

# Credibly **Capable**

## **Investor Presentation**

November 2016



# 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

Growth Segments

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

Five Year Financial Summary

Outlook

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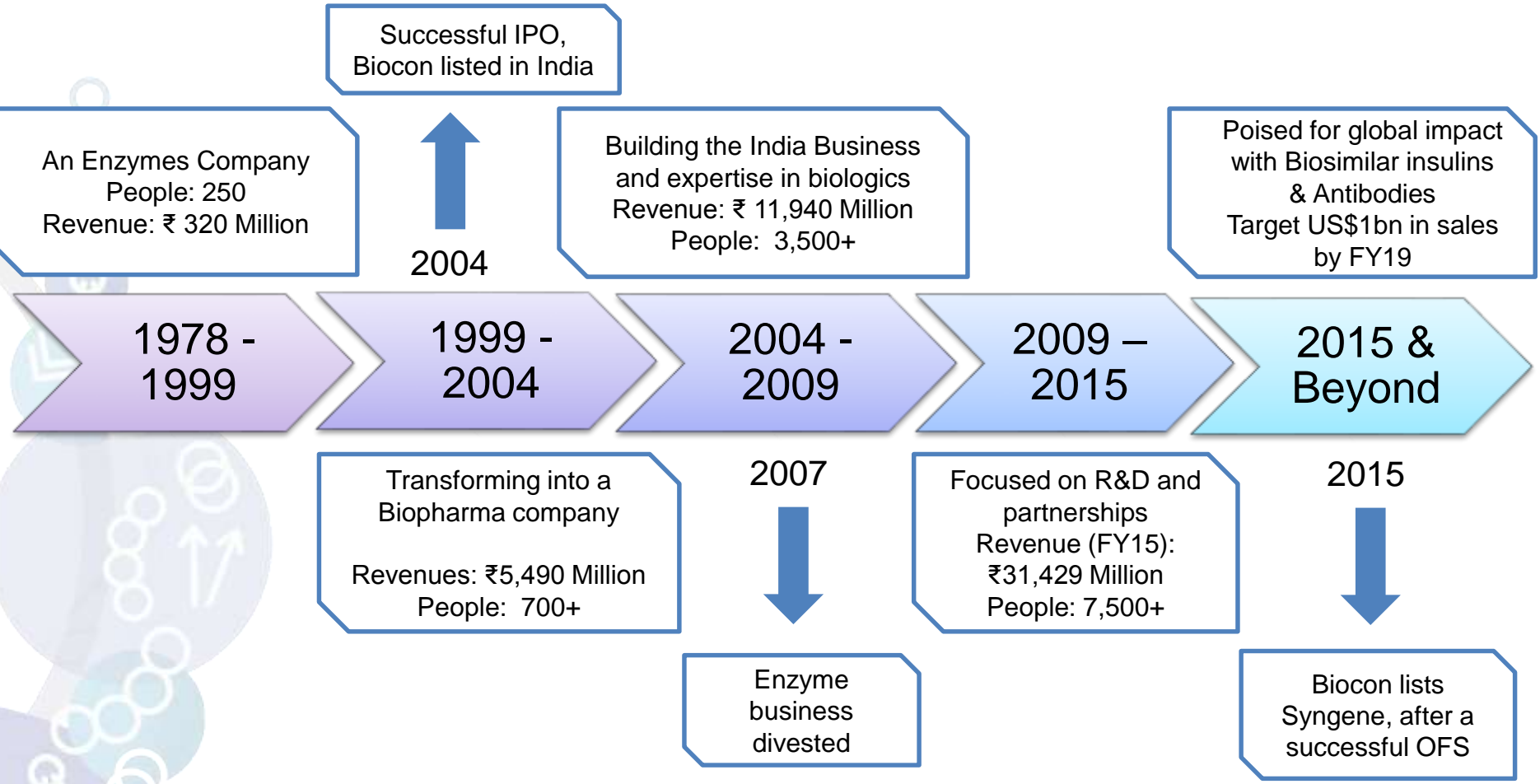
**Who are we?**

# 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-EGFR® 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



# Recent Business Highlights

- ❖ Marketing Authorization Application for biosimilar Pegfilgrastim, Trastuzumab and Insulin Glargine accepted for review by the European Medicines Agency. On track for filing biosimilar Adalimumab in FY17.
- ❖ Filed proposed biosimilar Trastuzumab with USDFA. Other planned US filings in FY17 for Pegfilgrastim, Insulin Glargine and Adalimumab on track.
- ❖ Biocon's Insulin Glargine launched in Japan on 15 July, 2016 by partner FUJIFILM Pharma.
- ❖ Positive outcomes of the Global Phase III clinical study of our Trastuzumab was presented by partner Mylan at the ASCO (American Society of Clinical Oncology) annual meeting in June, followed by a presentation of the 48 week data at European Society of Medical Oncology (ESMO) in October.
- ❖ Recombinant human insulin (rh-Insulin) manufactured at our Malaysian Insulins Facility received regulatory approval from the Malaysian Ministry for Health. Emerging market registrations for rh-Insulin from the Malaysian site underway.
- ❖ Insulin Glargine manufactured at the India site received approval from the Malaysian Ministry for Health. We expect to launch the product in the Malaysian market later this fiscal.
- ❖ Received FDA approval for Rosuvastatin Calcium, first ANDA approval for Biocon, to launch shortly.
- ❖ Suresh Subramanian appointed as Head of Branded Formulations (India) Business.
- ❖ Biocon Ranked Among Global Top Ten Biotech Employers; the only Asian Company to Feature in 2016 Rankings.



# Financial Highlights – Q2 & H1 FY17\*

All Figures in ₹ Million except %

Particulars	Q2 FY17	Q2 FY16	Growth	H1 FY17	H1 FY16	Growth
Revenue	9,925	8,186	21%	20,254	16,598	22%
EBITDA	2,784	1,916	45%	5,824	4,200	39%
Net Profit <sup>#</sup>	1,467	970	51%	3,133	2,210	42%
R&D Expenses in P&L	650	572	14%	1,164	1,069	9%
Gross R&D Spends	1,126	905	24%	2,041	1,834	11%
<b>EBITDA Margin</b>	<b>28%</b>	<b>23%</b>	<b>-</b>	<b>29%</b>	<b>25%</b>	<b>-</b>

\* Per Ind-AS, <sup>#</sup>Net Profit for Q2 FY16 and H1 FY16 adjusted for exceptional items

# Segmental Sales – Q2 & H1 FY17\*

All Figures in ₹ Million except %

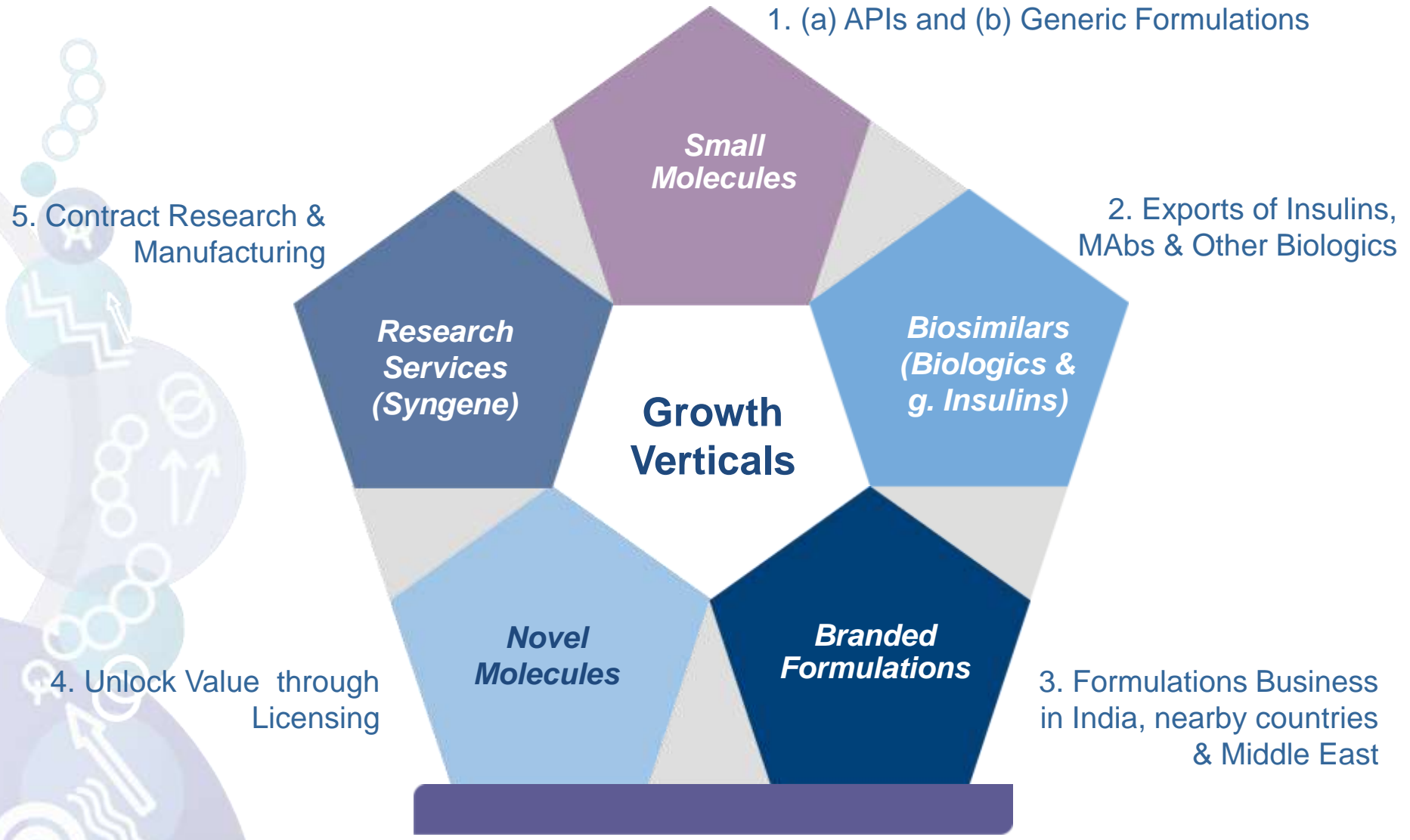
Particulars	Q2 FY17	Q2 FY16	Growth	H1 FY17	H1 FY16	Growth
Small Molecules	3,888	3,376	15%	8,097	6,767	20%
Biologics	962	764	26%	2,183	1,479	48%
Branded Formulations	1,366	1,192	15%	2,948	2,314	27%
Licensing	328	16	1950%	500	654	-24%
Syngene (Research Services)	2,860	2,504	14%	5,492	4,743	16%
<b>Total Sales</b>	<b>9,404</b>	<b>7,852</b>	<b>20%</b>	<b>19,220</b>	<b>15,957</b>	<b>20%</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	Constituents
Statins	Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, & Fluvastatin.
Immuno suppressants	Tacrolimus, Sirolimus, Everolimus, MMF & MPA
Other Biopharma	Orlistat, Fidaxomicin, multiple other molecules

# Small Molecule Generic Formulations

- ⌘ Nascent pipeline, to file ~15-20 dossiers in the next few years.
- ⌘ Rosuvastation Calcium ANDA approved by USFDA, to launch shortly.
- ⌘ Pipeline includes solid oral & parenteral products in both potent & non-potent categories of compounds.
- ⌘ Product pipeline comprises of 'difficult to make,' technology intensive molecules for emerging and developed markets.
- ⌘ Core therapeutic segments – Metabolics, Oncology, 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 CY 2017. 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 biosimilar Pegfilgrastim, Trastuzumab and Insulin Glargine accepted for review by the European Medicines Agency. On track for filing biosimilar Adalimumab in FY17.
- ❖ Proposed biosimilar Trastuzumab filed with USFDA. Other planned US filings in FY17 for Pegfilgrastim, Insulin Glargine and Adalimumab on track. These molecules have either completed Phase 3 clinical trials or are in advanced stages of completion.
- ❖ Amongst the largest portfolio of Biosimilars globally straddling human insulin/insulin analogs, monoclonal antibodies and other biologics. **Addressable market size: ~US\$60 Billion**
- ❖ 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 a few emerging markets in CY16.
- ❖ Meaningful near term growth to be driven by emerging markets with a significant ramp-up post entry into developed markets.

Biocon's Biosimilars portfolio is partnered with leading US generics major, Mylan

# 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\$18 Bn	~US\$42 Bn

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



# Global Biosimilars Pipeline – US\$60 bn opportunity

	Molecule	Type	Status	Market Size* (US\$ bn)
INSULINS	Rh Insulin	Recombinant Human Insulin	EU Phase III complete	3.1
	Glargine	Long Acting Basal Insulin	Global Phase III, filed in EU. US filing in FY17	7.1
	Aspart	Rapid Acting Insulin Analog	Preclinical/Scale Up	4.7
	Lispro	Rapid Acting Insulin Analog	Preclinical/Scale Up	2.8
				<b>Insulins Total Market Size (rounded off)</b>
BIOSIMILARS	Adalimumab	Chronic Plaque Psoriasis	Global Phase III, US/EU filing in FY17	14.0
	Trastuzumab	mBreast Cancer	Global Phase III, filed in EU & US	6.8
	Pegfilgrastim	Chemo-induced Neutropenia	Filed in EU, US filing in FY17	4.7
	Bevacizumab	mColorectal Cancer	Global Phase I, RoW Phase III	6.9
	Filgrastim	Chemo-induced Neutropenia	Preclinical/Scale Up	1.0
	Etanercept	Auto-immune	Preclinical/Scale Up	8.7
				<b>Biosimilars Total Market Size (rounded off)</b>

\*Market Size of innovator products in the current portfolio: Innovator Sales CY 2015

Conversion into USD done using average exchange rate for CY 2015 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</b> , Apotex - FDA, EMA; Coherus - FDA, Richter – EMA, Sandoz – EMA	
Trastuzumab	Oncobiologics, Dr. Reddy's	Hanhwa, Meiji Seika	<b>Biocon-EMA FDA</b> , Celltrion - EMA, Samsung – EMA, Amgen, Pfizer	
insulin glargine			<b>Biocon-EMA</b> , Samsung – EMA, FDA	<b>Biocon – JP</b> , Eli Lilly – EMA, FDA, JP
adalimumab	Epirus	Dr. Reddy's, Oncobiologics, Meiji Seika	<b>Biocon</b> , Amgen-EMA, Samsung-EMA, Sandoz, Boehringer Ingelheim, Coherus, Momenta, Pfizer, Merck Serono, Fujifilm-Kirin	Amgen - FDA
bevacizumab	Celltrion	<b>Biocon (Global)</b> , Sandoz, Daiichi, Oncobiologics, Cipla	<b>Biocon (RoW)</b> , Amgen-FDA, Boehringer Ingelheim, Pfizer, Samsung, Fujifilm-Kirin/Astra Zeneca	
filgrastim	<b>Biocon</b> , Pfizer		Apotex - FDA	Sandoz – US, EU; Teva, Accord, Apotex – all EU, Hospira – EU, ANZ, Fuji – JP,
etanercept	<b>Biocon</b> , Celltrion		Sandoz-EMA, Coherus-Baxalta	Samsung – EU, Sandoz – FDA
insulin aspart	<b>Biocon</b>			
insulin lispro	<b>Biocon</b>		Sanofi - EMA	
rh-insulin	<b>Biocon – US</b>		<b>Biocon - EU</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.
- ❖ Emerging market filings underway.
- ❖ Expected commercialization – H2 FY17

- ❖ Disposable insulins pen line in Bangalore starts commercial production.
- ❖ MAb's 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. Planned expansions into markets of Sri Lanka and Malaysia in the coming quarters.
- 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 8 divisions around chronic therapy areas – **Metabolics, Oncotherapeutics, Immunotherapy, Nephrology, Comprehensive Care, Virology, Market Access and Specialty.**
- **Metabolics** - Combination of brands in diabetes and cardiovascular therapies, flagship brands include **Insugen<sup>®</sup>, Basalog<sup>™</sup>, Blisto<sup>®</sup>, Statix<sup>®</sup>, Temlisat<sup>®</sup> and Metadoze<sup>®</sup>.**
- **Oncotherapeutics Division** - Niche portfolio of oncology drugs, flagship brands include **CANMAb<sup>™</sup>, BIOMAb EGFR<sup>®</sup> and Evertor<sup>™</sup>.**
- **Immunotherapy Division** - Portfolio of safe, efficacious and affordable drugs for the treatment of immune related disorders in dermatology. Flagship brands include, **PSORID<sup>™</sup>, TBIS<sup>™</sup>, Picon<sup>®</sup> and Calpsor<sup>™</sup>.**
- **Nephrology Division** – One of the widest range of products for the treatment of organ transplantation, coupled with innovative safety solutions for renal anaemia management. Flagship brands include **TACROGRAF<sup>™</sup>, RENODAPT<sup>®</sup>, and ERYPRO safe<sup>™</sup>.**
- **Comprehensive Care** – Caters to critical illness segment with an existing anti-infective portfolio and the introduction of novel therapies in surgical trauma and medical emergencies. Flagship Brands include **PENMER<sup>™</sup>, IVNEX<sup>™</sup>, Biopiper TZ<sup>®</sup> and THINLA<sup>™</sup>.**
- **Virology** - Products in this division address serious unmet needs in people living with hepatitis C and other liver related infectious diseases. Flagship brands include **CIMIVIR<sup>™</sup>, CIMIVIR-L<sup>™</sup>, and DACLAWIN<sup>™</sup>.**
- **Market Access** – Our government focused institutional business catering to state governments and central/state government bodies.
- **Specialty** – Newly created division currently having flagship brands **ALZUMAB<sup>™</sup> and Cytosorb<sup>®</sup>.**

# Novel Molecules - Pipeline & Therapeutic Area Focus

 <p><b>DIABETES</b></p>	<p><b>Insulin Tregopil (formerly IN-105)*</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>Oral, Ultra Rapid-Acting Prandial Insulin:</b> Post- prandial glyceemic control; Liver specific- portal delivery, Weight neutral <ul style="list-style-type: none"> <li>▪ Positive Phase I study data – DDI, Food Effect, PK/PD Data available</li> <li>▪ Phase I studies planned in T2DM patients requiring post prandial glyceemic control</li> <li>▪ Phase I study planned in T1DM patients</li> </ul>
<b>Itolizumab</b> Phase I Ongoing	<b>Novel CD-6 Biology:</b> Durable immune-modulatory benefits & superior clinical safety <ul style="list-style-type: none"> <li>▪ Clinical Validation of CD6 Target: Human POC in Psoriasis &amp; Rheumatoid Arthritis, Marketed in India for Plaque Psoriasis. Preclinical data in Multiple Sclerosis.</li> <li>▪ Initiated Phase I Single Ascending Dose study in Australia (S.C formulation)</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> Initiated trial enrolment in Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) patients (incl. India)
<b>BVX-20</b> IND ready	<b>Next - Generation humanized antibody targeting CD-20</b>
<b>EGFR mAb + TGFβRII (Fusion mAb)</b> IND Ready	<b>EGFR Targeted Immunotherapeutic to deliver TGFβ in Tumor Micro-Environment</b> <ul style="list-style-type: none"> <li>• Proof of Biology established in In-vivo models</li> </ul>

# Syngene (Research Services Business)

## Global High Growth CRO Company

- One of the leading India-based contract research organizations (CRO)
- Integrated discovery and development
- Focus on novel molecular entities
- 256<sup>(1)</sup> clients across multiple sectors
- 95%<sup>(1)</sup> of revenues from outside India
- 2,571 qualified scientists
- World-class R&D and manufacturing infrastructure spread over 950,000 sq. ft.
- Strong track record of top-line growth with best in class EBITDA (30+%) and Net Income (high teens)

## Attractive Blue Chip Customer Base

- Highly successful track-record in molecule development
- Client base includes 8 of the top 10 global pharma company by 2014 sales<sup>(2)</sup>
- 8 of top 10 clients have been associated for more than 5 years illustrating their longstanding and extensive relationship
- Total clients increased from little over 100 in FY12 to over 250 in FY16
- 69% of FY16 revenue from top 10 customers compared to 79% in FY12
- Clients across sectors – Pharma, Biotech, Animal Health, Nutrition

(1) For fiscal ended March 31, 2016

(2) Top 10 pharmaceuticals companies are by sales for 2014 as per IMS Health Midas, December 2014.

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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>25.4</b>	<b>20.7</b>	<b>24.8</b>	<b>44.8</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

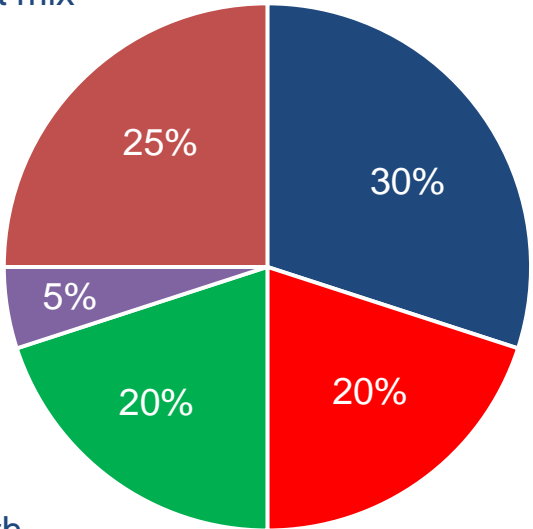
\*Net Profit is pre-exceptional

**Revenue mix (FY16): Ex-India 69% : India 31%**

# Aspiring for \$1 Billion in Revenues by FY 2018-19

## 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

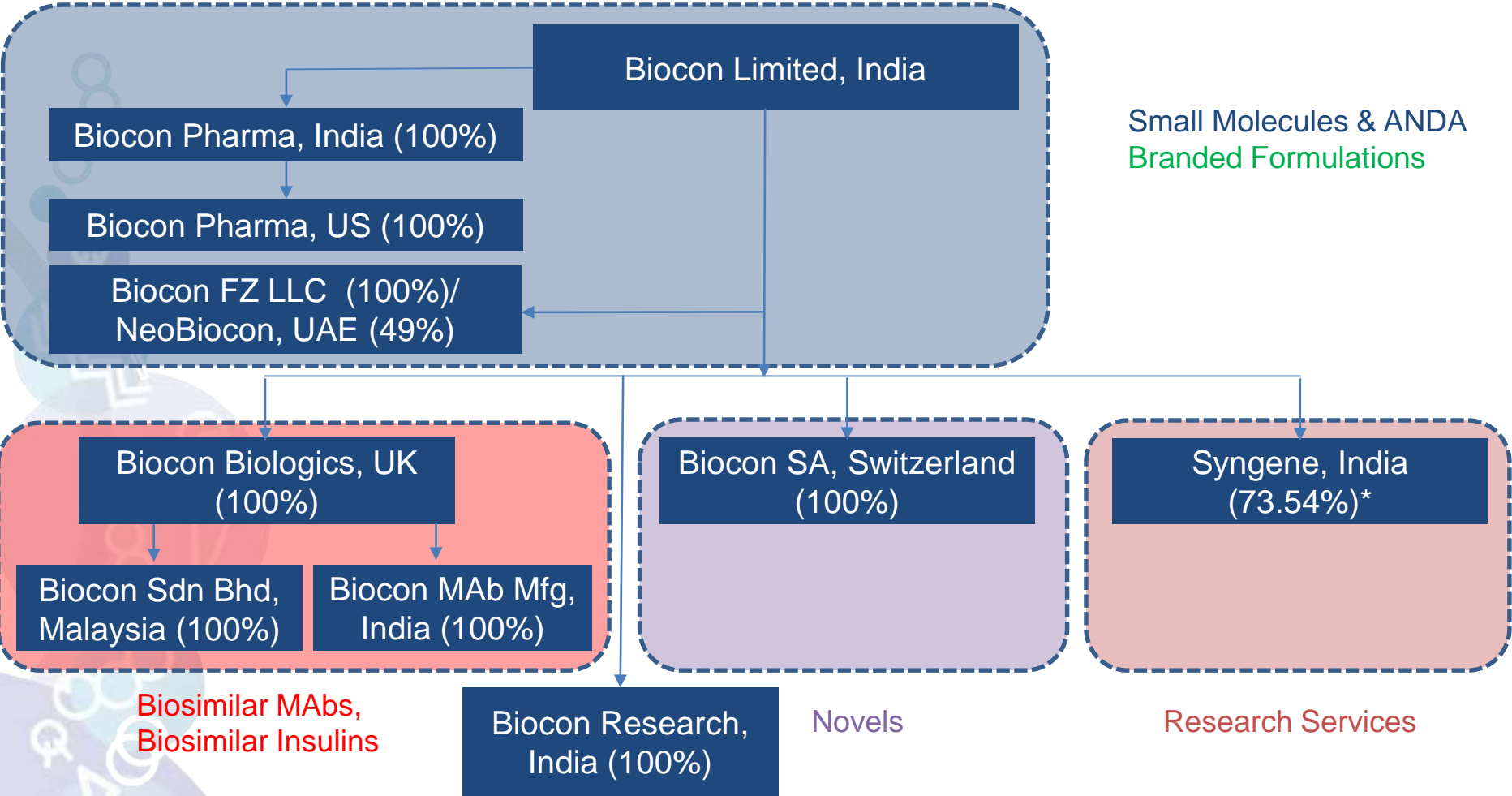


**Growth drivers supplemented by addition of new offerings (products, services & partnerships)**

# 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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