



**Biocon Limited**

20th KM Hosur Road

Electronics City

Bangalore 560 100, India

T 91 80 2808 2808

F 91 80 2852 3423

CIN : L24234KA1978PLC003417

June 11, 2020

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

**Ref: Regulation 30 of the SEBI Listing Obligations and Disclosure Requirements (LODR) Regulations, 2015.**

With reference to the captioned subject, please find enclosed Investor Presentation, presented at the Investor Meeting held on June 11, 2020.

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*

②

**Mayank Verma**

**Company Secretary & Compliance Officer**

**Encl: Investor Presentation**

# Biocon Biologics

## Investor Presentation

Transforming Healthcare. Transforming Lives

June 2020



## 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.

# Our Vision



## Biocon Biologics

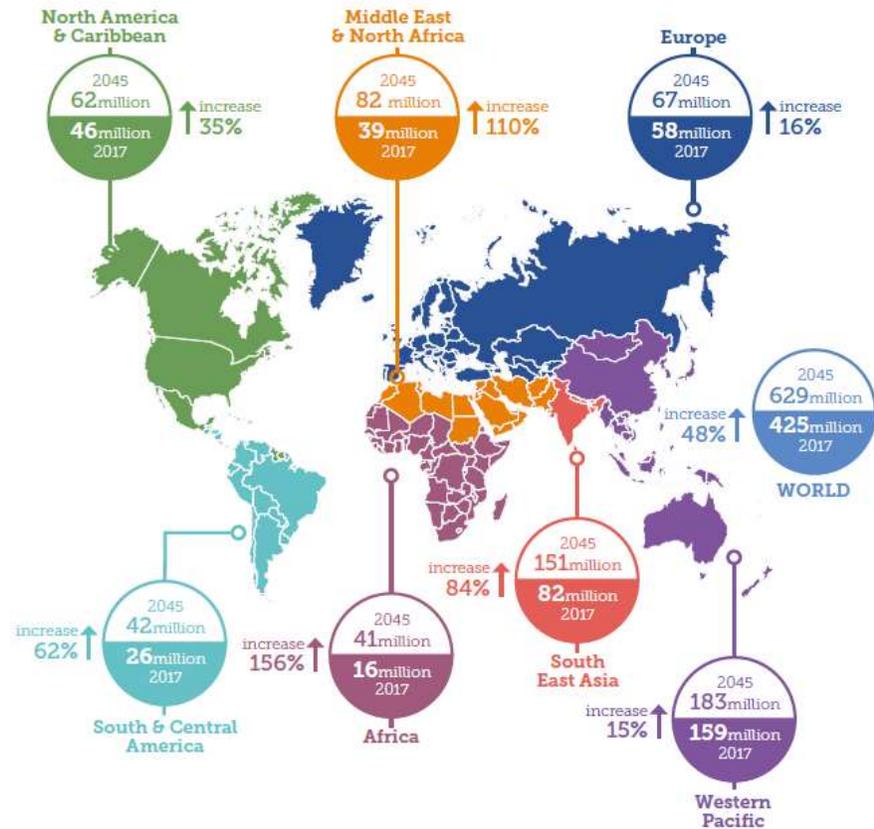
*'Transforming Healthcare, Transforming Lives.'*

Most inspiring global leader in Biologics delivering affordable access to innovative and inclusive healthcare solutions, transforming patient lives.



# We transform healthcare

## Example: 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 | Message | Set Alert

# Biocon Biologics

Committed to make a difference to patients' lives



**served 2.1 million patients\* in FY 20**  
**touch over 5 million patient lives\* by FY 22**

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

# 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 United Nation's Sustainable Development Goals\* (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
- Most innovative and disruptive healthcare company; aspires to transform patient lives through innovative and inclusive healthcare solutions
- Be a leader in MoW markets by delivering high quality and low cost medicines

\* <https://sustainabledevelopment.un.org/>



## OUR ADVANTAGE

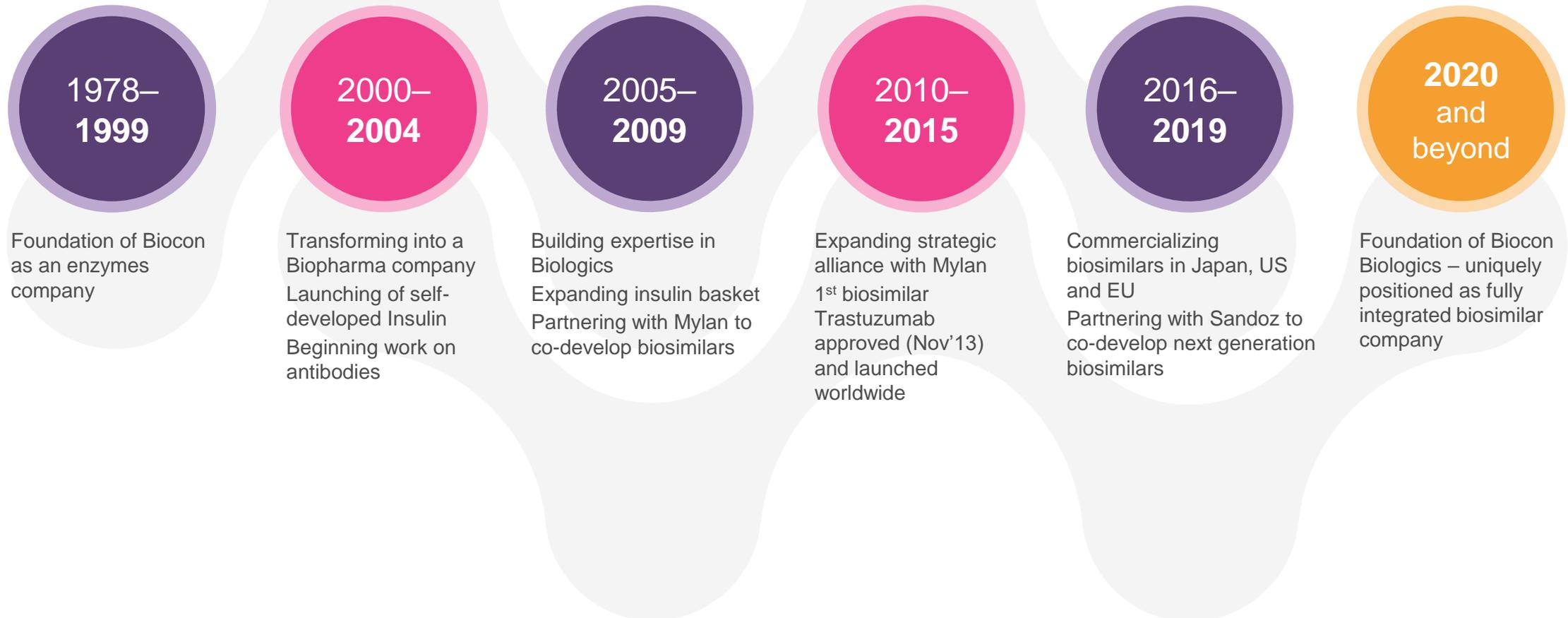
- ✓ **Competitive Cost**
- ✓ **Fully integrated from Lab to market and focused on biosimilars**

- ✓ **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**

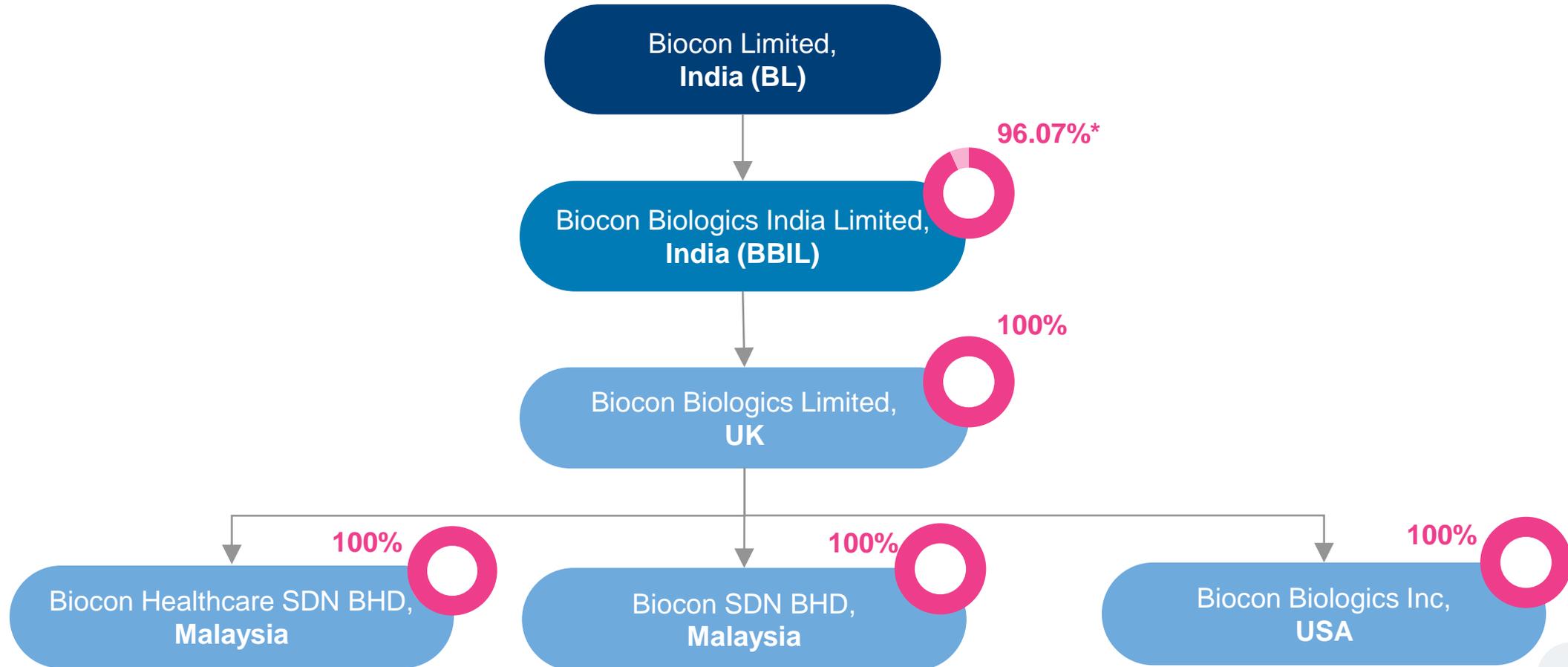
# Biocon Biologics

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



# Biocon Biologics Holding Structure

Independent and international management team with top talents



\* Private equity fund True North has invested \$75 mn for a 2.44% equity stake in Jan 2020, valuing BBIL at \$3B, pre-money.



# 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

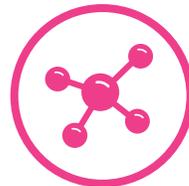


Carefully monitored to ensure consistent quality

## A biosimilar is highly similar to a reference product



Purity

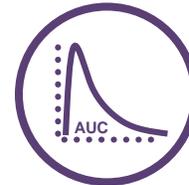


Molecular structure



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



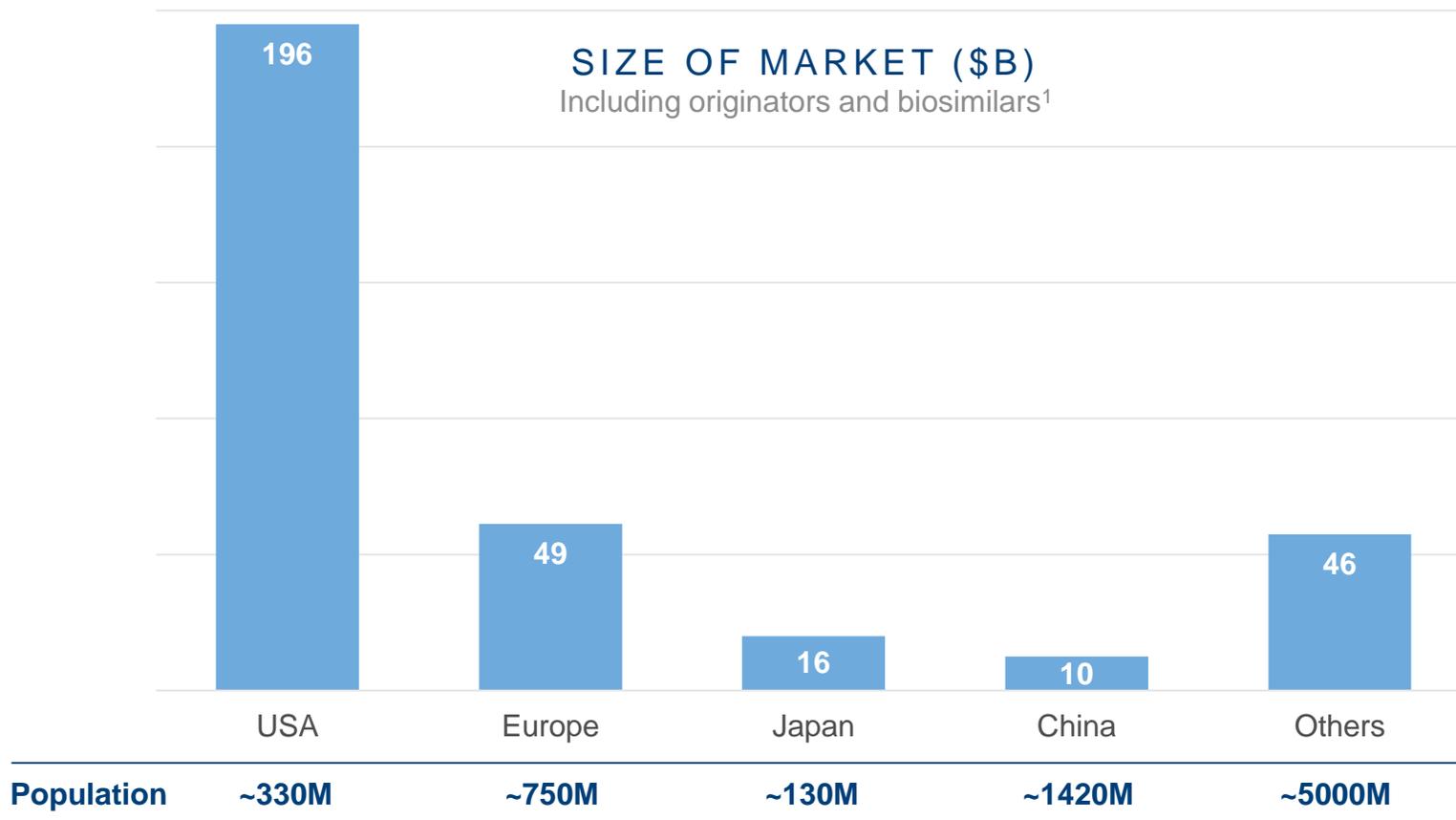
Are tracked as part of post-market surveillance to ensure continued safety



Meet FDA's rigorous standards for approval

# Biologics Market

## Significant opportunity for biosimilars



1. Excludes vaccines; 2. As of 2019

Note: size of market is indicative

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



# Biocon Biologics – Biosimilars is our **only** focus

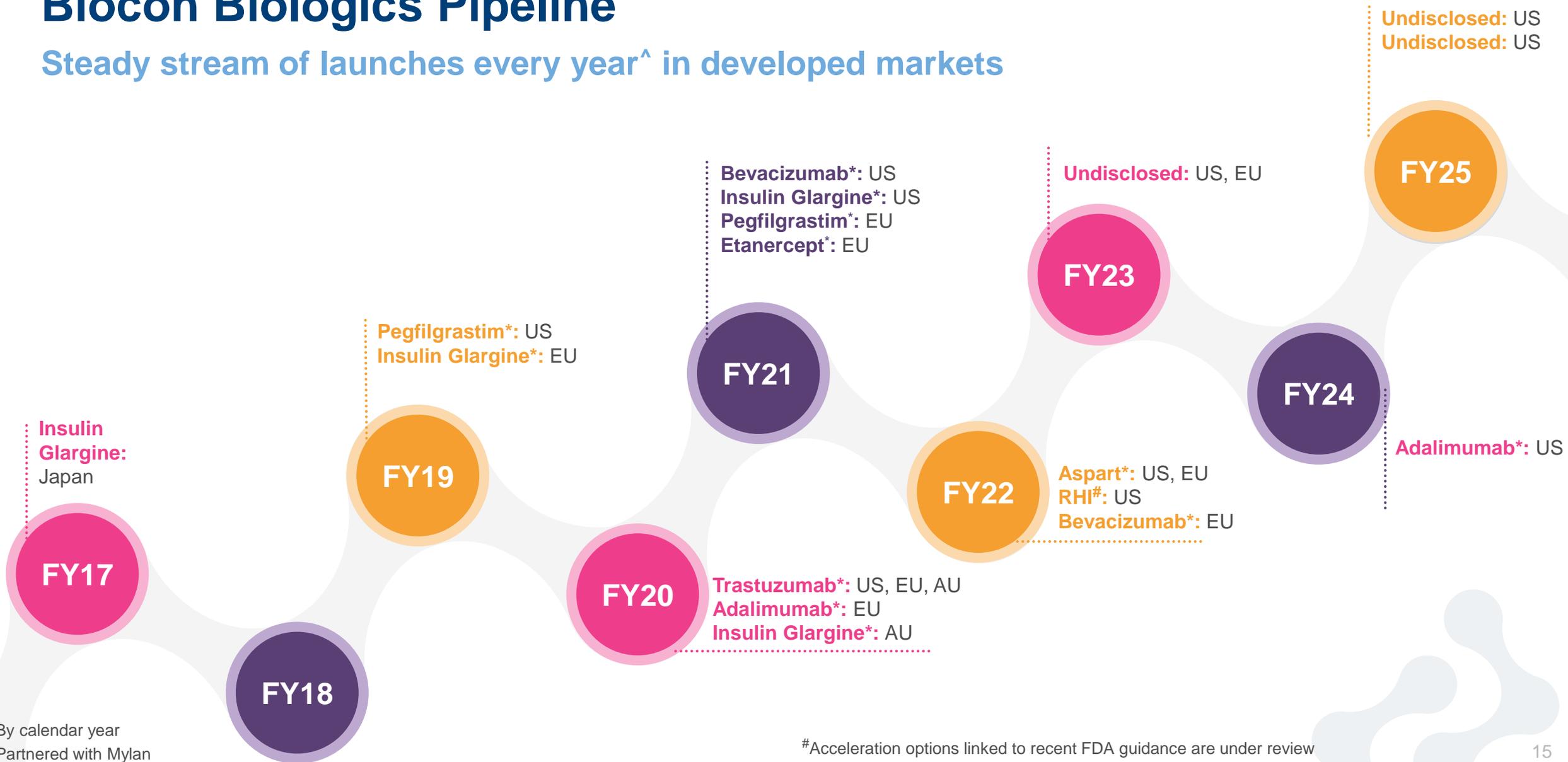
Major player with 28 molecules in pipeline

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

Note: Phase 3 or later assets displayed only as check marks; \*Samsung admits it failed to develop Rituxan biosimilar (<http://www.koreabiomed.com/news/articleView.html?idxno=6608>)

# Biocon Biologics Pipeline

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



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

#Acceleration options linked to recent FDA guidance are under review



**Business**

 ***Biocon Biologics***

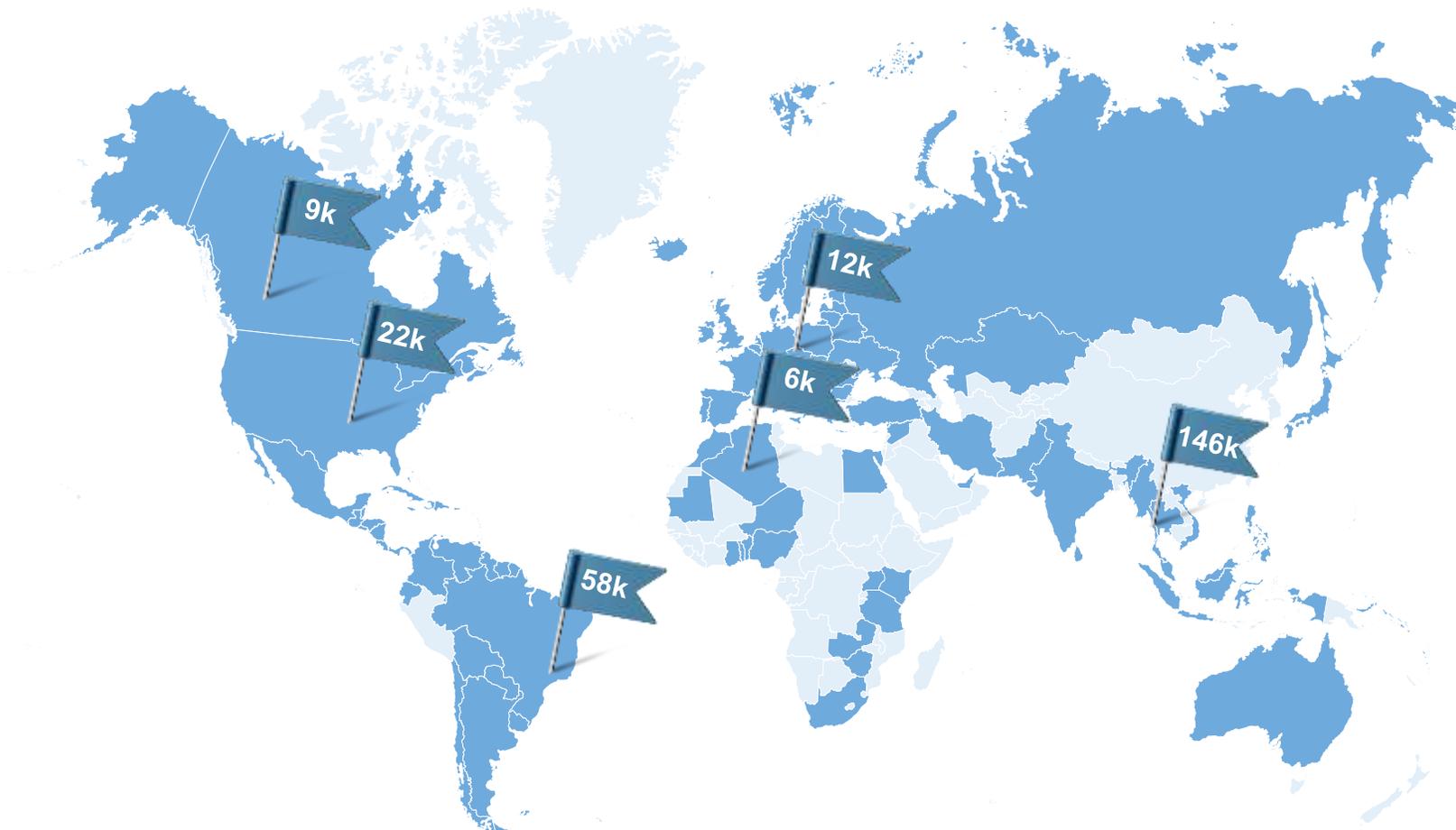
# Biocon Biologics footprint across the world

Serving patient needs in emerging & developed markets



# Biocon Biologics footprint across the world

~2M patients reached in FY20



Product	FY20 Planned Reach	FY20 Estimated Reach*
RHI	2.0M	1.7M
Glargine	479k	283k
Pegfilgrastim	26k	20k
Adalimumab	24k	24k
Trastuzumab	20k	18k
<b>Total</b>	<b>2.6M</b>	<b>2.0M</b>

*Number of patients = (Volume supplied in FY20) / (Dose per patient per year - PPPY) | Assume 70kg*  
*Trastuzumab (eBC/mBC) ~17x 440mg per year (Ogivri FDA label dosage) | Pegfilgrastim – Assume 6 cycles of treatment per year (Fulphila FDA label dosage)*  
*RHI ~50 units per day (Humulin FDA label dosage) | Glargine ~40 units per day (Basaglar FDA label dosage)*

# Biocon Biologics

## Global Product Portfolio



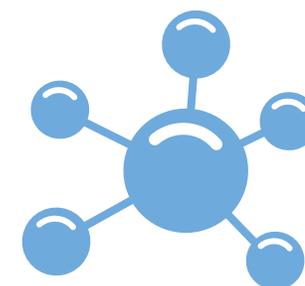
**BIOCON BIOLOGICS** is independently developing many biosimilar assets



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		
		US	EU	RoW
Oncology	Trastuzumab	\$ 2.8 B	\$ 1.5 B	Launched in Australia Canada & Emerging Markets.
	Pegfilgrastim	\$ 3.4 B	\$ 0.4 B	Launched in Canada and Australia
	Bevacizumab	\$ 3.1 B	\$ 1.8 B	Launched in India
	Filgrastim			-
	Pertuzumab			-
Diabetes	Glargine 100 IU/ml	\$ 2.2 B	\$ 0.8 B	Launched in Australia, Japan* & Emerging Markets. Approved in New Zealand.
	Glargine 300 IU/ml			-
	Aspart	\$ 1.3 B	\$ 0.85 B	-
	Lispro			-
Autoimmune	Adalimumab**	-	\$ 3.9^ B	-
	Etanercept**	-	\$ 1.8 B	-

Early Development/ Preclinical
Planned Submission/ Filed
Approved
Marketed

\*Japan is outside of Mylan partnership; \*\*Partner Mylan has in-licensed product (**Biocon benefits from economic interest**); ^assuming 2/3 of Humira reported international sales & Biosimilars IQVIA sales; \*\$ numbers indicate market size of innovator reported sales + Biosimilars IQVIA sales in CY 2019

# Pegfilgrastim - Fulphila

Pegfilgrastim biosimilars at 28%<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.
- Biosimilars to Pegfilgrastim captured a volume market share of 28%<sup>1</sup> in Mar'20.
- This growth reflects the increase in penetration and ease of adoption of biosimilars by prescribers, payers 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 41% 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
  - Launched in US in Dec 2019, Ogivri unit share ~2%<sup>1</sup> in Mar'20
- Unanimously recommended by the FDA Oncologic Drugs Advisory Committee (ODAC)
- Launched in the competitive, but sizable EU markets in Mar'19.
- In Aug'19, the first biosimilar trastuzumab approved and launched in Australia; available on the Pharmaceutical Benefits Scheme (PBS).

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

<sup>1</sup> IQVIA Data, Mar'20

<sup>2</sup> As on 31 Mar'20

# 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**, completed 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 in Jun'20
- Huge opportunity in a limited competition market

## Insulin Aspart

- Under review in the EU, expected to launch in FY21E.
  - EU net sales of ~\$0.85B<sup>1</sup> (2019),
- On track for US filing in mid-CY'20.
  - US net sales of ~\$1.3B<sup>1</sup> (2019),

# Bevacizumab

Launched in India in Nov 2017; global trial complete, US filing done in Dec'19

## Market Dynamics

- **US - 2 players approved by FDA, biosimilar share ~28%<sup>1</sup>**
  - Amgen was first to launch, Amgen launched in Jul'19, captured ~28%<sup>1</sup> by March 2020
  - Pfizer launched in Jan'20<sup>2</sup>
  - Samsung filed in US in Nov'19, 5 more late stage players
- **EU – 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
- Filed in US and EU in Dec'19 and Feb'20 respectively
- US launch planned in FY21 and EU launch in FY 22
- Filing in other markets in early FY21

# Biocon – Sandoz exclusive partnership

Co-development of next-generation biosimilars



Shared responsibility for...

- Development
- Manufacturing
- Global regulatory approvals



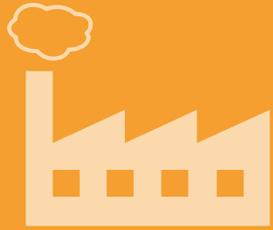
Costs & Profits are shared equally



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**

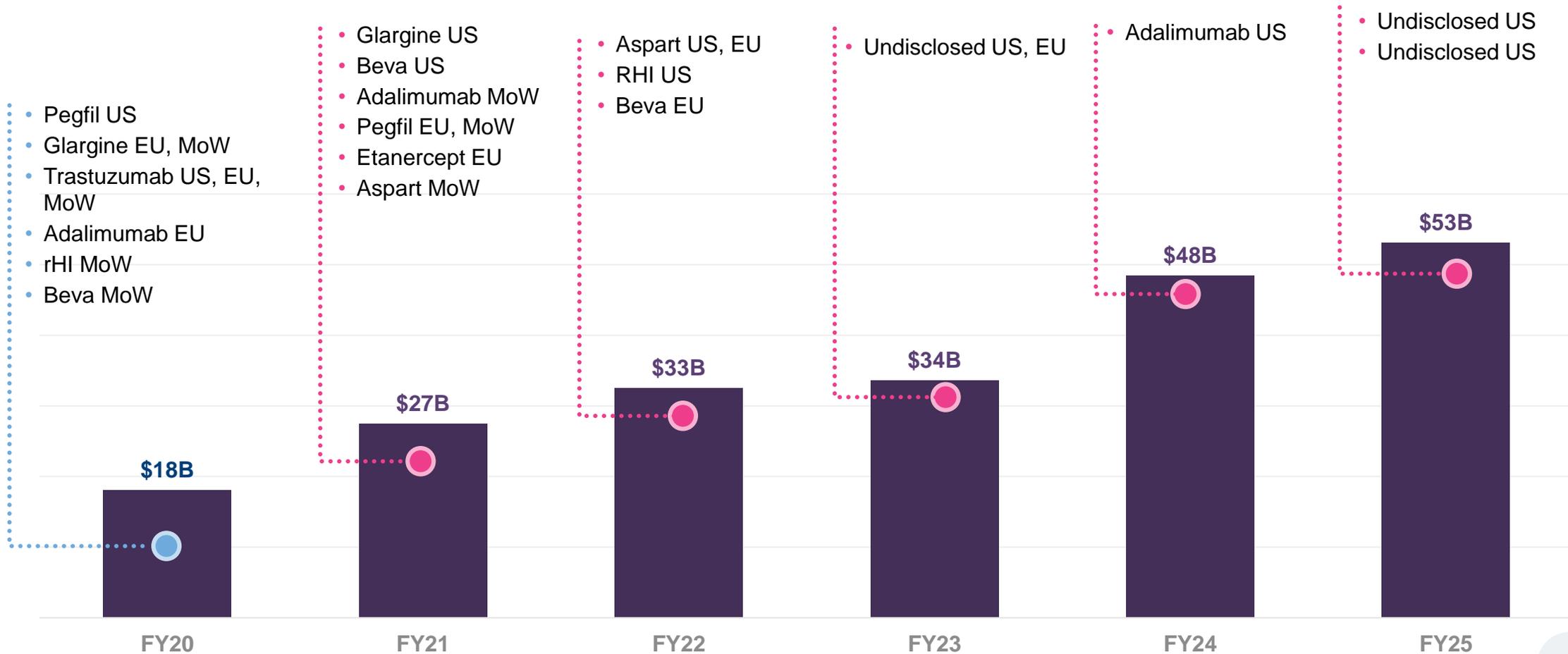


# Outlook



# Unlocking Market Opportunity

The opportunity expected to increase ~2.5x as new products are commercialized

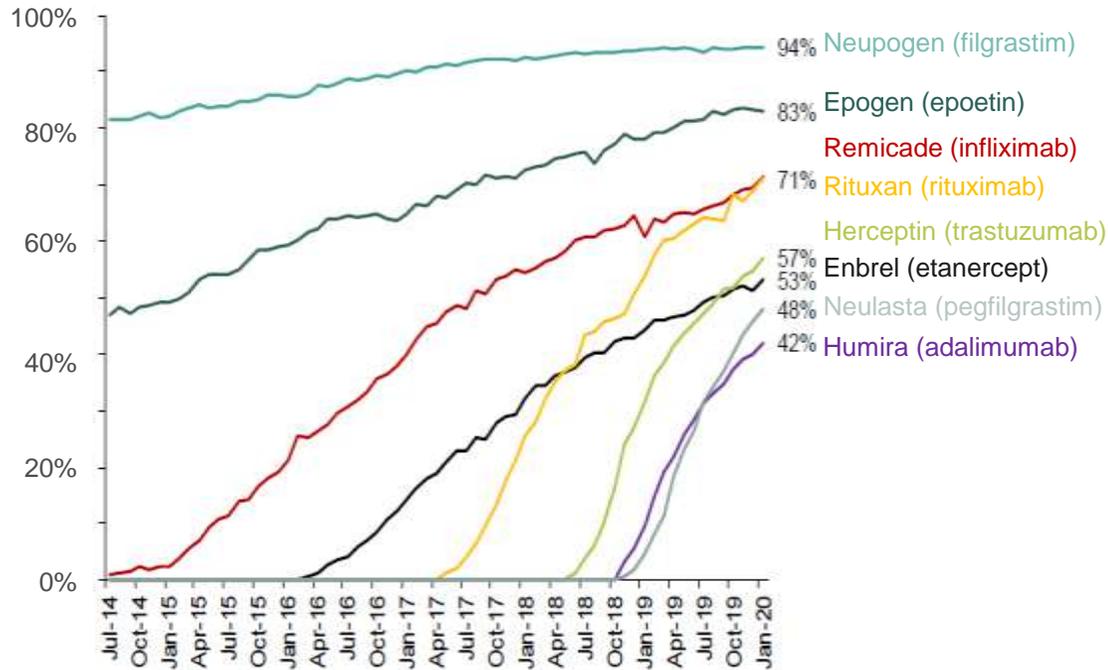


# Context of global leadership

## Biosimilar penetration

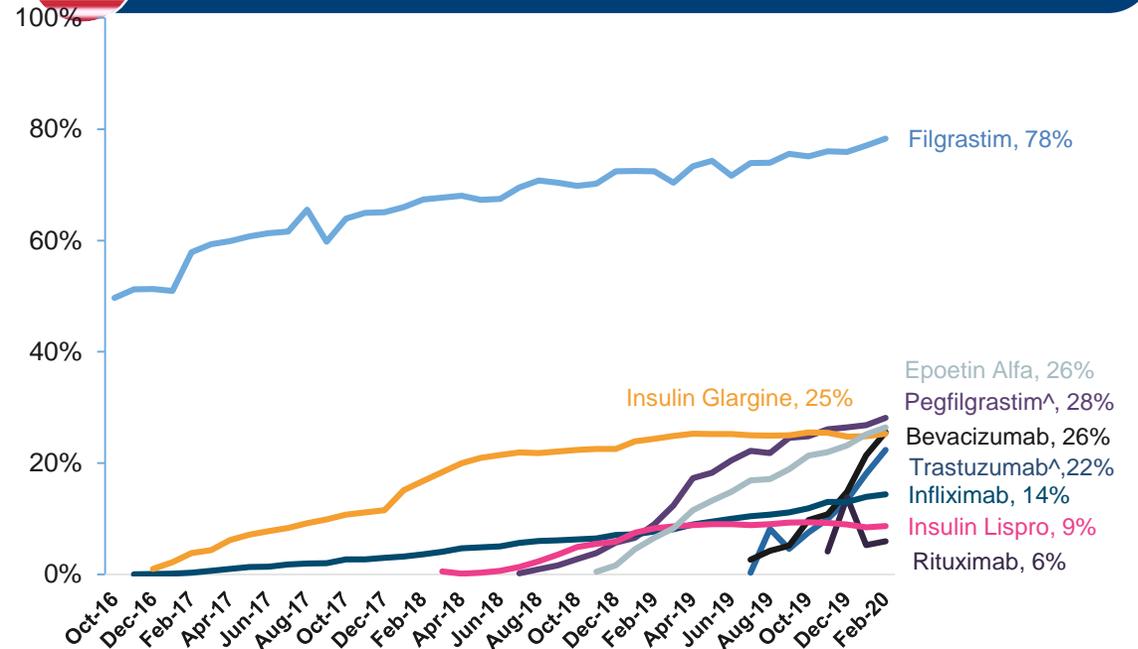
80%+ total biosimilar market shares open the door to leadership-level shares

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



Source: Bernstein report (Apr'20)

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



Source: IQVIA Data (Feb 2020)

\*Filgrastim 480MCG 0.8ML; Trastuzumab 150 MG; Rituximab 100 MG; Insulins 100U/ml 3ML; Epoetin Alfa 1000IU (also include Procrit in market definition);

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

# FY22 Aspiration of \$1Bn

Multiple levers to further accelerate growth in the next 2 years



## GROWTH DRIVER

- **Ramp up** of pegfilgrastim and trastuzumab and glargine
- **Launch of** insulin glargine in US
- **Continued growth** in existing developed and emerging markets
- **Launches of insulin aspart** and **bevacizumab** in various markets

**Launch of** recombinant insulin in US

Enhance **market share**



## GEOGRAPHIC MIX

Diversified mix across developed and emerging markets

- While US is biggest growth driver, MOW 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

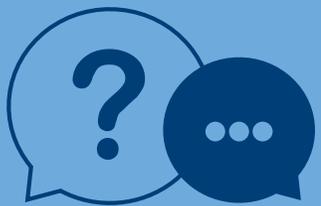
# Conclusion



# Key Investment Highlights

Highest quality, differentiated, transformative, pure play, scaled biosimilars company

- Global biosimilar market presents a large and attractive opportunity; Biocon Biologics is the best suited to tap into this opportunity
- Best-in-class platform with a de-risked first wave pipeline of 8 advanced products and deep pipeline of second wave products, supported by an efficient R&D engine
- Commercial partnerships with two of the largest pharma companies in the world; significantly reducing commercialization risk
- High quality, low cost, commercial scale manufacturing capabilities
- Vision to provide technology driven, personalized care to transform the Healthcare ecosystem
- Strong corporate governance, sponsorship and highly experienced management team



# Questions

