

# Credibly **Capable**

## **Investor Presentation**

June 2017



# Safe Harbor

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

Biocon: Who are we?

Highlights

- Business Highlights
- Financial Highlights

Business Segments

- Small Molecules
- Biosimilars
- Branded Formulations
- Novel Molecules
- Research Services - Syngene

Five Year Financial Summary

Outlook

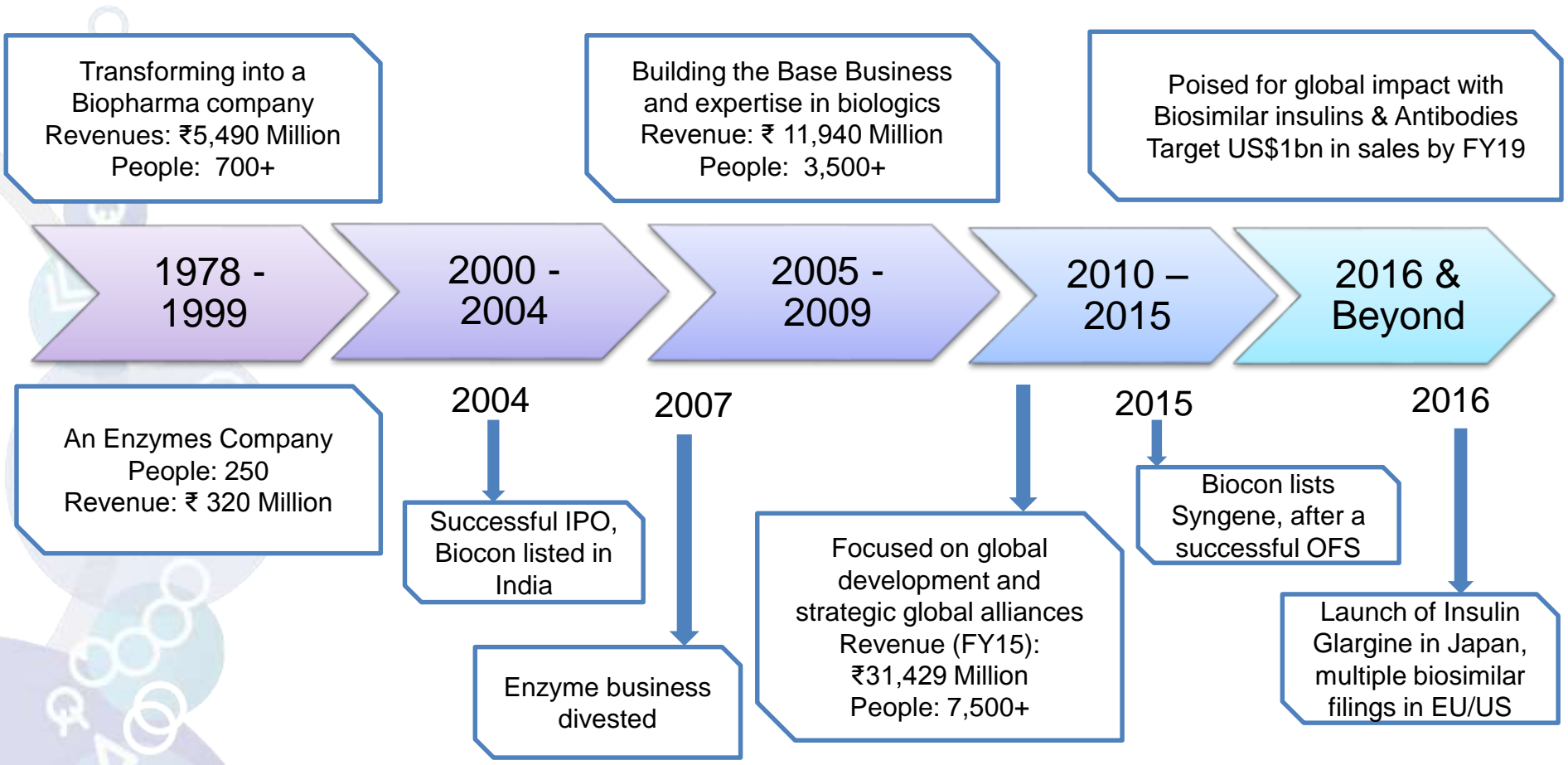
**Who are we?**

# 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*

# 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

# Evolution of Key Innovations: Making a Difference

**1979** - First Indian company to manufacture and export enzymes to US and Europe

**2001** - First Indian company to be approved by US FDA for the manufacture of lovastatin from solid state fermentation

**2004** - First company worldwide to commercialize generic recombinant human insulin developed on its proprietary fermentation technology

**2006** - India's first indigenously produced novel monoclonal antibody BIOMAb-EGR® to treat head & neck cancer launched

**2009** - Indigenously developed long lasting basal Insulin Glargine introduced in India as BASALOG®

**2013** - World's first anti-CD6 monoclonal antibody ALZUMAb™ to treat psoriasis launched in India

**2014** - CANMAb™, world's most affordable trastuzumab for treating metastatic breast cancer, launched in India

**2016** – Launch of Insulin Glargine in Japan by partner FUJIFILM Pharma, first developed market launch for a Biocon product





# Highlights – FY17 and recent

- ❖ Marketing Authorization Application for proposed biosimilars of Pegfilgrastim, Trastuzumab and Insulin Glargine accepted for review by the European Medicines Agency.
- ❖ Proposed biosimilars of Trastuzumab and Pegfilgrastim accepted for review by USFDA. Oncology Advisory Committee meeting for Trastuzumab scheduled for July 13, 2017.
- ❖ Biocon and Mylan presented Clinical Data on Insulin Glargine at the American Diabetes Association's 77th Scientific Sessions; data showed Comparable Efficacy, Safety and Immunogenicity to Lantus® in Type 1 and Type 2 Diabetes Patients
- ❖ Biocon's Insulin Glargine launched in Japan on 15 July, 2016 by partner FUJIFILM Pharma.
- ❖ Biocon's Malaysian subsidiary Biocon SDN. BHD. awarded a three year, MYR 300 million contract for supplying rh-Insulin cartridges and re-usable insulin pens under the Malaysian government's Off-Take Agreement (OTA) initiative. Commercial supplies from the Malaysia insulin plant have commenced.



## Highlights – FY17 and recent (cont.)

- ❖ Received FDA approval for Rosuvastatin Calcium, first ANDA approval for Biocon.
- ❖ Biocon Ranked Among Global Top Ten Biotech Employers; the only Asian Company to Feature in 2016 Rankings released by Science Career magazine.
- ❖ The Board of Directors had recommended for approval by shareholders a bonus issue of 2:1, i.e. 2 bonus shares for every one share held by an investor on April 27, 2017. Subsequently bonus shares were awarded to eligible shareholders on June 19, 2017.
- ❖ The Board also recommended for approval by shareholders a final dividend of Rs.3 per equity share (pre-bonus) for FY17. Given record date (July 21, 2017) for determination of eligible shareholders entitled to receive dividend is post the issue of bonus shares by the Company, the post-bonus final dividend, if approved, would be Re.1 per equity share.

# Financial Highlights\* – Q4 & FY17

All Figures in ₹ Million except %

Particulars	Q4 FY17	Q4 FY16	Growth	FY17	FY16	Growth
Revenue	9,743	9,727	0%	40,787	34,602	18%
EBITDA	2,307	2,206	5%	11,366	8,470	34%
Net Profit <sup>#</sup>	1,353	769	76%	6,199	4,021	54%
R&D Expenses in P&L	652	996	-35%	2,662	2,742	-3%
Gross R&D Spends	975	1,520	-36%	4,019	4,267	-6%
<b>EBITDA Margin</b>	<b>24%</b>	<b>23%</b>		<b>28%</b>	<b>24%</b>	
<b>EPS<sup>@</sup> (Rs.)</b>	<b>6.4</b>	<b>16.7</b>		<b>30.6</b>	<b>27.5</b>	

**~ Revenue mix (FY17): Ex-India 70% : India 30%**

\* Per Ind-AS, <sup>#</sup>Net Profit adjusted for exceptional items, <sup>@</sup>Reported EPS

# Segmental Sales\* – Q4 & FY17

All Figures in ₹ Million except %

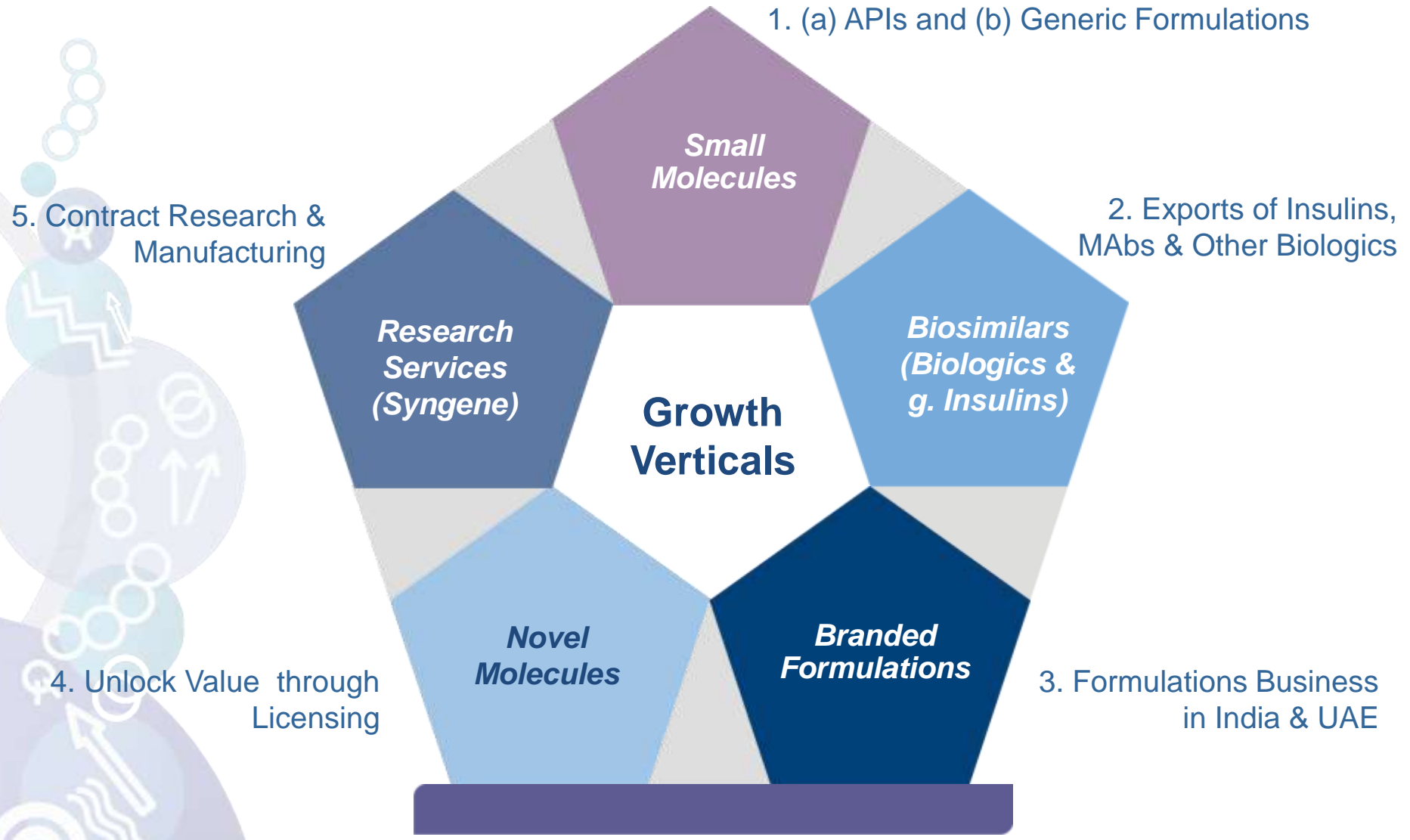
Particulars	Q4 FY17	Q4 FY16	Growth	FY17	FY16	Growth
<b>Biocon</b>	<b>6,528</b>	<b>6,298</b>	<b>4%</b>	<b>27,381</b>	<b>22,773</b>	<b>20%</b>
- Small Molecules	3,869	3,950	-2%	15,868	13,870	14%
- Biologics	1,194	1,193	0%	4,573	3,415	34%
- Branded Formulations	1,310	1,052	25%	5,491	4,411	24%
- Licensing	155	103	50%	1,449	1,077	35%
<b>Syngene (Research Services)</b>	<b>2,722</b>	<b>3,155</b>	<b>-14%</b>	<b>11,382</b>	<b>10,599</b>	<b>7%</b>
<b>Total Sales</b>	<b>9,520</b>	<b>9,453</b>	<b>-2%</b>	<b>38,763</b>	<b>33,372</b>	<b>16%</b>

\* Per Ind-AS, adopted w.e.f. April 2016

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# Business Segments

# Growth Verticals: Aligned with Shifting Paradigms



# Small Molecule APIs

- Product Portfolio which leverages our core fermentation capabilities and have a high degree of complexity.
- Early mover in niche products at commercial scale.
- One of the largest producers of various fermentation based statins and immunosuppressant API in India and across the globe.

Current Portfolio	Select Molecules
Statins	Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, & Fluvastatin.
Immuno suppressants	Tacrolimus, Sirolimus, Everolimus, MMF & MPA
Other Biopharma	Orlistat, Fidaxomicin

# Small Molecule Generic Formulations

- Vertically integrated business model with a nascent pipeline.
- Target to file ~10-15 dossiers in the next few years.
- Pipeline includes solid oral & parenteral products in both potent & non-potent categories of compounds.
- Focus therapeutic segments – Metabolics, Oncology, Immunology & Auto-immune indications.
- Construction of our first Oral Solid Dosage facility to support our future generic formulation filings in full swing in Bangalore. Estimated commissioning FY 2018. Total capex outlay - US\$25mn.

Continue to build momentum in dossier filing with a focus on specialty molecules in chronic therapeutic segments



# Biosimilars

- ❖ Marketing Authorization Application for proposed biosimilars of Pegfilgrastim, Trastuzumab and Insulin Glargine accepted and under review by the European Medicines Agency.
- ❖ Proposed biosimilars of Trastuzumab and Pegfilgrastim under review by USFDA.
- ❖ Generic Insulin Glargine in the US and Adalimumab biosimilar for US/EU continue to make progress towards filing.
- ❖ Strong scientific and technical capabilities and manufacturing expertise to address global opportunities.
- ❖ Human insulin and Insulin Glargine registered in over 60 and 20 emerging markets, respectively.
- ❖ Biocon's Trastuzumab launched in India in Feb-14 and has also been launched in multiple emerging markets in CY16.
- ❖ Work on our second fill-finish line in Bangalore to support future growth of biologics formulations close to completion. Estimated commissioning FY 2018. Total capex outlay - US\$25mn.

Amongst the largest portfolio of biosimilars globally with addressable market size of over US\$60 Billion

# Biosimilars: Growth through partnership

## 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<sup>#</sup>

	Generic Insulin Analogs	Biosimilar MABs & other Biologics
Mylan's Exclusive Commercialization Regions	US, Canada, Europe, Australia & New Zealand	Developed markets
Market Opportunity*	~US\$17 Bn	~US\$44 Bn

Strategic collaboration leverages Biocon's strong development & manufacturing capability and Mylan's regulatory & commercial excellence

# Global Biosimilars Pipeline – US\$61 bn opportunity

	Molecule	Type	Status	Market Size* (US\$ bn)
INSULINS	Rh Insulin	Regular Acting Insulin	Pre-clinical (US), Marketed in EM	3.2
	Glargine	Long Acting Insulin	Filed in EU, Australia & Canada. US filing in H1 FY18. Marketed in Japan (since Jul-16) & EM	6.4
	Aspart	Rapid Acting Insulin Analog	Preclinical	4.5
	Lispro	Rapid Acting Insulin Analog	Preclinical	2.8
			<b>Insulins Total Market Size (rounded off)</b>	<b>17.0</b>
BIOSIMILARS	Adalimumab	Auto-Immune	Global Phase III completed	16.1
	Trastuzumab	Cancer	Filed in US & EU. Marketed in EM	6.9
	Pegfilgrastim	Neutropenia	Filed in US, EU, Canada, Australia, EM	4.6
	Bevacizumab	Cancer	India/EM Phase III complete. Global Phase III commenced	6.9
	Filgrastim	Neutropenia	Early development	0.8
	Etanercept	Auto-Immune	Early Development	8.9
			<b>Biosimilars Total Market Size (rounded off)</b>	<b>44.0</b>

\*Market Size of innovator products in the current portfolio: Innovator Sales CY 2016

Conversion into USD done using average exchange rate for CY 2016 as given on <http://www.federalreserve.gov/releases/G5a/current/default.htm>

# Biosimilar Pipeline: Biocon well placed in the competitive landscape

Molecule	Biosimilar Development Pipeline <sup>®</sup>			
	Pre-Clinical	Phase I	Phase III/Filed	Approved/ Marketed
Pegfilgrastim	Pfizer	Dr. Reddy's	<b>Biocon-EMA, FDA</b> ; Apotex - FDA, EMA; Coherus - EMA; Sandoz, Cinfa	
trastuzumab	Oncobiologics, Dr. Reddy's	Meiji Seika	<b>Biocon- EMA, FDA</b> , Celltrion - EMA, Samsung – EMA, Amgen - EMA, Pfizer, Hanhwa	
insulin glargine			<b>Biocon - EMA</b> , Samsung – FDA	<b>Biocon – JP</b> , Eli Lilly – EU, US, JP,CAN, Sumsung - EU
adalimumab	Epirus		<b>Biocon</b> , Samsung-EMA, Sandoz -EMA, Boehringer Ingelheim – FDA, EMA, Coherus, Momenta, Pfizer, Fresenius, Fujifilm-Kirin - EMA, Oncobiologics	Amgen – FDA, EMA
bevacizumab	Celltrion	Sandoz, Daiichi, Oncobiologics, Cipla	<b>Biocon – Global, RoW</b> ; Amgen-FDA, EMA, Boehringer Ingelheim, Pfizer, Samsung, Fujifilm-Kirin/Astra Zeneca, Dr. Reddy's	
filgrastim	<b>Biocon</b> , Pfizer		Apotex - FDA	Sandoz – US, EU; Teva – JP, EU; Accord-EU, Apotex – EU, Hospira – EU, ANZ, Fuji – JP, CTA-EU
etanercept	<b>Biocon</b> , Celltrion	Hanhwa	Coherus, Lupin	Samsung – EU, Sandoz – FDA, EMA
insulin aspart	<b>Biocon</b>			
insulin lispro	<b>Biocon</b>		Sanofi – EMA	
rh-insulin	<b>Biocon – US</b>			

<sup>®</sup> Biosimilar Development Pipeline details may not be exhaustive, pipeline progress may not be perfectly accurate; Source: Company disclosures, various reports

# Biosimilars Manufacturing: Building Global Scale

## Biocon Malaysia: Asia's largest integrated insulins manufacturing facility



- ❖ Biocon's First Manufacturing expansion overseas in Iskandar, Johor.
- ❖ Investment of over US\$250mn in the first phase.
- ❖ Commercial supplies initiated with OTA award by Ministry of Health – Malaysia.
- ❖ Emerging market filings have started, commercial supplies to these markets expected to commence in FY18.

- ❖ Commercial supplies from Disposable insulins pen line in Bangalore ongoing.
- ❖ MAbs capacity to be augmented in Bangalore.




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

# Branded Formulations

- A Specialty Business with regional ambitions, currently in India and UAE. Strategy focused around biologics and differentiated products as anchor brands.
- The UAE business sells Branded generics and in-licensed Branded products.
- India business organized into 5 divisions around chronic therapy areas, namely **Metabolics, Oncotherapeutics, Immunotherapy, Nephrology, and Specialty**.
- Successfully developed and taken a range of Novel Biologics, Biosimilars, differentiated Small Molecules and affordable Recombinant Human Insulin and Analogs from 'Lab to Market'.
- Some of the key brands in India include INSUGEN® (rh-insulin), BASALOG® (Glargine), BIOMAb-EGFR™ (Nimotuzumab), BLISTO® (Glimepiride+Metformin), CANMAb™ (Trastuzumab), Evertor® (Everolimus), TACROGRAF™ (Tacrolimus) and ALZUMAb™ (Itolizumab), a 'first in class' anti-CD6 monoclonal antibody.
- Future growth to be driven by deeper penetration of existing brands and new product launches.

# Novel Molecules - Pipeline & Therapeutic Area Focus

 <p><b>DIABETES</b></p>	<p><b>Insulin Tregopil *</b> First-in-Class Oral, Prandial Insulin</p>	<p><b>Phase II Ready</b> <b>T1D/ T2D</b></p>
<p><b>INFLAMMATION</b></p>	<p><b>Itolizumab*</b> Novel, humanized CD6 Antibody</p>	<p><b>Phase I Ongoing</b></p>
	<p><b>BVX-20#</b> Novel, humanized CD20 Antibody</p>	<p><b>IND Ready</b></p>
	<p><b>QPI-1007\$</b> SiRNA for ophthalmic disease</p>	<p><b>Phase III Initiated</b> <b>in NAION</b></p>
	<p><b>QPI-1024\$</b> SiRNA for inflammatory disease</p>	<p><b>Preclinical</b></p>
<p><b>IMMUNO-ONCOLOGY</b></p>	<p><b>Tumor-Targeted Fusion mAb*</b></p>	<p><b>Preclinical</b></p>

- \* In-House program
- # BVX-20 with Vaccinex
- \$ QPI-1007 & QPI- 1024 with Quark Pharma. QPI-1007 Global Phase III trial includes India.



# Novel Molecules – Progressing to key milestones

Asset	Details
<b>Tregopil</b> Phase II Ready	<b>USP: Oral, Ultra Rapid-Acting</b> Post- prandial glycemic control; Liver specific- portal delivery, Weight neutral <ul style="list-style-type: none"> <li>▪ Safety &amp; tolerability established in Phase 1 studies in US – DDI, Food Effect, PK/PD Data available</li> <li>▪ Pivotal Phase III clinical study in T2DM patients in India (under an IND) finalized.</li> <li>▪ Phase I Multiple Ascending Dose study planned in T1DM patients</li> </ul>
<b>Itolizumab</b> Phase I Ongoing	<b>USP: Novel CD-6 Biology presenting durable immune-modulatory benefits and superior clinical safety</b> <ul style="list-style-type: none"> <li>▪ Successful PoC data: Phase 3 in psoriasis, Phase 2 in rheumatoid arthritis, preclinical in multiple sclerosis. Marketed in India for Plaque Psoriasis</li> <li>▪ Initiated Phase I (Stages 1&amp;2) - Single Ascending Dose study in Australia (S.C formulation). Stage 1 dosing completed; S.C route shows very good bioavailability. Stage 2 to be initiated shortly.</li> <li>▪ Global filing plans ongoing – Phase II studies planned in inflammatory diseases</li> </ul>
<b>QPI-1007</b> In Phase III	<b>Novel SiRNA for ophthalmic disease:</b> <ul style="list-style-type: none"> <li>▪ Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) – Patients randomized for global study (incl. in India)</li> </ul>
<b>BVX-20</b> IND ready	<b>2<sup>nd</sup> Generation humanized antibody targeting CD-20</b> <ul style="list-style-type: none"> <li>▪ Path to IND mapped out, to advance program in neuro-inflammatory disorder</li> </ul>
<b>EGFR mAb + TGFβRII (Fusion mAb)</b> IND Ready	<b>USP: Higher local tumor concentration of immuno-modulatory arm resulting in a better therapeutic window</b> <ul style="list-style-type: none"> <li>▪ Pharmacology &amp; MOA established in in-vitro &amp; in vivo tumour models</li> <li>▪ Proof of Concept established in in-vivo model</li> <li>▪ Clinical opportunity in multiple tumour types</li> </ul>

# Syngene (Research Services Business)

## Global High Growth CRO Company

- ❖ Established in 1994, as India's first Contract Research Organization – 22+ years of unparalleled experience in novel molecule discovery and development services
- ❖ One of the leading India-based contract research organizations (CRO)
- ❖ Integrated Service Platform for small and large molecules including Antibody-drug conjugates and oligonucleotides backed by best-in-class bioinformatics services
- ❖ End-to-end discovery, development and manufacturing capabilities
- ❖ World class infrastructure audited successfully by USFDA, EMA, AAALAC and major life science partners.
- ❖ 293<sup>(1)</sup> clients across multiple sectors
- ❖ 96%<sup>(1)</sup> of revenues from outside India
- ❖ 3,100+<sup>(1)</sup> qualified scientists
- ❖ World-class R&D and manufacturing infrastructure spread over 1.3 million sq. ft.
- ❖ Strong track record of top-line growth with best in class EBITDA (30+%) and Net Income (high teens to low 20's)

(1) For fiscal ended March 31, 2017

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# Five Year Financials & Outlook

# Financial Performance Summary (FY12-16)#

All Figures in ₹ Million except EPS

Business Segment	FY12	FY13	FY14	FY15	FY16
<b>Biopharmaceuticals</b>	<b>16,764</b>	<b>18,705</b>	<b>21,382</b>	<b>22,367</b>	<b>23,908</b>
- Biopharma	14,170	15,231	17,468	18,071	19,534
- Branded Formulations	2,594	3,474	3,914	4,296	4,374
<b>Contract Research</b>	<b>4,101</b>	<b>5,572</b>	<b>7,146</b>	<b>8,225</b>	<b>10,599</b>
<b>Total Sales</b>	<b>20,865</b>	<b>24,227</b>	<b>28,528</b>	<b>30,592</b>	<b>34,507</b>
Other Income	618	1,103	804	837	1,192
<b>Total Revenue</b>	<b>21,483</b>	<b>25,380</b>	<b>29,332</b>	<b>31,429</b>	<b>35,699</b>
EBITDA	5,792	5,957	7,429	7,489	9,045
EBITDA Margin (%)	27%	23%	25%	24%	25%
<b>Net Profit*</b>	<b>3,384</b>	<b>3,241</b>	<b>4,137</b>	<b>4,022</b>	<b>4,372</b>
Net Profit Margin	16%	13%	14%	13%	12%
<b>EPS*</b>	<b>16.9</b>	<b>16.2</b>	<b>20.7</b>	<b>20.1</b>	<b>21.9</b>
R&D Spends (in P&L)	1,566	1,640	1,310	1,688	2,750
R&D (as % of Biopharmaceuticals Sales)	9.3%	8.8%	6.1%	7.5%	11.5%

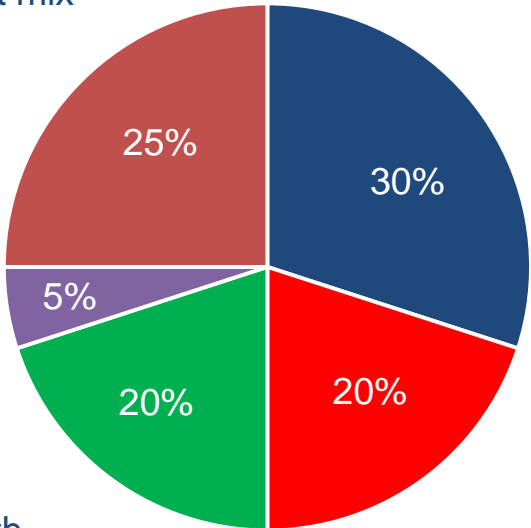
# Numbers as per old I-GAAP

\*Net Profit is pre-exceptional

# Aspiring for \$1 Billion in Revenues by FY19

## Key Focus Areas

- **Small Molecules & Generic Formulations** - Improved product mix incl. ANDAs
- **Biosimilars** - Meaningful near term growth to be driven by emerging markets, ramp up post developed market entry
- **Branded Formulations** – Strategy focused around biologics and differentiated products, geographical expansion
- **Novel Molecules** - Out-licensing and Global Development
- **Research Services** - Sustained growth momentum with increase in clients & services, moving from CRO to CRAMS with commercial manufacturing

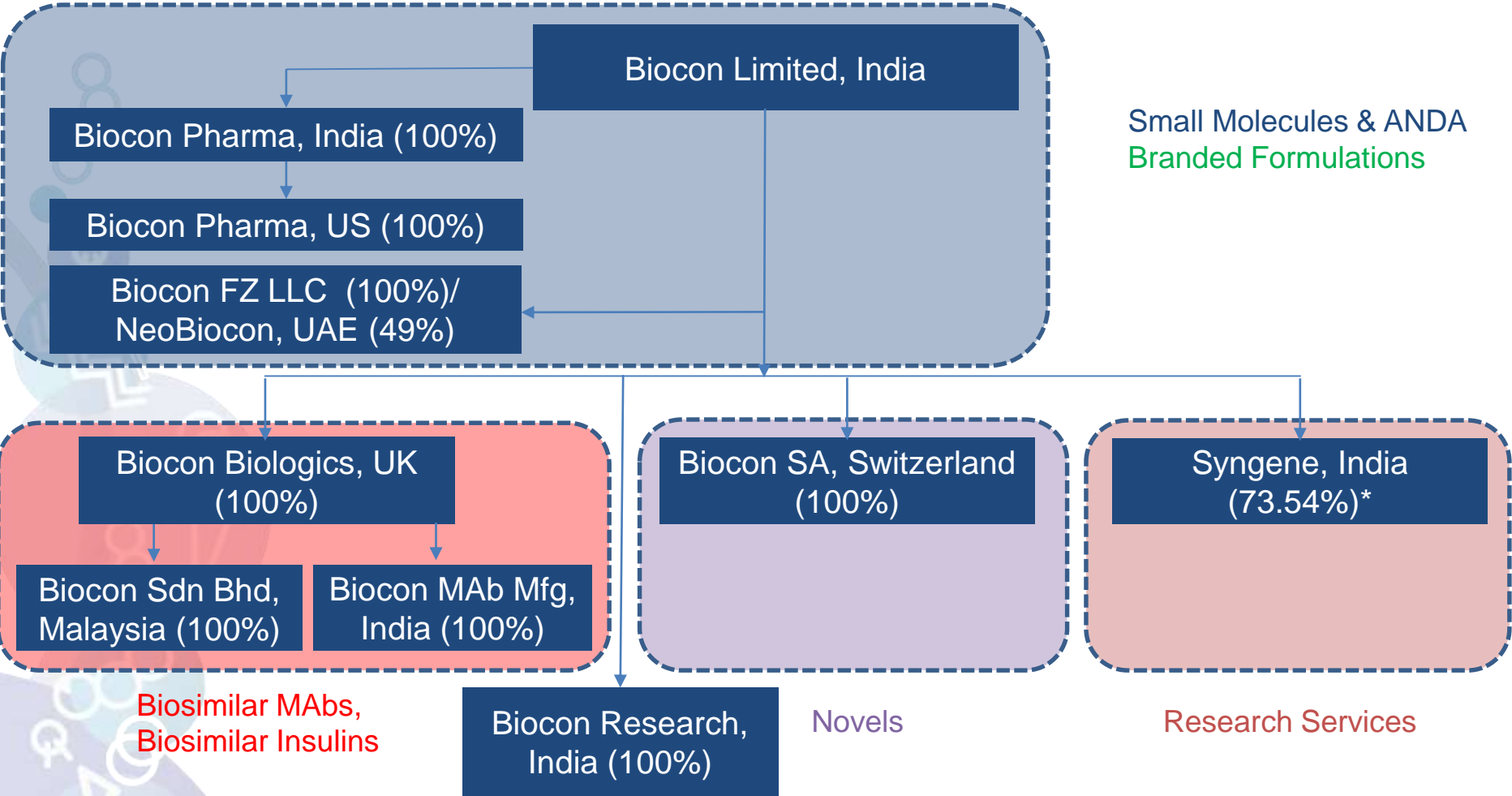


**Growth drivers supplemented by addition of new offerings (products, services & partnerships)**

# Appendix



# Business Holdings Structure



\* Includes 0.93% held by Biocon Research Limited



For further information, please visit

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



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