

#### **BIOCON: FOUR DECADES OF PIONEERING EXCELLENCE**

#### **COMMITTED TO AFFORDABILITY & ACCESS**

#### **CORPORATE PRESENTATION**

**June 2020** 



#### **An Innovation-Led Global Biopharmaceutical 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

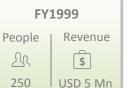


#### **Our Values**

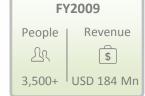
- Integrity & Ethical Behavior
- Performance driven Work Culture
- Value Creation through Innovation & Differentiation
- Quality through Compliance & Best Practices
- Collaboration, Team Work & Mutual Respect



#### **Our Business Evolution Over The Years**



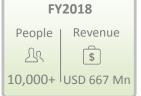




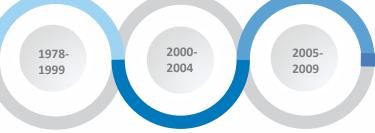


2010-

2015











An Enzymes Company Transforming into a Biopharma Company

Building the Base Business and Expertise in Biologics Strategic Global Alliance with Mylan for Biosimilars Expanded (2013) Commercializ ed Biosimilars for Diabetes & Cancer in Japan, U.S., EU Poised for Global Impact with Biosimilars

Successful IPO, Biocon listed in India (2004) Enzymes Business Divested (2007)

Global
Development of
Biosimilars in
Partnership with
Mylan (2009)

Generic Formulations Business Unit set up (2013)

IPO of Syngene (2015)

Global Partnership with Sandoz for Next-Gen Biosimilars (2018)

NOTE:

1 USD = 65 INR except FY2020; FY2020: 1 USD = 70 INR



#### **Ahead of the Curve**

1st company from India to manufacture and export enzymes to the U.S. & Europe

1st company globally to develop rh-insulin using a proprietary yeast platform based on *Pichia pastoris* 

1st biotech company to list on the Indian stock exchanges; crossed US\$1 billion market cap on Day 1

1<sup>st</sup> indigenously developed novel biologic, BIOMab EGFR® launched in India by Biocon

1st anti-CD6 monoclonal antibody in the world, ALZUMAb™, developed and launched in India by Biocon

2013



#### **Ahead of the Curve**

1st biosimilar Trastuzumab to be approved anywhere in the world developed and launched in India by Biocon as CANMAb™

2016 1st company from India to launch a biosimilar in Japan: Insulin Glargine

1<sup>st</sup> company globally to get U.S. FDA approval for biosimilar Trastuzumab; 1<sup>st</sup> company from India to have a biosimilar approved in the U.S.

1st company to commercialize biosimilar Pegfilgrastim in U.S.

1<sup>st</sup> Company from India to have 2 biosimilars commercialized in U.S. with launch of Trastuzumab

1<sup>st</sup> Company from India to commercialize biosimilar Trastuzumab, biosimilar Insulin Glargine in Australia through PBS



#### A Credible Biopharma Enterprise

270+

Patents granted (Small Molecules)\*

890+

Patents granted (Biologics)\*

~790

Registered Trademarks\*

7

Biologics taken from Lab to Market 2 Novels & 5 Biosimilars



120+

Countries where our products are available

25+

cGMP approvals from International regulatory agencies\*

Key regulatory approvals from US, EU, Japan, Canada, Australia, Brazil, Mexico, Turkey, GCC etc.



#### **Innovation Milestones in India**

First Novel Biologic



Launches

BIOMAb EGFR®

(Nimotuzumab)

2006

Launches

Second

Novel

**Biologic** 

ALZUMAb™

(Itolizumab)

2013

Launches

Basalog One™



(Insulin Glargine prefilled disposable pen)

2015

2004

Launches INSUGEN®

(rh-Insulin)

interest transfer Ca

To the second se

2009

Launches BASALOG®

(Insulin Glargine)

2014

Introduces CANMAb™

(Trastuzumab)



2017

Launches

**KRABEVA®** 

(biosimilar Bevacizumab)

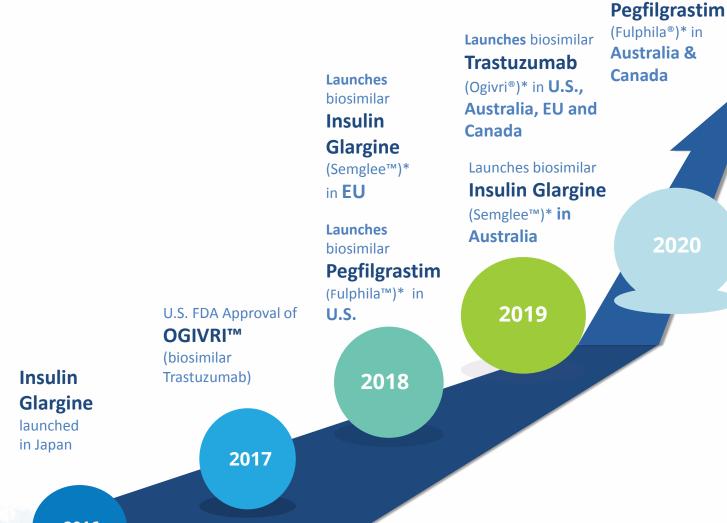






Launches biosimilar

#### **Making Global Impact with Biosimilars**



2016



# Biocon: Ranks 6th on Science Careers' Top 20 Global Pharma & Biotech Employers List 2019



#### **TOP TWENTY EMPLOYERS**

	Top Twenty Employers - 2019								
2019 Ranking	2018 Ranking	Employer (Global Headquarters)	Innovative Leader in the Industry	Treats Employees with Respect	ls socially responsi ble	Work culture values aligned	Leadership makes Changes Needed		
1	-	Alnylam Pharmaceuticals (Cambridge, MA)	✓	✓		✓			
2	1	Regeneron (Tarrytown, NY)	✓		✓	✓			
3	2	Incyte (Wilmington, DE)		<b>✓</b>	✓	✓			
4	5	Merck KGaA (Darmstadt, Germany)		<b>✓</b>	✓	✓			
5	-	Spark Therapeutics (Philadelphia, PA)	✓	✓		✓			
6	7	Biocon Limited (Bangalore, India)	✓		<b>✓</b>		✓		
7	3	Novozymes (Copenhagen, Denmark)	✓	✓	✓				
8	9	Genentech (South San Francisco, CA)	✓	<b>✓</b>		✓			
9	16	Eli Lilly and Company (Indianapolis, IN)		<b>✓</b>	<b>✓</b>	✓			
10	14	Syngenta (Basel, Switzerland)	✓	<b>✓</b>	✓				

- No. 6 on *Science* Magazine's 2019 list
- Moved up from No. 7 in 2018

- Key winning attributes: Innovative Industry Leader;
- Socially Responsible; Makes Changes Needed

Only Asian company in the Global Biotech and Pharma Companies' list since 2012







#### **Our Growth Verticals**

# Small Molecules

Differentiated APIs & Generic Formulations

#### **Novel Biologics**



#### **Biosimilars**



# **GROWTH VERTICALS**

# **Branded Formulations**

Finished Dosage
Business in India &
Overseas

**Research Services** 

Syngene

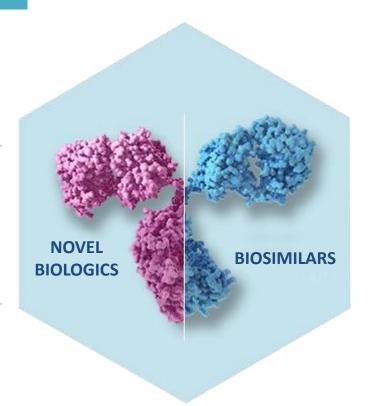




#### **Biologics: Biosimilars & Novel Biologics**

#### **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**

- Portfolio straddles rh-insulin, insulin analogs, mAbs and other recombinant proteins.
- 15+ years of experience is developing biologics.
- Positioned among early wave of entrants; several biosimilars commercialized in various markets globally.





#### **Biocon Biologics**



- An Integrated 'pure play' biosimilars player
- Core expertise in developing, manufacturing, commercializing high quality biosimilars
- Wide portfolio: rh-Insulin, Insulin Analogs, Monoclonal Antibodies and other Recombinant Proteins
- Focus on Chronic Diseases: Diabetes, Cancer & Autoimmune Conditions
- **FY20** Revenue rose 29% to **Rs. 1,951 Crore**





#### **Our Value Proposition: Science, Scale & Expertise**

- Developing high quality, affordable biosimilars
- Expanding access to a cutting-edge class of therapies
- Cost competitive, complex manufacturing capabilities
- Offering significant cost savings to patients, insurers, healthcare systems globally

Years
of expertise in providing
biosimilar
insulins
globally

Doses
of biosimilar
insulins
provided to
patients

2+ Bn

2.1 Mn
Patients
served
through our
biosimilars in
FY20

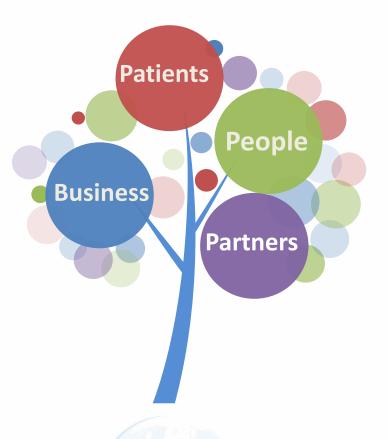
5 Biosimilars
Commercialized:
Trastuzumab,
Pegfilgrastim,
Bevacizumab,
rh-Insulin,
Insulin Glargine





#### **Biocon Biologics: Central To Our Mission**

#### PATIENTS, PEOPLE, PARTNERS, BUSINESS



- Aim to touch ~5 million PATIENTS by FY22
- Build a **PEOPLE** centric organization
- Penetrate global markets with PARTNERS
- Create a successful innovation-drivenBUSINESS





#### Policy Engagement: Reaffirming Commitment to Enable Affordable Access

Initial Steps Towards Greater Focus on Global Policy Engagement and Visibility





- US-India Leaders Summit, Washington DC
- UNAIDS Health Innovation Exchange meeting on sidelines of the 74<sup>th</sup> session of United Nations General Assembly (UNGA), New York
- US FDA Public Hearing on Increasing Access to Insulins,
   White Oak, Maryland
- International Diabetes Federation Annual Congress 2019, Busan
- 2020 World Economic Forum, Davos



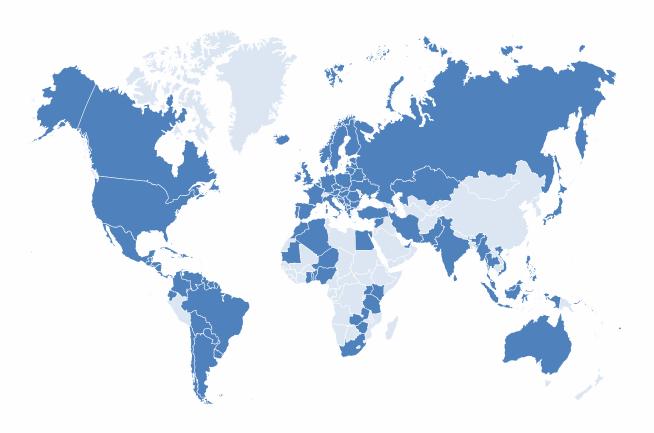


#### **Serving Patient Needs in Emerging & Developed Markets**

#### **Biosimilars Footprint Across the World**

3 Key Biosimilars Commercialized in Global Markets like US, Europe, Australia, Canada, Japan:

- INSULIN GLARGINE
- TRASTUZUMAB
- PEGFILGRASTIM







Countries where BIOCON BIOLOGICS Biosimilars have been approved or commercialized on its own or through partners.



#### **Biocon Biologics Global Product Portfolio**

## 28 Direct & Partnered



With MYLAN, 11 biosimilars being codeveloped for global markets



With **SANDOZ**, set of next-gen immunology, oncology biosimilars being co-developed for global markets



**BIOCON BIOLOGICS** is independently developing many biosimilar assets

THERAPY FOCUS: Diabetes, Oncology, Immunology, Dermatology, Ophthalmology, Neurology, Rheumatology and Inflammatory Diseases.



#### **Biocon's Global Partnership with Mylan**



Molecule	KEY MOLECULE STATUS			
TRASTUZUMAB	Launched in U.S., Canada, EU, Australia & Emerging Markets.			
PEGFILGRASTIM	Launched in U.S., Canada & Australia. Approved in EU			
BEVACIZUMAB	Launched in India and Sri Lanka			
INSULIN GLARGINE 100 IU/mL	Launched in EU, Australia, Japan* & Emerging Markets. Approved in New Zealand. Under review in U.S.			
INSULIN ASPART	Global Phase III			
RECOMBINANT HUMAN INSULIN	Launched in Emerging Markets. In active development for U.S.			

#### 11 BIOSIMILARS BEING CO-DEVELOPED FOR GLOBAL MARKETS

- Partnership Leverages Biocon's Strong Development & Manufacturing Capabilities & Mylan's Regulatory & Commercial Excellence
- Cost and Profit Share Model



#### **Biocon's Exclusive Partnership with Sandoz**



- Set of next-gen immunology, oncology biosimilars being co-developed for global markets.
- Various Assets are in early stage development stage for global markets.

- Both Partners have Shared Responsibility for Development,
   Manufacturing, Global Regulatory approvals
- Costs & Profits are Shared Equally
- Broader Biocon Participation in End-to-End Development and Commercialization





#### **Novel Molecules: Pipeline & Therapeutic Area Focus**

**INSULIN TREGOPIL** 

First-in-Class Oral, **Prandial Insulin** 

India Phase II in T2D Completed; **Commenced Phase Ib in** T1D in Germany<sup>^</sup>

**DIABETES** 

ITOLIZUMAB\*@

Novel, Humanized CD6 Antibody

Clinical trials ongoing in aGVHD#, Severe Asthma, Lupus Nephritis, COVID-19

**ACUTE GRAFT-VS-HOST** DISEASE, ASTHMA, LUPUS, COVID-19

**BVX-20**\$

Novel, 2<sup>nd</sup> Generation Humanized CD20 Antibody

Path to IND Mapped

**INFLAMMATION** 



BICARA

New entity incorporated in poster, end
of Biocon to focus on developing Immuno-Oncology assets New entity incorporated in Boston, U.S. as a wholly owned subsidiary

FMAb2 **Fusion Protein**  EGFR mAb + TGFβRII **Tumor-Targeted** Fusion mAb

IND Filed, Received 'study may proceed' advice from US FDA

**IMMUNO-ONCOLOGY** 



- \* Licensed to EQUILLIUM US, Canada, Australia & New Zealand # Acute Graft-VS-Host Disease
- ^ Supported by JDRF
- @ Undergoing clinical trials in India for COVID-19 complications
- S Partnered with Vaccinex



#### **Small Molecules: APIs**

#### **Differentiated Portfolio**

- Product portfolio leverages core fermentation technology strengths
- Among world's largest manufacturers of statins & immunosuppressant APIs
- Biocon's API is one of the global leaders in statin pills
- Forward Integration to Formulations augurs well for the Business

<b>Current Portfolio</b>	Constituents				
Statins	Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, Fluvastatin				
Immunosuppressants	Tacrolimus, Sirolimus, Everolimus, Mycophenolate Mofetil, Mycophenolate Acid				
Other Key Products	Glatiramer Acetate, Fingolimod, Teriflunomide, Orlistat, Mirabegron				





#### **Small Molecules: Generic Formulations**

- Formulations Under its own Label
- Solid oral & parenteral products in both potent & non-potent categories for emerging and developed markets.
- Generic Formulations strategy includes First-to-Files and Para IVs.
- Rosuvastatin, Simvastatin and Atorvastatin Calcium tablets launched in U.S. are gaining market share.

# BIOCON EXPANDS GEOGRAPHIC FOOTPRINT INTO CHINA: 2nd LARGEST PHARMA MARKET in 2019

- Licensed out 3 Generic Formulations products to China Medical System Holdings (CMS)
- Aim to address a Market Opportunity of U\$\$
   0.8 Bn
- Biocon will develop & manufacture while CMS will Commercialize



Biocon's 1st oral solid dosage facility successfully completes pre-approval U.S. FDA inspection in January 2020.



#### **Syngene: Research Services Business**

- India's first Contract Research Organization 25+ years of unparalleled experience in novel molecule discovery & development services
- End-to-end discovery, development and manufacturing capabilities
- Integrated service platform for small & 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
- Over 330\* global clients across diverse industries
- 1.3 Mn sq. ft. of world-class R&D and manufacturing infrastructure
- 4,100+ scientists
- Value Creation through Public Listing in 2015



\* For fiscal ended March 31, 2019







#### **Manufacturing Expertise**

- Large Scale Fermentation-Derived Complex APIs and Generic Formulations facilities
- Global Scale Biologics Manufacturing Capability; both Drug Substance & Drug Product
- 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.

## Manufacturing Locations

- Bangalore
- Telangana
- Vishakhapatnam
- Malaysia



**Insulins Facility In Bangalore** 

Global Scale And Cost Competitive, Complex Manufacturing Capabilities To Address
Global Market Opportunities



#### **Biocon Campus: First Manufacturing Facility Set Up**



**Established:** 1978, Spread over 25 acres

#### **REGULATORY APPROVALS:**

- U.S. FDA
- EMA,
- TGA (Australia)
- COFEPRIS (Mexico)

#### Manufactures:

- Fermentation-derived and Synthetic Chemistry-based Small Molecule APIs.
- Drug Substance for Insulins



#### Largest Biotech Hub in India: Biocon Park, Bangalore



## **Established:** 2006, Spread over 90 acres **REGULATORY APPROVALS:**

- U.S. FDA
- EMA,
- Health Canada
- PMDA (Japan)
- TGA (Australia)
- ANVISA (Brazil)
- COFEPRIS (Mexico)
- MCC (South Africa)

#### **Manufactures:**

- Drug Substances & Drug Products for Monoclonal Antibodies & Other Recombinant Proteins
- Drug Products & Devices for Insulins



# Biocon Malaysia: Asia's Largest Integrated Insulins Manufacturing Facility

- Biocon's first overseas manufacturing facility built with an Investment of ~US\$300 Mn
- Manufactures Drug Substance, Drug Products in vials, cartridges and devices
- GMP approvals from EMA, NPRA etc
- Insulin Glargine from this facility has been launched in Europe
- Addressing the needs of 350,000 people with diabetes in Malaysia
- Commercial supplies to some of the emerging markets being served from Malaysia





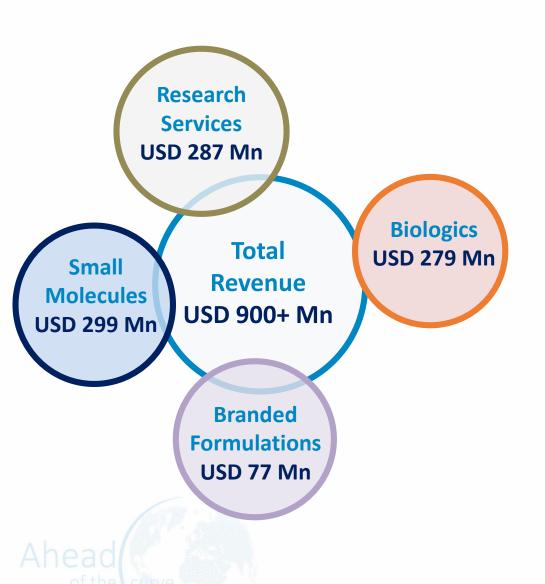








#### **FY20:** Business Segment Highlights



**Annual Segmental Growth:** 

**BIOLOGICS: + 29%** 

**SMALL MOLECULES: + 18%** 

**BRANDED FORMULATIONS: (18%)** 

**RESEARCH SERVICES: + 10%** 

NOTE: 1 USD = 70 INR



#### Financial Highlights: Q4FY20 & FY2020

In Rs. Million (except Growth numbers)

#### As per IND-AS

	Q4FY20	Q4FY19	Growth	FY20	FY19	Growth
Revenue	16,441	15,570	6%	65,286	56,588	15%
Net Profit	1,234	2,137	(42%)	7,482	9,053	(17%)
EBITDA	3,817	4,312	(11%)	17,645	15,381	15%
	Q4FY20	Q4FY1	.9 Growth	FY20	FY19	Growth
Small Molecules	5,407	4,719	15%	20,937	17,728	18%
Biologics	3,574	4,511	(21%)	19,513	15,169	29%
Branded Formulations	1,172	1,330	(12%)	5,362	6,564	(18%)
Research Services	6,073	5,339	14%	20,119	18,256	10%
<b>Total Sales</b>	15,810	15,28	8 3%	63,672	55,144	15%



**Beyond Business: CSR** 



CORPORATE SOCIAL RESPONSIBILITY





#### **Beyond Business: CSR**

# Promoting Social and Economic Inclusion





#### **HEALTHCARE** – Key Initiatives

- Tech enabled Primary Health Centres: eLAJ Smart Clinics
- Focus on Non Communicable Diseases
  - Oral , Cervical, and Breast Cancer Screenings
  - Cancer Task Force
  - Mental Health Awareness
- Women & Child Health: Well Baby Clinic, Midday meals
   PMSA ANC Camps, Balspandana

# **COMMUNITY DEVELOPMENT – Addressing Community Needs**

#### **Key Initiatives**

- WASH initiative: School Toilets & Safe Drinking Water
- Hennagara School Building
- Girls' Hostel
- Lake Rejuvenation
- Namma BioCommunity

#### **EDUCATION** – Key Initiatives

• Chinnara Ganitha





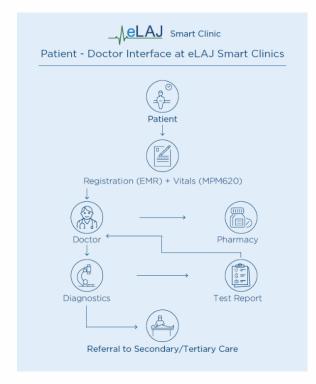
# **eLAJ Smart Clinics - Strengthening Delivery of Primary Healthcare in India**

- Based on robust EMR system.
- Patients' records digitised; ensures continuum of care.
- 3 interconnected modules Registration, Medical Consultation and Diagnostics.
- Centralized EHRs Health records accessible from anywhere.

### IMPACT OF eLAJ CLINICS

**Patient Visits** 

~400,000 since launch









# **Sustainability Programs: Lake Revival**

# **HEBBAGODI LAKE: 35 Acres, Electronic City**

# **Before**





YouTube link: https://www.youtube.com /watch?v=WKmWeIPoFd4

- Rejuvenated **Hebbagodi Lake** inaugurated and dedicated to local community
- Used 3-step eco-friendly Bioremediation Process to revive dying lake
- Children's Park and RO-based safe drinking water facility also dedicated to local community
- Makes it to Limca Book of World Records as the 'Largest Area of Artificial Floating Wetlands Created in a Lake in India'
- Taken up revival of one more lake in the vicinity: Yarandahalli lake









#### **Adding Value, Enhancing Skills**

# Center of Excellence for Advanced Learning in Applied Biosciences



#### **Developing high end talent for Biotech Sector**

#### **PROGRAMS**

- Biocon-KGI Certificate Program in Biosciences
- BITS Biocon Certificate Program in Applied Industrial Microbiology
- Biocon-KGI Certificate Program in Clinical Development
- Biocon Academy Certificate Program in Faculty Development
  - Biocon Ramaiah Certificate Program in Quality Control Analytical



- A combination of academic and experiential learning
- Scholarship up to 75% of course fee
- KGI Program 16 batches completed
- BITS Biocon Program: 6 batches completed
- 600+ students graduated
- 100% Placement Record





Thank you



www.biocon.com