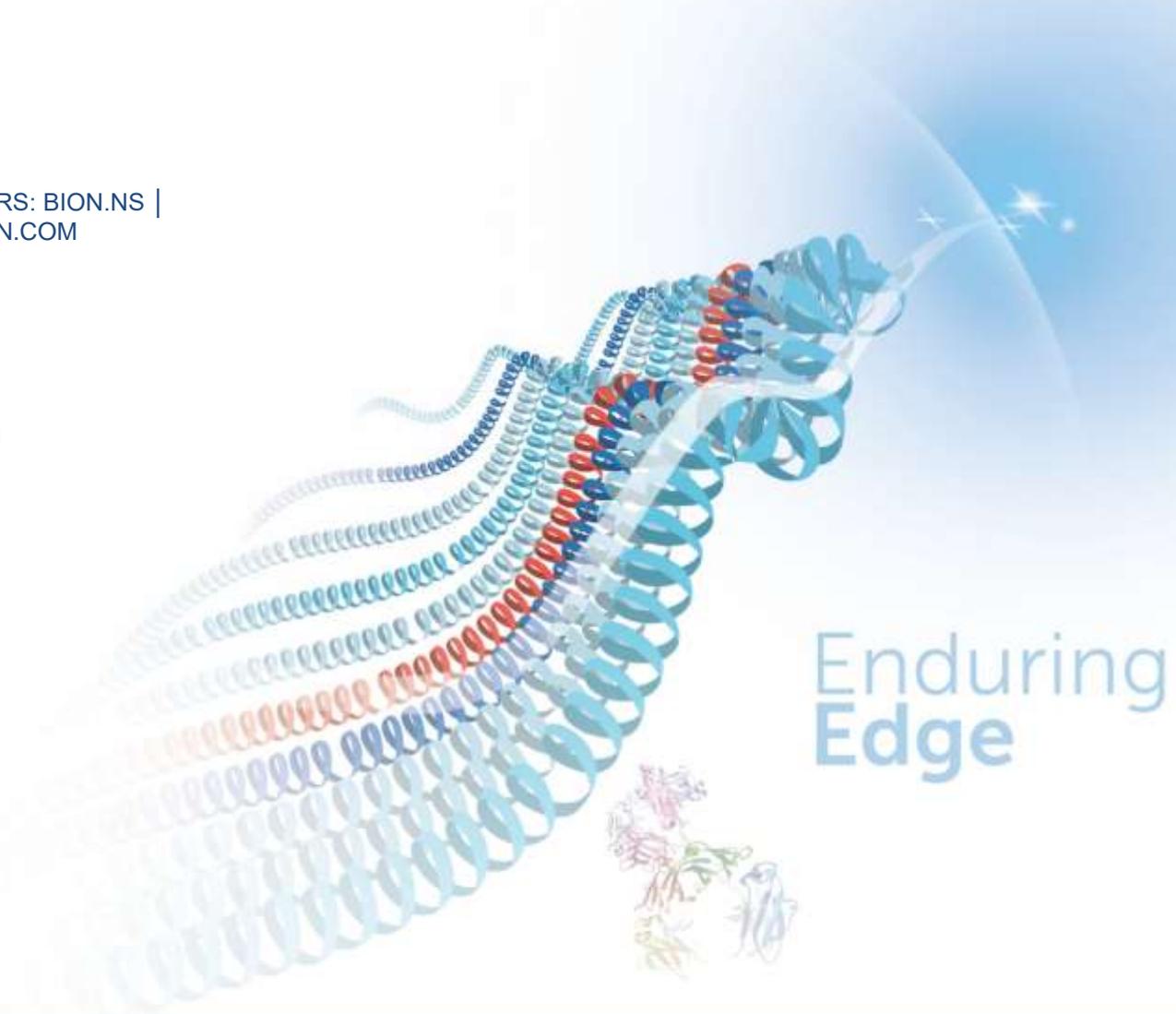


# Biocon Limited

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

## Investor Presentation

September 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



## 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

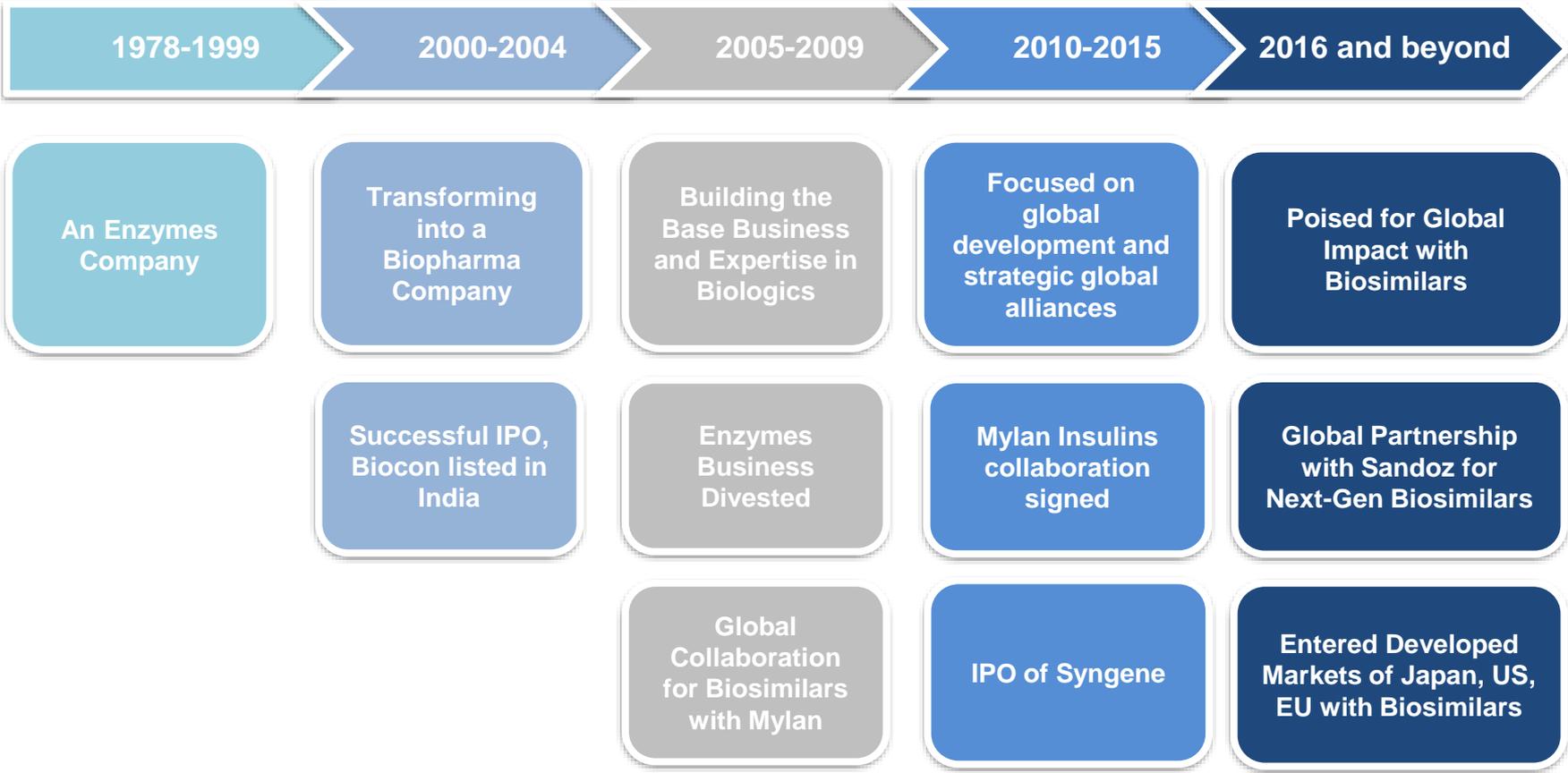
- ❖ Integrity & Ethical Behavior
- ❖ Performance driven Work Culture
- ❖ Value Creation through Innovation & Differentiation
- ❖ Quality through Compliance & Best Practices
- ❖ Collaboration, Team Work & Mutual Respect

A large group of diverse people, including men and women of various ages and ethnicities, are standing in a large circle. They are dressed in a variety of colorful clothing, representing a global and inclusive community. The circle is formed by the people standing close together, with their shadows cast on the light blue background.

# Committed to Affordable Access

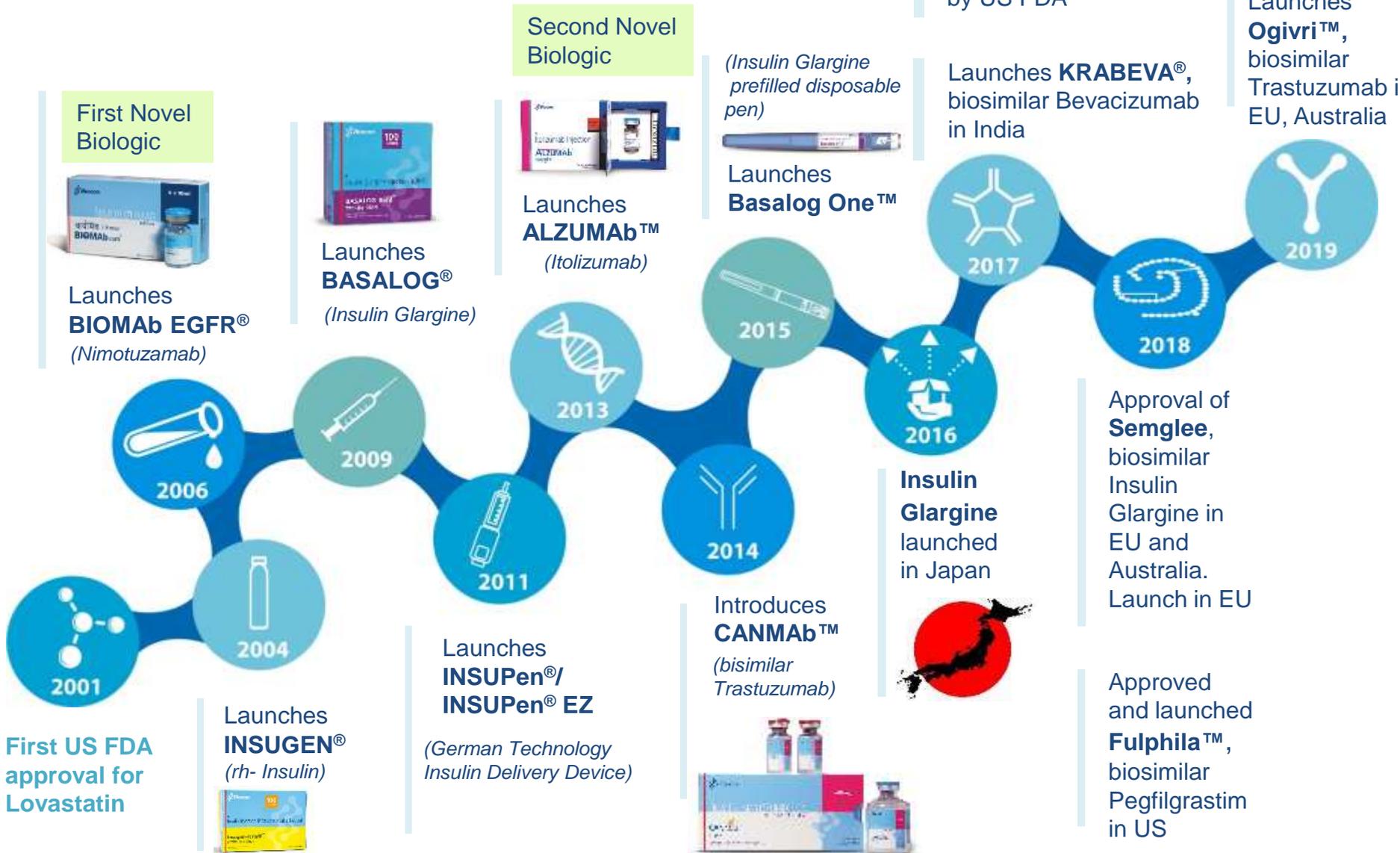
**Aiming to develop products that can  
potentially benefit a billion patients**

# 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®**  
(Nimotuzamab)



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, Australia

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



# Financial Highlights



# Financial Summary

All Figures in ₹ Million except %

Particulars	Q1 FY20	Q1 FY19	Growth	FY19	FY18	Growth (%)
Revenue	14,900	11,926	25%	56,588	43,359	31%
EBITDA	4,616	3,066	51%	15,381	10,353	49%
Net Profit <sup>#</sup>	2,229	1,197	86%	7,291	3,724	96%
R&D Expenses in P&L	787	442	78%	2,899	2,158	34%
Gross R&D Spends	1,101	883	25%	4,796	3,804	26%
<b>EBITDA Margin</b>	<b>31%</b>	<b>26%</b>		<b>27%</b>	<b>24%</b>	
<b>EPS<sup>#</sup> (Rs.)</b>	<b>1.9</b>	<b>1.0</b>		<b>6.1</b>	<b>3.1</b>	

<sup>#</sup> Adjusted for any exceptional items, EPS adjusted for bonus

# Revenue Highlights

All Figures in ₹ Million except %

Particulars by segment	Q1 FY20	Q1 FY19	Growth	FY19	FY18	Growth
- Small Molecules	4,796	4,001	20%	17,728	15,077	18%
- Biologics	4,896	2,497	96%	15,169	7,702	97%
- Branded Formulations	1,334	1,473	-9%	6,654	6,115	7%
- Syngene (Research Services)	4,209	4,060	4%	18,255	14,231	28%
- Inter-segment	(576)	(793)	-27%	(2,572)	(1,828)	41%
<b>Revenue from Operations</b>	<b>14,659</b>	<b>11,238</b>	<b>30%</b>	<b>55,144</b>	<b>41,297</b>	<b>34%</b>
- Other Income	241	688	-65%	1,444	2,062	-30%
<b>Total Revenue</b>	<b>14,900</b>	<b>11,926</b>	<b>25%</b>	<b>56,588</b>	<b>43,359</b>	<b>31%</b>

# Key Financial Metrics – Evolution over last 5 quarters

All Figures in ₹ Million except %

Particulars	FY 2019				FY 2020	
	Q1	Q2	Q3	Q4	FY19	Q1
<b>SEGMENT REVENUE</b>						
a. Small Molecules	4,001	4,319	4,689	4,719	17,728	4,796
b. Biologics	2,497	3,675	4,486	4,511	15,169	4,896
c. Branded Formulations	1,473	1,639	2,122	1,330	6,564	1,334
d. Research Services	4,060	4,186	4,671	5,338	18,255	4,209
Total	12,031	13,819	15,968	15,898	57,716	15,235
Less: Inter-segment revenue	(793)	(609)	(560)	(610)	(2,572)	(576)
<b>Net sales / Income from continuing operations</b>	<b>11,238</b>	<b>13,210</b>	<b>15,408</b>	<b>15,288</b>	<b>55,144</b>	<b>14,659</b>
<b>SEGMENT MARGINS* (PBIT/Segment Revenue)</b>						
a. Small Molecules	18%	20%	21%	14%	18%	22%
b. Biologics	11%	25%	30%	33%	26%	38%
c. Branded Formulations	12%	7%	13%	4%	9%	-2%
d. Research Services	20%	23%	23%	24%	23%	21%
<b>Consolidated Margins</b>	<b>17%</b>	<b>20%</b>	<b>18%</b>	<b>19%</b>	<b>19%</b>	<b>21%</b>
<b>ROCE* (PBIT/Capital Employed)</b>						
a. Small Molecules	22%	22%	23%	22%	22%	27%
b. Biologics	4%	7%	9%	11%	11%	20%
c. Branded Formulations	74%	58%	79%	81%	81%	-11%
d. Research Services	20%	23%	21%	21%	21%	17%
<b>Consolidated ROCE (Annualized)</b>	<b>13%</b>	<b>15%</b>	<b>15%</b>	<b>15%</b>	<b>15%</b>	<b>18%</b>

\* Segment margins are before interest & other un-allocable expenditure / (income) and segment ROCE is before un-allocable assets/ liabilities.

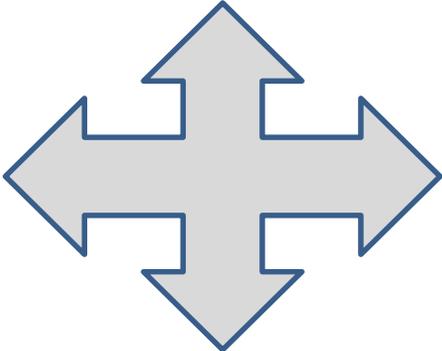
# Our Business



# Business Segments

**Biologics**  
**Novel Biologics & Biosimilars**  
*Innovation in biologics development including novel molecules & biosimilars*

**Small Molecules**  
*Differentiated APIs & Generic Formulations*



**Research Services**  
**Syngene**  
*CRO offering integrated service platform for novel molecule drug discovery & development for small & large molecules*

**Branded Formulations**  
*Finished Dosage Business in India & Overseas*

<b>Complex Small Molecule APIs to Biologics</b>  <b>Novels &amp; Biosimilars</b>	<b>Comprehensive Presentation in Biologics</b>		
	<b>Drug Substance</b>	<b>Drug Products</b> Vials, Cartridges & Prefilled Syringes	<b>Delivery Devices</b> 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**

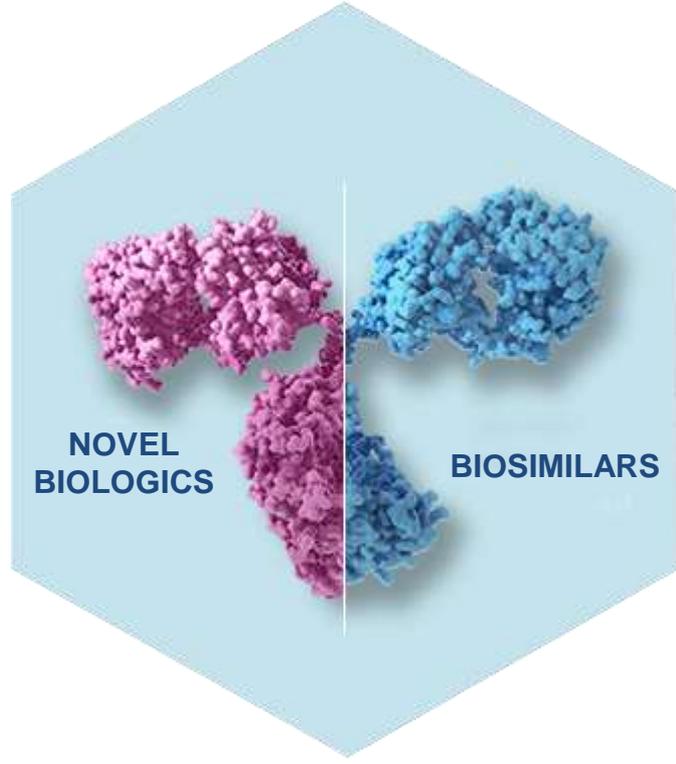
# Biologics: Biosimilars & Novel Biologics

## 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 4000+ 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#**

	<b>Generic Insulin Analogs</b>	<b>Biosimilar MAb &amp; other Biologics</b>
<b>Mylan's Exclusive Commercialization Regions</b>	US, Canada, Europe, Australia & New Zealand	Developed markets

# In Developed Markets only

# Strategic Partnership with Sandoz for next generation Biosimilars

**Broader Biocon Biologics 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

<b>Sandoz</b>	<b>Biocon Biologics</b>
<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>

# Status of Biocon Biologics Global Biosimilars Portfolio\*

	Therapeutic Area	Molecule	Status
MYLAN & LOCAL PARTNERS	Oncology	TRASTUZUMAB	Launched in EU, Australia & Emerging Markets. Approved in U.S. & Canada.
	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 <sup>#</sup> & 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. Phase I for U.S. (partnered with Lab Pisa)
	Autoimmune	ADALIMUMAB	Partner Mylan has launched in-licensed product Hulio <sup>®</sup> 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

<sup>#</sup> Japan launch is outside of the Mylan partnership

# Biocon Biologics Well Placed in Competitive Global Landscape (1)

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

<sup>§</sup> Based on publically available information

# Biocon Biologics Well Placed in Competitive Global Landscape (2)

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

<sup>§</sup> 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 EMA. To support future growth of biologics formulations and help expand access across global markets.
- ❖ Construction of second antibody manufacturing facility in Bangalore ongoing, expected commissioning in FY20.



## 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, NPRA, Malaysia and other Emerging Market regulators.
- ❖ Sales commenced in E.U. & Emerging Markets; include OTA award by Ministry of Health – Malaysia.

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

# Biocon Biologics: Transforming Healthcare, Transforming Lives

*Vision: “Most Inspiring Global Leader in Biologics” delivering affordable access to innovative and inclusive healthcare solutions, transforming patient lives.*

Implement strategic initiatives going beyond the product in our aspiration to reach dominant market share in key markets, unlock underserved markets, and differentiate us from competition

THE FOUR PILLARS	PATIENTS	<b>Patient-Centricity &amp; Therapeutic Area Leadership</b> <ul style="list-style-type: none"> <li>• Leader with a vision that resonates strongly with global scientific communities</li> </ul>
	PEOPLE	<b>Unique Culture with Talent Diversity</b> <ul style="list-style-type: none"> <li>• Unique culture of constant innovation</li> <li>• Inherent strengths in co-creation and leveraging diversity</li> </ul>
	PARTNERS	<b>Disruptive &amp; Differentiated Portfolio</b> <ul style="list-style-type: none"> <li>• Leader in a disruptive, differentiated portfolio offering</li> <li>• Achieve scientific excellence by leveraging cutting-edge technology</li> </ul>
		<b>Agile Delivery Capability</b> <ul style="list-style-type: none"> <li>• Global scale manufacturing with AI/ML equipped systems</li> <li>• Innovative delivery models that optimize number of intermediaries</li> </ul>
BUSINESS	<b>Innovative, Technology-Driven Operating Models</b> <ul style="list-style-type: none"> <li>• Archetype-based technology-driven operating model leveraging partnerships</li> <li>• Ability to serve patients at the centre of the income pyramid</li> </ul>	
		<b>Excellence in Market Shaping</b> <ul style="list-style-type: none"> <li>• Leader in creating sustainable market advantages and policy shaping</li> </ul>

# Branded Formulations: Now aligned with Biologics Growth Strategy

- ❖ 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™



# Novel Molecules - Pipeline & Therapeutic Area Focus

<p><b>DIABETES</b></p>	<p><b>Insulin Tregopil (<i>In-house program</i>)</b>                  First-in-Class Oral, Prandial Insulin</p> <ul style="list-style-type: none"> <li>• Liver specific- portal delivery, Weight neutral</li> <li>• Pivotal Phase II/III clinical study in T2DM patients in India ongoing</li> <li>• JDRF supported Phase I Multiple Ascending Dose study planned in T1DM patients</li> </ul>	<p><b>India Phase II/III in T2D ongoing</b></p>
<p><b>INFLAMMATION</b></p>	<p><b>Itolizumab (<i>Licensed to Equillum for US &amp; Canada</i>)</b>                  Novel, humanized CD6 Antibody</p> <ul style="list-style-type: none"> <li>• Novel CD-6 Biology presenting durable immune-modulatory benefits and superior clinical safety</li> <li>• Marketed in India for plaque Psoriasis</li> </ul>	<p><b>Clinical Trial initiated in aGVHD, Severe Asthma</b></p>
	<p><b>BVX-20# (<i>Partnered with Vaccinex</i>)</b>                  Novel, 2<sup>nd</sup> Generation humanized CD20 Antibody</p> <ul style="list-style-type: none"> <li>• Path to IND mapped out, to advance program in neuro-inflammatory disorder</li> </ul>	<p><b>Path to IND mapped</b></p>
	<p><b>QPI-1007 (<i>licensed from Quark Pharma</i>)</b>                  SiRNA for ophthalmic disease</p> <ul style="list-style-type: none"> <li>• Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION)</li> <li>• Patients randomized for global study (incl. in India)</li> </ul>	<p><b>Phase III in NAION</b></p>
<p><b>IMMUNO-ONCOLOGY</b></p>	<p><b>EGFR mAb + TGFβrII (<i>In-house program</i>)</b>                  Tumor-Targeted Fusion mAb*</p> <ul style="list-style-type: none"> <li>• Higher local tumor concentration of immuno-modulatory arm resulting in a better therapeutic window</li> <li>• Opportunity to target multiple tumor types</li> </ul>	<p><b>Pre-clinical</b></p>



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

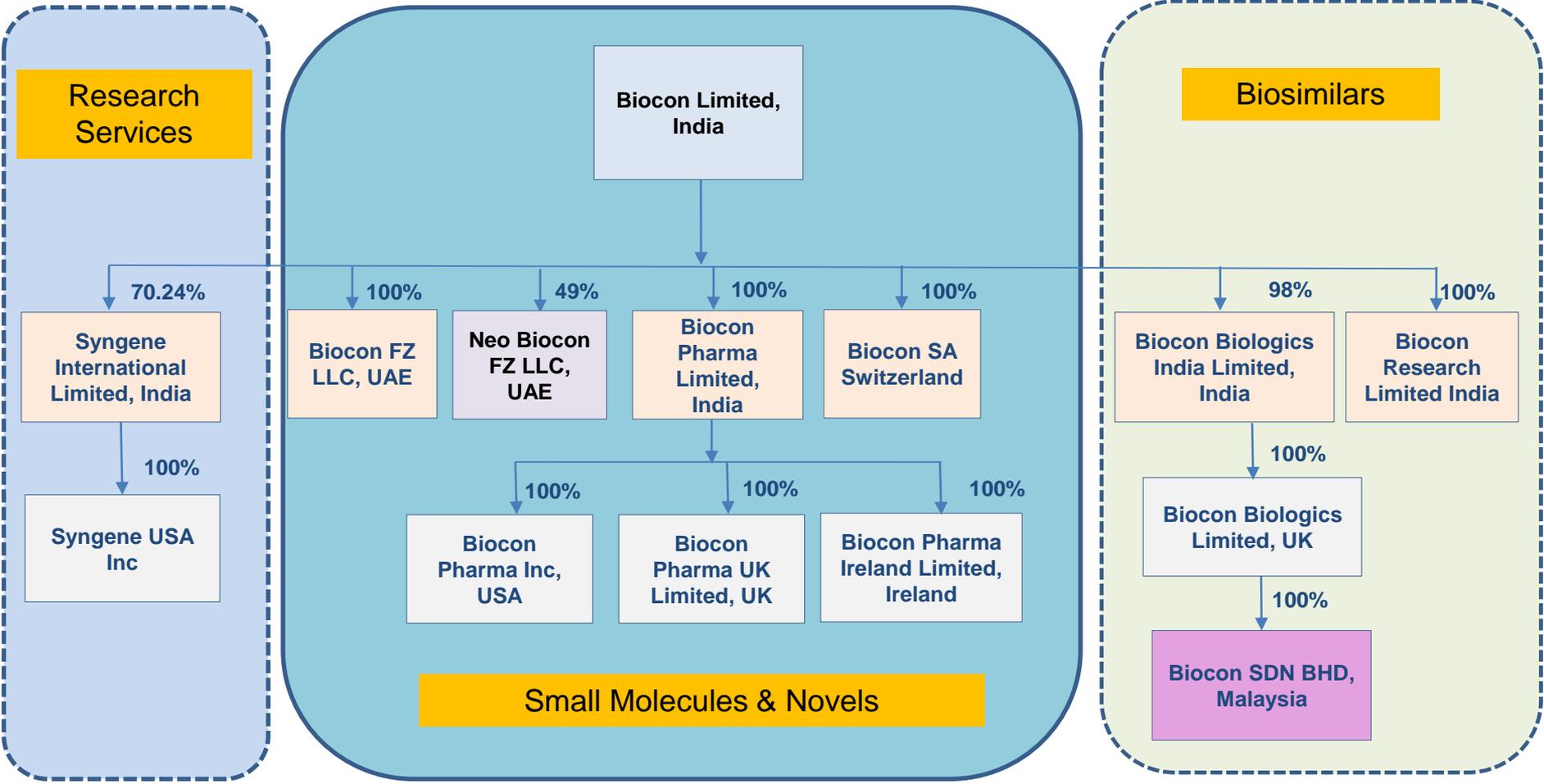
# Research Services Business: Syngene

- ❖ 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 1.5 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

# Biocon: Group Structure



% Depict voting power  
 Details are as on July 31, 2019

Legend:	Ultimate Holding Company	Joint Venture	Direct Subsidiary	Step-down subsidiary	2nd Step-down subsidiary
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