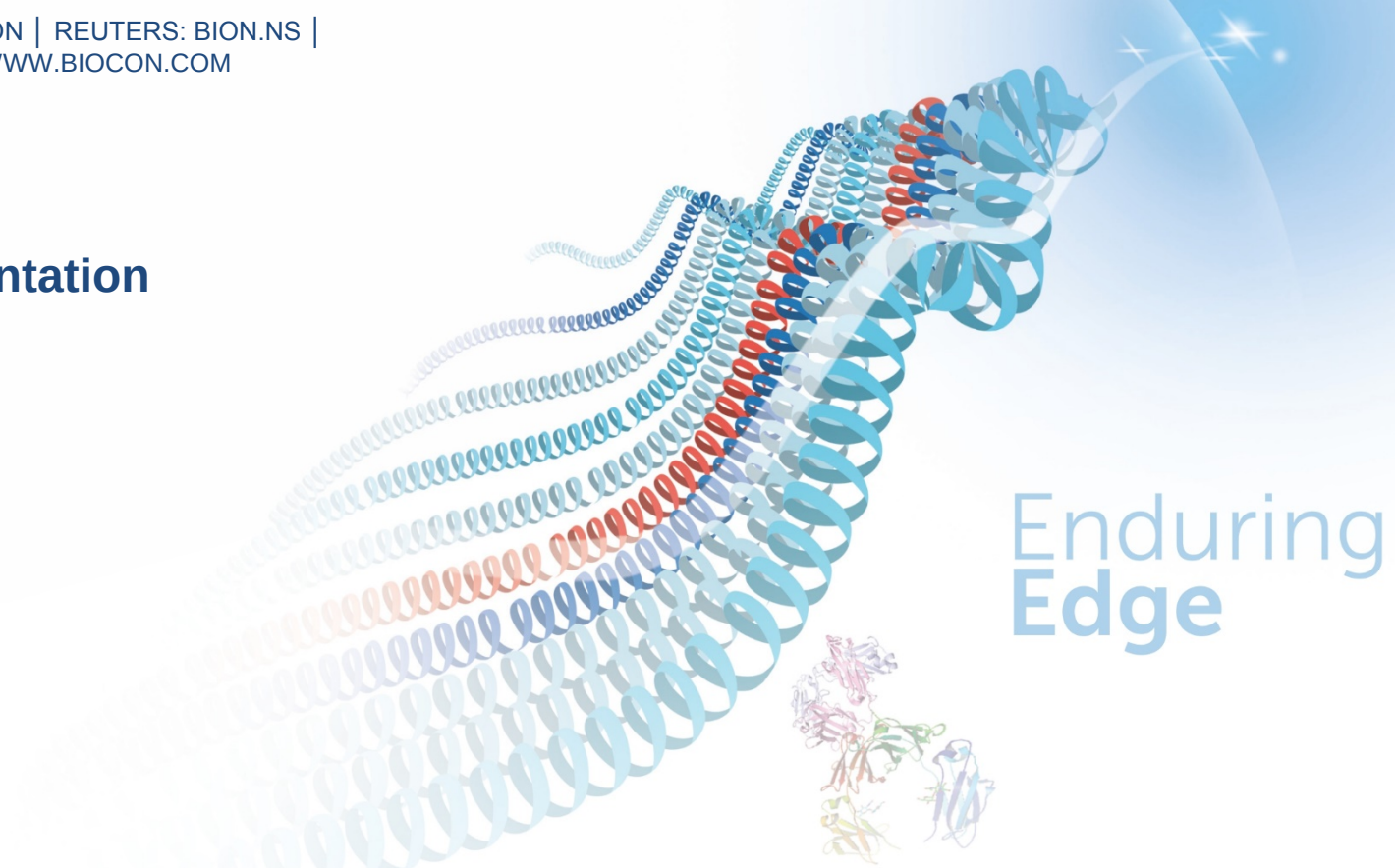
Biocon Limited

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

Investor Presentation

November 2018



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

Our Journey

Business & Financial Highlights

Our Business

- Small Molecules
- Biologics
- Branded Formulations
- Research Services - Syngene

Five Year Financials

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

Our Mission

To be an integrated Biotech enterprise of global distinction

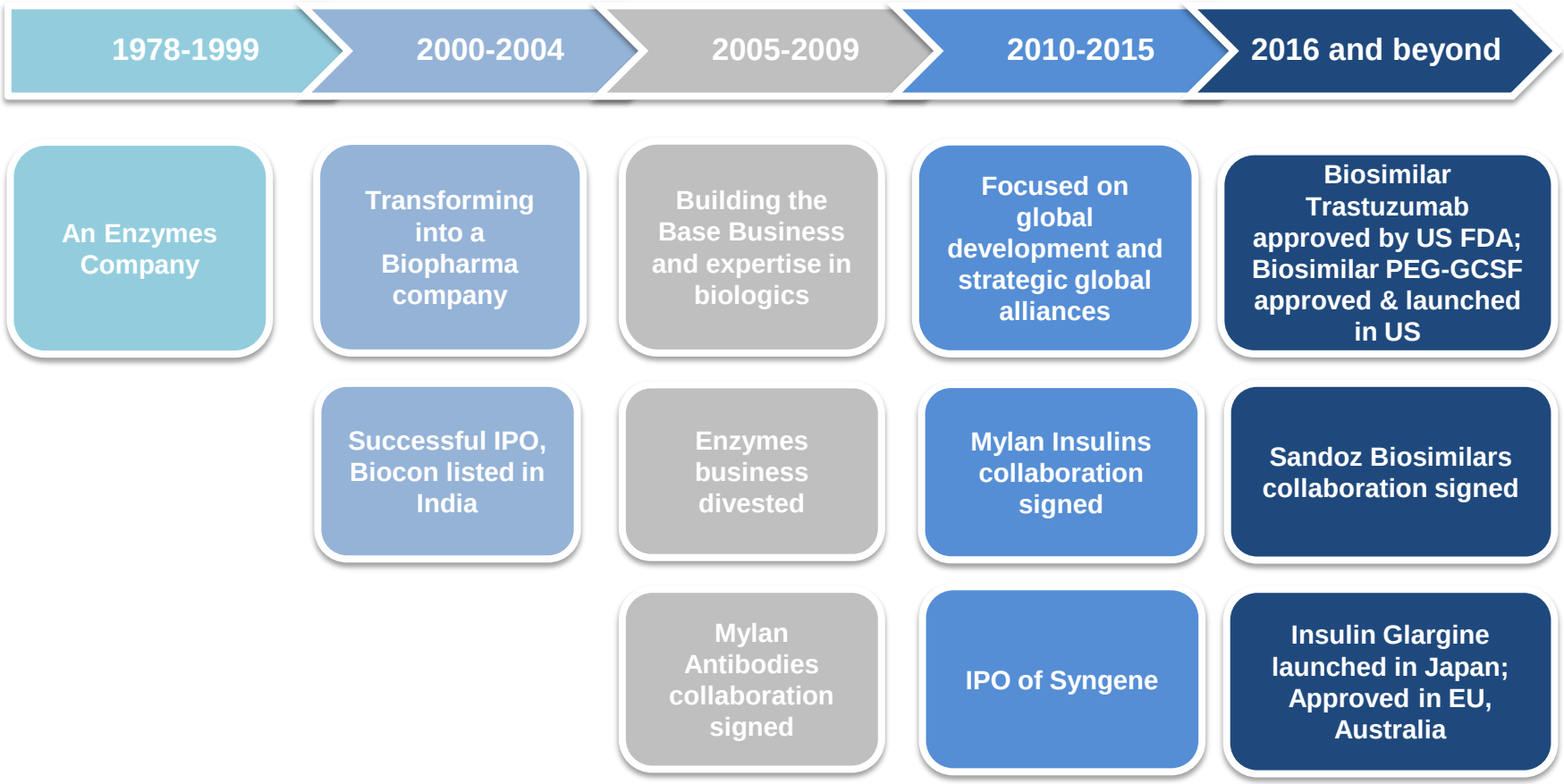
Our Values

- Integrity & Ethical Behavior
- Performance driven Work Culture
- Value Creation through Innovation & Differentiation
- Quality through Compliance & Best Practices
- Collaboration, Team Work & Mutual Respect

Committed to Affordable Access

Aiming to develop products that can potentially benefit a billion patients

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

Key Innovations: Making a Difference

2001
First US FDA approval for Lovastatin

2004
Launches
INSUGEN®
(rh- Insulin)

2006
First Novel Biologic

Launches
BIOMAb EGFR®
(Nimotuzamab)

2009

Launches
BASALOG®
(Insulin Glargine)

2011
Launches
INSUPen®/ INSUPen® EZ
(German Technology Insulin Delivery Device)

2013
Second Novel Biologic

Launches
ALZUMAb™
(Itolizumab)

2014
Introduces
CANMAb™
(Trastuzumab)

2015
(Insulin Glargine prefilled disposable pen)

Launches
Basalog One™

2016
Insulin Glargine launched in Japan

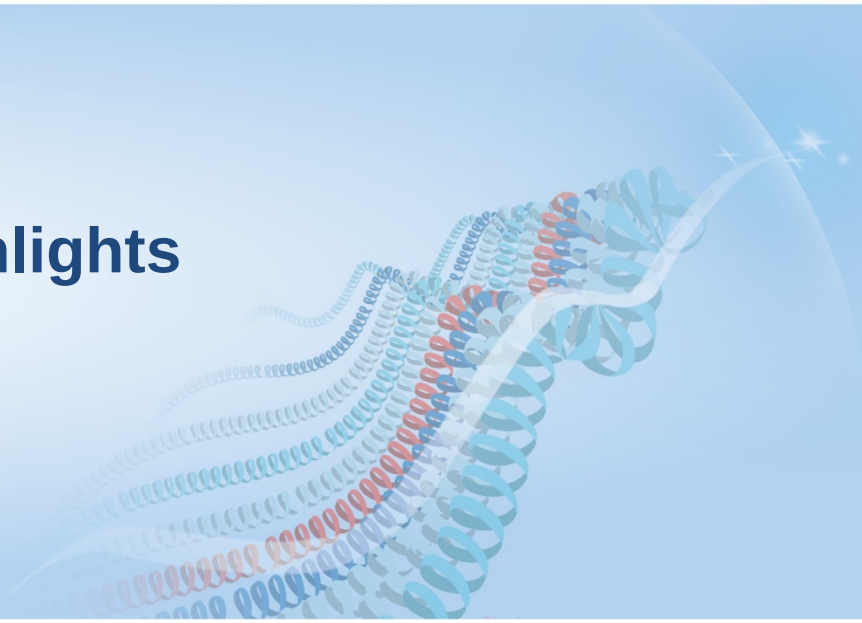
2017
Ogivri™, first biosimilar Trastuzumab approved by US FDA

Launches **KRABEVA®** in India

2018
Approval of **Semglee™** in EU and Australia

Approved and launched **Fulphila™** in US

Business & Financial Highlights



Business: Recent Highlights

- Our partner Mylan commenced commercial sales of Fulphila™ (biosimilar Pegfilgrastim) in the U.S. It is the first biosimilar Pegfilgrastim to be approved and commercialized in the U.S. and the first product from our joint portfolio to be launched there.
- Our partner, Equillium, filed an Investigative New Drug (IND) application and received go ahead from the US FDA to progress Itolizumab, our novel anti CD6 molecule, into clinical development in the United States in orphan indications.
- The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) issued positive opinions recommending approval of Fulphila™, biosimilar pegfilgrastim and approval of Ogivri®, biosimilar Trastuzumab. The decisions on approval of these two biosimilars by the European Commission are expected by November'18 and December'18, respectively.
- Our partner Mylan initiated the commercial launch of biosimilar Adalimumab (FKB product) across major markets in Europe, post Oct 16, 2018. Biocon will receive economic benefit for this product in line with our global collaboration with Mylan.
- Syngene, our Research Services subsidiary commissioned a new dedicated facility for Bristol-Myers Squibb (BMS) and renewed its collaboration with Baxter with a widened scope of engagement.

Revenue Highlights

All Figures in ₹ Million except %

Particulars	Q2 FY19	Q2 FY18	Growth (%)	H1 FY19	H1 FY18	Growth (%)	FY18
- Small Molecules	4,319	3,505	23	8,320	7,134	17	15,077
- Biologics	3,675	1,557	136	6,172	3,396	82	7,702
- Branded Formulations	1,639	1,759	(7)	3,112	3,063	2	6,115
- Syngene (Research Services)	4,186	3,352	25	8,246	6,263	32	14,231
- Inter-segment	(609)	(487)		(1,402)	(833)		(1,828)
Revenue from Operations	**13,210**	**9,686**	**36**	**24,448**	**19,023**	**29**	**41,297**
- Other Income	544	508	7	1,232	1,048	18	2,062
Total Revenue	**13,754**	**10,194**	**35**	**25,680**	**20,071**	**28**	**43,359**

Financial Summary

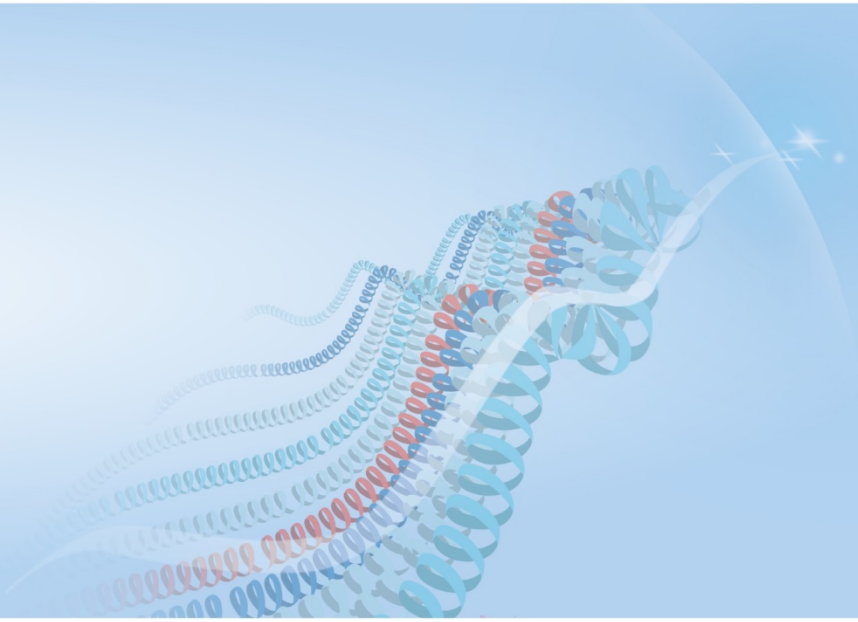
All Figures in ₹ Million except %

Particulars	Q2 FY19	Q2 FY18	Growth (%)	H1 FY19	H1 FY18	Growth (%)	FY18
Revenue	13,754	10,194	**35**	25,680	20,071	**28**	43,359
EBITDA	3,940	2,331	**69**	7,006	4,792	**46**	10,353
Net Profit[#]	1,840	688	**167**	3,037	1,501	**102**	3,724
R&D Expenses in P&L	769	539	**43**	1,211	1,121	**8**	2,158
Gross R&D Spends	1,196	956	**25**	2,079	1,887	**10**	3,804
EBITDA Margin	***29%***	***23%***		***27%***	***24%***		***24%***
EPS[#@] (Rs.)	**3.1**	**1.1**		**5.1**	**2.5**		**6.2**

[#] Adjusted for any exceptional items, [@] Adjusted for bonus

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

Our Business



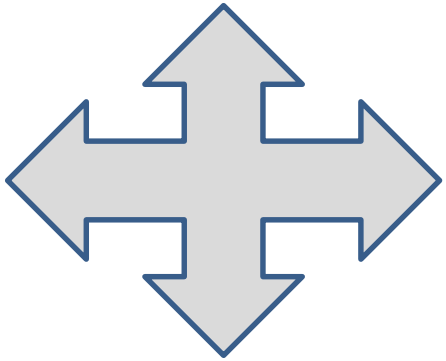
Business Segments

Branded Formulations

Finished Dosage Business in India & Overseas

Small Molecules

Differentiated APIs & Generic Formulations



Research Services

Syngene

CRO offering integrated service platform for novel molecule drug discovery & development for small & large molecules

Biologics

Novel Biologics & Biosimilars

Innovation in biologics development including novel molecules & biosimilars

Complex Small Molecule APIs to Biologics Novels & Biosimilars	Comprehensive Presentation in Biologics		
	Drug Substance	**Drug Products** Vials, Cartridges & Prefilled Syringes	**Delivery Devices** Reusable & Disposable Prefilled, Pens

Small Molecule : APIs & Generic Formulations

Differentiated APIs

- Product Portfolio leverages core fermentation technology strengths
- Among world's largest manufacturers of statins & immunosupressant APIs
- Early mover in niche products at commercial scale

Current Portfolio	Constituents
Statins	Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, & Fluvastatin.
Immuno suppressants	Tacrolimus, Sirolimus, Everolimus, MMF & MPA
Other Biopharma	Orlistat, Fidaxomicin, Glatiramer Acetate, other molecules

Generic Formulations

- Niche pipeline; Solid oral & parenteral products in both potent & non-potent categories for emerging and developed markets.
- Focus therapeutic segments – Metabolics, Oncology, Immunology & Auto-immune indications
- Generic Formulations strategy includes First-to-Files and Para IVs.
- Launched generic Rosuvastatin, Simvastain & Atorvastatin tablets in US

Focus on vertically integrated development of molecules in chronic therapeutic areas

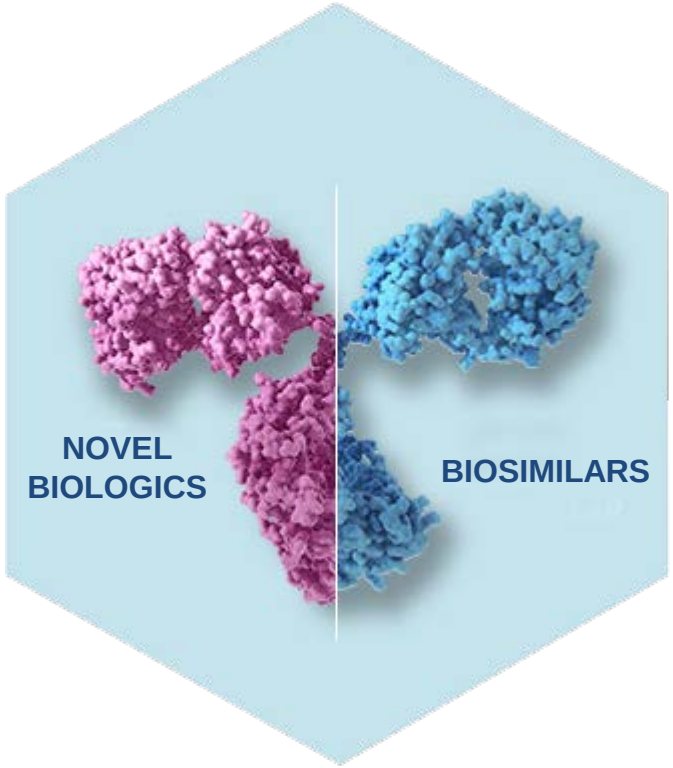
Biologics: Biosimilars & Novel Biologics

Biosimilars

15+ years of experience is developing biologics with multiple biosimilars commercialized globally

Strong scientific and technical capabilities. Over 1500 people dedicated to support this business across various functions

Portfolio straddles rh-insulin, insulin analogs, mAbs and other recombinant proteins.



Novel Biologics

Creating market leadership in Innovation e.g., Insulin Tregopil, Itolizumab

Pipeline includes oral insulin; mAbs against targets like CD6, CD20 & EGFR; bispecific fusion mAbs; siRNA.

Potential to change the treatment paradigm in diabetes, immunology.

Biocon is a pioneer in bringing high quality, yet affordable, novel biologics & biosimilars to patients globally

Strategic Partnership with Mylan for Biosimilars: Insulins & mAbs

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 Biologics
Mylan's Exclusive Commercialization Regions	US, Canada, Europe, Australia & New Zealand	Developed markets

In Developed Markets only

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

Strategic Partnership with Sandoz for next generation Biosimilars

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
1. North America (US & Canada) 2. EU (European Free Trade Association (EFTA) and Balkan states)	1. Japan, Australia, New Zealand 2. All Emerging Markets

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

Status of Biocon's Global Biosimilars Portfolio

Partner	Therapeutic Area	Molecule	Status
MYLAN & LOCAL PARTNERS	Oncology	Trastuzumab	Approved in U.S. Received positive opinion recommending approval from EMA's CHMP. Under review in Canada and Australia. Launched in emerging markets
	Diabetes	Insulin Glargine	Approved in EU & Australia. Under review in U.S. and Canada. Launched in Japan through partner FUJIFILM Pharma. Launched in emerging markets
	Oncology	Pegfilgrastim	Approved and launched in U.S. Received positive opinion recommending approval from EMA's CHMP. Under review in Canada and Australia
	Diabetes	Insulin Aspart	Global Phase I completed
	Diabetes	Insulin Lispro	Preclinical
	Autoimmune	Adalimumab	Mylan has launched Hulio in EU. Biocon benefits from economic interest.
	Oncology	Bevacizumab	Launched in India. Global Phase III ongoing
	Oncology	Filgrastim	Preclinical
	Autoimmune	Etanercept	Mylan's in-licensed product filed for approval in Europe. Biocon retains economic interest
LOCAL PARTNERS	Diabetes	Recombinant Human Insulin	Launched in several emerging markets. In active development for U.S. (partnered with Lab Pisa)
SANDOZ	Oncology & Immunology	Various	Early stage development

Biocon Well Placed in Competitive Global Landscape

Molecule	Biosimilar Development Pipeline@					
	Phase I	Phase 3	Regulatory Submission		Approved/ Marketed	
			EMA	FDA	EMA	FDA
pegfilgrastim	DRL, Pfizer, Adello, Lupin, Zydus		Richter, USV	Apotex, Sandoz	Biocon (+CHMP), Coherus, Accord, Sandoz (+CHMP), Cinfa (+CHMP)	Biocon, Coherus
trastuzumab	DM Bio, United BioPharma, Alteogen	Hanwha, Tanvex, EirGen, Shanghai Henlius / Accord		Amgen, Celltrion, Pfizer, Samsung	Biocon (+CHMP), Pfizer Samsung, Celltrion, Amgen	Biocon
insulin glargine		Biocon, Gan & Lee		Biocon	Biocon, Eli Lilly	Eli Lilly
adalimumab	Oncobiologics, DM Bio, Alvotech	Coherus, Biocon, Momenta, Pfizer	Fresnius	Samsung	Amgen, Samsung, BI, Sandoz, Mylan-Fuji Kirin	Amgen, BI, Sandoz
bevacizumab	Sandoz, Daiichi, Cipla, DRL, Tanvex, Apobiologix, Celltrion	Biocon, BI, Pfizer, Samsung, Fuji-Kirin/ Astra Zeneca, Hanwha, Bio-Thera, mAbxience, Centus, Luye, Shanghai Henlius, Oncobiologics	Pfizer		Amgen	Amgen
insulin aspart	Biocon	Sanofi				

@ In clinical development, excludes pre-clinical assets

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.

Insulins Facility In Bangalore

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

Novel Molecules - Pipeline & Therapeutic Area Focus

DIABETES	**Insulin Tregopil *** First-in-Class Oral, Prandial Insulin	**India Phase II/III in T2D commenced**
INFLAMMATION	**Itolizumab*** Novel, humanized CD6 Antibody	**IND Approved for orphan indications**
	BVX-20# Novel, humanized CD20 Antibody	**Path to IND mapped**
	QPI-1007$ SiRNA for ophthalmic disease	**Phase III in NAION**
IMMUNO-ONCOLOGY	**EGFR mAb + TGFβrII*** Tumor-Targeted Fusion mAb*	**Preclinical**

- * In-House program, out licensed to Equillium for US & Canada
- # BVX-20 with Vaccinex
- $ QPI-1007 licensed from Quark Pharma.

Novel Molecules: Progressing to key milestones

Asset	Details
Insulin Tregopil Phase II/III Ongoing	**USP: Oral, Ultra Rapid-Acting** Post- prandial glycemic control; Liver specific- portal delivery, Weight neutral ▪ Safety & tolerability established in Phase 1 studies in US – DDI, Food Effect, PK/PD Data available ▪ Pivotal Phase II/III clinical study in T2DM patients in India initiated, patient dosing ongoing ▪ JDRF supported Phase I Multiple Ascending Dose study planned in T1DM patients
Itolizumab IND Approved for orphan indications	**USP: Novel CD-6 Biology presenting durable immune-modulatory benefits and superior clinical safety** ▪ Marketed in India for Plaque Psoriasis, licensed to Equillium for US & Canada ▪ Phase 1b/2 clinical trial for the treatment of acute graft-versus-host disease, or aGVHD, planned in early 2019 ▪ Phase 2 clinical trial for the treatment of chronic graft-versus-host disease, or cGVHD, planned in H1 2019 ▪ Proof-of-concept clinical trial for the treatment of severe asthma planned in H1 2019
QPI-1007 In Phase III	**Novel SiRNA for ophthalmic disease:** ▪ Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) – Patients randomized for global study (incl. in India)
BVX-20 IND ready	**2nd Generation humanized antibody targeting CD-20** ▪ Path to IND mapped out, to advance program in neuro-inflammatory disorder
EGFR mAb + TGFβRII (Fusion mAb) IND Ready	**USP: Higher local tumor concentration of immuno-modulatory arm resulting in a better therapeutic window** ▪ Pharmacology & MOA established in in-vitro & in vivo tumour models ▪ Proof of Concept established in in-vivo model ▪ Opportunity to target multiple tumour types

Branded Formulations: India & UAE

- Specialty business with regional ambitions; strong value builder for Biocon.
- Biologics-led specialty products focused on chronic therapy areas.
- Comprehensive offering of products, patient and physician support programs

INDIA

- India's largest Insulins & leading Oncology Company
- Presence across therapies: Metabolics, Oncotherapeutics, Immunotherapy, Nephrology and Comprehensive Care Division.
- Several brands ranked amongst 'Top 3' brands in respective segments.

UAE

- Ranked among Top 15 pharmaceutical companies in UAE.
- Most branded generic products in Top 2 in respective segments.
- Ranked at No 4 in the cardiovascular segment.

- **Insugen®** ranks among Top 3 human insulin brands in India
- **CANMAb™** is No. 1 brand of Trastuzumab in India
- **KRABEVA®**, biosimilar Bevacizumab, benefiting large number of patients in India

Key Brands

Insugen®
Basalog®
BIOMAb EGFR®
CANMAb™
ALZUMAb™
KRABEVA®
TACROGRAF™

Research Services Business: Syngene

- One of leading India based CROs, a global high growth CRO company
- Offers an integrated drug discovery and development platform for both small and large molecules, antibody-drug conjugates and oligonucleotides backed by best-in-class bioinformatics services
- End-to-End discovery, development and manufacturing capabilities with focus on novel molecular entities
- World class infrastructure audited successfully by US FDA, EMA, AAALAC and major life sciences partners
- Over 316* global clients across multiple sectors
- World-class R&D and manufacturing infrastructure spread over 1.3 million sq. ft
- 3,500* qualified scientists
- Strong track record of top-line growth with best in class EBITDA margins (30+%) and Net Profit margin (high teens to low 20's)

* For fiscal ended March 31, 2018

Five Year Financials

All Figures in ₹ Million except EPS

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

Investor Relations contact:

Saurabh Paliwal

Tel : +91 80 6775 2040

Email: investor.relations@biocon.com

For further information, please visit
www.biocon.com