marketing Authorization for Psoriasis approved by the Indian drug regulator
- Anti CD 20 (BVx 20) has entered the clinic in India
- Multiple Global Trials planned for Oral Insulin in collaboration with BMS

## **Growth Segment: Novel Molecules**



#### **IN-105** Option Agreement: BMS (First-in-Class Oral Prandial Insulin)



Combines Biocon's novel asset and development experience with BMS' novel drug development, regulatory & commercialization capabilities.

Biocon will **continue global development** of the molecule through Phase II via redesigned trials.

Partnership encompasses Financial, Strategic and Clinical Support throughout the development phase

BMS will have an **exclusive option post phase II** to further develop & commercialise the asset worldwide (excl. India)

Biocon will receive licensing fee in addition to potential regulatory & commercialization milestones, when BMS exercises its option.

## **Growth Segment: Novel Molecules**



#### **Alzumab** (Itolizumab- First-in-Class Anti CD6)

Marketing Authorization for *Itolizumab* (*IV* delivery) received from Indian Drug regulator for **Psoriasis** 

Alzumab India launch in 2013

**2<sup>nd</sup> Novel Biologic** from Biocon's repertoire: **First Novel MAb** for Psoriasis developed in **India** 

**US IND to be filed in 2013** to facilitate global clinical trials in Psoriasis, RA and other indications as Sub  $\Omega$ 

**First-in-Class** Therapy :Novel MOA with an excellent safety profile

**Very low Infection** rates vis-à-vis other approved therapies

Promising preclinical and clinical efficacy data in **other auto immune diseases** (RA, MS)

Partnership discussions initiated for global development of this late stage opportunity

**Baseline** 



12 Weeks



28 Weeks



Treatment Arm



**Financial Highlights** 

#### **Financial Performance**



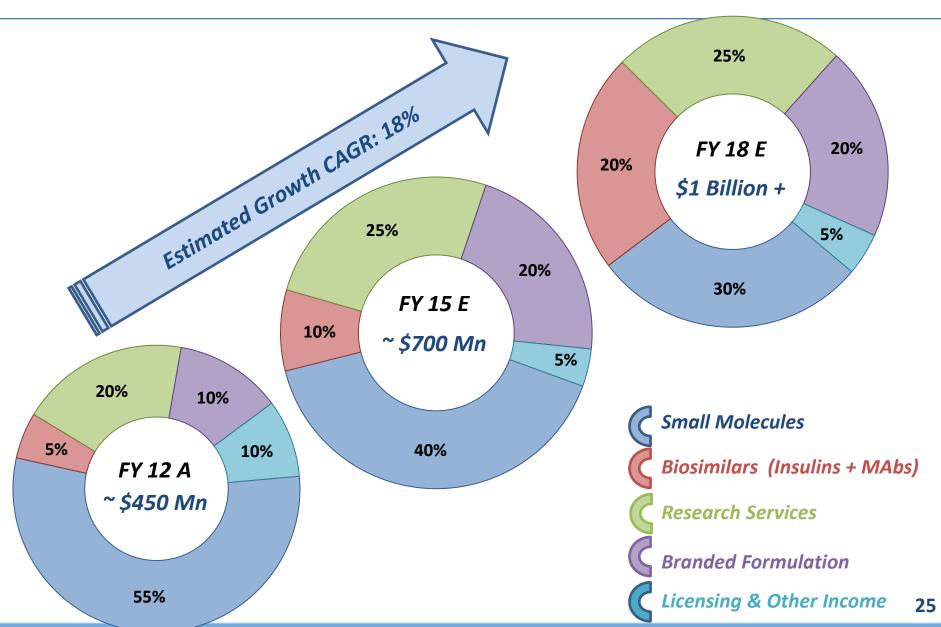
₹ crore/USD mn

	FYo8	FY09	FY10	FY11	FY12
Revenue	1,090   273	1,194   260	1,493   318	1,858   407	2,148   445
R&D Spend	47 12	60 13	79 17	118 26	157 33
<b>EBITDA</b>	335 83	372 81	455 97	573 125	579 120
Net profit*	225 56	238 52	273 58	340 74	338 70

	9M FY13	9M FY12
Revenue	1,890   <b>346</b>	1,537   <b>324</b>
R&D Spends	121   <b>22</b>	84   <b>18</b>
% of Biopharma Sales #	11%	9%
EBITDA	472   <i>86</i>	423   <i>89</i>
EBITDA Margin	25%	27%
PAT	260  <b>48</b>	241   <i>51</i>
PAT Margin	14%	16%
EPS	13.3	12.3

#### **Leveraging Challenges For Sustained Growth**









### **Thank You**

**Investor Contact: Sweta Pachlangiya** sweta.pachlangiya@biocon.com





## **APPENDIX**

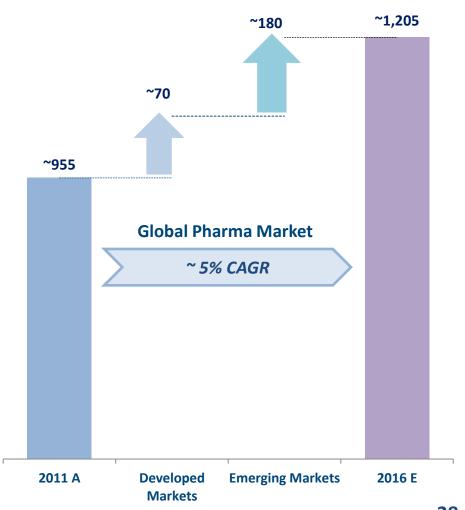
### **Global Pharma Growth Catalyst: Emerging Markets**



**USD Bn** 

#### Emerging Markets to contribute ~ 75% of the Total Pharma Growth by 2016

- Global Pharma Spending expected to cross\$1.2 Trillion by 2016
- Emerging Markets projected growth CAGR:~10%
- Developed Markets expected growth CAGR: ~2%
- Emerging Markets growth driven by:
  - Increased Government Healthcare Spending
  - Growing Affluence

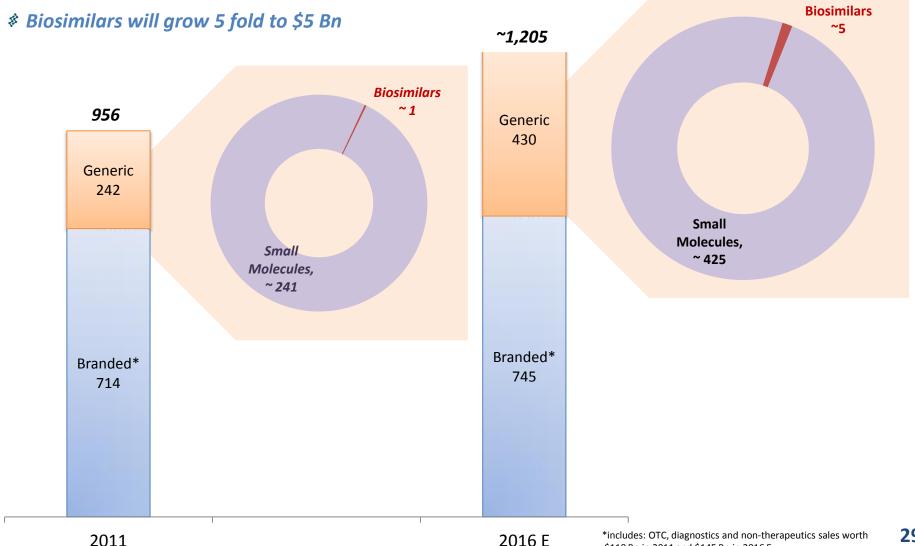


### **Global Pharma Growth Catalyst: Generics & Biosimilars**



\* Generic Spending to Increase by ~75% in the next 5 years vs. Branded drugs' growth of 9%

**USD Bn** 



## **STRATEGIC PARTNERSHIPS**



	BMS	Diabetology	Oral Insulin (IN-105)	
Discovery &	CIMAb	Oncology	BioMAb EGFR, Itolizumab	
Development	IATRICa	Oncology	Immuno-conjugated MAbs	
	Vaccinex	Oncology	Biobetter MAbs	
Co-Development & Commercialization	Mylan	Oncology & Auto Immune	Biosimilar MABs & Biologics	
Commercialization	Optimer	First in Class Anti Infective	Fidaxomicin	
Research Services	BMS	Discovery to Commercialization	Integrated DD Services	
	Abbott	Nutrition R&D	Integrated discovery services	