



Biocon Limited

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CIN : L24234KA1978PLC003417

www.biocon.com

Letter No: 2017/SEC/NOV/152

November 08, 2017

National Stock Exchange of India Limited
"Exchange Plaza", 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex
Bandra (East), Mumbai – 400051

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai – 400001

NSE - Symbol - BIOCON

BSE - Scrip code - 532523

Dear Sirs,

Sub: Presentation on financial results of the Company for the quarter and half year ended September 30, 2017.

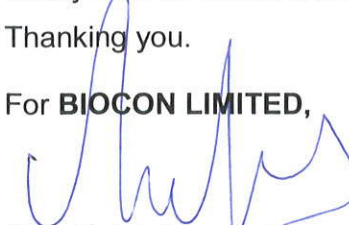
In compliance with the provisions of regulation 30 (6) of SEBI (Listing Obligations & Disclosure Requirements), Regulations, 2015, please find enclosed herewith, a presentation on financial results of the Company for the quarter and half year ended September 30, 2017.

The above mentioned presentation will be made by the Company to the Analysts/ Institutional Investors and a copy of the same is also available on the website of the Company www.biocon.com.

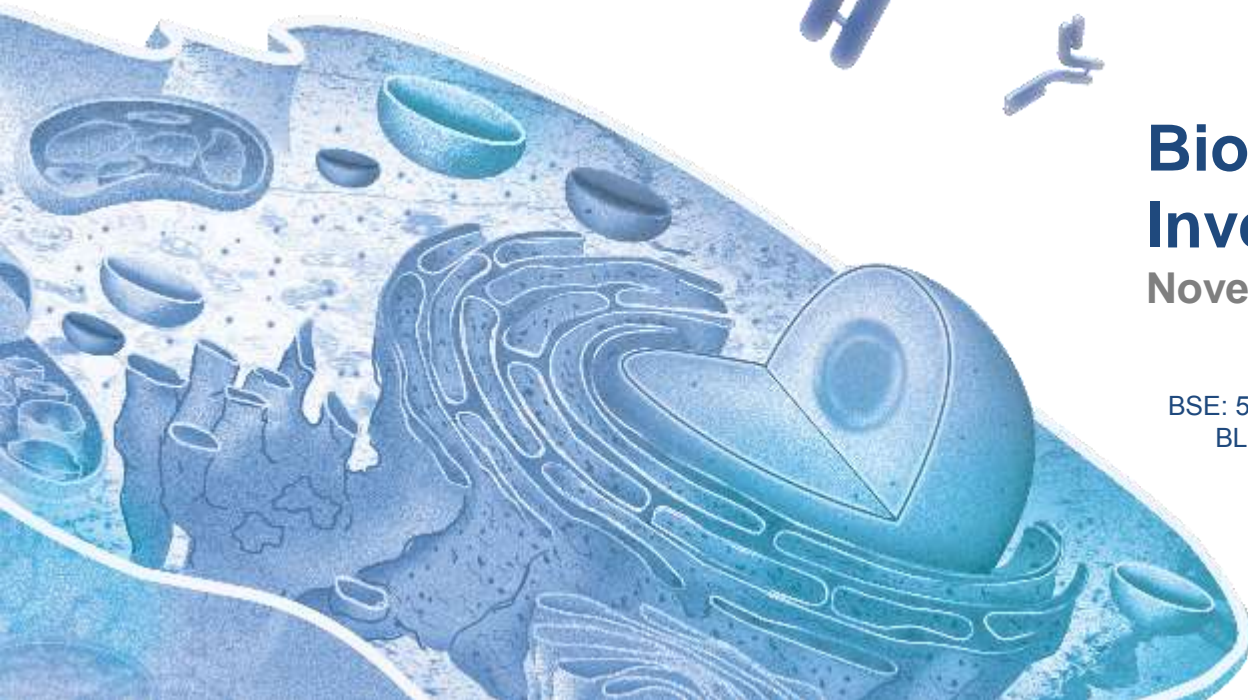
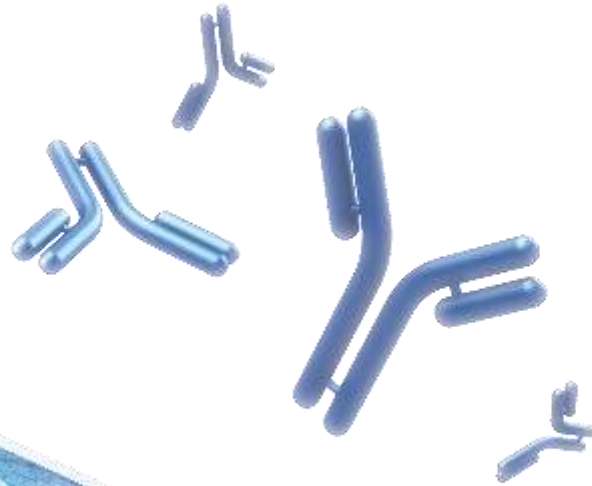
Kindly take on record the same.

Thanking you.

For **BIOCON LIMITED**,


Rajiv Balakrishnan
Company Secretary

Ahead
of the curve



Biocon Limited
Investor Presentation
November 2017

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?

Highlights

- Business Highlights
- Financial Highlights

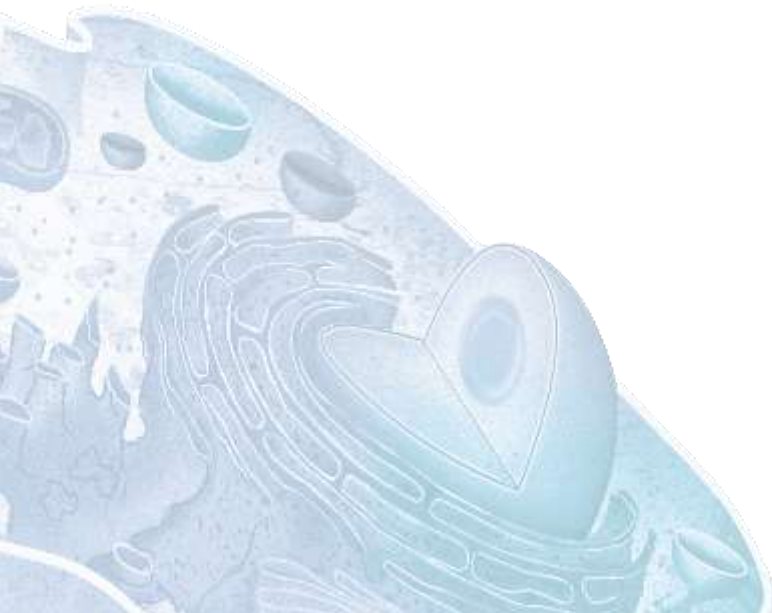
Business Segments

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

Five Year Financial Summary

Outlook

Who are we?



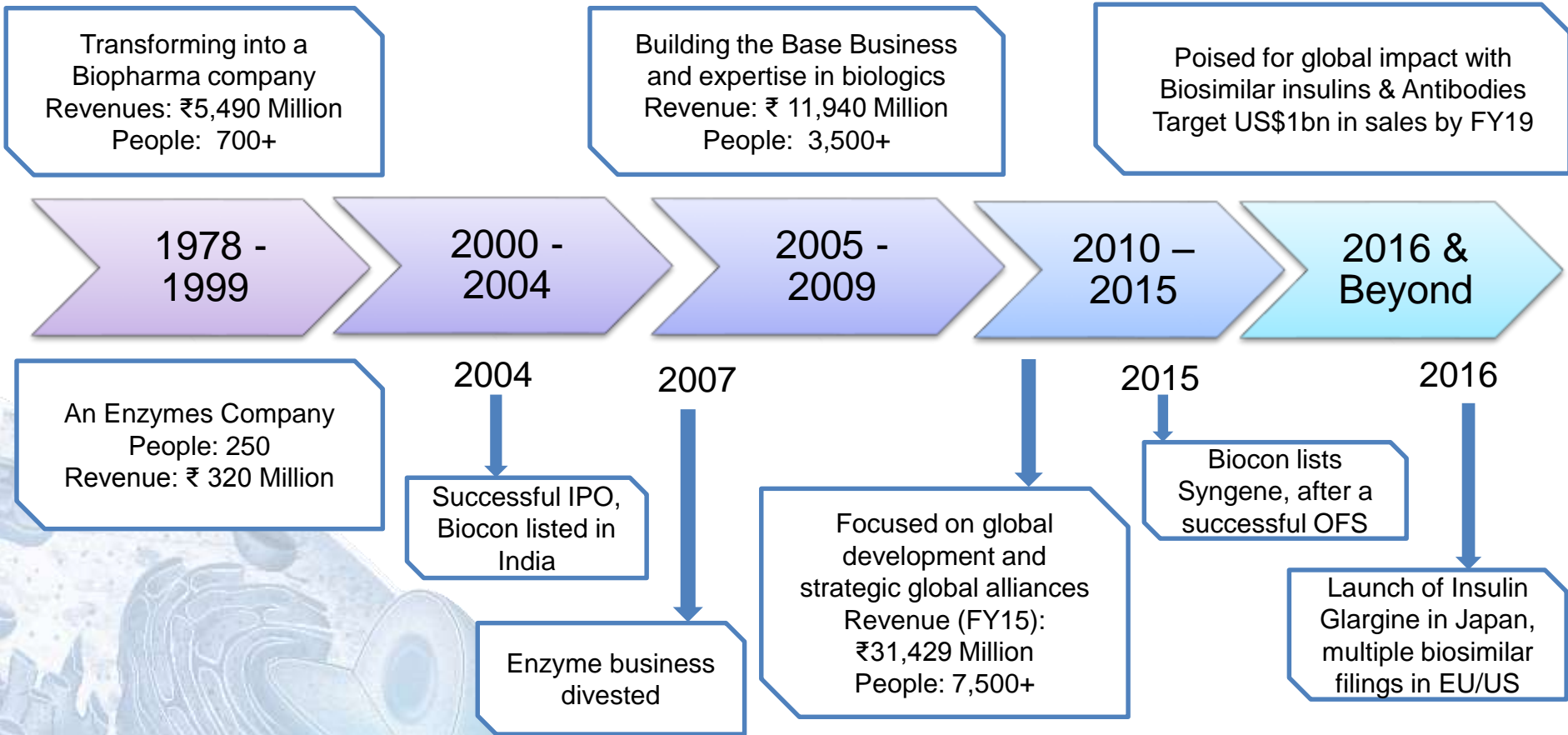
Biocon: Asia's Leading Biopharma Company

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



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-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



Recent Highlights

- ❖ Biocon's partner Mylan submitted our 505(b)(2) application for **Insulin Glargine with US FDA**
- ❖ US FDA extended the BsUFA goal date for Mylan/Biocon's proposed biosimilar **Trastuzumab to December 3, 2017**
- ❖ Biocon's partner Mylan has resubmitted the **Marketing Authorization Applications (MAAs)** for proposed biosimilar **Trastuzumab** and **Pegfilgrastim** with the **European Medicines Agency (EMA)** as per the administrative protocol. **Biocon has completed the Corrective and Preventive Actions (CAPAs)**, including the facility modifications, in response to the audit observations and expects these to be verified during re-inspection.
- ❖ The US FDA issued a **Complete Response Letter (CRL)** for Mylan/Biocon's proposed biosimilar **Pegfilgrastim**. The CRL relates to the pending update of the BLA with certain CMC data from facility requalification activities post recent plant modifications. The CRL did not raise any questions on biosimilarity, pharmacokinetic/pharmacodynamic data, clinical data or immunogenicity. We are working to expeditiously respond to the CRL.
- ❖ **Biocon's Malaysia Insulins facility** received GMP certificate from EMA
- ❖ **JDRF** supports Biocon Study of Novel, Fast-acting Oral Insulin Tregopil for Type 1 Diabetes Treatment

Revenue Highlights

All Figures in ₹ Million except %

Particulars	Q2 FY18	Q2 FY17	Growth (%)	H1 FY18	H1 FY17	Growth (%)	FY17
- Small Molecules	3,505	4,034	(13)	7,134	8,388	(15)	16,405
- Biologics	1,557	1,555	0	3,396	3,161	7	7,018
- Branded Formulations	1,759	1,366	29	3,063	2,946	4	5,489
- Syngene (Research Services)	3,352	3,030	11	6,263	5,775	8	11,925
- Inter-segment	(487)	(444)	10	(833)	(809)	3	(1,621)
Revenue from Operations	9,686	9,541	2	19,023	19,461	(2)	39,216
- Other Income	508	384	32	1,048	793	32	1,571
Total Revenue	10,194	9,925	3	20,071	20,254	(1)	40,787

Financial Summary

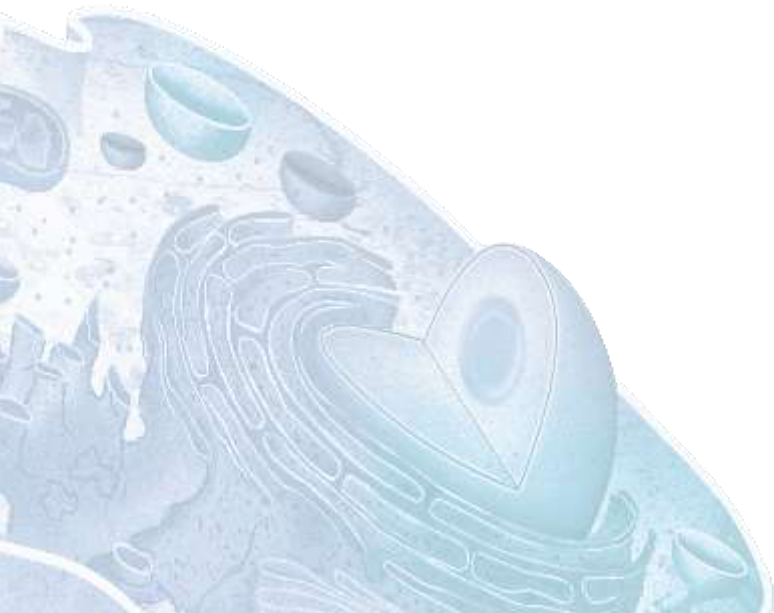
All Figures in ₹ Million except %

Particulars	Q2 FY18	Q2 FY17	Growth (%)	H1 FY18	H1 FY17	Growth (%)	FY17
Revenue	10,194	9,925	3	20,071	20,254	(1)	40,787
EBITDA	2,330	2,784	(16)	4,791	5,824	(18)	11,366
Net Profit [#]	687	1,467	(53)	1,500	3,133	(52)	6,199
R&D Expenses in P&L	539	650	(17)	1,121	1,164	(4)	2,662
Gross R&D Spends	931	1,126	(17)	1,887	2,041	(8)	4,019
EBITDA Margin	23%	28%		24%	29%		28%
EPS^{#@} (Rs.)	1.1	2.4		2.5	5.2		10.3

~ Revenue mix (FY17): Ex-India 70% : India 30%

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

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.
- ❖ Target to file ~10-15 dossiers in the next few years.
- ❖ Pipeline includes solid oral & parenteral products in both potent & non-potent categories of compounds.
- ❖ Focus therapeutic segments – Metabolics, Oncology, Immunology & Auto-immune indications.
- ❖ Oral Solid Dosage facility to support our future generic formulation applications has been commissioned. Will enable regulatory filings in developed and emerging markets. Investment made - US\$25mn.

Focus on niche specialty molecules in chronic therapeutic segments

Biosimilars

- ❖ **In July 2017, U.S. Food and Drug Administration (USFDA) Oncologic Drug Advisory Committee (ODAC)** recommended for approval Biocon-Mylan's proposed biosimilar Trastuzumab in all eligible indications; **first biosimilar Trastuzumab to be recommended by the Committee**. Our BsUFA goal date is Dec 3, 2017
- ❖ The US FDA issued a **Complete Response Letter (CRL)** for Mylan/Biocon's proposed biosimilar **Pegfilgrastim**. The CRL relates to the pending update of the BLA with certain CMC data from facility requalification activities post recent plant modifications
- ❖ 505(b)(2) application for **Insulin Glargine** under active review **with US FDA**. Biosimilar **Insulin Glargine** in the last leg of the review process with the **European Medicines Agency (EMA)**. Malaysia insulin facility has received EU GMP certificate
- ❖ **Marketing Authorization Applications (MAAs)** for proposed biosimilar **Trastuzumab** and **Pegfilgrastim resubmitted** with the **European Medicines Agency (EMA)** as per the administrative protocol.
- ❖ Work on our second fill-finish sterile injectable facility in Bangalore to support future growth of biologics formulations close to completion. Facility commissioned; validation in progress. Investment made - US\$25mn

Amongst the largest portfolio of biosimilars globally with addressable market size of over US\$61 Billion

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 Biologics
Mylan's Exclusive Commercialization Regions	US, Canada, Europe, Australia & New Zealand	Developed markets
Market Opportunity*	~US\$17bn	~US\$44bn

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

Global Biosimilars Pipeline – US\$61bn opportunity

	Molecule	Type	Status	Market Size* (US\$ bn)
INSULINS	Rh Insulin	Regular Acting Insulin	Pre-clinical (US), Marketed in EM	3.2
	Glargine	Long Acting Insulin	Filed in EU, US, Australia & Canada. Marketed in Japan (since Jul-16) & EM	6.4
	Aspart	Rapid Acting Insulin Analog	Preclinical	4.5
	Lispro	Rapid Acting Insulin Analog	Preclinical	2.8
				Insulins Total Market Size (rounded off)
BIOSIMILARS	Adalimumab	Auto-Immune	Global Phase III completed	16.1
	Trastuzumab	Cancer	Filed in US, EU, Canada, Australia, Filed/ Marketed in EM	6.9
	Pegfilgrastim	Neutropenia	Filed in US, EU, Canada, Australia, EM	4.6
	Bevacizumab	Cancer	Global Phase III	6.9
	Filgrastim	Neutropenia	Early development	0.8
	Etanercept	Auto-Immune	Early Development	8.9
				Biosimilars Total Market Size (rounded off)

*Market Size of innovator products in the current portfolio: Innovator Sales CY 2016

Conversion into USD done using average exchange rate for CY 2016 as given on <http://www.federalreserve.gov/releases/G5a/current/default.htm>

Biosimilar Pipeline: Biocon well placed in the competitive landscape

Molecule	Biosimilar Development Pipeline [®]					
	Phase I	Phase 3	Regulatory Submission		Approved/ Marketed	
			EMA	FDA	EMA	FDA
pegfilgrastim	Dr. Reddy's, Pfizer	Apotex, Cinfa, Sandoz,	Biocon, Coherus	Biocon	None	None
trastuzumab		Hanwha, Pfizer, Samsung	Biocon, Amgen, Pfizer, Celltrion, Samsung	Biocon (+ve ODAC), Amgen, Celltrion	None	None
insulin glargine			Biocon	Biocon	Eli Lilly, Merck	Eli Lilly, Merck (TA)
adalimumab		Coherus, Biocon, Momenta, Pfizer, Fresenius, Sandoz, Fuji-Kirin, Oncobiologics,	BI, Fuji-Kirin, Sandoz	Samsung	Amgen, Samsung	Amgen, BI
bevacizumab	Sandoz, Daiichi, Oncobiologics,	BI, Pfizer, Samsung, Fuji-Kirin/ Astra Zeneca, Biocon, Dr.Reddy's	Amgen	Amgen (+ve ODAC)	None	None
filgrastim	Pfizer			Apotex	Sandoz, Teva, Pfizer, Stada, Apotex	Sandoz, Teva
etanercept	Hanwha	Coherus, Lupin, Samsung			Samsung, Sandoz	Sandoz
insulin aspart						
insulin lispro					Sanofi	Sanofi (TA)
rh-insulin						

[®] 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.
- ❖ Commercial supplies initiated with OTA award by Ministry of Health – Malaysia.
- ❖ Emerging market filings underway, commercial supplies to these markets expected to contribute to sales in FY18 and beyond
- ❖ Plant has received EMA GMP certificate for drug substance and drug product

- ❖ Commercial supplies from Disposable insulins pen line in Bangalore ongoing.
- ❖ Construction of second antibody manufacturing facility in Bangalore has commenced. 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 in India include INSUGEN® (rh-insulin), BASALOG® (Glargine), BIOMAb-EGFR™ (Nimotuzumab), BLISTO® (Glimepiride+Metformin), CANMAb™ (Trastuzumab), 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

DIABETES	Insulin Tregopil * First-in-Class Oral, Prandial Insulin	Phase II Ready T1D/ T2D
INFLAMMATION	Itolizumab* Novel, humanized CD6 Antibody	Phase I Ongoing
	BVX-20# Novel, humanized CD20 Antibody	IND Ready
	QPI-1007\$ SiRNA for ophthalmic disease	Phase III Initiated in NAION
	QPI-1024\$ SiRNA for inflammatory disease	Preclinical
IMMUNO-ONCOLOGY	Tumor-Targeted Fusion mAb*	Preclinical

- * In-House program
- # BVX-20 with Vaccinex
- \$ QPI-1007 & QPI- 1024 with Quark Pharma. QPI-1007 Global Phase III trial includes India.

Novel Molecules – Progressing to key milestones

Asset	Details
Tregopil Phase II Ready	USP: Oral, Ultra Rapid-Acting Post- prandial glycemic control; Liver specific- portal delivery, Weight neutral <ul style="list-style-type: none"> ▪ 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 (under an IND) finalized. ▪ Phase I Multiple Ascending Dose study planned in T1DM patients
Itolizumab Phase I Ongoing	USP: Novel CD-6 Biology presenting durable immune-modulatory benefits and superior clinical safety <ul style="list-style-type: none"> ▪ Successful PoC data: Phase 3 in psoriasis, Phase 2 in rheumatoid arthritis, preclinical in multiple sclerosis. Marketed in India for Plaque Psoriasis ▪ Initiated Phase I (Stages 1&2) - Single Ascending Dose study in Australia (S.C formulation). Stage 1 dosing completed; S.C route shows very good bioavailability. Stage 2 to be initiated shortly. ▪ Global filing plans ongoing – Phase II studies planned in inflammatory diseases
QPI-1007 In Phase III	Novel SiRNA for ophthalmic disease: <ul style="list-style-type: none"> ▪ 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 <ul style="list-style-type: none"> ▪ 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 <ul style="list-style-type: none"> ▪ Pharmacology & MOA established in in-vitro & in vivo tumour models ▪ Proof of Concept established in in-vivo model ▪ Clinical opportunity in multiple tumour types

Syngene (Research Services Business)

Global High Growth CRO Company

- ❖ Established in 1994, as India's first Contract Research Organization – 23 years of unparalleled experience in novel molecule discovery and development services
- ❖ One of the leading India-based contract research organizations (CRO)
- ❖ 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.
- ❖ 293⁽¹⁾ clients across multiple sectors
- ❖ 96%⁽¹⁾ of revenues from outside India
- ❖ ~3,053⁽¹⁾ qualified scientists
- ❖ 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 (30+%) and Net Income (high teens to low 20's)

(1) For fiscal ended March 31, 2017

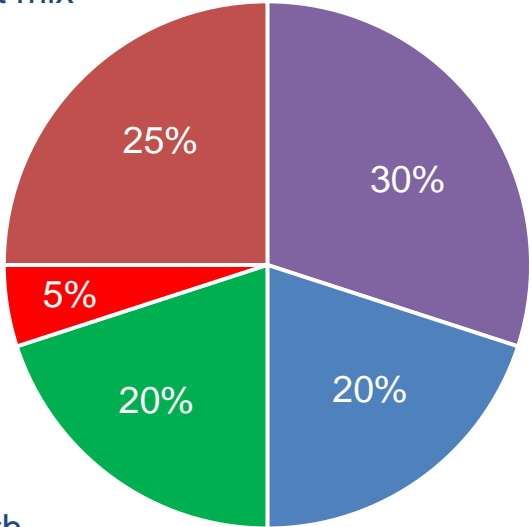
Outlook



Aspiring for \$1 Billion in Revenues by FY19

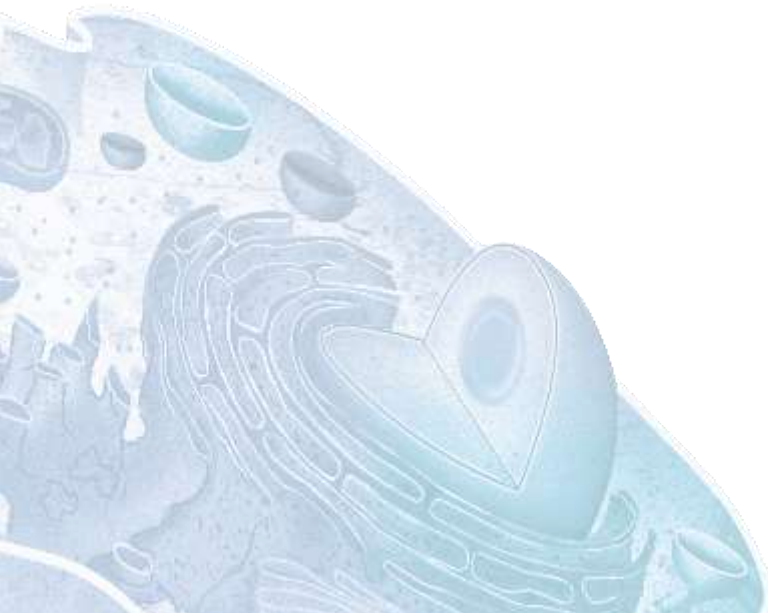
Key Focus Areas

- **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

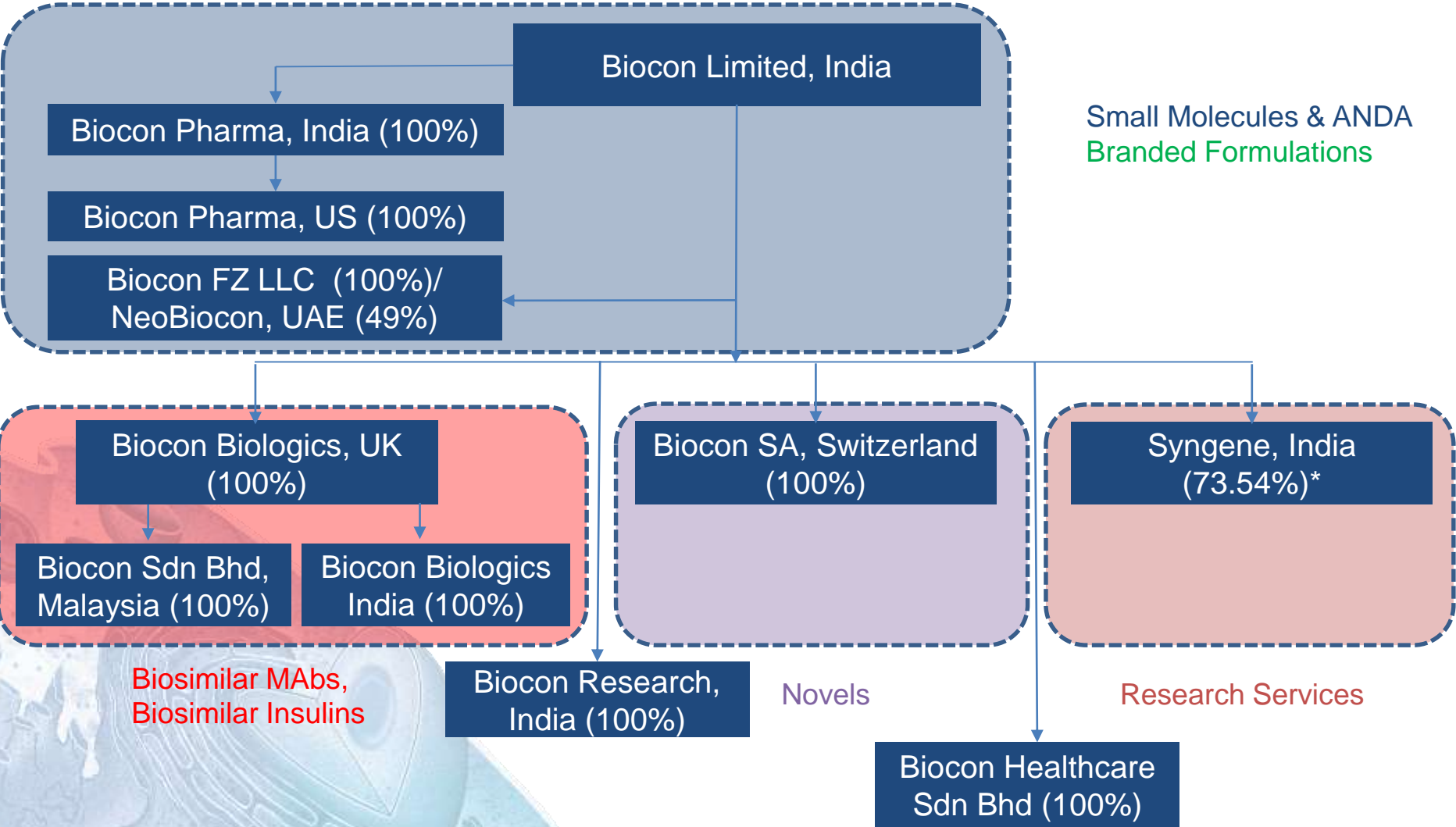


Growth drivers supplemented by addition of new offerings (products, services & partnerships)

Appendix



Business Holdings Structure



* Includes 0.93% held by Biocon Research Limited

Five Year Financial Performance Summary (FY13-17)#

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

For further information, please visit
www.biocon.com



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Email: saurabh.paliwal@biocon.com

