

Biocon Limited

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

Investor Presentation

May 2019



Enduring
Edge

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

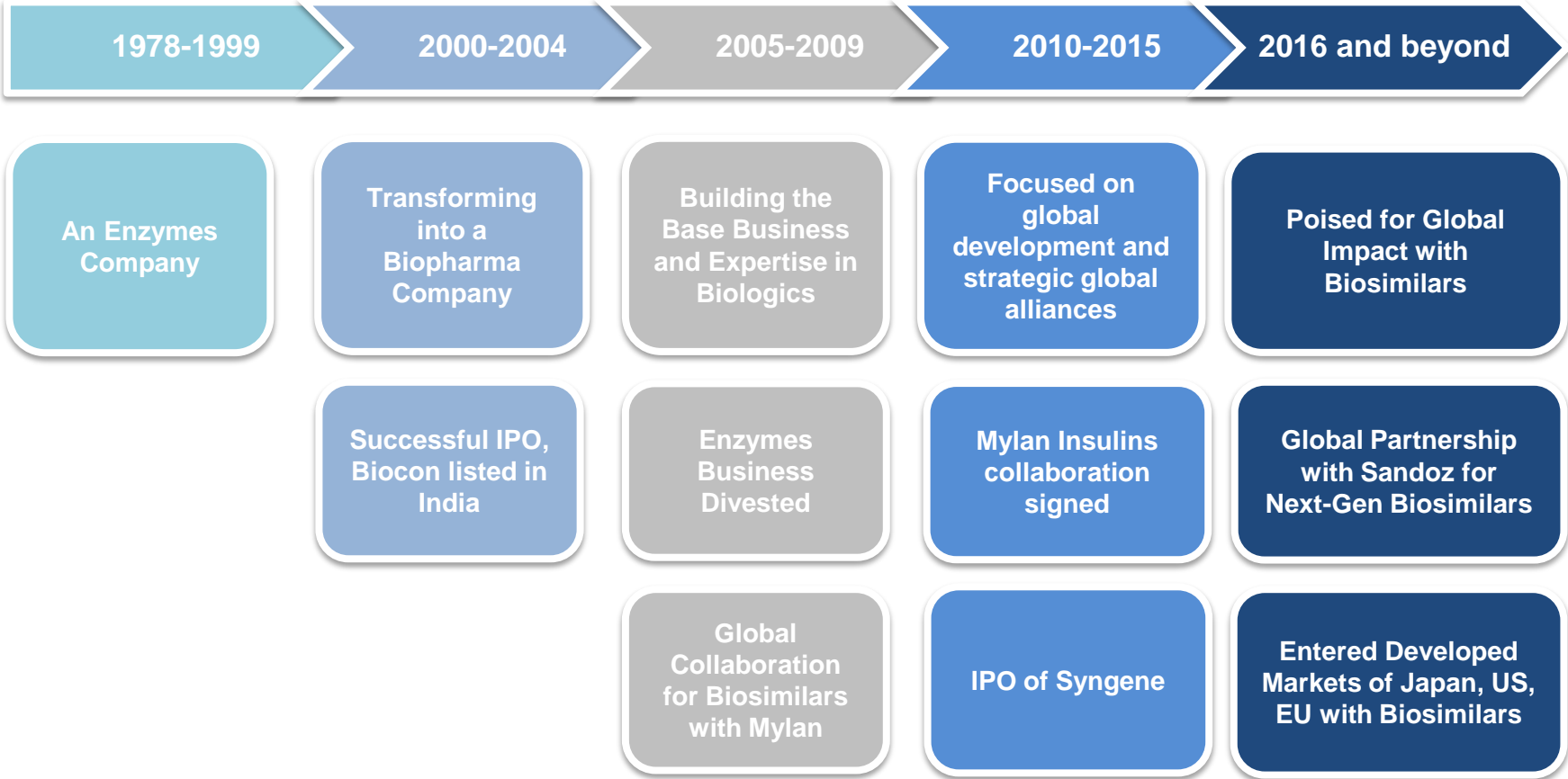
- ✦ Integrity & Ethical Behavior
- ✦ Performance driven Work Culture
- ✦ Value Creation through Innovation & Differentiation
- ✦ Quality through Compliance & Best Practices
- ✦ Collaboration, Team Work & Mutual Respect

A large, diverse group of stylized human figures is arranged in a large circle that frames the central text. The figures are of various ethnicities, ages, and genders, wearing a wide range of colorful clothing. They are standing on a light blue surface against a light blue background.

Committed to Affordable Access

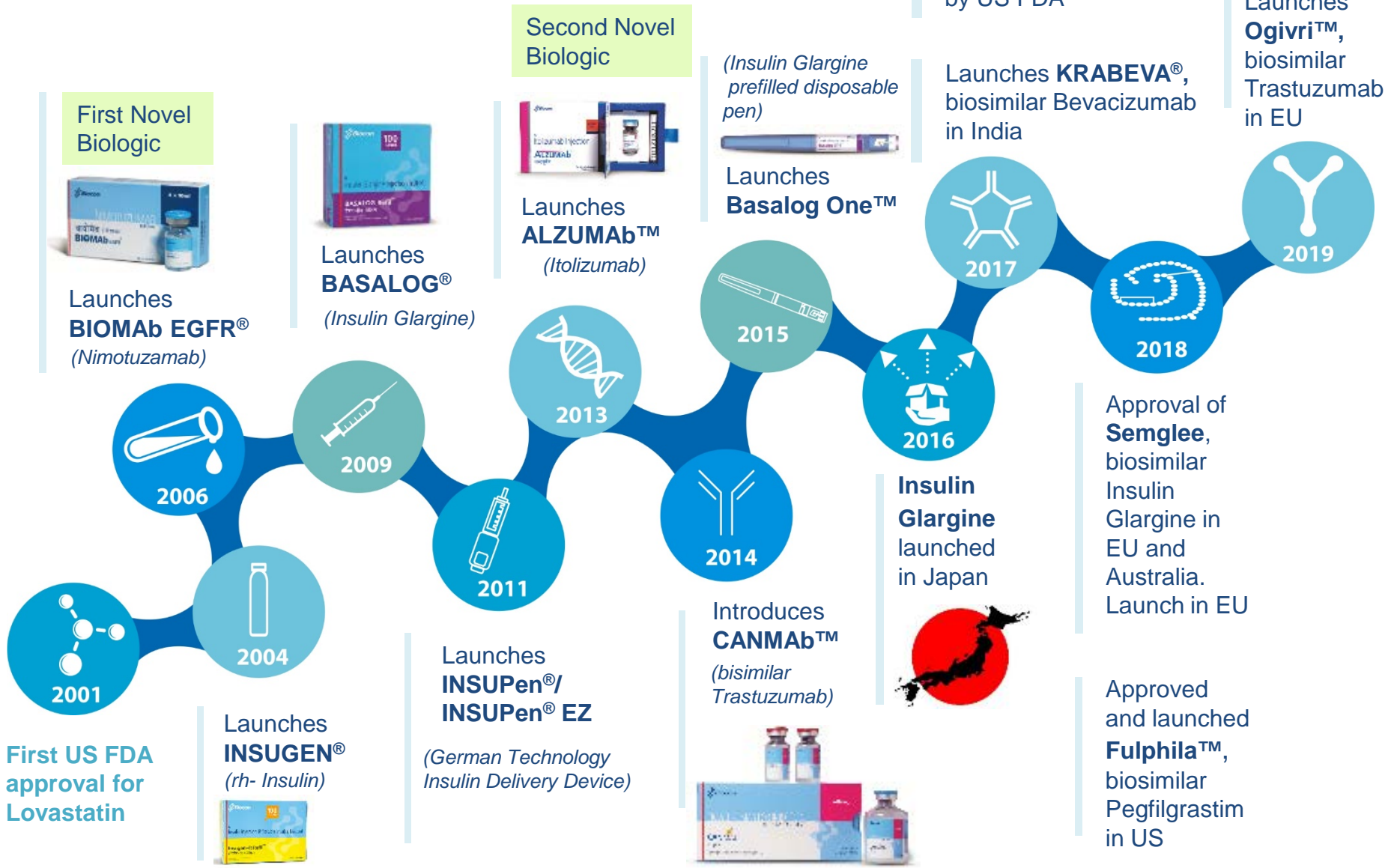
**Aiming to develop products that can
potentially benefit a billion patients**

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



First Novel Biologic



Launches **BIOMAb EGFR®**
(Nimotuzumab)



Launches **BASALOG®**
(Insulin Glargine)

Second Novel Biologic



Launches **ALZUMAb™**
(Itolizumab)

(Insulin Glargine prefilled disposable pen)



Launches **Basalog One™**

Ogivri™, first biosimilar Trastuzumab approved by US FDA

Launches **KRABEVA®**, biosimilar Bevacizumab in India

Launches **Ogivri™**, biosimilar Trastuzumab in EU

First US FDA approval for Lovastatin

Launches **INSUGEN®**
(rh- Insulin)



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

Introduces **CANMAb™**
(bisimilar Trastuzumab)

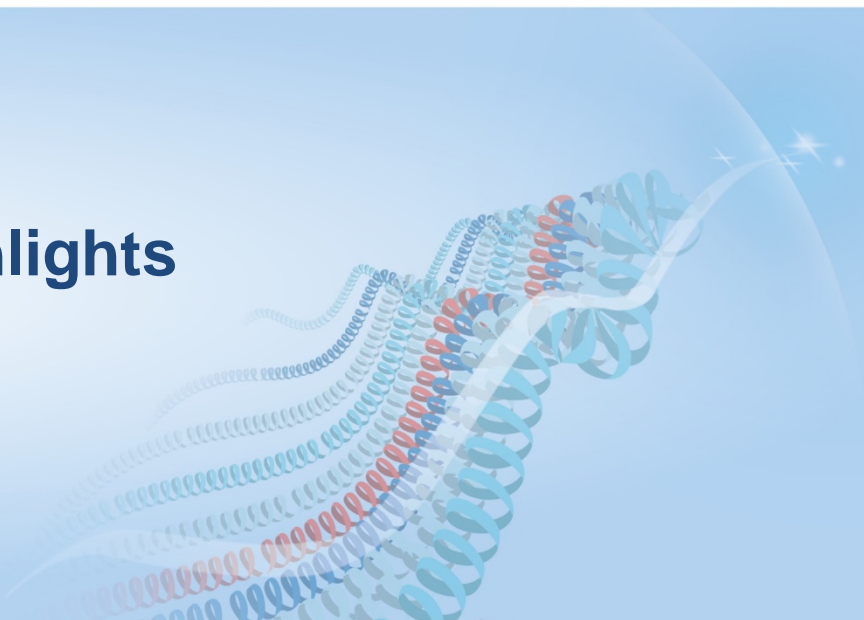


Insulin Glargine launched in Japan

Approval of **Semglee**, biosimilar Insulin Glargine in EU and Australia. Launch in EU

Approved and launched **Fulphila™**, biosimilar Pegfilgrastim in US

Business & Financial Highlights



Business: Recent Highlights

- ❖ On March 1, 2019, Dr. Christiane Hamacher was appointed the CEO of Biocon Biologics India Limited, to lead Biocon's Biosimilars business and transform it into a major global player in biologics.
- ❖ Ogivri®, biosimilar Trastuzumab was launched in Europe by our partner Mylan in the quarter ended March 31, 2019
- ❖ Health Canada approved Biocon and Mylan's Ogivri™, the first Trastuzumab biosimilar, for the Treatment of HER2-Positive Breast and Gastric Cancers
- ❖ Following the successful approval and European launch of Hulio®, (biosimilar Adalimumab) in-licensed by our partner Mylan from Fujifilm Kyowa Kirin Biologics, the commercialization rights have been extended from Europe to Global Markets.
- ❖ Syngene, our Research Services subsidiary, announced the opening of its Centre for Advanced Protein Studies, set up in collaboration with the Biotechnology Industry Research Assistance Council or BIRAC, at Syngene's campus in Bengaluru.
- ❖ To commemorate the 40th anniversary of Biocon the Board of Directors of the Company at the meeting held on April 25, 2019 recommended the issue of 1 bonus share for every 1 share held in Biocon.
- ❖ The Board also recommended a Final Dividend of Re 1/- per share (pre-bonus) for FY19.

Revenue Highlights

All Figures in ₹ Million except %

Particulars	Q4 FY19	Q4 FY18	Growth	FY19	FY18	Growth
- Small Molecules	4,719	4,255	11%	17,728	15,077	18%
- Biologics	4,511	2,408	87%	15,169	7,702	97%
- Branded Formulations	1,330	1,491	-11%	6,654	6,115	7%
- Syngene (Research Services)	5,338	4,091	30%	18,255	14,231	28%
- Inter-segment	(610)	(550)	11%	(2,572)	(1,828)	41%
Revenue from Operations	15,288	11,695	31%	55,144	41,297	34%
- Other Income	282	675	-58%	1,444	2,062	-30%
Total Revenue	15,570	12,370	26%	56,588	43,359	31%

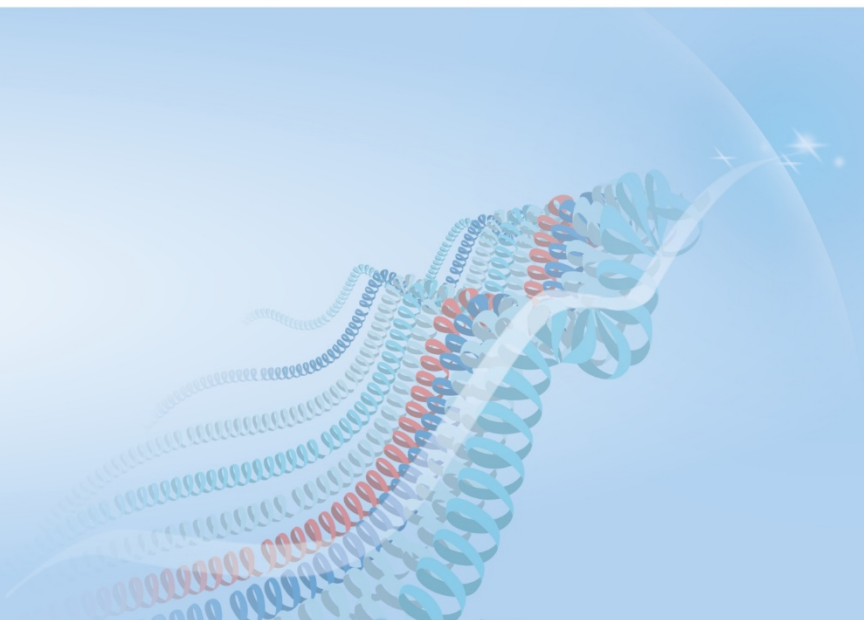
Financial Summary

All Figures in ₹ Million except %

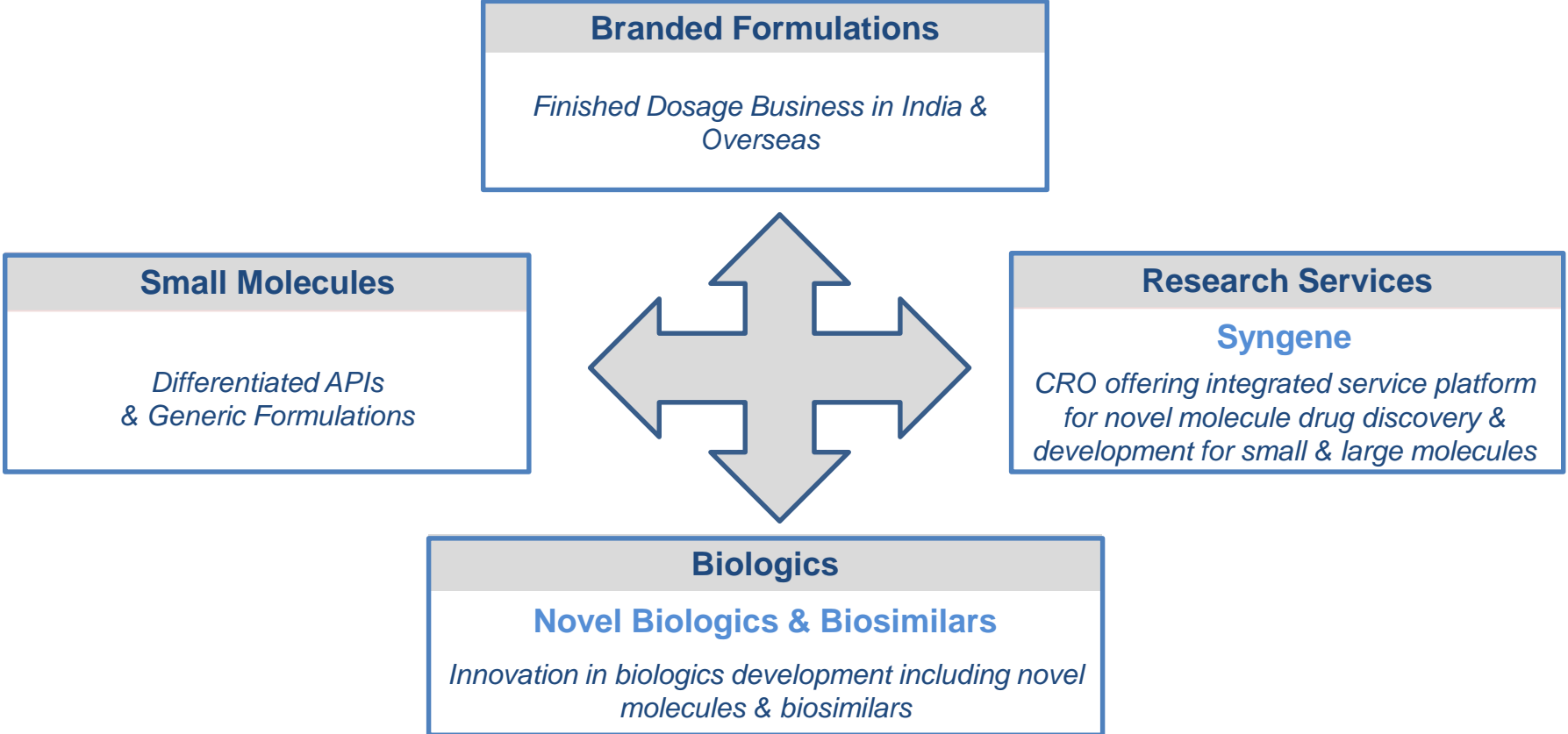
Particulars	Q4 FY19	Q4 FY18	Growth	FY19	FY18	Growth (%)
Revenue	15,570	12,370	26%	56,588	43,359	31%
EBITDA	4,312	3,005	43%	15,381	10,353	49%
Net Profit [#]	2,137	1,304	64%	7,291	3,724	96%
R&D Expenses in P&L	921	508	81%	2,899	2,158	34%
Gross R&D Spends	1,659	975	70%	4,796	3,804	26%
EBITDA Margin	28%	24%		27%	24%	
EPS[#] (Rs.)	3.6	2.2		12.2	6.2	

[#] Adjusted for any exceptional items

Our Business



Business Segments



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 & immunosuppressant APIs
- Early mover in niche products at commercial scale

Current Portfolio	Constituents
Statins	Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, & Fluvastatin.
Immuno suppressants	Tacrolimus, Sirolimus, Everolimus, Mycophenolate Mofetil & Mycophenolate Sodium
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, Simvastatin & Atorvastatin tablets in US

Focus on vertically integrated development of molecules in chronic therapeutic areas

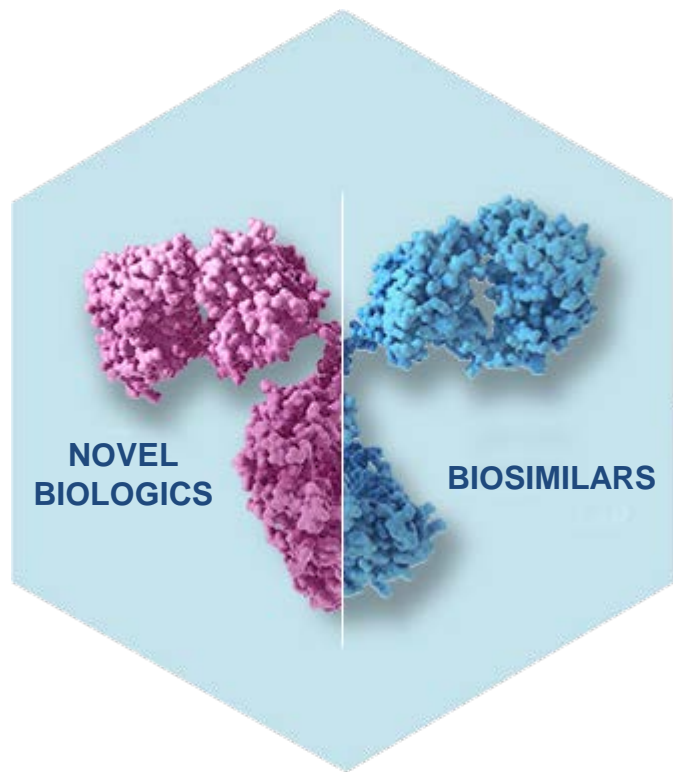
Biologics: Biosimilars & Novel Biologics

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

Potential to change the treatment paradigm in diabetes, immunology.



Biosimilars

Positioned among early wave of entrants with multiple biosimilars commercialized globally. 15+ years of experience is developing biologics.

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

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

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

Strategic Partnership with Mylan for Biosimilars: Insulins & mAbs

Partnership leverages Biocon's Strong Development & Manufacturing Capability and Mylan's Regulatory & Commercial Excellence

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 Partnership with Sandoz for next generation Biosimilars

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

Portfolio addresses next wave of immunology and oncology biosimilars

Market opportunity to open up by middle of next decade

Both partners 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">1. North America (US & Canada)2. EU (European Free Trade Association (EFTA) and Balkan states)	<ol style="list-style-type: none">1. Japan, Australia, New Zealand2. All Emerging Markets

Status of Biocon's Global Biosimilars Portfolio*

	Therapeutic Area	Molecule	Status
MYLAN & LOCAL PARTNERS	Oncology	TRASTUZUMAB	Launched in EU & Emerging Markets. Approved in U.S., Canada & Australia.
	Oncology	PEGFILGRASTIM	Launched in the U.S. Approved in EU, Australia & Canada.
	Oncology	BEVACIZUMAB	Launched in India. Global Phase III.
	Oncology	FILGRASTIM	Preclinical
	Oncology	PERTUZUMAB	Early Development
	Diabetes	INSULIN GLARGINE	Launched in the EU, Japan [#] & Emerging Markets. Approved in Australia & New Zealand. Under review in U.S.
	Diabetes	INSULIN GLARGINE 300 IU/ML	Early Development
	Diabetes	INSULIN ASPART	Global Phase III
	Diabetes	INSULIN LISPRO	Preclinical
	Diabetes	RECOMBINANT HUMAN INSULIN	Launched in Emerging Markets. In active development for U.S. (partnered with Lab Pisa)
	Autoimmune	ADALIMUMAB	Partner Mylan has launched in-licensed product Hulio [®] in EU. Biocon benefits from economic interest
	Autoimmune	ETANERCEPT	Partner Mylan's in-licensed product filed for approval in EU. Biocon retains economic interest
	SANDOZ	Oncology & Immunology	VARIOUS ASSETS

[#] Japan launch is outside of the Mylan partnership

Biocon Well Placed in Competitive Global Landscape (1)

Molecule	Biosimilar Development Pipeline ^{\$}					
	Phase I	Phase 3	Regulatory Submission		Approved/ Marketed	
			EMA	FDA	EMA	FDA
ADALIMUMAB	DM Bio	Coherus, Momenta, Celltrion, Alvotech,		Samsung, Pfizer	Amgen, Samsung, Sandoz, Fresenius/DRL, BI, Fuji Kirin/ Mylan/BIOCON	Amgen, BI, Sandoz
ETANERCEPT		Coherus, Hanwha	Lupin/Mylan/ BIOCON		Samsung, Sandoz	Sandoz
TRASTUZUMAB	DM Bio, United BioPharma, Alteogen, Sino, NeuClone	Hanwha/ Prestige, Tanvex, EirGenix, Shanghai Henlius / Accord		Amgen	Amgen, Celltrion, Pfizer Samsung, BIOCON	BIOCON, Celltrion, Samsung, Pfizer,
BEVACIZUMAB	Sandoz, Daiichi, Fresenius/DRL, Tanvex, Apobiologix, Zhejiang Teruisi	BI, Samsung, BIOCON Fuji-Kirin/ Astra, Cipla, mAbxience/ Amneal, Centus, Hanwha/ Prestige, Bio-Thera, Shanghai Henlius, Luye, Celltrion, JHL		Pfizer	Amgen, Pfizer	Amgen
PEGFILGRASTIM	Fresenius/DRL, Pfizer, Kashiv (Adello), Lupin, Zydus		USV	Apotex/ Intas, Sandoz	BIOCON, Coherus, Apotex/ Intas, Sandoz, Mundipharma (Cinfa)	BIOCON, Coherus
FILGRASTIM	Lupin			Apotex, Kashiv (Adello), Tanvex	Sandoz, Teva, Hospira, Stada, Intas, Hexal	Sandoz, Pfizer

^{\$} Based on publically available information

Biocon Well Placed in Competitive Global Landscape (2)

Molecule	Biosimilar Insulin Development Pipeline [§]					
	Phase I	Phase 3	Regulatory Submission		Approved/ Marketed	
			EMA	FDA	EMA	FDA
INSULIN GLARGINE		Gan & Lee/ Sandoz		BIOCON	BIOCON, Eli Lilly, Merck	Eli Lilly, Merck (TA)
INSULIN ASPART		Sanofi, BIOCON				
INSULIN LISPRO					Sanofi	Sanofi
RH-INSULIN		Rechon (EU)				

[§] Based on publically available information

Biosimilars Manufacturing: Building Global Scale

Global Scale Manufacturing Capabilities in India

- ❖ State-of-the-art manufacturing facilities – mammalian & microbial
- ❖ Facilities conform to most stringent cGMP guidelines - Inspected by EMA, USFDA, Health Canada, ANVISA, COFEPRIS, PMDA, TGA etc.
- ❖ 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, expected commissioning in 2021.



Biocon Malaysia: Asia's largest integrated insulins manufacturing facility

- ❖ Biocon's First Manufacturing expansion overseas in Iskandar, Johor.
- ❖ Investment of ~US\$300 mn in the first phase.
- ❖ Plant has received GMP certificate from EMA and NPRA, Malaysia
- ❖ Sales commenced in E.U. & Emerging Markets; include OTA award by Ministry of Health – Malaysia.



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 ongoing
INFLAMMATION	Itolizumab* Novel, humanized CD6 Antibody	Clinical Trial initiated in aGVHD
	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

* Out licensed to Equillum for US & Canada; # BVX-20 with Vaccinex; \$ QPI-1007 licensed from Quark Pharma.



Incorporated in Boston, U.S. as a wholly owned subsidiary of Biocon to focus on developing Immuno-oncology assets

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 <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 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 <ul style="list-style-type: none"> Marketed in India for Plaque Psoriasis, licensed to Equillum for US & Canada Phase 1b/2 clinical trial for the treatment of acute graft-versus-host disease or aGVHD initiated. Fast track designation accorded by US FDA 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: <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 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.
- ❖ Glaricon (Biosimilar Insulin Glargine) and Canhera (Biosimilar Trastuzumab) launched in UAE

- ❖ **Insugen®** ranks among Top 3 human insulin brands in India
- ❖ **CANMAb™** is No. 1 brand of Trastuzumab in India
- ❖ **Basalog®**, is No 2 brand of Insulin Glargine 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
- ❖ End-to-end discovery, development and manufacturing capabilities with focus on novel molecular entities
- ❖ Offers an integrated drug discovery, development and manufacturing platform for both small and large molecules, antibody-drug conjugates and oligonucleotides backed by best-in-class bioinformatics services
- ❖ World class infrastructure audited successfully by US FDA, EMA, AAALAC and major life sciences partners
- ❖ 331* global clients across multiple sectors
- ❖ World-class R&D and manufacturing infrastructure spread over 1.4 million sq. ft
- ❖ ~4,000* 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)
- ❖ Listed in India on BSE and NSE in 2015



* For fiscal ended March 31, 2019

Five Year Financials

All Figures in ₹ Million except EPS

Particulars	FY14 [#]	FY15 [#]	FY16 [#]	FY17 [§]	FY18 [§]
Biopharmaceuticals Revenue	21,382	22,367	23,908	28,912	28,894
- Biopharma	17,468	18,071	19,534	23,423	22,779
- Branded Formulations	3,914	4,296	4,374	5,489	6,115
Contract Research Revenue	7,146	8,225	10,599	11,925	14,231
Total	28,528	30,592	34,507	40,837	43,125
Less: Inter-segment revenue				(1,621)	(1,828)
Other Income	804	837	1,192	1,571	2,062
Total Revenue	29,332	31,429	35,699	40,787	43,359
EBITDA	7,429	7,489	9,045	11,366	10,353
EBITDA Margin (%)	25%	24%	25%	28%	24%
Net Profit*	4,137	4,022	4,365	6,199	3,724
Net Profit Margin	14%	13%	12%	15%	8.5%
EPS*	20.7	20.1	21.8	30.9	6.2 [@]
R&D Spends (in P&L)	1,310	1,688	2,750	2,662	2,158
R&D (as % of Biopharmaceuticals Revenue)	6.1%	7.5%	11.5%	9.7%	7.9%

[#] Numbers as per old I-GAAP; ^{*} Pre-Exceptional items; [§] FY17, FY18 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; [@] Adjusted for bonus issues of shared in FY18
In FY17, FY18 – Biopharma includes Small Molecules & Biologic segments as per Ins-AS framework

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For further information, please visit
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