

# Credibly **Capable**

## Investor Presentation

June 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 Highlights

Outlook

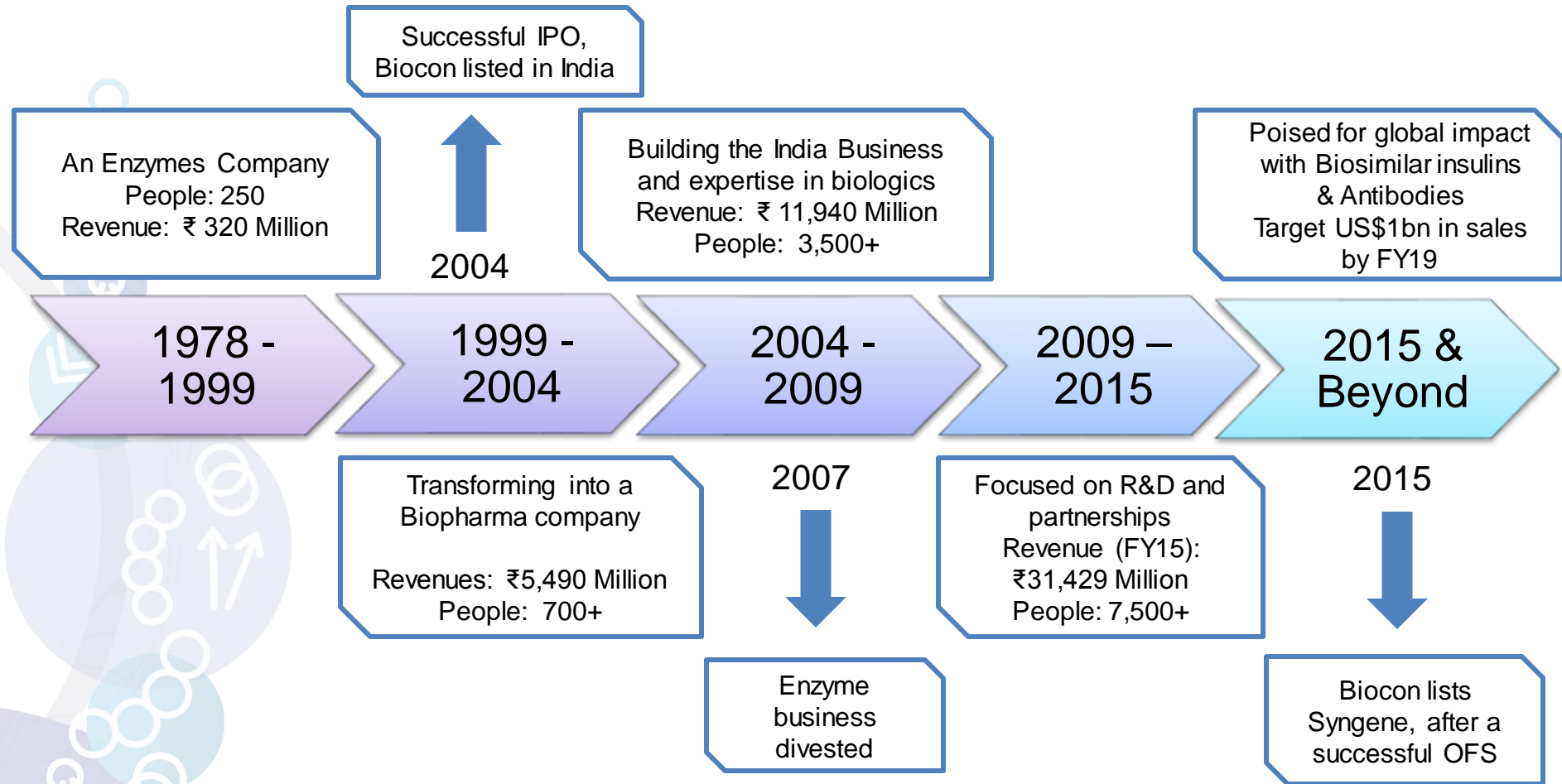
**Who are we?**

# 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-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



# FY16 - Business Highlights

- ❖ Biocon's Insulin Glargine received regulatory approval in Japan
- ❖ Biocon successfully listed Syngene, its Biocon's Research Services subsidiary after a highly successful IPO
- ❖ Four lead biosimilars programs progressed further through the clinic. US/EU biosimilar filings planned for trastuzumab, pegfilgrastim, insulin glargine and adalimumab in FY17
- ❖ Insulin glargine and trastuzumab launched in emerging markets
- ❖ Malaysian Insulin Facility received local cGMP certification from National Pharmaceutical Control Bureau (NPCB), Malaysia
- ❖ Basalog One™ – Biocon's disposable glargine device launched in India
- ❖ Positive clinical data from key studies for Insulin Tregopil announced
- ❖ Biocon acquired the business assets of the pharmaceutical manufacturing unit of M/s. Acacia Lifesciences Private Limited located at Vishakhapatnam, a step towards vertical integration in potent oncology APIs and generic formulations



# Financial Highlights – Q4 & FY16

All Figures in ₹ Million except %

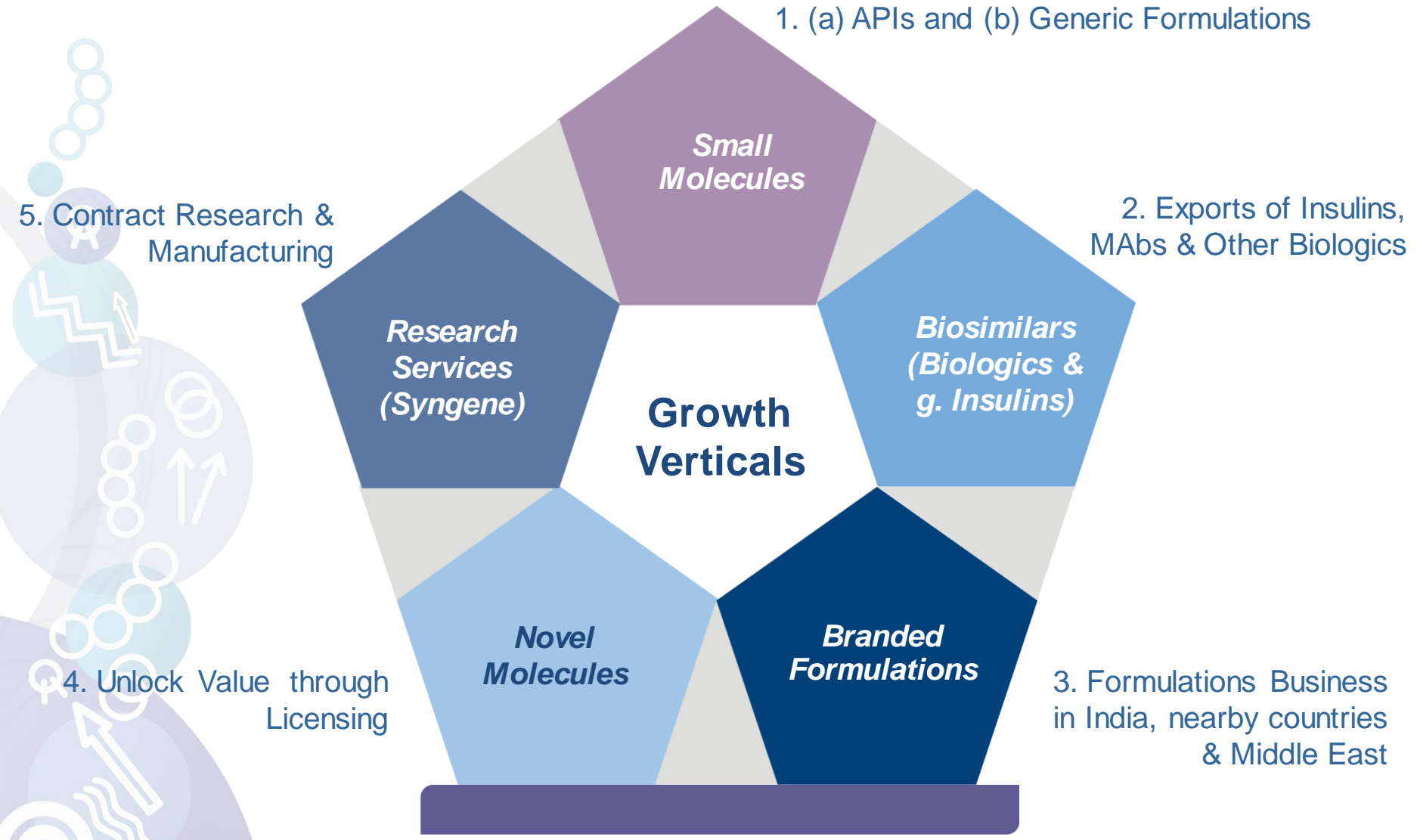
Particulars	Q4 FY16	Q4 FY15	Growth	FY16	FY15	Growth
Revenue	10,035	8,545	17%	35,699	31,429	14%
EBITDA	2,378	2,020	18%	9,045	7,489	21%
Net Profit*	3,609	2,015	79%	8,961	4,974	80%
R&D Expenses in P&L	998	560	78%	2,750	1,688	63%
Gross R&D Spends	1,524	993	53%	4,270	3,284	30%
<b>EBITDA Margins</b>	<b>24%</b>	<b>24%</b>	<b>-</b>	<b>25%</b>	<b>24%</b>	<b>-</b>

- \* For Q4FY16 – includes exceptional income of INR 2,561 million (net of tax). For Q4FY15 – includes exceptional income of INR 952 million (net of tax)
- \* For FY16 – includes exceptional income of INR 4,589 million (net of tax). For FY15 - Includes exceptional income of INR 1,051 million

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# Business Segments

# Growth Verticals: Aligned with Shifting Paradigms



# 1a. 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

# 1b. Small Molecules Generics Formulations

- ❖ Nascent pipeline
- ❖ To file ~20-25 dossiers in the next few years
- ❖ 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.
- ❖ Initiated construction of Biocon's first oral solid dosage facility located in Bangalore to support our future generic filings with capex of US\$25mn. Estimated completion CY 2017

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

## 2. Biosimilars

- ⌘ 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.
- ⌘ ***On track to file four molecules for regulatory approval in FY17, across the US and EU. These molecules have either completed Phase 3 clinical trials or are in advanced stages of completion..***
- ⌘ Human insulin and Insulin Glargine registered in over 60 and 20 emerging markets, respectively.
- ⌘ Biocon's Trastuzumab launched in India in Feb-14.
- ⌘ 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 3 complete	3.1
	Glargine	Long Acting Basal Insulin	Global Phase 3	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 3	14.0
	Trastuzumab	mBreast Cancer	Global Phase 3	6.8
	Pegfilgrastim	Chemo-induced Neutropenia	Global Phase 3 completed	4.7
	Bevacizumab	mColorectal Cancer	Global Phase 1, RoW Phase 3	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>	<b>42.0</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	2015 Sales* (US\$ bn)	Biosimilar Development Pipeline <sup>@</sup>		
		Pre-Clinical	Phase I	Phase III/Filed
pegfilgrastim	4.7	Pfizer	Dr. Reddy's	<b>Biocon</b> , Sandoz, Apotex, Coherus, Richter
trastuzumab	6.8	Oncobiologics, Dr. Reddy's	Hanhwa, Genor, Meiji Seika	<b>Biocon</b> , Celltrion, Amgen, Pfizer, Samsung
insulin glargine	7.1			<b>Biocon</b> <sup>&amp;</sup> , Samsung, Eli Lilly <sup>#</sup>
adalimumab	14.0	Epirus	Dr. Reddy's, Oncobiologics	<b>Biocon</b> , Amgen, Samsung, Sandoz, Boehringer Ingelheim, Coherus, Fuji Kirin, Momenta-Baxalta, Pfizer, Merck Serono
bevacizumab	6.9	Celltrion	<b>Biocon (Global)</b> , Sandoz, Daiichi, Fuji Kirin – Astra Zeneca, Oncobiologics, Cipla	<b>Biocon (RoW)</b> , Amgen, Boehringer Ingelheim, Pfizer, Samsung
filgrastim	1.0	<b>Biocon</b> , Pfizer		Sandoz <sup>**</sup> , Apotex, Multiple approvals in EU (Teva, Hospira (Pfizer), Stada, Accord etc.)
etanercept	8.7	<b>Biocon</b> , Celltrion		Samsung, Sandoz, Coherus-Baxalta
insulin aspart	4.7	<b>Biocon</b>		
insulin lispro	2.8	<b>Biocon</b>		Sanofi
rh-insulin	3.1	<b>Biocon – US</b>		<b>Biocon - EU</b>

\*Reported sales of Innovator Companies, conversion from reported currency into USD

& Approved in Japan. # Approved in Japan, EU and US. Launched in Japan & EU

\*\* Launched in EU & US. <sup>@</sup> Biosimilar Development Pipeline details may not be exhaustive, 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.
- ❖ Capital Investment of over US\$200mn in the first phase.
- ❖ Emerging market filings planned for FY17.

- ❖ Disposable insulins pen line in Bangalore starts commercial production.
- ❖ 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

### 3. Branded Formulations

- A Specialty Business with Regional Ambitions
- Strategy focused around biologics and differentiated products as anchor brands
- In India, organized into 6 key divisions around chronic therapy areas
- **Metabolics Division** - Combination of brands in diabetes and cardiovascular therapies, flagship brands include **Insugen®** & **Basalog®**. Division launched in 2004.
- **Oncotherapeutics Division** - Niche portfolio of oncology drugs, flagship brands include **CANMAb™**, **BIOMAb EGFR®**. Division launched in 2006.
- **Immunotherapy Division** - Portfolio of safe, efficacious and affordable immunomodulator drugs for the treatment of immune related disorders in dermatology. Flagship brands include **ALZUMAB™**, **PSORID™** and **TBIS™**. Division launched in 2010.
- **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™**, **RENODAPT®**, and **ERYPRO safe™**.
- **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 **Cytosorb®** and **PENMER™**. Division launched in 2010.
- **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™**, **CIMIVIR-L™**, and **DACLAWIN™**. Division launched in 2015.



## 4. Novel Molecules

### **Insulin Tregopil**

First-in-Class Oral Prandial Insulin

In-house program

- Positive Phase 1 clinical data sets the stage for further development by Biocon

### **Itolizumab**

Novel, humanized antibody directed at CD6

In-house program

- Commercialized in India for Psoriasis.
- Phase 1 study in normal healthy volunteers in progress in Australia will enable global development

### **SiRNA platform**

QPI- 1007 for Rare Diseases

Partnered with Quark Pharma

- Phase 3 study has been initiated in Non-arteritic Anterior Ischemic Optic Neuropathy (NAION) - Rare ophthalmic disease

### **Fusion Proteins**

In-house program

- Differentiated class of Fusion Antibody platform in Immuno-Oncology

## 5. 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 900,000 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%

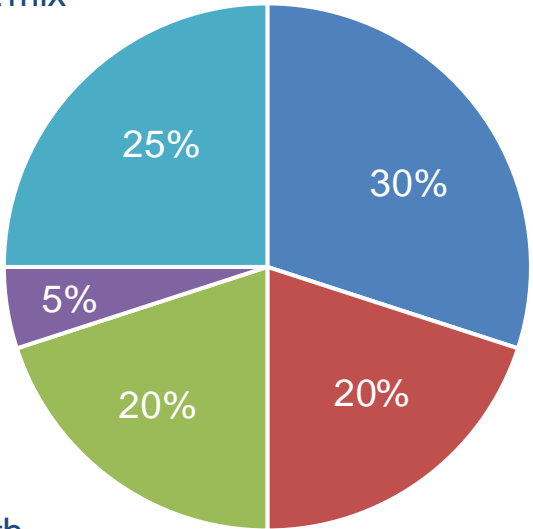
\*Net Profit is pre-exceptional

**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



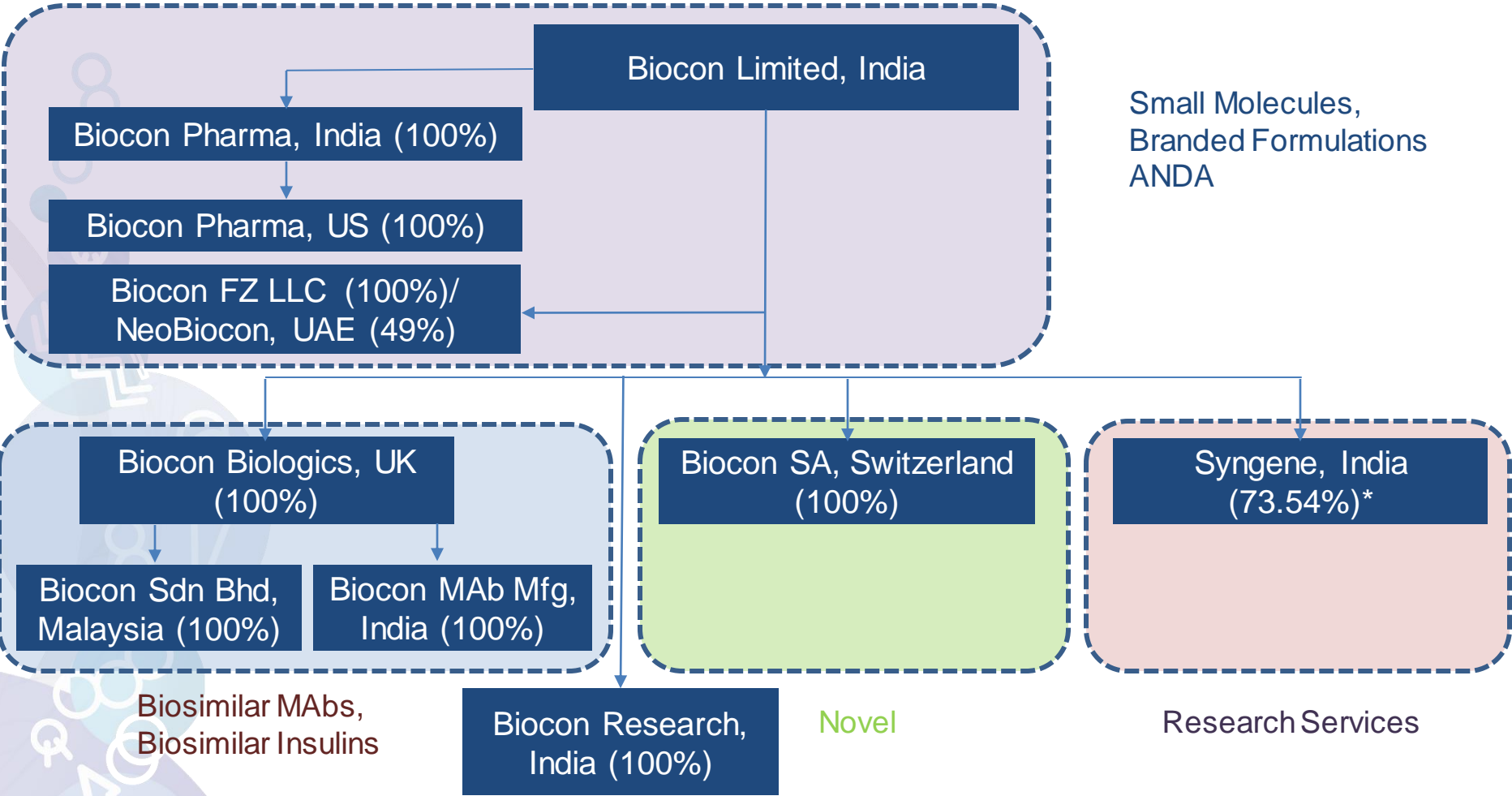
**Growth drivers supplemented by addition of new offerings (products, services & partnerships)**



# 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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