

**Biocon Limited**

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CIN : L24234KA1978PLC003417

December 13, 2019

[www.biocon.com](http://www.biocon.com)

To The Secretary <b>BSE Limited</b> Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001 <b>Scrip Code - 532523</b>	To The Secretary <b>National Stock Exchange of India Limited</b> Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050 <b>Scrip Symbol- BIOCON</b>
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Dear Sir/Madam,

**Sub: Updated Investor Presentation on “Biocon Biologics- Transforming Healthcare. Transforming Lives”.**

With reference to our letter dated December 11, 2019, we have submitted Investor Presentation titled “Biocon Biologics- Transforming Healthcare. Transforming Lives”, please find enclosed updated version of the same.

The above information will also be available on the website of the Company at [www.biocon.com](http://www.biocon.com).

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

For **BIOCON LIMITED***Mayank Verma*

**Mayank Verma**  
Company Secretary & Compliance Officer

**Encl: Investor Presentation**

# Biocon Biologics

## Investor Presentation

Transforming Healthcare. Transforming Lives  
December 2019



# Safe Harbour

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, 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 biotechnology and pharmaceuticals industries, changes in political conditions and changes in the foreign exchange control regulations. 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



# Introduction



# Biocon Biologics

Uniquely positioned as fully integrated player for biosimilars

2 

Development Partnerships  
(Mylan, Sandoz)

740+ 

Registered  
Trademarks\*

28 

Products  
in pipeline

5 

Products taken  
from Lab to Market

 4000+

High Quality, Diverse  
Employees

 ~860

Patents granted  
(Biologics)\*

 ~120

Countries where our  
products are available

2 

R&D sites  
(Bangalore, Chennai)

3 

Manufacturing sites (2  
Bangalore, 1 Malaysia)

25+ 

cGMP approvals from  
International regulatory agencies\*\*

4 

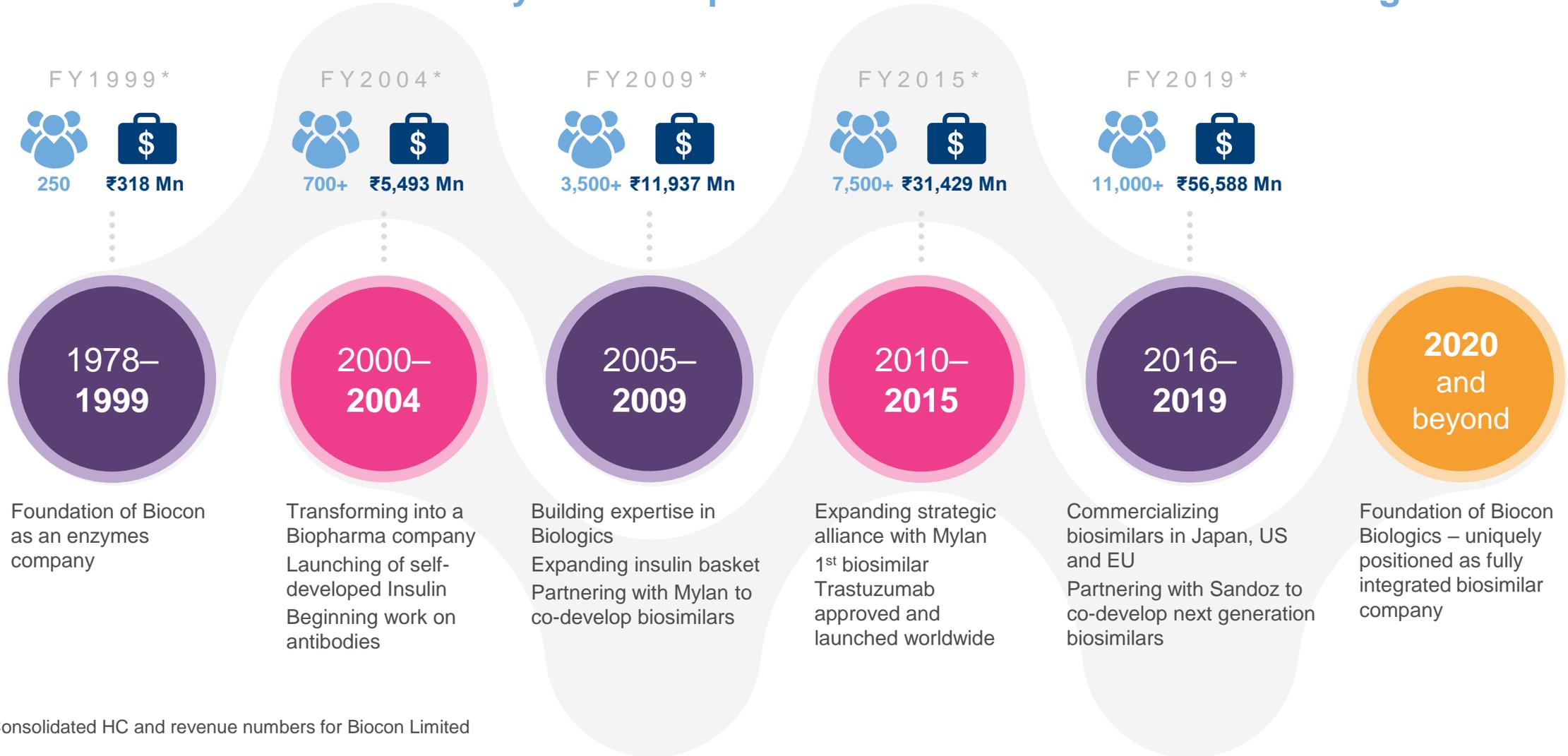
Office locations  
around the globe

\*Status Jun 2019

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

# Biocon Biologics

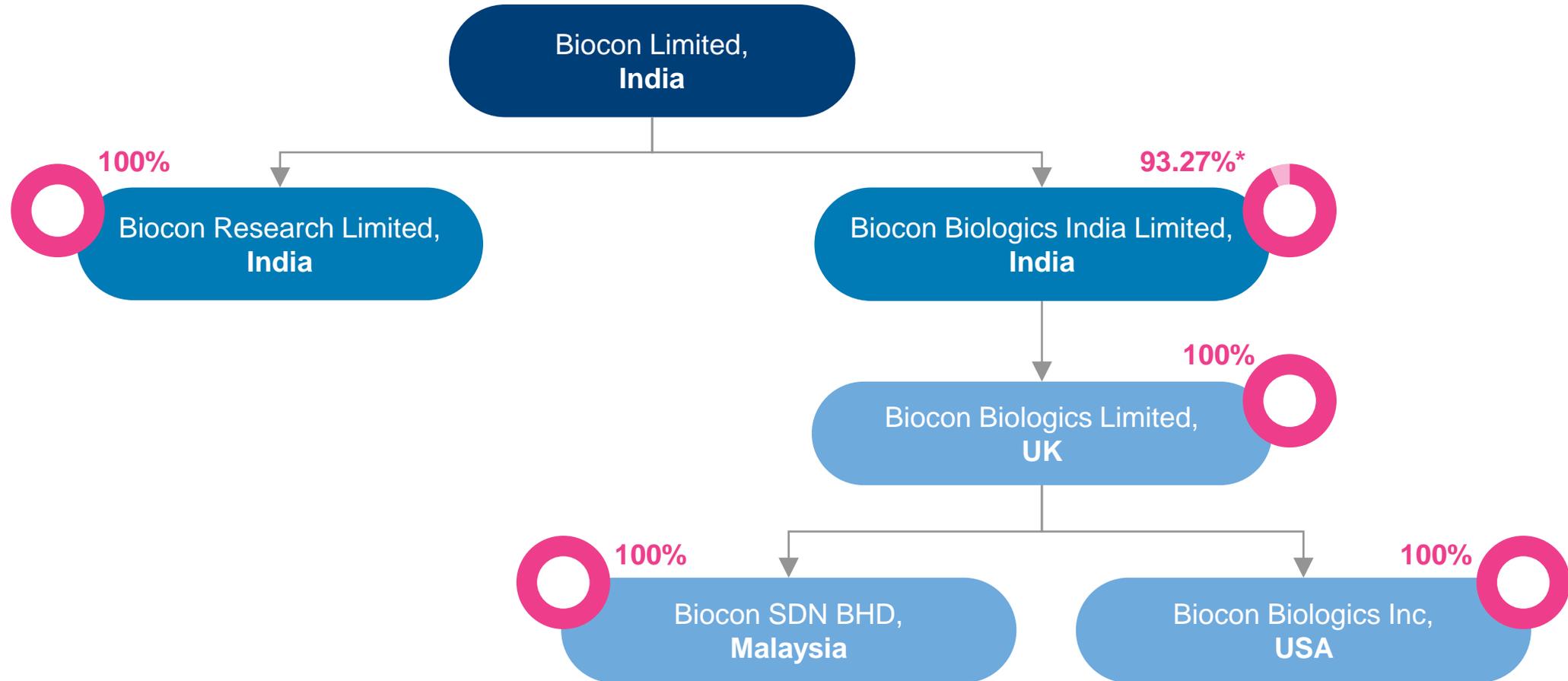
Foundation based on over 40 years of experience in science and manufacturing



\*Consolidated HC and revenue numbers for Biocon Limited

# Biocon Biologics Holding Structure

Independent and international management team with top talents



% depict equity shares held

\* Corporate actions pending, post completion of which shareholding of Biocon Limited will rise to 98.47%



# Market overview



# Nature of Biosimilars

High investments, quality focus and scale needed to deliver biosimilars across the world

## A biosimilar is a biological product



Large and generally complex molecules



Produced from living organisms

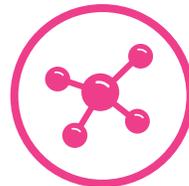


Carefully monitored to ensure consistent quality

## A biosimilar is highly similar to a reference product



Purity

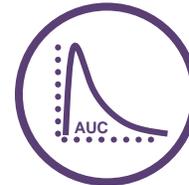


Molecular structure



Bioactivity

## A biosimilar has no clinically meaningful differences from a reference product



Pharmacokinetic and, if needed, pharmacodynamic studies



Immunogenicity



Additional clinical studies as needed

## A biosimilar is approved by FDA after rigorous evaluation and testing by the applicant



Are manufactured in FDA-licensed facilities



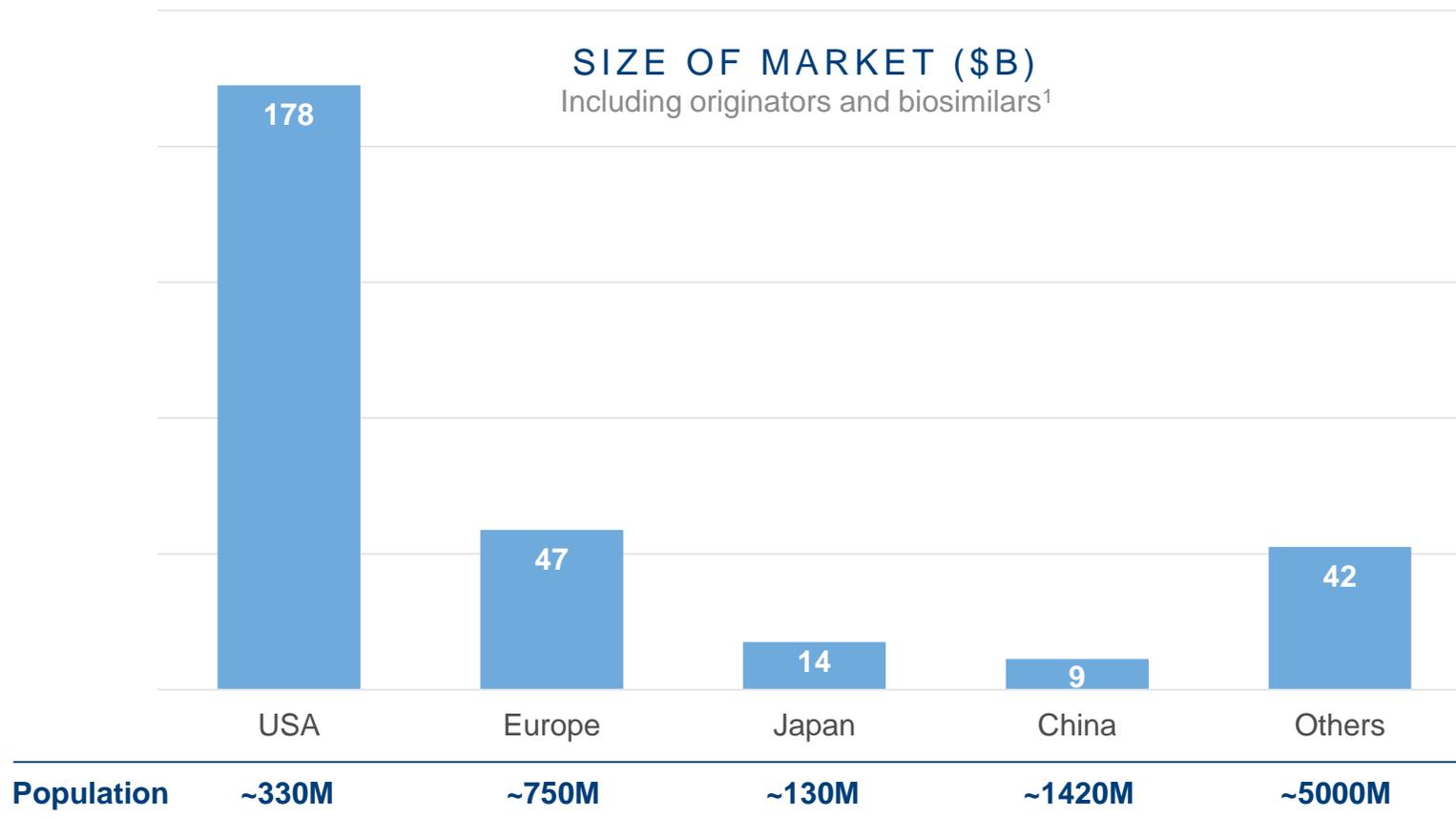
Are tracked as part of post-market surveillance to ensure continued safety



Meet FDA's rigorous standards for approval

# Biologics Market

## Significant opportunity for biosimilars



1. Excludes vaccines; 2. As of 2018

Note: size of market is indicative

Source: IMS, FDA, gabionline, Worldometers, press search, BCG analysis



# Biocon Biologics – Biosimilars is our only focus

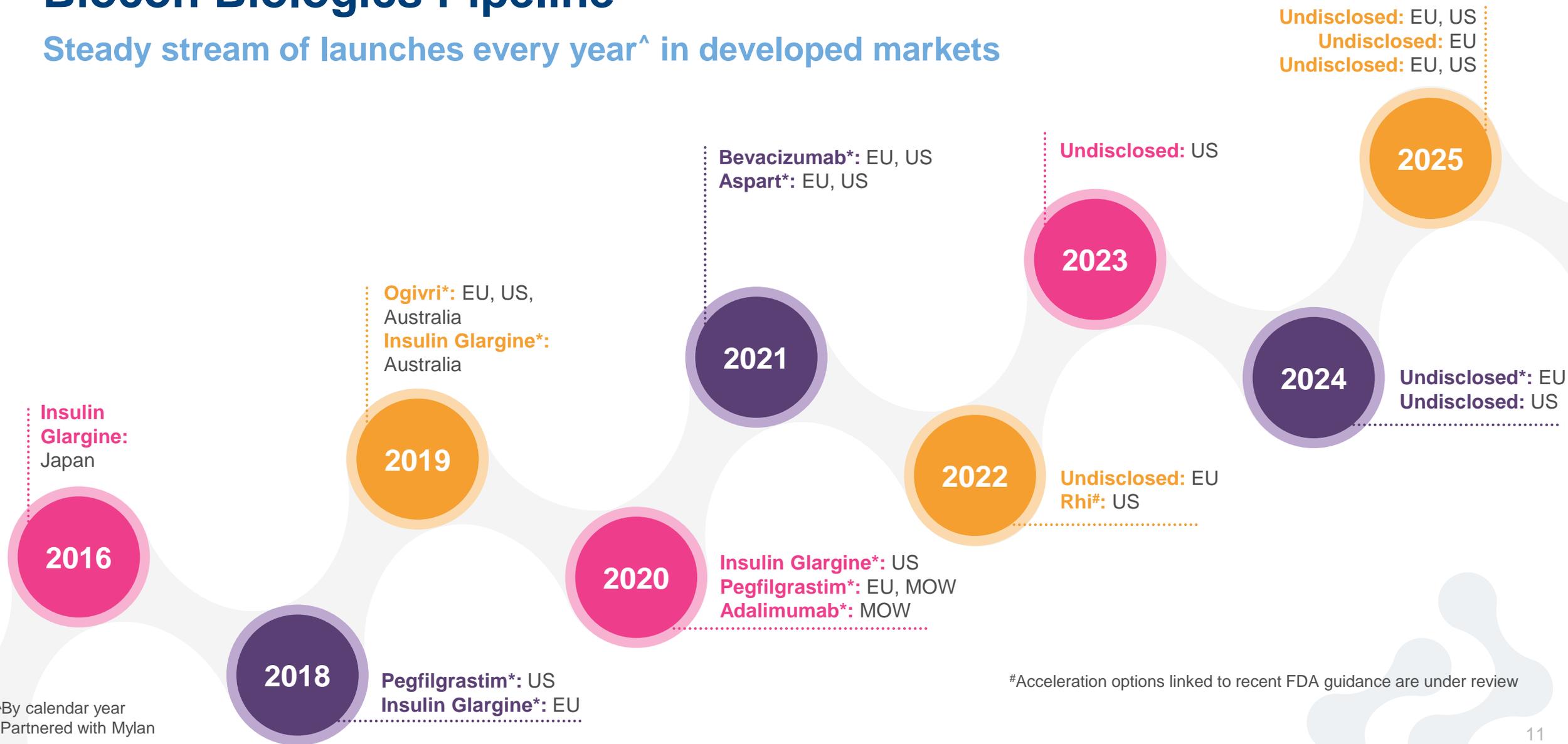
One of the major players from a portfolio perspective with 28 molecules in pipeline

	PRODUCT	BIOCON BIOLOGICS	PFIZER	AMGEN	SAMSUNG	SANDOZ	CELLTRION	COHERUS	LILLY	SANOFI
UNIQUE SOLID TUMOUR OFFERING	Filgrastim		✓			✓				
	Pegfilgrastim	✓				✓		✓		
	Trastuzumab	✓	✓	✓	✓	✓	✓			
	Bevacizumab	✓	✓	✓	✓		✓			
	Infliximab		✓	✓	✓	✓	✓			
	Rituximab		✓	✓	✓	✓	✓			
STRONG INSULINS FRANCHISE	Adalimumab	✓	✓	✓	✓	✓	✓	✓		
	Etanercept	✓			✓	✓		✓		
	Glargine	✓			✓	✓			✓	
	Aspart	✓								✓
	Lispro									✓

Note: Phase 3 or later assets displayed only as check marks

# Biocon Biologics Pipeline

Steady stream of launches every year<sup>^</sup> in developed markets



#Acceleration options linked to recent FDA guidance are under review

<sup>^</sup>By calendar year  
\*Partnered with Mylan



# Strategic overview



# Biocon Biologics' unique approach

It is not about drug cost cutting, it is about finding innovative ways to transform the patient ecosystem



Re-Imagining the Patient ecosystem in an innovative way

**30%**

Spend for drugs



**70%**

Spend for services & others

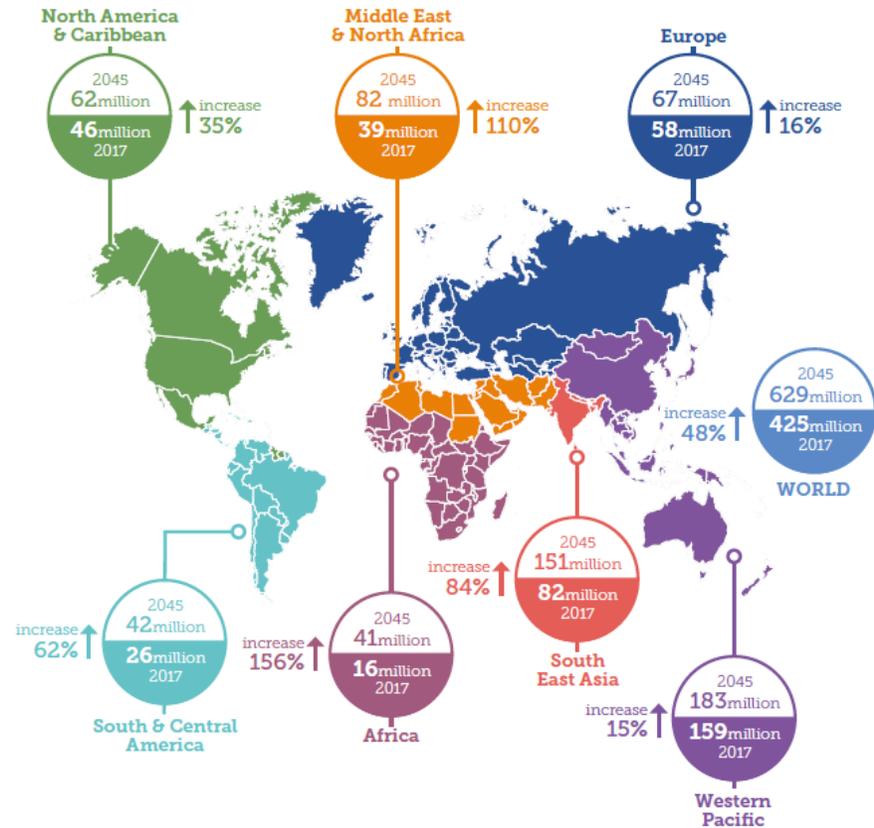
**Task shifting**

**Technology driven personalized care**

- New partners in disruptive models
- Better patient care & outcomes while reducing costs
- Risk stratification to allow focused hypercare for patients

# We transform healthcare

## Diabetes – a global epidemic



Graphic Source: International Diabetes Federation

### Why Biocon's 10 cents insulin offer could be a game changer in fighting diabetes

Currently, blended median patient prices in LMICs are \$9 per 10 ml vial translating to 36 US cents per day

Viswanath Pilla  
@viswanath\_pilla



Last week, Kiran Mazumdar-Shaw, Chairperson and Managing Director of Biocon made an announcement offering recombinant human insulin (rh-Insulin) at less than 10 US cents per day in low and middle-income countries (LMICs). This is almost 70 percent cheaper than the existing prices.

The offer is for vials sourced by the government directly from Biocon, assuming an insulin



Biocon

+ Watchlist | + Portfolio | M Message | Set Alert

# Biocon Biologics presents at US FDA Public Hearing on Increasing Insulins Access

**A unique opportunity for accelerating approval of biosimilar human insulin**  
– the most important insulin for patients struggling to afford their medicines

- © Biocon presented at the US FDA public hearing held in May 2019
- © Discussed how to facilitate the development of insulin biosimilars and other interchangeable insulin products
- © Requests FDA to fast track approval of 'human insulin'



# Biocon Biologics Policy Engagement

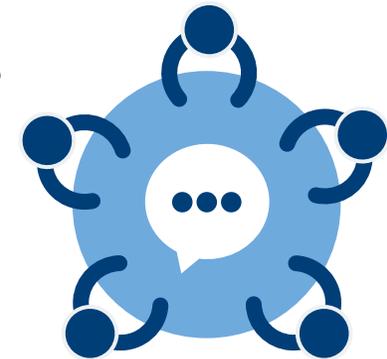
Initial steps towards greater focus on global policy engagement and visibility



## US-India Leaders Summit at National Press Club in Washington DC

- Attended by business leaders from US & India, senior US legislative staffers representing committees including trade, healthcare & foreign affairs
- Meetings on Capitol Hill with legislators and The White House focusing on advancing principled policy solutions

## Prior meetings with key Members of Congress in conjunction with Biosimilars Council





**Business**

 ***Biocon Biologics***

# Biocon Biologics - Set Up For Success

Well positioned in therapeutic areas like diabetes and oncology and inflammatory diseases

Business & commercial strategy tailored to market archetypes, aim to be disruptive

- As a committed stakeholder of the SDG framework, Biocon Biologics is committed to UNIVERSAL healthcare both for diabetes and cancer treatments
- Business and commercial strategy will be aligned to address needs of patients and healthcare systems based on specific market archetypes
- Aspire to transform patient lives through innovative and inclusive healthcare solutions, be the AMAZON of healthcare
- Going beyond the product with technology driven operating model for developed markets and building on our scale and cost of production advantages to compete effectively in MoW markets



## OUR ADVANTAGE

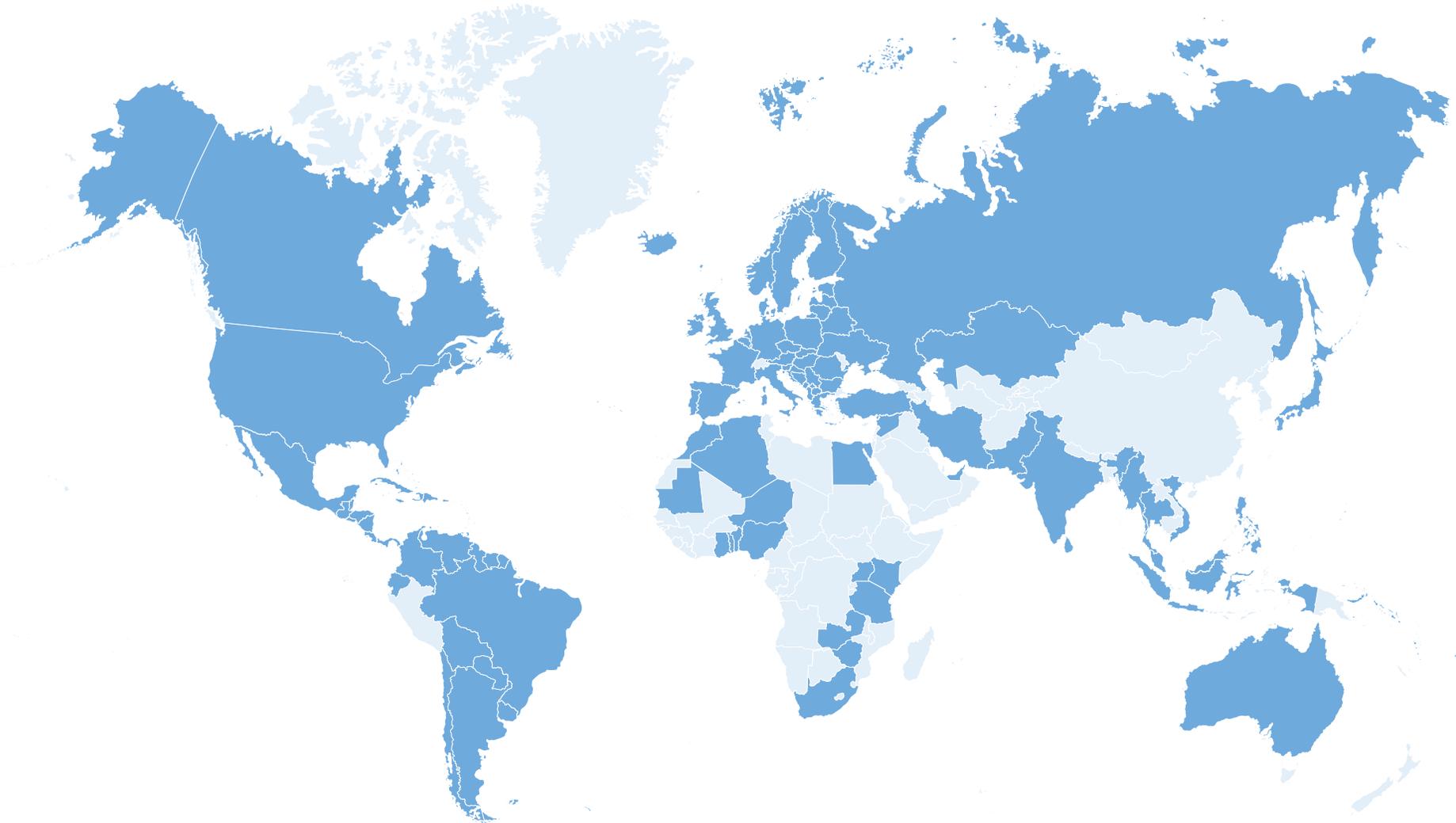
- ✓ **Competitive Cost**
- ✓ **Fully integrated from Lab to market and focused on biosimilars**

- ✓ **Capacity enhancement aligned with expanding global demand**
- ✓ **Next wave of biosimilars through direct commercialization**

- ✓ **Investing in digital marketing and new technologies across the value chain**

# Biocon Biologics footprint across the world

Serving patient needs in emerging & developed markets



# Biocon Biologics

## Global Product Portfolio



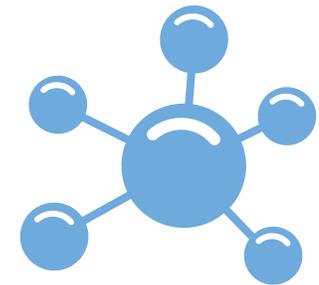
**BIOCON BIOLOGICS** is independently developing many biosimilar assets



With **MYLAN**, 11 biosimilars being co-developed for global markets



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



**28**

MOLECULES

# Biocon – Mylan Partnered Product Pipeline

Early mover in first wave of biosimilar launches in the next 3–5 years



Biocon's strong development and manufacturing capabilities




Mylan's regulatory and commercial excellence



Cost and profit share model

THERAPEUTIC AREA	MOLECULE	STATUS
 <b>Oncology</b>	Trastuzumab	Launched in US, EU, Australia & Emerging Markets. Approved in Canada
	Pegfilgrastim	Launched in US. Approved in EU, Canada & Australia
	Bevacizumab	Launched in India. US submission planned by YE'19, EU submission Q1'CY20
	Filgrastim	Preclinical
	Pertuzumab	Early development
 <b>Diabetes</b>	Glargine 100 IU/ml	Launched in EU, Australia, Japan* & Emerging Markets. Approved in New Zealand. Under review in U.S.
	Glargine 300 IU/ml	Early development
	Aspart	Under review in EU, US submission H1'CY20
	Lispro	Preclinical
 <b>Autoimmune</b>	Adalimumab	Partner Mylan has launched in-licensed product Hulio in EU. <b>Biocon benefits from economic interest</b>
	Etanercept	Partner Mylan's in-licensed product filed for approval in EU. <b>Biocon retains economic interest</b>

\*Japan is outside of Mylan partnership

# Pegfilgrastim - Fulphila

Pegfilgrastim biosimilars still only at 25%<sup>1</sup> of total US market; with the additional approval of a new manufacturing facility, Fulphila is well-positioned to grow rapidly in the US and expand in other markets

## Biocon/ Mylan first to launch in US

- Fulphila<sup>®</sup> was one of the most successful biosimilar launches in the U.S.
- Biosimilar Pegfilgrastims captured a volume market share reaching 25%<sup>1</sup> in Sep'19.
- This growth reflects the increase in penetration and ease of adoption of biosimilars by prescribers, payors and patients

## Expanded capacity to drive U.S. growth, enter new markets

- Biocon and Mylan's sBLA for Pegfilgrastim Drug Substance to be manufactured at Biocon's new Biologics manufacturing facility, approved by the U.S. FDA in Nov'19.
- This facility will enable Biocon Biologics to scale up capacity multi-fold.
- This capacity expansion will help address growing patient needs in EU, Australia and Canada, where Fulphila<sup>®</sup> is approved.

# Trastuzumab

First biosimilar trastuzumab approval globally with CANMAb™ in India; Ogivri™ launched in the US, EU and Australia  
Biocon Biologics has sufficient manufacturing capacity to fulfil demand for global markets

## Emerging Markets

- Regulatory approval in more than 80 countries worldwide including India, Brazil, Algeria, Turkey and UAE
- CANMAb™, the world's first trastuzumab biosimilar, launched in India in 2014.
- In Brazil, Biocon's biosimilar trastuzumab, ZEDORA enjoys a 34% share of the non-tender market<sup>2</sup>.

## Developed Markets

- First biosimilar trastuzumab approved by the U.S. Food and Drug Administration (FDA) in Dec 2017
- Unanimously recommended by the FDA Oncologic Drugs Advisory Committee (ODAC)
- Launched in the competitive, but sizable and growing EU markets in Mar'19.
- In Aug'19, the first biosimilar trastuzumab approved and launched in Australia; available on the Pharmaceutical Benefits Scheme (PBS).
- Launched in US in Dec 2019

BBL's Biosimilar Trastuzumab aims to address the huge unmet need for patients and for healthcare savings, and is well positioned to succeed as a global leader in a competitive market

# Insulins Portfolio

Equitable access to more affordable insulins is critical to address the growing incidence of diabetes globally  
 Biocon Biologics is among the Top 5 insulins players globally, vertically integrated and cost competitive

## Recombinant Human Insulin (rh-insulin)

- Currently registered in ~45 countries and commercialized in many emerging markets.
- BBL is committed to universal access to rh-insulin by reducing prices for low and middle-income countries (LMIC) to less than 10 US cents/day
- **Independent development program for the US market**, currently in Phase-1 studies.
- Acceleration impact on US launch timing, linked to recent positive FDA guidance for insulin biosimilars, is under review

## Insulin Glargine

- Approved in ~70 countries and commercialized in key emerging markets such as Brazil, Mexico, Malaysia, South Korea, UAE
- Launched in Japan, EU and Australia.
- Confident of securing approval from US FDA by Mar'20.
- Huge opportunity in a limited competition market

## Insulin Aspart

- Under review in the EU, expected to launch in FY21E.
- On track for US filing in mid-CY'20.

# Bevacizumab

Launched in India in Nov 2017; global trial complete and on-track for US filing in Dec'19

## Market Dynamics

- **2 players approved by FDA, Amgen was first to launch**
  - Amgen launched in Jul'19
  - Pfizer plans to launch on Dec 31, 2019<sup>1</sup>
  - Samsung filed in US in Nov'19
- **2 players approved by EMA, no launches so far**
  - Amgen approved in Jan'18
  - Pfizer approved in Feb'19
  - Samsung filed in EU in Jul'19

## BBL's Bevacizumab

- Kraveva launched in India in Nov 2017
- US filing expected in Dec'19
- Launch in US planned in FY 22
- Filing in other markets in early 2020

# Biocon – Sandoz exclusive partnership

Co-development of next-generation biosimilars



Shared responsibility for...

- Development
- Manufacturing
- Global regulatory approvals



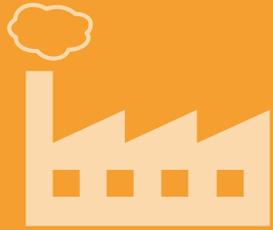
Costs & Profits are shared equally



Broader Biocon participation in end-to-end development and commercialization



Various assets are in early stage development stage for global markets



# R&D and manufacturing



# Research & Development

World class research talents and infrastructure



## FACILITIES

- 85,000 sq. ft. state of the art research facility in BLR
- 8,000 sq. ft. microbial and cell culture pilot plants
- 60,000 sq. ft. research center in Chennai
- 45,000 sq. ft. pilot plant in Malaysia



*Biocon Research Centre, Bangalore*



## TALENT

- 450+ employees
- 20% with MDs or PhD's
- 60% with Masters Degrees
- Alumni from leading Indian & International Universities



# Research & Development

## Capabilities and Structure



### CAPABILITIES

- Drug Discovery
- Process Development
- Scale Up & TT to manufacturing
- Analytical Sciences
- Bioanalytical Sciences
- Intellectual Property Rights



### PLATFORM EXPERTISE

- *Pichia pastoris*
- *E. Coli*
- CHO
- NS0
- Fusion Proteins

### 1 Process sciences

- Drug Substance: Upstream
- Drug Substance: Downstream
- Formulation & Drug Product

### 2 Analytical & bioanalytical sciences

- Analytical Method Development
- Physico-chemical characterization
- Functional characterization
- PK & Immunogenicity
- Toxicology

### 3 Intellectual property rights

- Patents
- Trademarks
- Litigation support

# Global Scale Manufacturing Expertise

Largest Biologics manufacturing capacity in India

- ✓ State-of-the-art manufacturing facilities – mammalian & microbial
- ✓ Facilities conform to most stringent cGMP guidelines
- ✓ Regulatory approvals - EMA, US FDA, Health Canada, ANVISA, COFEPRIS, PMDA, TGA, MCC etc.
- ✓ Second fill-finish sterile injectable line in Bangalore has been approved by key regulators including EMA and US FDA. It will support future growth of biologics formulations
- ✓ Construction of second antibody manufacturing facility in Bangalore ongoing. First phase to be operationally qualified in FY20

# Manufacturing Sites

## Largest Biotech Hub in India



### CAMPUS



↖ 25 acres ↗



### PARK



↖ 90 acres ↗



### JOHOR



↖ 40 acres ↗



#### Regulatory approvals

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

- U.S. FDA
- Health Canada
- TGA (Australia)
- COFEPRIS (Mexico)
- MCC (South Africa)

- EMA
- TGA (Australia)
- NPRA



#### Manufacturing

- Drug Substance for Insulins
- Drug Substance for Microbials

- Drug Substances & Products for monoclonal antibodies and other recombinant proteins
- Drug Products & Devices for Insulins

- Drug Substance and Product for Insulins

**Capabilities To Address Global Market Opportunities:  
Global Scale - Cost Competitive - Complex Manufacturing**



# Outlook



# Biocon Biologics

Committed to make a difference to patients' lives



**serve ~2.6 million patients\* in FY 20**  
**touch over 5 million patient lives\* by FY 22**  
**Crossing a revenue milestone of US\$ 1 billion**

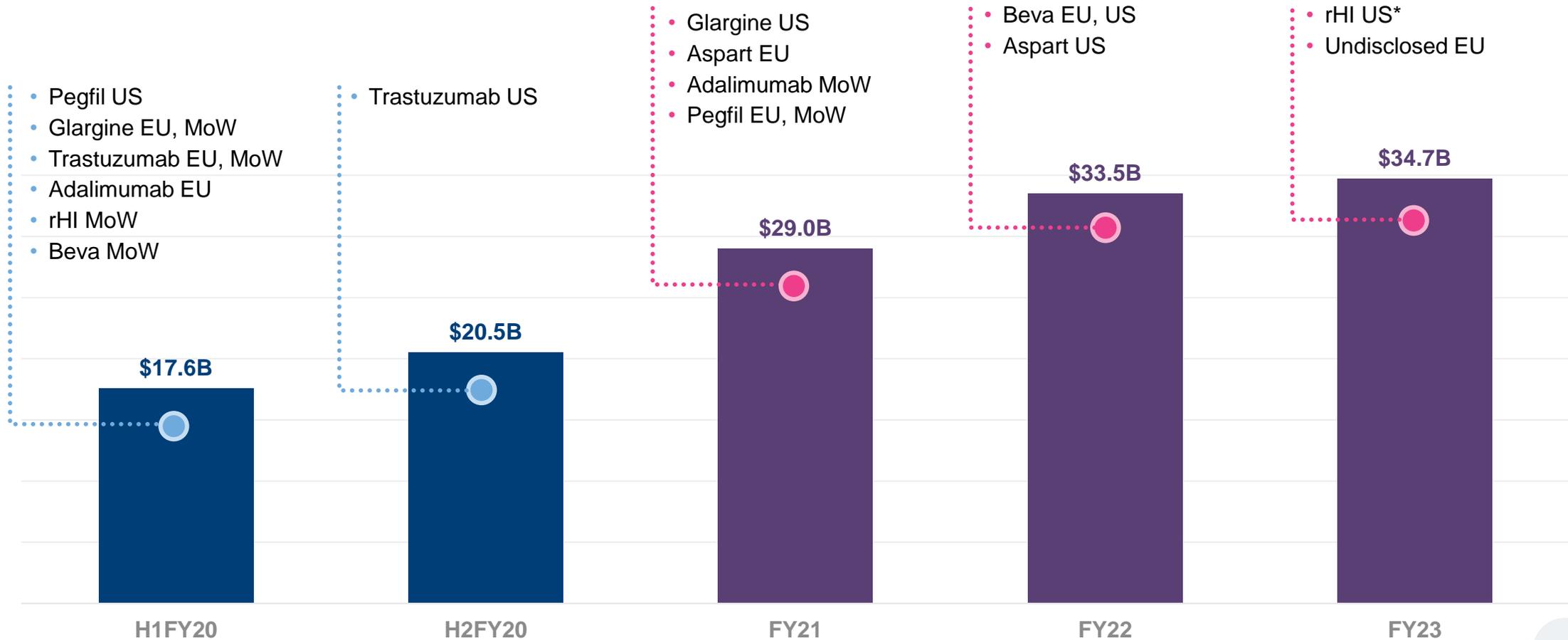
**We are serving global patient needs with high quality, affordable Biosimilars**

\* Calculated basis standard dosing and drug substance expected to be manufactured/sold

# FY22 Aspiration of \$1Bn

## Unlocking market opportunity

The opportunity expected to increase ~2x as new products are commercialized



\*Acceleration options linked to recent FDA guidance are under review

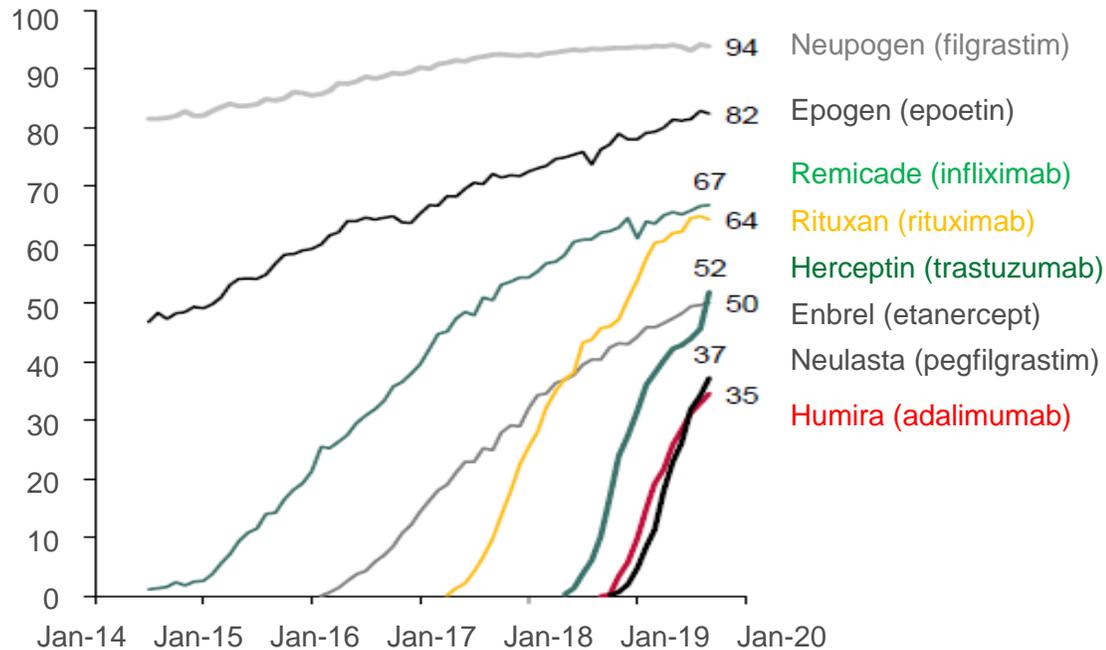
# Context of global leadership

## Biosimilar penetration

80%+ total biosimilar market shares open the door to leadership-level shares



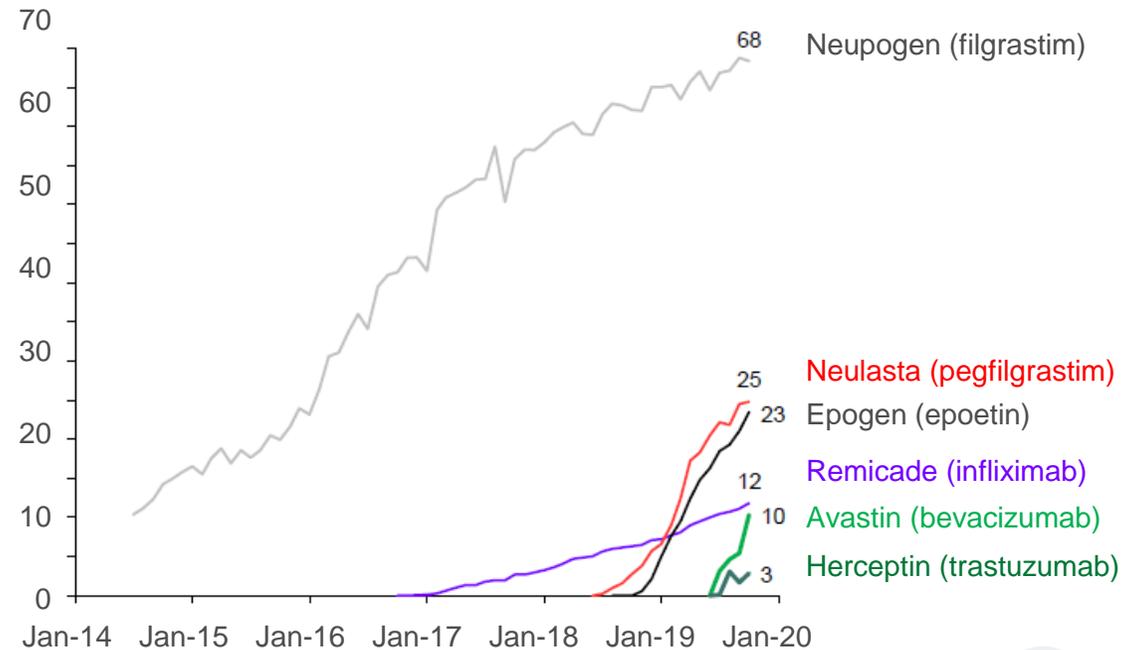
### EU biosimilar market share (by standard units)



Source: Bernstein report (Dec'19)



### US biosimilar market share (by standard units)



Source: Bernstein report (Dec'19)

Note: Epogen market is defined as Epogen, Procit, Mircera and Retacrit (biosimilar)

Encouraging trend of significant biosimilar adoption in both Europe and US provides an opportunity for Biocon to capture a dominant share of the market

# FY22 Aspiration of \$1Bn

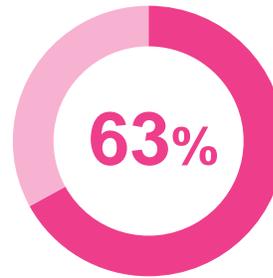
## The future has already started

Based solidly on actual performance



### FY 19 PERFORMANCE

- Revenue nearly doubled to Rs.1517 Crore, recording a growth of 97%
- Profit Before Interest and Tax (PBIT) margin at 26% in FY19 (*Improved from -2% in FY18*)



### H1 FY20 PERFORMANCE

- Revenue crossed the Rs.1000 Cr landmark to Rs.1006 Crore, a growth of 63%
- Profit Before Interest and Tax (PBIT) margin at 31% (*Improved from 19% in H1 FY19*)

### EXPECTATIONS FOR H2 FY20 AND BEYOND

- Performance in H2 FY20 to be even stronger, driven by new launches and availability of new capacities, helping both revenue growth as well as margin profile
- Full impact of new launches and additional capacities should reflect in FY21 P&L with substantial full year growth projected over FY20E
- FY22 expected to build upon FY21 with expected launches of Insulin Aspart and Bevacizumab

# FY22 Aspiration of \$1Bn

Multiple levers to further accelerate growth in the next 2 years



## GROWTH DRIVER

- **US launches** of trastuzumab and glargine
- **Continued growth** in existing developed and emerging markets
- **Launches of insulin aspart** and **bevacizumab** in various markets
- Enhance **market share**



## GEOGRAPHIC MIX

Diversified mix across developed and emerging markets

- While US is biggest growth driver, ROW growth is also significant
- Continued performance in key Markets: Algeria and Brazil for trastuzumab, Malaysia and Mexico for insulins
- Early entry into China as potential upside

# What to Expect In The Next Decade?

Only a few players will succeed in the BS market and we will be one of them!



**Accelerating** the growth path



Further **strengthening** the broad pipeline



Ability to further **differentiate** and disrupt healthcare

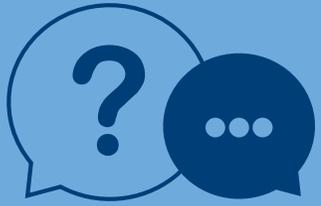


**Leveraging** our affordable innovation model & global scale R&D



## OUR ADVANTAGE

- ✓ Competitive Cost
- ✓ Fully integrated from Lab to market and focused on biosimilars
- ✓ Capacity enhancement aligned with expanding global demand
- ✓ Next wave of biosimilars through direct commercialization
- ✓ Investing in digital marketing and new technologies across the value chain



# Questions

