

Ahead of the curve

Biocon Limited Investor Presentation September 2017

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

Biocon

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?	
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	Highlights Business Highlights Financial Highlights Business Segments Small Molecules Biosimilars Branded Formulations Novel Molecules Research Services - Syngene Five Year Financial Summary



Who are we?



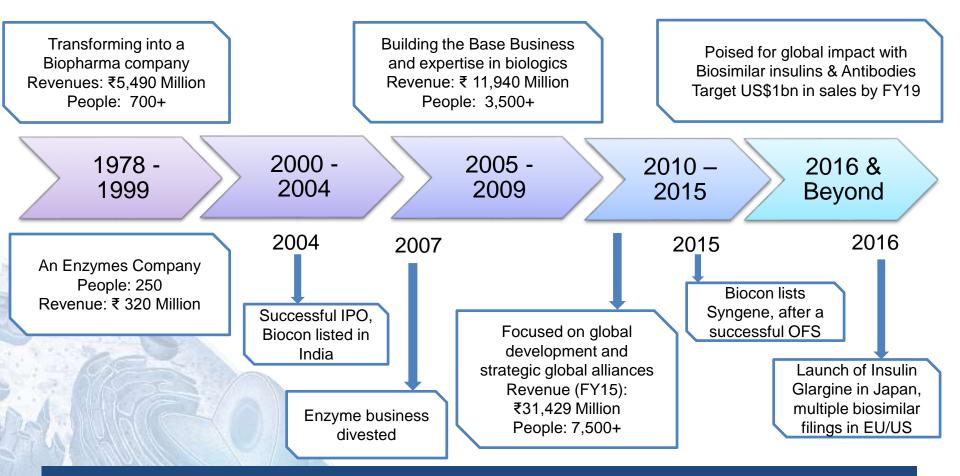
Biocon: Asia's Leading Biopharma Company

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 FUIJIFILM Pharma, first developed market launch for a Biocon product





Recent Highlights

- 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.
- Proposed biosimilars of Trastuzumab and Pegfilgrastim under review by USFDA while biosimilar Insulin Glargine is under review by the European Medicines Agency (EMA). Mylan-Biocon to refile biosimilar Trastuzumab and Pegfilgrastim with EMA post completion of implementation of Corrective Action Preventive Action plan.
- Biocon's Malaysia Insulins facility received GMP certificate from EMA
- Drug Controller General of India approved Biocon's biosimilar Bevacizumab, prescribed for various cancers including metastatic colorectal cancer and lung cancer. India launch expected shortly
- **JDRF** Supports Biocon Study of Novel, Fast-acting Oral Insulin Tregopil for Type 1 Diabetes Treatment



Revenue Highlights

All Figures in ₹ Million except %

Particulars	Q1 FY18	Q1 FY17	Growth (%)	FY17	FY16
- Small Molecules	3,629	4,354	(17)	16,405	14,583
- Biologics	1,839	1,606	15	7,018	5,296
- Branded Formulations	1,304	1,580	(17)	5,489	4,409
- Syngene (Research Services)	2,911	2,745	6	11,925	11,070
- Inter-segment	(346)	(365)	(5)	(1,621)	(1,548)
Revenue from Operations	9,337	9,920	(6)	39,216	33,810
- Other Income	540	409	32	1,571	792
Total Revenue	9,877	10,329	(4)	40,787	34,602



Financial Summary

All Figures in ₹ Million except %

Particulars	Q1 FY18	Q1 FY17	Growth (%)	FY17	FY16
Revenue	9,877	10,329	(4)	40,787	34,602
EBITDA	2,461	3,040	(-19)	11,366	8,470
Net Profit [#]	813	1,666	(51)	6,199	4,021
R&D Expenses in P&L	582	514	13	2,662	2,742
Gross R&D Spends	956	915	4	4,019	4,267
EBITDA Margin	25%	29%		28%	24%
EPS ^{#@} (Rs.)	1.4	2.8		10.3	6.7

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



Business Segments



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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.
- Construction of our first Oral Solid Dosage facility to support our future generic formulation filings in full swing in Bangalore. Estimated commissioning FY 2018. Total capex outlay -US\$25mn.

Focus on niche specialty molecules in chronic therapeutic segments



Biosimilars

- 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.
- Proposed biosimilars of Trastuzumab and Pegfilgrastim under review by USFDA while biosimilar Insulin Glargine is under review by the European Medicines Agency (EMA). Mylan-Biocon to refile biosimilar Trastuzumab and Pegfilgrastim with EMA post completion of implementation of Corrective Action Preventive Action plan.
- Engaged with USFDA to determine requirements to enable filing of generic Insulin Glargine in the US since we have decided to include the manufacturing site variations from Bangalore to Malaysia
 up-front in the application rather than a post-approval change
- 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. Total capex outlay -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

1	Deal Structure: Upfront Payment + Cost Sharing + Supplies + Profit Sharing [#]			
		Generic Insulin Analogs	Biosimilar MAbs & other Biologics	
1.14	Mylan's Exclusive Commercialization Regions	US, Canada, Europe, Australia & New Zealand	Developed markets	
Market C	Market Opportunity*	~US\$17bn	~US\$44bn	

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

In Developed Markets only; * Market Size of innovator products in the current portfolio: Innovator Sales CY 2016



Global Biosimilars Pipeline – US\$61bn opportunity

	Molecule	Туре	Status	Market Size* (US\$ bn)
	Rh Insulin	Regular Acting Insulin	Pre-clinical (US), Marketed in EM	3.2
INSULINS	Glargine	Long Acting Insulin	Filed in EU, Australia & Canada. Marketed in Japan (since Jul-16) & EM	6.4
NSL	Aspart	Rapid Acting Insulin Analog	Preclinical	4.5
=	Lispro	Rapid Acting Insulin Analog	Preclinical	2.8
			Insulins Total Market Size (rounded off)	17.0
	Adalimumab	Auto-Immune	Auto-Immune Global Phase III completed	
S	Trastuzumab	Cancer	Filed in US. Marketed in EM	6.9
AR	Pegfilgrastim	Neutropenia	Filed in US, Canada, Australia, EM	4.6
BIOSIMILARS	Bevacizumab	Cancer	Global Phase III commenced	6.9
SOI	Filgrastim	Neutropenia Early development		0.8
Ξ	Etanercept	Auto-Immune	Early Development	8.9
			Biosimilars Total Market Size (rounded off)	44.0

*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		Approve	ed/ Marketed
			EMA	FDA	EMA	FDA
pegfilgrastim	Dr. Reddy's, Pfizer	Biocon, Apotex, Cinfa, Sandoz,	Coherus	Biocon	None	None
trastuzumab		Biocon, Hanwha, Pfizer, Samsung	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, Fresnius, 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		D				

[®] Biosimilar Development Pipeline details may not be exhaustive, pipeline progress may not be perfectly accurate; Source: Company disclosures, research reports

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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

Commercial supplies from Disposable insulins pen line in Bangalore ongoing.

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



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), 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
	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
ONCOLOGY In-House program	Tumor-Targeted Fusion mAb*	Preclinical

BVX-20 with Vaccinex

• \$ QPI-1007 & QPI- 1024 with Quark Pharma. QPI-1007 Global Phase III trial includes India.

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Novel Molecules – Progressing to key milestones

Asset		Details
Tregopi Phase II		 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 (under an IND) finalized. Phase I Multiple Ascending Dose study planned in T1DM patients
Itolizum Phase I	hab Ongoing	 USP: Novel CD-6 Biology presenting durable immune-modulatory benefits and superior clinical safety 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-100 In Phase		 Novel SiRNA for ophthalmic disease: Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) – Patients randomized for global study (incl. in India)
BVX-20 IND read		 2nd Generation humanized antibody targeting CD-20 Path to IND mapped out, to advance program in neuro-inflammatory disorder
EGFR n (Fusion IND Rea		 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 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)

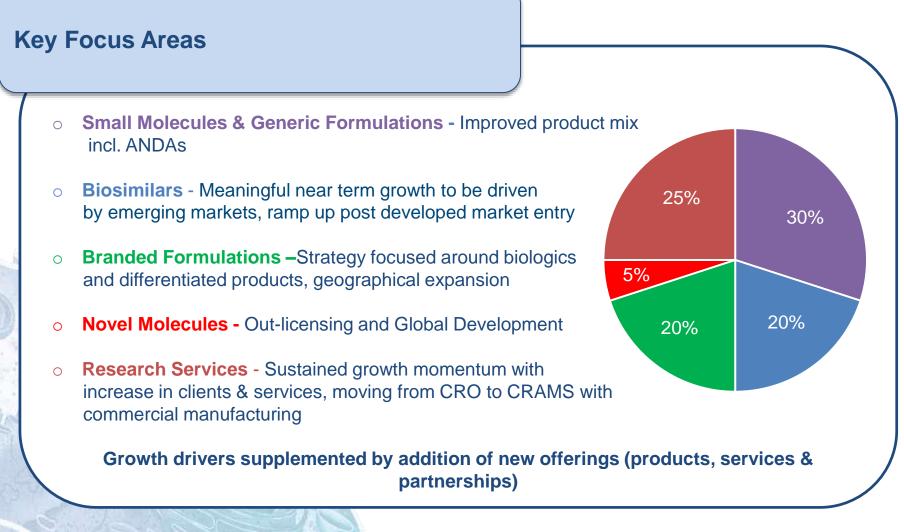


Outlook





Aspiring for \$1 Billion in Revenues by FY19



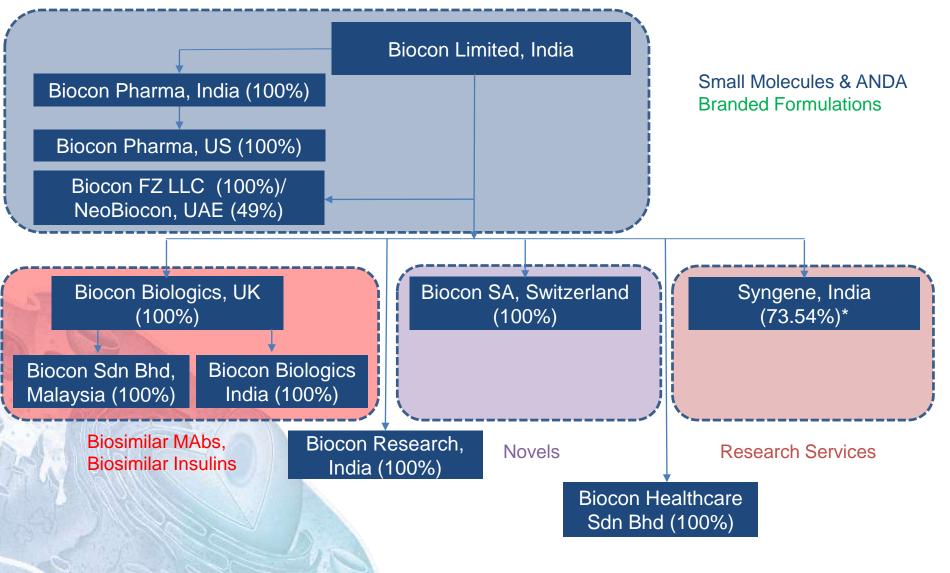


Appendix





Business Holdings Structure



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



All Figures in ₹ Million except					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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