





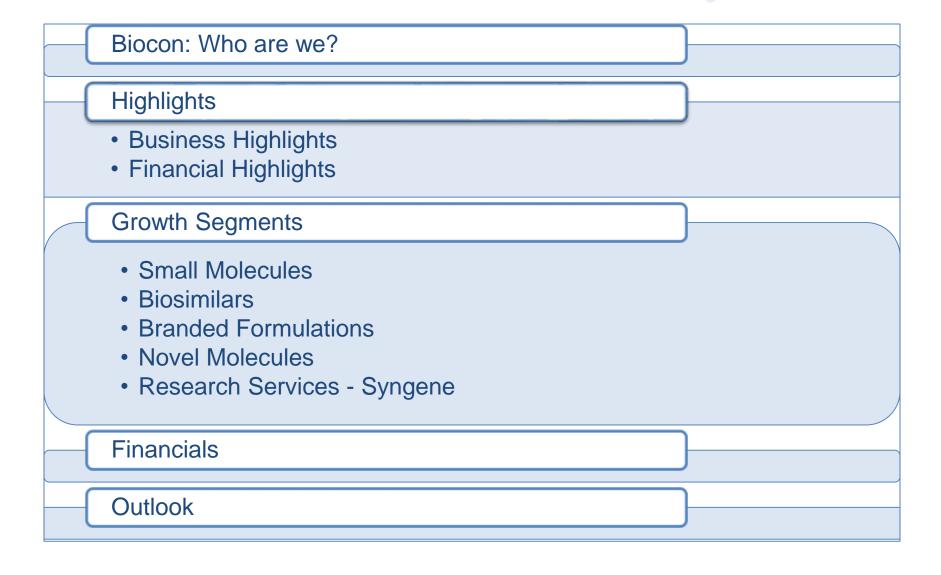
Investor Presentation
February 2016

BSE: 532523 | NSE: BIOCON | REUTERS: BION.NS | BLOOMBERG: BIOS IN | WWW.BIOCON.COM

### 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**





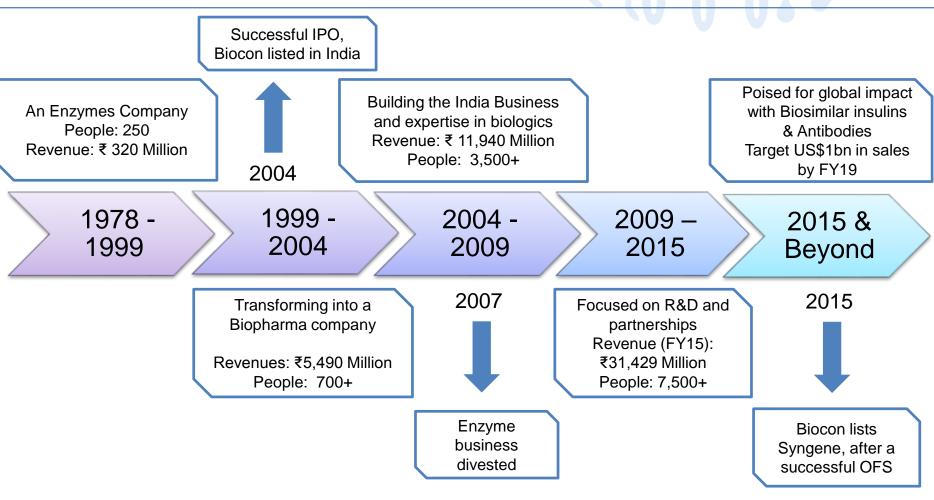
Biocon: Who are we?

## **Biocon: Asia's Leading Biopharma Company**

Our Vision

To enhance global healthcare through innovative and affordable biopharmaceuticals for patients, partners and healthcare systems across the globe

## The Biocon Journey: A continuous evolution



Unwavering focus through the years on Innovation & Difficult to make, niche products to create tangible differentiators for sustainable growth

## **Evolution of Key Innovations: Making a Difference**

**1979 -** First Indian company to manufacture and export enzymes to US and Europe

**2001 -** First Indian company to be approved by US FDA for the manufacture of lovastatin from solid state fermentation

**2004 -** First company worldwide to commercialize generic recombinant human insulin developed on its proprietary fermentation technology

**2006 -** India's first indigenously produced novel monoclonal antibody BIOMAb-EGFR® to treat head & neck cancer launched

**2009 -** Indigenously developed long lasting basal Insulin Glargine introduced in India as BASALOG®

**2013 -** World's first anti-CD6 monoclonal antibody ALZUMAb™ to treat psoriasis launched in India

**2014 -** CANMAb™, world's most affordable trastuzumab for treating metastatic breast cancer, launched in India



## **YTD Business Highlights**

- Biocon successfully listed Syngene, its Biocon's Research Services subsidiary

  - Listed on NSE and BSE on August 11, 2015
- Biosimilar programs accelerating through the clinic
  - Biocon continues to cross critical milestones in global Phase III clinical trials of Biosimilars Trastuzumab, Pegfilgrastim, Adalimumab and Insulin Glargine. Developed market filings (US/EU) planned for FY17 by partner Mylan
  - Bevacizumab in RoW focused Phase III, EU Phase I
- Malaysian Insulin Facility received local cGMP certification from National Pharmaceutical Control Bureau (NPCB), Malaysia
- Insulin Glargine launched in Mexico and Colombia
- **Basalog One™ Biocon's disposable glargine device launched in India**
- Biocon reports positive clinical data from key studies for Insulin Tregopil
- Biocon acquired the business assets of the pharmaceutical manufacturing unit of M/s. Acacia Lifesciences Private Limited located at Vishakhapatnam

<sup>\*</sup> Per closing price on NSE, 19th Feb 2016

## Financial Highlights – Q3 & 9M FY16

All Figures in ₹ Million except %

|                     |         |         |        |         |        | ·      |
|---------------------|---------|---------|--------|---------|--------|--------|
| Particulars         | Q3 FY16 | Q3 FY15 | Growth | 9M FY16 | 9MFY15 | Growth |
| Revenue             | 8,561   | 7,790   | 10%    | 25,704* | 22,883 | 12%    |
| EBITDA              | 2,088   | 1,697   | 23%    | 6,667   | 5,483  | 22%    |
| Net Profit          | 1,030   | 909     | 13%    | 5,352** | 2,959  | 81%    |
| R&D Expenses in P&L | 679     | 467     | 45%    | 1,752   | 1,128  | 55%    |
| Gross R&D<br>Spends | 912     | 850     | 7%     | 2,746   | 2,291  | 20%    |
| EBITDA<br>Margins   | 24%     | 22%     | -      | 26%     | 24%    | -      |

<sup>\*</sup> Includes one time capacity reservation fee of INR 446 million | \*\* Includes exceptional income of INR 2,028 million

## Segmental Sales – Q3 & 9M FY16

All Figures in ₹ Million except %

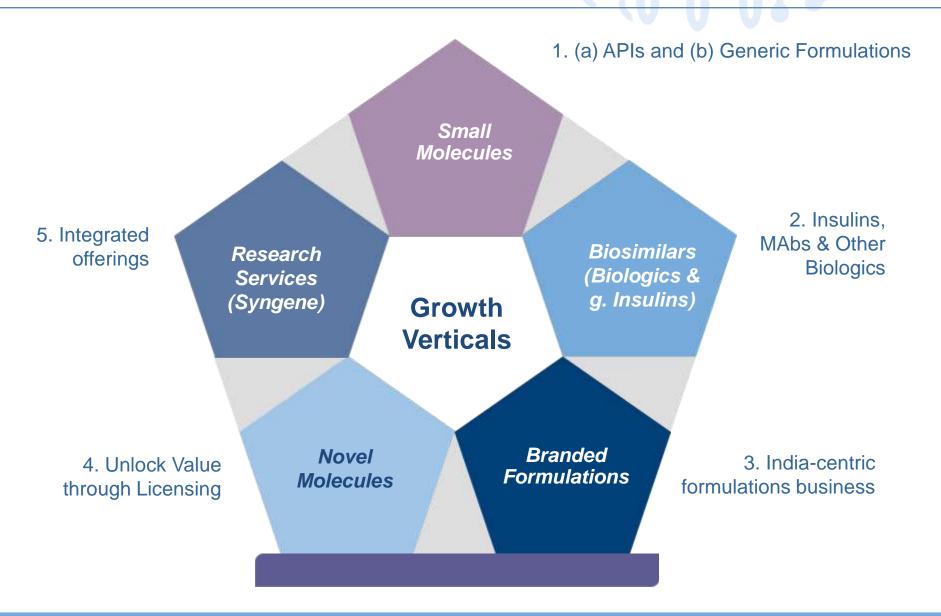
| Particulars             | Q3 FY16 | Q3 FY15 | Growth | 9M FY16 | 9M FY15 | Growth |
|-------------------------|---------|---------|--------|---------|---------|--------|
| Biopharma               | 4,536   | 4,366   | 4%     | 14,007* | 13,137  | 7%     |
| Branded<br>Formulations | 1,045   | 1,047   | 0%     | 3,357   | 3,312   | 1%     |
| Research<br>Services    | 2,701   | 2,196   | 23%    | 7,444   | 5,841   | 27%    |
| Total                   | 8,282   | 7,609   | 9%     | 24,808  | 22,290  | 11%    |

<sup>\* 9</sup>M Biopharma sales includes one time capacity reservation fee of INR 446 million



**Business Segments** 

# **Growth Verticals: Aligned with Shifting Paradigms**



## 1a. Small Molecule APIs

- Product Portfolio which leverages our core fermentation capabilities and have a high degree of complexity.
- Early mover in niche products at commercial scale.
- One of the largest producers of various fermentation based statins and immunosuppressant API in India and across the globe.

| <b>Current Portfolio</b> | Constituents   |
|--------------------------|--|
| Statins                  | Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, & Fluvastatin. |
| Immuno<br>suppressants   | Tacrolimus, Sirolimus, Everolimus, MMF & MPA                         |
| Other Biopharma          | Orlistat, Fidaxomicin, multiple other molecules                      |

## 1b. Small Molecules Generics Formulations

- Nascent pipeline
- To file ~20-25 dossiers in the next few years
- Pipeline includes solid oral & parenteral products in both potent & non-potent categories of compounds.
- Product pipeline comprises of 'difficult to make,' technology intensive molecules for emerging and developed markets.
- Core therapeutic segments Metabolics, Oncology, Auto-immune indications.
- Initiated construction of Biocon's first oral solid dosage facility located in Bangalore to support our future generic filings with capex of US\$25mn. Estimated completion CY 2017

Continue to build momentum in dossier filing with a focus on specialty molecules in in chronic therapeutic segments

## 2. Biosimilars

- Amongst the largest portfolio of Biosimilars globally straddling human insulin/insulin analogs, monoclonal antibodies and other biologics. Addressable market size: ~US\$60 Billion
- Strong scientific and technical capabilities and manufacturing expertise to address global opportunities.
- Four molecules in advanced Global Phase III studies. To file for regulatory approvals in US and Europe, in FY17.
- Human insulin and Glargine registered in 60 and 20 emerging markets, respectively.
- Biocon's Trastuzumab launched in India in Feb-14, the first biosimilar Trastuzumab to be commercialized globally.
- Meaningful near term growth to be driven by emerging markets with a significant ramp-up post entry into developed markets.

Biocon's Biosimilars portfolio is partnered with leading US generics major, Mylan

## Biosimilars: Growth through partnership

### **BIOCON**

- Global-scale, complex biologics manufacturing capabilities
- Facilities accredited by international regulatory agencies
- Decade-long experience & demonstrated expertise in developing MAbs and other biologics

#### **MYLAN**

- Strength in Regulatory/ filings strategy
- Strong commercialization capability in US and EU.
- Market agility and speed

| Deal Structure: Upfront Payment + Cost Sharing + Supplies + Profit Sharing# |  |                   |  |  |  |  |  |
|---|--|-------------------|--|--|--|--|--|
| Generic Insulin Analogs Biosimilar MAbs & other Biolog                      |  |                   |  |  |  |  |  |
| Mylan's Exclusive<br>Commercialization<br>Regions                           | US, Canada, Europe,<br>Australia & New Zealand | Developed markets |  |  |  |  |  |
| Market Opportunity*   | ~US\$18 Bn                                     | ~US\$42 Bn        |  |  |  |  |  |

Strategic collaboration leverages Biocon's strong development & manufacturing capability and Mylan's regulatory & commercial excellence

# **Biosimilars: Insulins Pipeline**

| Molecule   | Туре                        | Status                          | Market Size*<br>(US\$ bn) |
|------------|-----------------------------|---------------------------------|---------------------------|
| Rh Insulin | Recombinant Human Insulin   | EU Phase III complete           | 3.1                       |
| Glargine   | Long Acting Basal Insulin   | Global Phase III                | 7.1                       |
| Aspart     | Rapid Acting Insulin Analog | Preclinical/Scale Up            | 4.7                       |
| Lispro     | Rapid Acting Insulin Analog | Preclinical/Scale Up            | 2.8                       |
|            |                             | Total Market Size (rounded off) | 18.0                      |

<sup>\*</sup>Market Size of innovator products in the current portfolio: Innovator Sales CY 2015

# **Biosimilars: MAbs & Biologics Pipeline**

| Molecule      | Indication                   | Status                          | Market Size*<br>(US\$ bn) |
|---------------|------------------------------|---------------------------------|---------------------------|
| Adalimumab    | Chronic Plaque Psoriasis     | Global Phase III                | 14.0                      |
| Trastuzumab   | mBreast Cancer               | Global Phase III                | 6.8                       |
| Pegfilgrastim | Chemo-induced<br>Neutropenia | Global Phase III                | 4.7                       |
| Bevacizumab   | mColorectal Cancer           | EU Phase 1, RoW Phase III       | 6.9                       |
| Filgrastim    | Chemo-induced<br>Neutropenia | Preclinical/Scale Up            | 1.0                       |
| Etanercept    | Auto-immune                  | Preclinical/Scale Up            | 8.7                       |
|               |                              | Total Market Size (rounded off) | 42.0                      |

<sup>\*</sup>Market Size of innovator products in the current portfolio: Innovator Sales CY 2015

# Biosimilars: Biocon well placed in the Competitive Landscape

| Top 10 Biologics <sup>1</sup> | Company        | Patent<br>Term –<br>US | 2014<br>Sales<br>(US\$ bn) | Biosimilar Development Pipeline* |                  |  |  |  |
|-------------------------------|----------------|------------------------|----------------------------|----------------------------------|------------------|--|--|--|
|                               |                |                        |                            | Pre-Clinical                     | Phase I          | Phase III/Filed  |  |  |
| Humira (adalimumab)           | AbbVie         | 2016                   | 11.8                       | OO<br>• CELLTRION                | Dr.Reddy's 💝     | SANDOZ (SBiocon) Coherus.  HOMESTA AMGEN  SAMSUNG BIOEPIS  SAMSUNG BIOEPIS |  |  |
| Lantus (insulin glargine)     | Sanofi         | 2015                   | 10.3                       |                                  |                  | SAMSUNG BIOEPIS BIOCON Lilly   |  |  |
| Enbrel (etanercept)           | Amgen/Pfizer   | 2028                   | 8.7                        | © CELLTRION Biocon               |                  | Coherus. S SANDOZ SAMSUNG BIGEPIS  |  |  |
| Remicade (infliximab)         | Merck/J&J      | 2018                   | 8.1                        | ₩EPIRUS  A SANDOZ                | AMGEN            | SAMSUNG BIDEPIS  |  |  |
| Rituxan(rituximab)            | Roche/Biogen   | 2013                   | 6.6                        |                                  | Dr.Reddy's AMGEN | SANDOZ CELLTRION   |  |  |
| Avastin (bevacizumab)         | Roche          | 2019                   | 6.1                        | HOMENTA .                        | SANDOZ SANDOZ    | AMGEN  Boehringer Blocon  Boehringer Blocon                                |  |  |
| Herceptin (trastuzumab)       | Roche          | 2019                   | 5.6                        | Ong cashlander                   |                  | AMGEN PARTS SAMSUNG RIGERS BIOCON  |  |  |
| Novolog (insulin aspart)      | Novo Nordisk   | 2014                   | 4.7                        | SANOFI SBiocon                   |                  |  |  |  |
| Neulasta (pegfilgrastim)      | Amgen          | 2015                   | 4.6                        |                                  | Dr.Reddy's       | SANDOZ Coherus.  |  |  |
| Lucentis (ranibizumab)        | Roche/Novartis | 2020                   | 4.4                        |                                  | PFEnex           |  |  |  |

<sup>(1)</sup> Ranking based on 2014 Sales, IMS Health MIDAS, December 2014

<sup>\*</sup> Biosimilar Development Pipeline details may not be exhaustive, Source: Various Reports

# Biosimilars Manufacturing: Building Global Scale

### Biocon Malaysia: Asia's largest integrated insulins manufacturing facility



- Biocon's First Manufacturing expansion overseas in Iskandar, Johor.
- Capital Investment of over US\$200mn in the first phase.
- Emerging market filings planned for FY17.

- Disposable insulins pen line in Bangalore starts commercial production.
- MAbs capacity to be augmented in Bangalore



Biocon over the years have built global scale and cost competitive, complex manufacturing capabilities to address global market opportunities

## 3. Branded Formulations: Introduction

- Presently an India focused Specialty Business with Regional Ambitions
- Organized into 5 key divisions around chronic therapy areas
- Strategy focused around biologics and differentiated products as anchor brands.
- Portfolio highlights:
  - Insugen® & Basalog®: Dominant position in generic insulin & insulin Glargine. Complete portfolio spanning vials, cartridges and disposable pens.
  - CANMAb™: World's first biosimilar Trastuzumab commercialized in Feb-14.
  - BIOMAb EGFR®: First indigenous novel Mab, for head & neck cancer.
  - Abraxane: Novel nab paclitaxel, launched in Sep-06.
  - Alzumab™:Indigenously developed first in class novel MAb, for Psoriasis
  - Cytosorb®: Cytokine Filter, first-in-class therapy for Sepsis.











## 4. Novel Molecules

#### **Insulin Tregopil**

First-in-Class Oral Prandial Insulin

- Multiple sets of studies completed to establish Post Prandial glycemic control.
- Sizeable global opportunity

#### **Itolizumab**

Novel, humanized antibody directed at CD6

In – house program

- Commercialized in India for Psoriasis.
- Studies to be conducted across multiple indications (Rare and Common diseases)

### **SiRNA** platform

QPI- 1007 for Rare Diseases

Partnered with Quark Pharma

QPI-1007 has entered Pivotal trial in NAION (Rare ophthalmic disease)

#### **Fusion Proteins**

In – house program

Anti-CD 20

In - house program

#### **ADXS-HPV**

Partnered with Advaxis

- Differentiated class of Fusion Antibody platform in Immuno-Oncology
- Oncology asset currently in Phase I of development
- Developed for cervical cancer Currently in Phase II study

## 5. Syngene (Research Services Business)

### Global High Growth CRO Company

- One of the leading India-based contract research organizations (CRO)
- Integrated discovery and development
- Over 200 clients across multiple sectors
- 95%<sup>(1)</sup> of revenues from outside India
- Over 2,100<sup>(2)</sup> qualified scientists
- World-class R&D and manufacturing infrastructure spread over 900,000 sq. ft.
- Strong track record of top-line growth with best in class EBITDA (30+%) and Net Income (high teens)
- Listed on Indian stock exchanges, BSE
   & NSE on August 11, 2015.

### Attractive Blue Chip Customer Base

- Highly successful track-record in molecule development
- Client base includes 8 of the top 10 global pharma company by 2014 sales<sup>(3)</sup>
- 8 of our top 10 clients have been associated for more than 5 years illustrating their longstanding and extensive relationship
- Total clients increased from little over 100 in FY12 to over 200 in FY15
- 71% of FY15 revenue from top 10 customers compared to 79% in FY12
- Clients across sectors Pharma,
   Biotech, Agrichem, Nutrition

<sup>(1)</sup> For fiscal ended March 31, 2015; (2) As of May 31, 2015

## Syngene: Value unlocking through a successful IPO

- Subscription: IPO Oversubscribed 31x
- Allotment Price: INR 250 (Implied market cap US\$770mn)
- Listing Price: INR 295
- Closing on Listing Day (August 11, 2015): INR 310 (25% premium)
- Price Range since listing: INR.295-436
- Current Market Cap: US\$1.1bn
- Biocon owns 73.5% of Syngene



**Five Year Financials** 

# **Consolidated Financial Performance (FY11-15)**

All Figures in ₹ Million except EPS

| FY11   | FY12   | FY13   | FY14   | FY15  |
|--------|--|--|--|---|
| 14,866 | 16,764   | 18,705   | 21,382   | 22,367  |
| 13,023 | 14,170   | 15,231   | 17,468   | 18,071  |
| 1,863  | 2,594  | 3,474  | 3,914  | 4,296   |
| 3,177  | 4,101  | 5,572  | 7,146  | 8,225   |
| 18,063 | 20,865   | 24,227   | 28,528   | 30,592  |
| 516    | 618  | 1,103  | 804  | 837   |
| 18,579 | 21,483   | 25,380   | 29,332   | 31,429  |
| 5,733  | 5,792  | 5,957  | 7,429  | 7,489   |
| 31%    | 27%  | 23%  | 25%  | 24%   |
| 3,399  | 3,384  | 3,241  | 4,137  | 4,022   |
| 18%    | 16%  | 13%  | 14%  | 13%   |
| 18.4   | 16.9   | 25.4   | 20.7   | 24.8  |
| 1,183  | 1,566  | 1,640  | 1,310  | 1,688   |
| 7.9%   | 9.3%   | 8.8%   | 6.1%   | 7.5%  |
|        | 14,866 13,023 1,863 3,177 18,063 516 18,579 5,733 31% 3,399 18% 18.4 1,183 | 14,86616,76413,02314,1701,8632,5943,1774,10118,06320,86551661818,57921,4835,7335,79231%27%3,3993,38418%16%18.416.91,1831,566 | 14,866       16,764       18,705         13,023       14,170       15,231         1,863       2,594       3,474         3,177       4,101       5,572         18,063       20,865       24,227         516       618       1,103         18,579       21,483       25,380         5,733       5,792       5,957         31%       27%       23%         3,399       3,384       3,241         18%       16%       13%         18.4       16.9       25.4         1,183       1,566       1,640 | 14,866       16,764       18,705       21,382         13,023       14,170       15,231       17,468         1,863       2,594       3,474       3,914         3,177       4,101       5,572       7,146         18,063       20,865       24,227       28,528         516       618       1,103       804         18,579       21,483       25,380       29,332         5,733       5,792       5,957       7,429         31%       27%       23%       25%         3,399       3,384       3,241       4,137         18%       16%       13%       14%         18.4       16.9       25.4       20.7         1,183       1,566       1,640       1,310 |

<sup>\*</sup>Net Profit is pre-exceptional



**Appendix** 

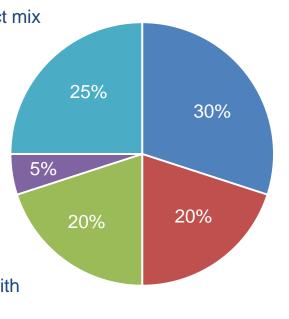
## Aspiring for \$1 Billion in Revenues by FY 2018-19

### **Key Focus Areas**

 Small Molecules & Generic Formulations- Improved product mix incl. ANDAs

- Biosimilars Meaningful near term growth to be driven by emerging markets, ramp up post developed market entry
- Branded Formulations –Strategy focused around biologics and differentiated products, geographical expansion
- Novel Molecules Out-licensing and Global Development
- Research Services Sustained growth momentum with increase in clients & services, moving from CRO to CRAMS with commercial manufacturing

Growth drivers supplemented by addition of new offerings (products, services & partnerships)



Exchange Rate: 1 US\$=₹ 50

## **Shareholding Pattern & Business Holdings\***



#### **BIOPHARMA SUBSIDIARIES**

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

Biocon Pharma, India | 100% Manufacturing - Generic Formulations

Biocon Pharma Inc., USA | 100% Step Down Subsidiary

Biocon Sdn. Bhd, Malaysia | 100% Overseas subsidiary

Biocon SA, Switzerland | 100% Overseas subsidiary

NeoBiocon, UAE | **51%** Overseas subsidiary

Biocon FZ LLC, UAE | 100% Overseas subsidiary

#### RESEARCH SERVICES

Syngene International, India | **73.5%** *Leading Indian CRO* 



For more information, please visit <a href="https://www.biocon.com">www.biocon.com</a>

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