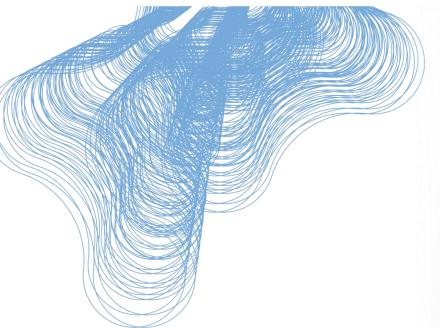


## Investor Presentation July 2012

## Innovative Science Affordable Medicine





### **SAFE HARBOR**



Certain statements in this release 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, 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 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.

**AGENDA** 





3



## **SNAPSHOT**



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* 

## Q1 FY13 HIGHLIGHTS



## **Financial Performance**

- Group Revenue at Rs. 593 Crores (28% YoY growth)
- Growth across all verticals: Biopharma (23%), Branded Formulations (52%), Research Services (40%)
- EBITDA at Rs. 139 Crores (EBITDA Margin: 23%)

## **Research & Development**

- Global Phase I trial for Biosimilar Insulin Glargine successfully completed.
- Itolizumab Phase III, 52-week study successfully meets primary & multiple secondary endpoints.

## **Corporate Milestones**

- Inauguration of Biocon Research Centre
- Commencement of Abbott Nutrition Research & Development Centre





### **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

### **MANAGING THE FUTURE**



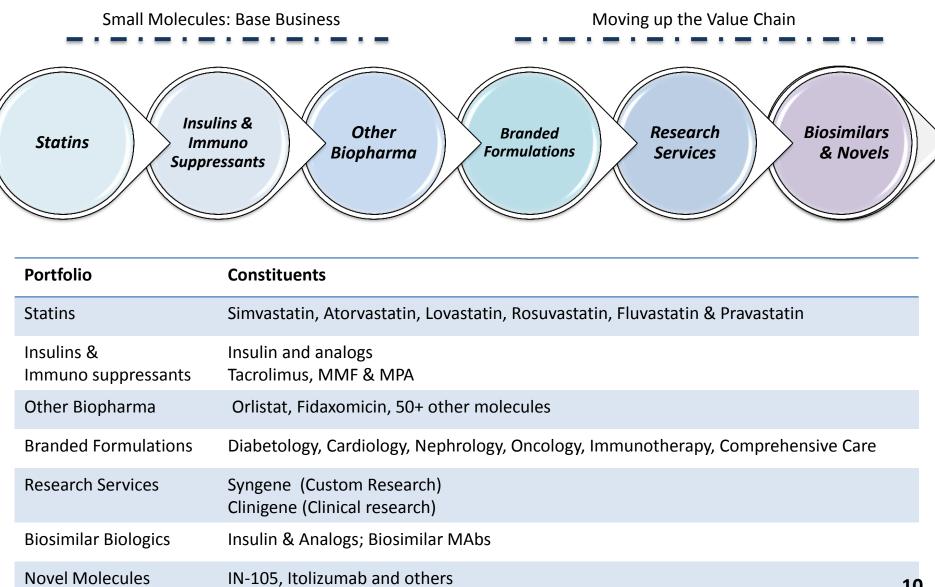




## **PORTFOLIO SPREAD**

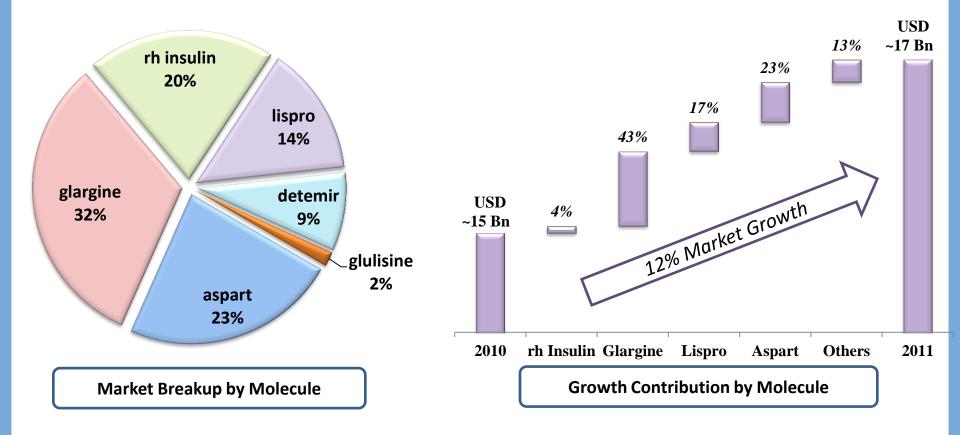
### **DIVERSIFIED OFFERINGS**







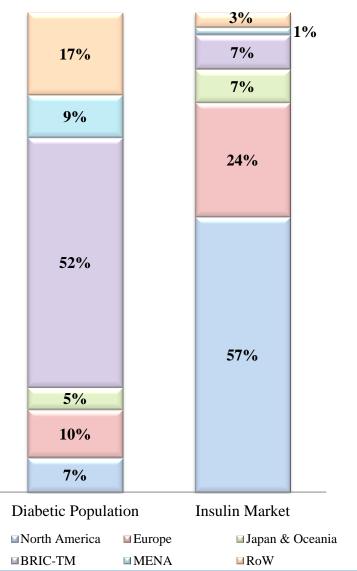
## Total 2011 Insulin Market: USD ~17 Bn



## **INSULINS: GLOBAL OPPORTUNITY (2)**







## The shift underway

- ☑ Total Diabetic Population 2011: 366 Mn
  - Developed Markets: 80 Mn
  - Emerging markets: 286 Mn
- ☑ Diabetes Population 2030E: 552 Mn
  - Developed Markets: 96 Mn
  - Emerging markets: 456 Mn
- ✓ Diabetes prevalence expected to go up from current levels of 8% to 10% in 2030
- ☑ Diabetes prevalence expected to rapidly increase in Africa, MENA and Urban Areas of BRIC-TM
- ✓ More than half of the current diabetic population in emerging markets remains undiagnosed with limited access to affordable healthcare



## Committed to delivering affordable, quality insulin to global markets

- rh-Insulin
- Basal insulin analog
- Rapid acting insulin analogs

## Portfolio



- 30+ registrations in Emerging markets
- Strong regional partners in major markets including Japan & China

Regional Partnerships



- rh-Insulin:
  - Phase 3 trial in EU ongoing
  - Commercialized in several geographies including India
- Glargine
  - Active US-IND
  - Global Phase 1 trial completed
  - Commercialized in India

Molecule Status



## **BRANDED FORMULATIONS : THERAPEUTIC SEGMENTS**









## **BRANDED FORMULATIONS : CARVING A NICHE**



|  |  | Affordability Index* | INDIA PRODUCT RANKINGS# |   |  |  |
|--|--|----------------------|-------------------------|---|--|--|
|  |  |                      | Cardiology              |   |  |  |
|  |  | Basalog: 40%         | Clotide                 | 1 |  |  |
|  |  | Insugen: 13%         | Myokinase               | 2 |  |  |
|  |  | Bestor: 30%          | Oncotherapeutics        |   |  |  |
|  |  | Statix: 25%          | BioMAb EGFR             | 2 |  |  |
|  |  |                      | Abraxane                | 3 |  |  |
|  |  | Advacan: 45%         | Immunotherapy           |   |  |  |
|  |  | Tacrograf: 30%       | Psorid                  | 1 |  |  |
|  |  |                      | Picon                   | 1 |  |  |
|  |  | Evertor: 59%         | Tbis                    | 2 |  |  |
|  |  | BioMAb EGFR: 53%     | Nephrology              |   |  |  |
|  |  | Picon: 37%           | Tacrograf               | 2 |  |  |
|  |  | Psorid: 26%          | Renodapt & Renodapt S   | 3 |  |  |

\*: Compared to the top selling competitor brand; #: ORG IMS May MAT 2012

## **BRANDED FORMULATIONS: #1 Indian Insulin Company**



Biocon's Volume Market share\*

100 IU Insulin: 17%

Glargine vials: 85%

Value Growth YoY\*

Fastest growing Insulin company

Biocon: 50%

Sanofi Aventis: 29%

Novo Nordisk: 26%

**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>™</sup> & Basalog<sup>™</sup> launched in India





### **DISCOVERY SERVICES**

#### CLIENTS

Large & mid-size Pharma & Biotech Companies

On-going collaboration with over **60** companies worldwide

### SERVICES

Biology R&D Chemistry R&D Custom Synthesis Biologics Production Pre-Clinical & Pharmacology Pharmaceutical Development Syngene

## Clinigene

### **CLINICAL RESEARCH**

### CLIENTS

Large & mid-size Pharma & Biotech Companies

### SERVICES

Clinical Operations & Development

**Clinical Data Management** 

Central & Bioanalytical Research Lab

Human Pharmacology Unit

**Regulatory Services** 

Integrated discovery model

Collaborative Partnerships Risk sharing projects FTE based programs

Project based service Fee based models

## **RESEARCH SERVICES: VALUE-BASED POSITIONING**

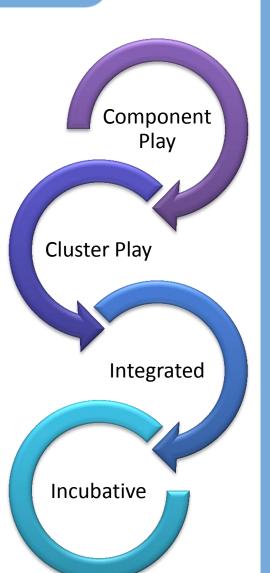


Integrated Model spanning discovery & early development to late stage clinical studies

Large Portfolio of Offerings combining **Chemistry & Biologics expertise** with cost advantage

**Custom partnership models** ranging from FTE based to risk-reward models

Clientele comprising of **100+ large and mid-size** pharma & biotech companies





## STRATEGIC ALLIANCES



|                   | Apolio   | Diabetes                          | Dontido Hybrid                   |  |  |  |
|-------------------|----------|-----------------------------------|----------------------------------|--|--|--|
|                   | Amylin   | Diabetes                          | Peptide Hybrid                   |  |  |  |
| Discovery         | CIMAb    | Oncology                          | BioMAb EGFR, Itolizumab          |  |  |  |
| Discovery         | IATRICa  | Oncology                          | Immuno-conjugated MAbs           |  |  |  |
|                   | Vaccinex | Oncology                          | <b>Biobetter MAbs</b>            |  |  |  |
|                   |          |                                   |                                  |  |  |  |
| Commercialization | Optimer  | First in Class<br>Anti Infective  | Fidaxomicin                      |  |  |  |
| Commercialization | Mylan    | Oncology &<br>Auto Immune         | Biosimilars                      |  |  |  |
|                   |          |                                   |                                  |  |  |  |
| Research Services | BMS      | Discovery to<br>Commercialization | Integrated DD Services           |  |  |  |
| Research services | Abbott   | Nutrition R&D                     | Integrated discovery<br>services |  |  |  |



## Monoclonal Antibodies (MAbs)



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

## Market Value of Portfolio in 2011: ~33 Bn USD

Exclusive collaboration for development and commercialization of

complex biosimilars.

Basket of Products with patent expiries 2015 onward

(Trastuzumab, Peg-filgrastim, Bevacizumab, Adalimumab, Eternacept)

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.



## First-in-class Anti-Infective



Combines Biocon's R&D and manufacturing prowess of novel biologics with Optimer's proprietary molecule technology

Collaboration for manufacture & supply of Fidaxomicin API : DIFICID<sup>™</sup> & DIFICLIR<sup>™</sup> tablets

Extension of prior relationship where Biocon assisted Optimer

with product development

Launched in US & select East European nations in first phase;

Alliances established for Japan & Brazil



## **MATERNAL & CHILD NUTRITION**



*Combines Syngene's integrated drug development prowess with Abbott's capabilities in maternal and child nutrition* 

Exclusive collaboration for setting up a nutrition R&D centre: The Abbott Nutrition R&D Centre

Focus on the development of affordable nutrition products for maternal and child nutrition and diabetes care

Products being developed for the Indian market are meal complements for diabetics and pre-diabetics.

Long term Contract commencing with 50+ scientists .



## Research & Development

## **RESEARCH PARTNERSHIPS : HIGH POTENTIAL PRODUCT PIPELINE**



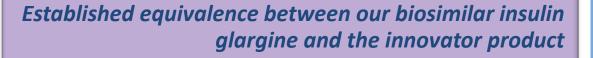
| Product          | Therapeutic Area                            | Drug                | Partner  | Discovery            | Preclinical | Phase I            | Phase II     | Phase III N | larket |
|------------------|---|---------------------|----------|----------------------|-------------|--------------------|--------------|-------------|--------|
|                  | Diabetes                                    | IN 105              |          |                      |             |                    |              |             |        |
| ules*            | Oncology /<br>Inflammation /<br>Auto immune | Itolizumab          | CIMAb    |                      |             |                    |              | #           |        |
| Voleci           | Oncology                                    | Nimotuzumab         | CIMAb    |                      |             |                    |              |             |        |
| Novel Molecules* | Oncology                                    | Anti-CD 20          | Vaccinex |                      |             |                    |              |             |        |
| 2                | Oncology                                    | Fusion Proteins     | IATRICa  |                      |             |                    |              |             |        |
|                  | Diabetes                                    | Peptide Hybrid      | Amylin   |                      |             |                    |              |             |        |
| lars*            | Oncology/<br>Immunology                     | Biosimilar MAbs     | Mylan    | Other MAI<br>PEG- GC |             | similar<br>tuzumab |              |             |        |
| Biosimilars*     | Diabetes                                    | Insulin & Analogues |          | Lispro,              | Aspart      | r                  | H Insulin, G | largine     |        |
| Bid              | Oncology                                    | Others              |          |                      |             | (                  | GCSF, EPO    |             |        |

\* Includes molecules from collaborative programs;

# Phase 3 TREAT PLAQ study In India, Phase 2(b) globally



Successfully Completed the Global PK-PD Study All Primary & Secondary Endpoints Achieved



The clinical data along with characterization details would be used to start the global Phase 3 program.

Conducted under International Standards employing the gold standard for assessment of insulin preparations.

Biocon 100 IU/ml R Insulin Glargine Injection (r DNA Origin)

BASALOG™ बेसल्लौग Solution for Subcutaneous





### **Drug Highlights**

### **Targets CD6**

CD6 is a type 1 cell membrane glycoprotein belonging to the scavenger receptor cysteine-rich (SRCR) super family 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.

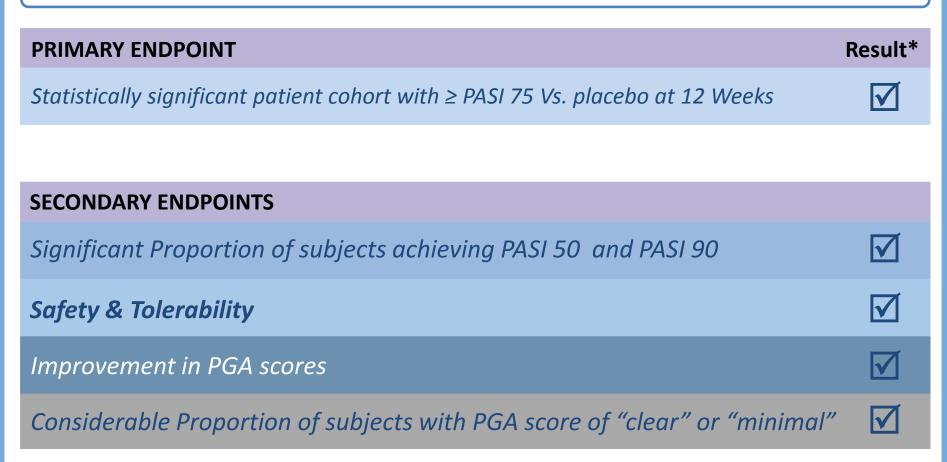
Skin fibroblasts, keratinocytes, rheumatoid arthritis synovium.

### **TREAT-PLAQ Study in Psoriasis**

| Total Patient Enrollment | 223      |
|--------------------------|----------|
| Trial Duration           | 52 Weeks |
| Interim Data Shared      | 28 Weeks |



52-Week data confirms achievement of multiple, key primary and secondary end-points



## **TREAT PLAQ STUDY : EFFICACY RESULTS**

Biocon

### Representative patient samples from each arm.



## **ORAL INSULIN : IN 105**



- Hepatic portal-vein-delivery  $\checkmark$
- Prime liver effect and  $\mathbf{\nabla}$ benefit of **"hepatic** buffering"
- Physiological Denetits No sustained peripheral  $\square$ hyper-insulinemia
- **Emulates innate**  $\square$ insulin physiology

- Adequate post-prandial  $\square$ glucose control
- $\square$ Reduces the risk of hypoglycaemia
- $\overline{\mathbf{V}}$ Weight neutral

CIHIICAL BEILERICA

 $\overline{\mathbf{V}}$ Action independent of pancreas functionality

## **Potential Therapeutic Use**

- Potential use across the diabetic treatment continuum  $\mathbf{\nabla}$ 
  - Concomitant use with OADs or monotherapy  $\geq$
  - "Bridge therapy" to intensive insulin therapy  $\geq$
  - Post-prandial control component with basal insulin therapy  $\geq$

## **IN-105 INDIA PHASE III RESULT SUMMARY**



| IN-105 shows clear efficacy as a prandial insulin in lowering post-prandial glucose levels  |              |  |  |  |
|---|--------------|--|--|--|
| Parameter   | Result       |  |  |  |
| SECONDARY END POINTS  |              |  |  |  |
| <b>Efficacy – Secondary Endpoints</b><br>Statistically significant reduction in PPG during STM  | $\checkmark$ |  |  |  |
| Significant reduction in SMBG post prandial glucose excursion   | $\checkmark$ |  |  |  |
| Safety – Secondary Endpoints<br>No clinically significant hypoglycemia  | $\checkmark$ |  |  |  |
| Very low immunogenicity   | $\checkmark$ |  |  |  |
| No neutralizing antibodies detected   | $\checkmark$ |  |  |  |
| No effect on liver enzymes  | $\checkmark$ |  |  |  |
| No effect on lipid profiles   | $\checkmark$ |  |  |  |
| No effect on renal function   | $\checkmark$ |  |  |  |
| <b>Efficacy – Primary Endpoint</b><br>Change in Hb1Ac for IN-105 not statistically significant due to higher than anticipated<br>placebo effect | X            |  |  |  |



## FINANCIAL HIGHLIGHTS



INR crore / USD mn

|             | FYo8      | FY09      | FY10          | FY11      | FY12      |
|-------------|-----------|-----------|---------------|-----------|-----------|
| Revenue     | 1,090 273 | 1,194 260 | 1,493 318     | 1,858 407 | 2,148 445 |
| EBITDA      | 335 83    | 372 81    | 455 <b>97</b> | 573 125   | 579 120   |
| Net profit* | 225 56    | 238 52    | 273 58        | 340 74    | 338 70    |
|             |           |           |               |           |           |

|         | Q1 FY13          | Q1 FY12          |
|---------|------------------|------------------|
| Revenue | 593   <b>109</b> | 464   <b>106</b> |
| EBITDA  | 139   <b>26</b>  | 132   <b>29</b>  |
|         | 23%              | 28%              |
| PAT     | 79   <b>15</b>   | 70   <b>16</b>   |
|         | 13%              | 15%              |
| EPS     | 4.0              | 3.5              |

*FY08-12:* Avg.exch.rate in that fiscal ; Q1 FY13: USD 1 = INR 54.17; Q1 FY12: USD 1= INR 44.89 \* Net profit is pre-exceptional in table 1.No exceptional items in FY10, FY11 and FY12.



# Thank You