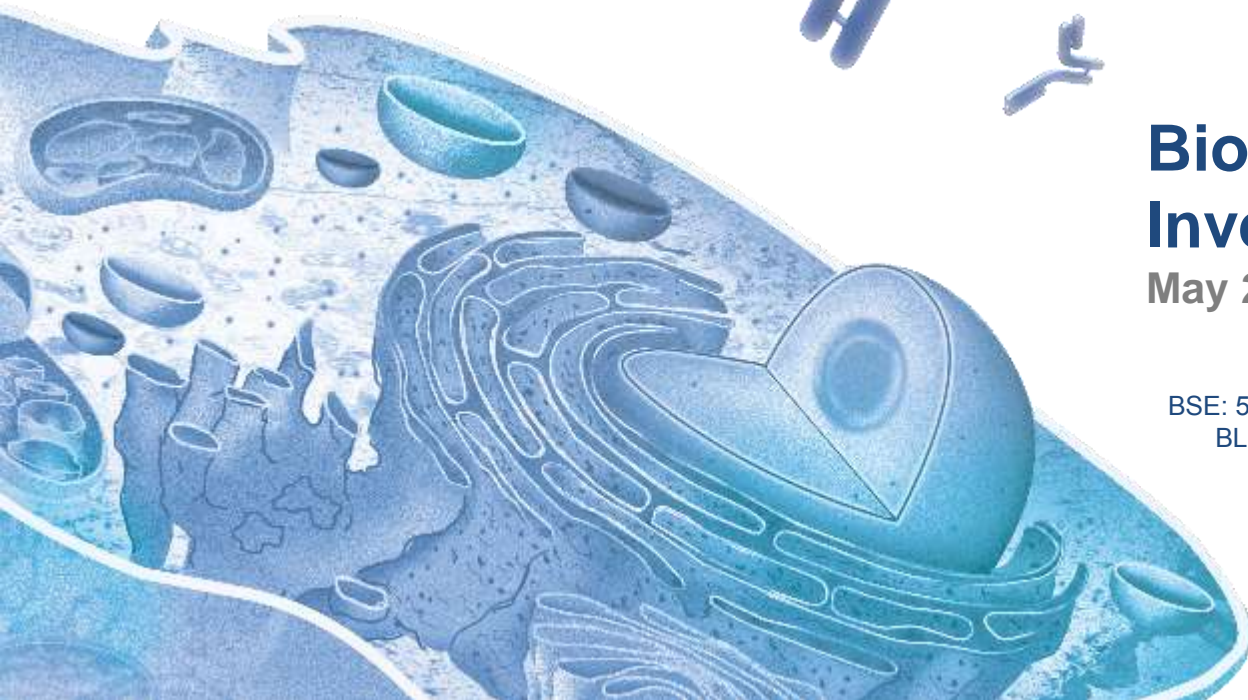
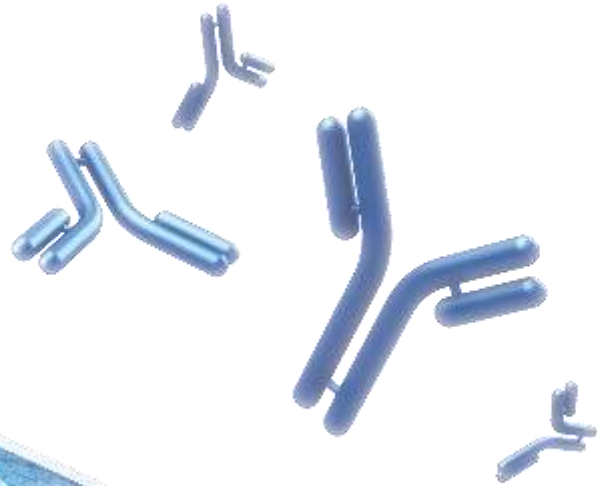


Ahead  
of the curve



# Biocon Limited Investor Presentation

May 2018

BSE: 532523 | NSE: BIOCON | REUTERS: BION.NS |  
BLOOMBERG: BIOS IN | [WWW.BIOCON.COM](http://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?

Highlights

- Business Highlights
- Financial Highlights

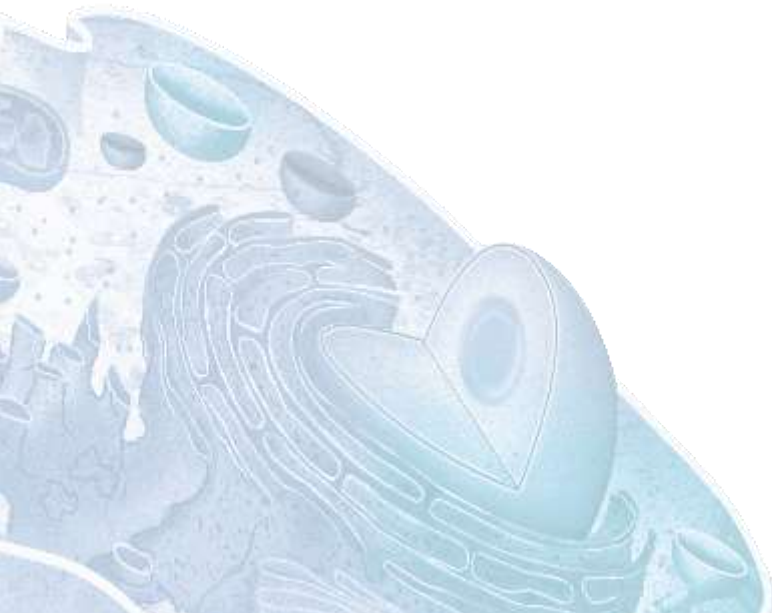
Business Segments

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

Five Year Financial Summary

Outlook

**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



An Enzymes Company

Transforming into a Biopharma company

Building the Base Business and expertise in biologics

Focused on global development and strategic global alliances

Insulin Glargine approval and launch in Japan, approval in EU

Successful IPO, Biocon listed in India

Enzymes business divested

Mylan Insulins collaboration signed

Biosimilar Trastuzumab approved by US FDA

Mylan Antibodies collaboration signed

IPO of Syngene

Sandoz Biosimilars collaboration signed

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** - Manufacture and export of enzymes, food ingredients and brewing aids to 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-EGR® 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
- 2016** - Launch of Insulin Glargine in Japan by partner FUJIFILM Pharma, first developed market launch for a Biocon product
- 2017** – KRABEVA®, biosimilar bevacizumab launched in India
- 2017** - Ogrivi™, first biosimilar trastuzumab approved by US FDA
- 2018** - Semglee™, biosimilar insulin glargine approved by European Commission



# Business Highlights - FY18

- ❖ **US FDA** approved Mylan/Biocon's biosimilar **Trastuzumab** on **December 1, 2017**
- ❖ **European Commission** approved Mylan/ Biocon Insulin Glargine **Semglee™**
- ❖ **Biocon** and **Sandoz** announced an **exclusive global collaboration** to develop next generation biosimilar immunology and oncology products.
- ❖ Mylan/ Biocon's proposed biosimilar **Pegfilgrastim** is under review with the **US FDA**. Target action date for FDA decision is June 4, 2018.
- ❖ **Marketing Authorisation Applications** for proposed biosimilars of **Trastuzumab** and **Pegfilgrastim** are under review with the **European Medicines Agency (EMA)**.
- ❖ Mylan/ Biocon's **Insulin Glargine** application submitted under the NDA pathway is under review with the **US FDA**.
- ❖ Biocon and Mylan agreed to accelerate the introduction of biosimilar **Adalimumab** in Europe through Mylan's in-licensing arrangement with Fujifilm Kyowa Kirin Biologics, to enable launch in EU, around market formation
- ❖ Mylan/Biocon received approval for Biosimilar **Trastuzumab** in **Brazil** through partner Libbs Farmaceutica

- Highlights continued on next page



# Business Highlights - FY18 (continued)

- ❖ Biocon and Mylan to expand their long-standing collaboration to add two new next-generation biosimilar programs with **Insulin Glargine 300 units/mL** and **Pertuzumab**.
- ❖ Biocon's **Insulin Glargine** received regulatory approval in **South Korea** while our biosimilar **Trastuzumab** was the first biosimilar Trastuzumab approved in **Turkey**.
- ❖ Launched **Rosuvastatin Calcium** formulation in the US; partner launched the same in EU
- ❖ Biocon received approval from DCGI and subsequently launched biosimilar **Bevacizumab**, prescribed for various cancers including metastatic colorectal cancer and lung cancer in India.
- ❖ Biocon initiated Phase2/3 study in type 2 diabetes patients for our oral insulin candidate **Insulin Tregopil**. **JDRF** to support a planned Phase 1 study for the molecule in type 1 diabetes patients.
- ❖ **Syngene** expanded its ongoing collaboration with **Bristol Myers Squibb (BMS)** through 2026 that will see the addition of a new facility and allow for expansion of the team of scientists working exclusively for BMS.
- ❖ **Syngene** signed a strategic, multi-year collaboration with **GlaxoSmithKline (GSK)** focusing on new drug discovery using Syngene's discovery services platform. The collaboration also involves the setting up of a customized research facility for GSK

# Revenue Highlights

All Figures in ₹ Million except %

Particulars	Q4 FY18	Q4 FY17	Growth (%)	FY18	FY17	Growth (%)
- Small Molecules	4,255	3,948	8	15,077	16,405	(8)
- Biologics	2,408	1,633	47	7,702	7,018	10
- Branded Formulations	1,491	1,310	14	6,115	5,489	11
- Syngene (Research Services)	4,091	2,828	45	14,231	11,925	19
- Inter-segment	(550)	(408)	35	(1,828)	(1,621)	13
<b>Revenue from Operations</b>	<b>11,695</b>	<b>9,311</b>	<b>26</b>	<b>41,297</b>	<b>39,216</b>	<b>5</b>
- Other Income	675	432	56	2,062	1,571	31
<b>Total Revenue</b>	<b>12,370</b>	<b>9,743</b>	<b>27</b>	<b>43,359</b>	<b>40,787</b>	<b>6</b>

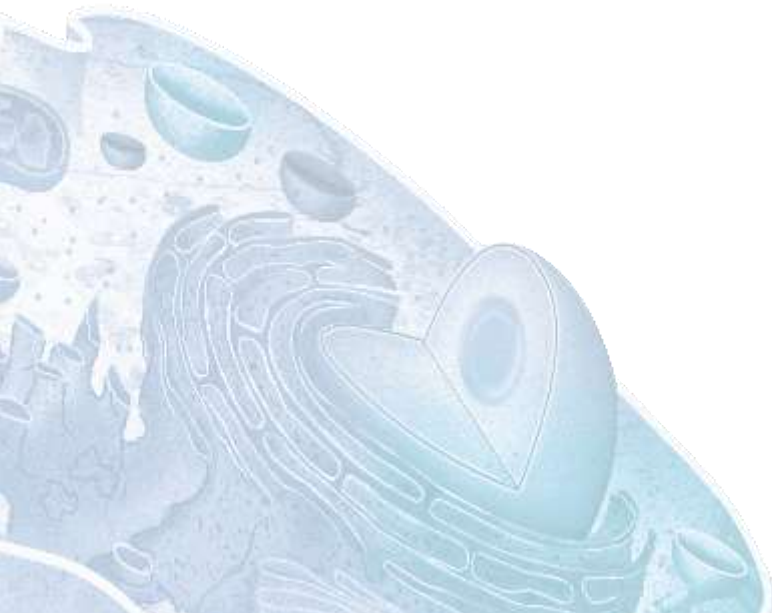
# Financial Summary

All Figures in ₹ Million except %

Particulars	Q4 FY18	Q4 FY17	Growth (%)	FY18	FY17	Growth (%)
Revenue	12,370	9,743	27	43,359	40,787	6
EBITDA	3,005	2,307	30	10,353	11,366	(9)
Net Profit	1,304	1,275	2	3,724	6,121	(39)
R&D Expenses in P&L	508	652	(22)	2,158	2,662	(19)
Gross R&D Spends	975	975	0	3,804	4,019	(5)
<b>EBITDA Margin</b>	<b>24%</b>	<b>24%</b>		<b>24%</b>	<b>28%</b>	
<b>EPS@ (Rs.)</b>	<b>2.2</b>	<b>2.1</b>		<b>6.2</b>	<b>10.2</b>	

**~ Product Revenue Mix (FY18): Ex-India 70% : India 30%**

# Business Segments



# Growth Segments: Aligned with Shifting Paradigms



**Small Molecules** – APIs and Generic Formulations

**Biologics** – Biosimilars & Novel Biologics

**Branded Formulations** - Formulations Business in India & UAE

**Research Services** - Contract Research & Manufacturing

# 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.

Current Portfolio	Select Molecules
Statins	Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, & Fluvastatin.
Immuno suppressants	Tacrolimus, Sirolimus, Everolimus, MMF & MPA
Other Biopharma	Orlistat, Fidaxomicin

# Small Molecule Generic Formulations

- ❖ Vertically integrated business model with a nascent pipeline.
- ❖ Pipeline includes solid oral & parenteral products in both potent & non-potent categories of compounds.
- ❖ Focus therapeutic segments – Metabolics, Oncology, Immunology & Auto-immune indications.
- ❖ Invested ~US\$ 25mn in our Oral Solid Dosage facility to support our future generic formulation applications.



Focus on vertically integrated development of molecules in chronic therapeutic areas

# Biosimilars

- ❖ Over 15 years of experience is developing biologics with four biosimilars commercialized in various markets across the globe.
- ❖ Strong scientific and technical capabilities with manufacturing expertise and scale to address global opportunities. Over 1500 people dedicated to support this business across various functions.
- ❖ A large diverse portfolio which straddles across insulin and insulin analogs, monoclonal antibodies and recombinant proteins addressing diabetes, oncology and immunology indications.
- ❖ Along with our partners, have invested in multiples of hundred million dollars in R&D and capex
- ❖ Strategic partnership with global companies like Mylan and Sandoz to cross leverage development and commercialization capabilities in a risk and reward share model
- ❖ Meaningful near term growth to be driven by emerging markets with a significant ramp-up post entry into developed markets.

**Strong end to end global player with a large diverse biosimilar portfolio**



# Biosimilars: Partnership with Mylan

## 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<sup>#</sup>

	Generic Insulin Analogs	Biosimilar MAbs & other Biologics
Mylan's Exclusive Commercialization Regions	US, Canada, Europe, Australia & New Zealand	Developed markets

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

# Biosimilars: Partnership with Sandoz

## Deal Structure

Portfolio addresses next wave of immunology and oncology biosimilars

Both companies share responsibility for end-to-end development, manufacturing and global regulatory approvals for a number of biosimilars

Costs & profits are shared equally

## Commercialization Responsibilities

Sandoz	Biocon
<ol style="list-style-type: none"><li>1. North America (US &amp; Canada)</li><li>2. EU (European Free Trade Association (EFTA) and Balkan states)</li></ol>	<ol style="list-style-type: none"><li>1. Japan, Australia, New Zealand</li><li>2. All Emerging Markets</li></ol>

Broader Biocon participation in end to end development and commercialization with a global leader in biosimilars

# Disclosed Biosimilars Pipeline – a multi-billion dollar opportunity

INSULINS

Molecule	Type	Status
Rh Insulin	Regular Acting Insulin	Preclinical (US), Marketed in EM
Glargine 100 IU/ml	Long Acting Insulin	Approved in EU & Australia. Under review in US & Canada. Marketed in Japan & Emerging Markets
Aspart	Rapid Acting Insulin Analog	Global Phase I completed
Lispro	Rapid Acting Insulin Analog	Preclinical

BIOSIMILARS

Adalimumab	Auto-Immune	Phase III complete.
Trastuzumab	Cancer	Approved in US. Under review in EU, Canada, Australia, Filed/ Marketed in Emerging Markets
Pegfilgrastim	Neutropenia	Filed in US, EU, Canada, Australia
Bevacizumab	Cancer	Global Phase III ongoing. Marketed in India
Filgrastim	Neutropenia	Preclinical
Etanercept	Auto-Immune	Preclinical

# Disclosed Biosimilar Pipeline: Biocon well placed in the competitive landscape

Molecule	Biosimilar Development Pipeline <sup>®</sup>					
	Phase I	Phase 3	Regulatory Submission		Approved/ Marketed	
			EMA	FDA	EMA	FDA
pegfilgrastim	DRL, Pfizer		Biocon, Coherus, Sandoz, Cinfa, USV, Apotex, Geodon Richter	Biocon, Coherus, Apotex, Sandoz	None	None
trastuzumab		Hanwha	Biocon, Pfizer,	Amgen, Celltrion, Pfizer, Samsung	Samsung, Celltrion, Amgen (+CHMP)	Biocon
insulin glargine				Biocon	Biocon, Eli Lilly, Merck	Eli Lilly, Merck (TA)
adalimumab	Oncobiologics	Coherus, Biocon, Momenta, Pfizer, Fresenius,	Mylan-Fuji-Kirin, Sandoz	Samsung, Sandoz	Amgen, Samsung, BI	Amgen, BI
bevacizumab	Sandoz, Daiichi, Oncobiologics, Cipla, DRL	Biocon, BI, Pfizer, Samsung, Fuji-Kirin/ Astra Zeneca			Amgen	Amgen
filgrastim		Pfizer		Apotex, Adello	Sandoz, Teva, Pfizer, Stada, Intas	Sandoz, Teva
etanercept	Hanwha	Coherus, Lupin, Samsung	Lupin		Samsung, Sandoz	Sandoz
insulin aspart	Biocon					
insulin lispro					Sanofi	Sanofi
rh-insulin						

<sup>®</sup> Biosimilar Development Pipeline details may not be exhaustive, pipeline progress may not be perfectly accurate; Source: Company disclosures, research reports

# Biosimilars Manufacturing: Building Global Scale

Biocon Malaysia: Asia's largest integrated insulins manufacturing facility



- ❖ Biocon's First Manufacturing expansion overseas in Iskandar, Johor.
- ❖ Investment of over US\$275mn in the first phase.
- ❖ Sales commenced in Emerging Markets; include OTA award by Ministry of Health – Malaysia.
- ❖ Plant has received EMA GMP certificate for drug substance and drug product.

- ❖ Second fill-finish sterile injectable line in Bangalore has been approved by the DCGI. Will support future growth of biologics formulations
- ❖ Construction of second antibody manufacturing facility in Bangalore ongoing. To be built in two phases over 3-4 years.



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

# Branded Formulations

- A Specialty Business with regional ambitions, currently in India and UAE. Strategy focused around biologics and differentiated products as anchor brands.
- The UAE business sells Branded generics and in-licensed Branded products.
- India business organized into 5 divisions around chronic therapy areas, namely **Metabolics, Oncotherapeutics, Immunotherapy, Nephrology, and Specialty.**
- Successfully developed and taken a range of Novel Biologics, Biosimilars, differentiated Small Molecules and affordable Recombinant Human Insulin and Analogs from 'Lab to Market'.
- Some of the key brands are in India include INSUGEN® (rh-insulin), BASALOG® (Glargine), BIOMAb-EGFR™ (Nimotuzumab), BLISTO® (Glimepiride+Metformin), CANMAb™ (Trastuzumab), KRABEVA® (Bevacizumab), Evertor® ( Everolimus), TACROGRAF™ (Tacrolimus) and ALZUMAb™ (Itolizumab), a 'first in class' anti-CD6 monoclonal antibody.
- Future growth to be driven by deeper penetration of existing brands and new product launches.

# Novel Molecules - Pipeline & Therapeutic Area Focus

<p><b>DIABETES</b></p>	<p><b>Insulin Tregopil *</b> First-in-Class Oral, Prandial Insulin</p>	<p><b>India Phase II/III in T2D commenced</b></p>
<p><b>INFLAMMATION</b></p>	<p><b>Itolizumab*</b> Novel, humanized CD6 Antibody</p>	<p><b>IND Ready</b></p>
	<p><b>BVX-20#</b> Novel, humanized CD20 Antibody</p>	<p><b>IND Ready</b></p>
	<p><b>QPI-1007\$</b> SiRNA for ophthalmic disease</p>	<p><b>Phase III in NAION</b></p>
<p><b>IMMUNO- ONCOLOGY</b></p>	<p><b>Tumor-Targeted Fusion mAb*</b></p>	<p><b>Preclinical</b></p>

- \* In-House program
- # BVX-20 with Vaccinex
- \$ QPI-1007 with Quark Pharma. QPI-1007 Global Phase III trial includes India.

# Novel Molecules – Progressing to key milestones

Asset	Details
<b>Tregopil</b> Phase II/III Ongoing	<b>USP: Oral, Ultra Rapid-Acting</b> Post- prandial glycemic control; Liver specific- portal delivery, Weight neutral <ul style="list-style-type: none"> <li>▪ Safety &amp; tolerability established in Phase 1 studies in US – DDI, Food Effect, PK/PD Data available</li> <li>▪ Pivotal Phase II/III clinical study in T2DM patients in India initiated, patient dosing ongoing</li> <li>▪ JDRF supported Phase I Multiple Ascending Dose study planned in T1DM patients</li> </ul>
<b>Itolizumab</b> IND ready	<b>USP: Novel CD-6 Biology presenting durable immune-modulatory benefits and superior clinical safety</b> <ul style="list-style-type: none"> <li>▪ Successful PoC data: Phase 3 in psoriasis, Phase 2 in rheumatoid arthritis, preclinical in multiple sclerosis. Marketed in India for Plaque Psoriasis</li> <li>▪ Preparations for IND commenced</li> </ul>
<b>QPI-1007</b> In Phase III	<b>Novel SiRNA for ophthalmic disease:</b> <ul style="list-style-type: none"> <li>▪ Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) – Patients randomized for global study (incl. in India)</li> </ul>
<b>BVX-20</b> IND ready	<b>2<sup>nd</sup> Generation humanized antibody targeting CD-20</b> <ul style="list-style-type: none"> <li>▪ Path to IND mapped out, to advance program in neuro-inflammatory disorder</li> </ul>
<b>EGFR mAb + TGFβRII (Fusion mAb)</b> IND Ready	<b>USP: Higher local tumor concentration of immuno-modulatory arm resulting in a better therapeutic window</b> <ul style="list-style-type: none"> <li>▪ Pharmacology &amp; MOA established in in-vitro &amp; in vivo tumour models</li> <li>▪ Proof of Concept established in in-vivo model</li> <li>▪ Opportunity to target multiple tumour types</li> </ul>



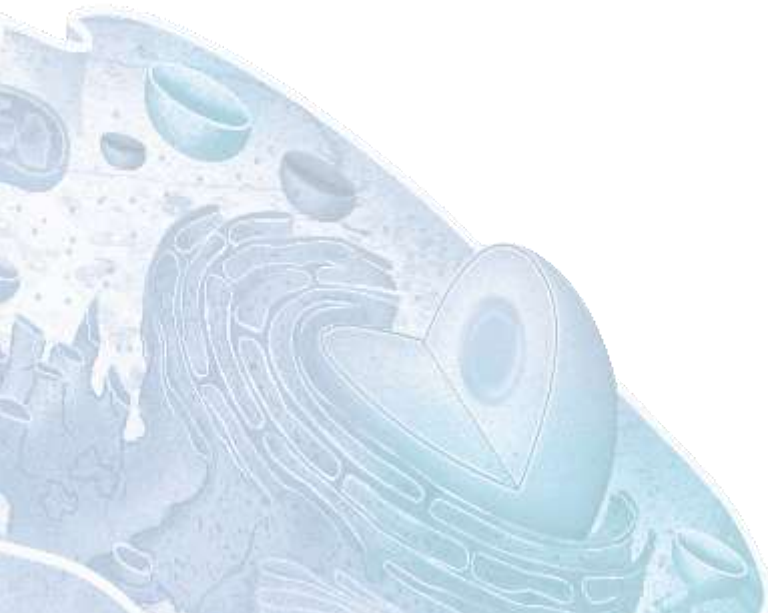
# Syngene (Research Services Business)

## Global High Growth CRO Company

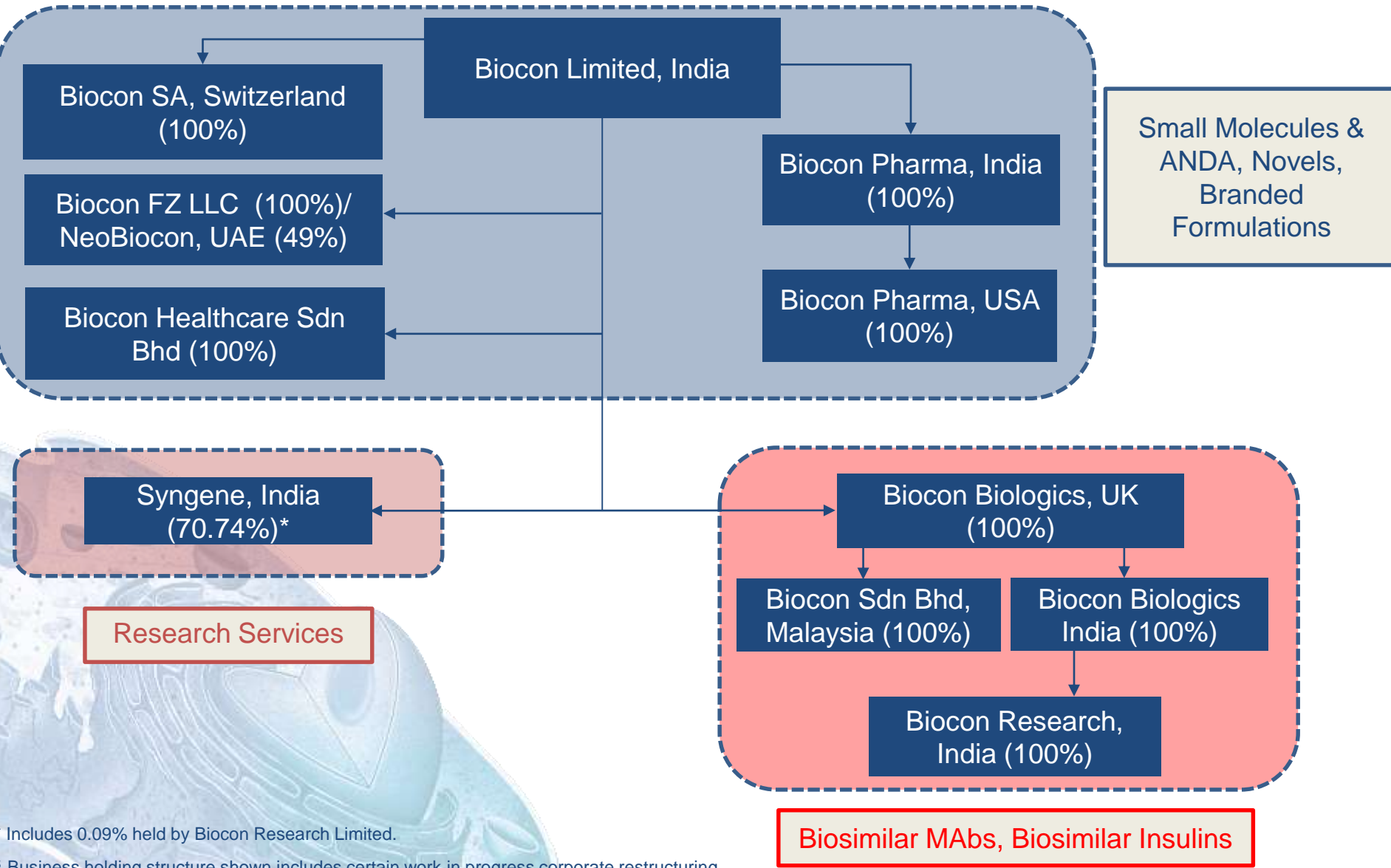
- ❖ Established in 1994, as India's first Contract Research Organization – 24 years of unparalleled experience in novel molecule discovery and development services
- ❖ Integrated Service Platform for small and large molecules, antibody-drug conjugates and oligonucleotides backed by best-in-class bioinformatics services
- ❖ End-to-end discovery, development and manufacturing capabilities
- ❖ World class infrastructure audited successfully by USFDA, EMA, AAALAC and major life science partners.
- ❖ 316<sup>(1)</sup> clients across multiple sectors
- ❖ 95%<sup>(1)</sup> of revenues from outside India
- ❖ 3,500<sup>(1)</sup> qualified scientists
- ❖ One of India's leading CROs
- ❖ World-class R&D and manufacturing infrastructure spread over 1.3 million sq. ft.
- ❖ Strong track record of top-line growth with best in class EBITDA margins (30+%) and Net Profit margin (high teens to low 20's)

(1) For fiscal ended March 31, 2018

# Appendix



# Business Holdings Structure\$



\* Includes 0.09% held by Biocon Research Limited.

\$ Business holding structure shown includes certain work in progress corporate restructuring

# Five Year Financial Performance Summary (FY13-17)#

All Figures in ₹ Million except EPS

Business Segment	FY13	FY14	FY15	FY16	FY17\$
<b>Biopharmaceuticals</b>	<b>18,705</b>	<b>21,382</b>	<b>22,367</b>	<b>23,908</b>	<b>26,259</b>
- Biopharma	15,231	17,468	18,071	19,534	20,764
- Branded Formulations	3,474	3,914	4,296	4,374	5,495
<b>Contract Research</b>	<b>5,572</b>	<b>7,146</b>	<b>8,225</b>	<b>10,599</b>	<b>11,382</b>
<b>Total Sales</b>	<b>24,227</b>	<b>28,528</b>	<b>30,592</b>	<b>34,507</b>	<b>37,641</b>
Other Income	1,103	804	837	1,192	1,913
<b>Total Revenue</b>	<b>25,380</b>	<b>29,332</b>	<b>31,429</b>	<b>35,699</b>	<b>39,554</b>
EBITDA	5,957	7,429	7,489	9,045	10,656
EBITDA Margin (%)	23%	25%	24%	25%	27%
<b>Net Profit*</b>	<b>3,241</b>	<b>4,137</b>	<b>4,022</b>	<b>4,365</b>	<b>5,879</b>
Net Profit Margin	13%	14%	13%	12%	15%
<b>EPS*</b>	<b>16.2</b>	<b>20.7</b>	<b>20.1</b>	<b>21.8</b>	<b>29.4</b>
R&D Spends (in P&L)	1,640	1,310	1,688	2,750	2,665
R&D (as % of Biopharmaceuticals Sales)	8.8%	6.1%	7.5%	11.5%	10.1%

# Numbers as per old I-GAAP.

\* Pre-Exceptional items

\$ FY17 numbers have not been restated for comparative purposes, hence not comparable. Effective Apr 1, 2016, the Company has moved to Ind-AS accounting framework, FY runs Apr to Mar

For further information, please visit  
[www.biocon.com](http://www.biocon.com)



### **Investor Relations contact:**

Saurabh Paliwal  
Tel : +91 80 6775 2040  
Email: [investor.relations@biocon.com](mailto:investor.relations@biocon.com)

