



# 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

Financials

Outlook

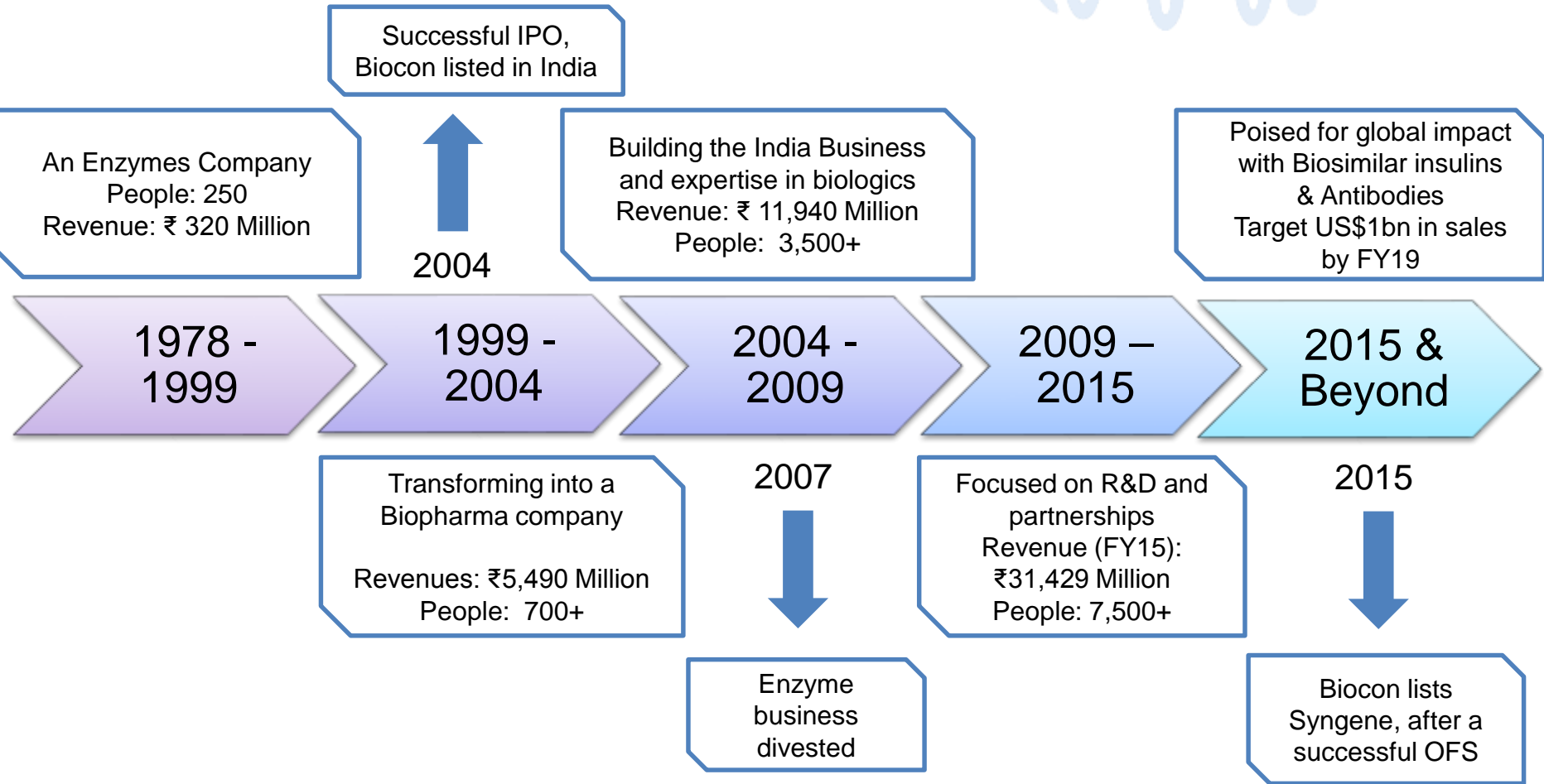


# Biocon: Asia's Leading Biopharma Company

## *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



# YTD Business Highlights

- ❖ **Biocon successfully lists Syngene, its Biocon's Research Services subsidiary**
  - ❖ IPO oversubscribed 31 times, market capitalization\* of INR 73.8 bn
  - ❖ Listed on NSE and BSE on August 11, 2015
- ❖ **Biosimilar programs accelerating through the clinic**
  - ❖ Insulin Glargine, Trastuzumab, Adalimumab, Pegfilgrastim in global phase III. Developed market filings (US/EU) planned for FY17 by partner Mylan
  - ❖ Bevacizumab in RoW focused Phase III, EU Phase I
- ❖ **Malaysian Insulin Facility receives local cGMP certification from National Pharmaceutical Control Bureau (NPCB), Malaysia**
- ❖ **Insulin Glargine launched in Mexico and Colombia**
- ❖ **Basalog One™ – Biocon's disposable glargine device launched in India**
- ❖ **Biocon acquired the business assets of the pharmaceutical manufacturing unit of M/s. Acacia Lifesciences Private Limited located at Vishakhapatnam.**

\* Per closing price on NSE, 19<sup>th</sup> Nov 2015



# Financial Highlights – Q2 & H1 FY16

All Figures in ₹ Million except %

Particulars	Q2 FY16	Q2 FY15	Growth	H1 FY16	H1FY15	Growth
Revenue	8,618	7,726	12%	17,183*	15,146	13%
EBITDA	2,222	1,879	18%	4,579	3,786	21%
Net Profit**	3,059	1,020	200%	4,322	2,050	111%
R&D Expenses in P&L	574	350	64%	1,073	661	62%
Gross R&D Spends	905	807	12%	1,834	1,441	27%
<b>EBITDA Margins</b>	<b>26%</b>	<b>24%</b>	-	<b>27%</b>	<b>25%</b>	-

\* Includes one time capacity reservation fee of INR 446 million | \*\* Includes exceptional income of INR 2,028 million

# Segmental Sales – Q2 & H1 FY16

All Figures in ₹ Million except %

Particulars	Q2 FY16	Q2 FY15	Growth	H1 FY16	H1 FY15	Growth
Biopharma	4,558	4,414	4%	9,471*	8,771	8%
Branded Formulations	1,190	1,160	3%	2,312	2,265	2%
Research Services	2,504	1,921	30%	4,743	3,645	30%
<b>Total</b>	<b>8,282</b>	<b>7,495</b>	<b>11%</b>	<b>16,526</b>	<b>14,681</b>	<b>13%</b>

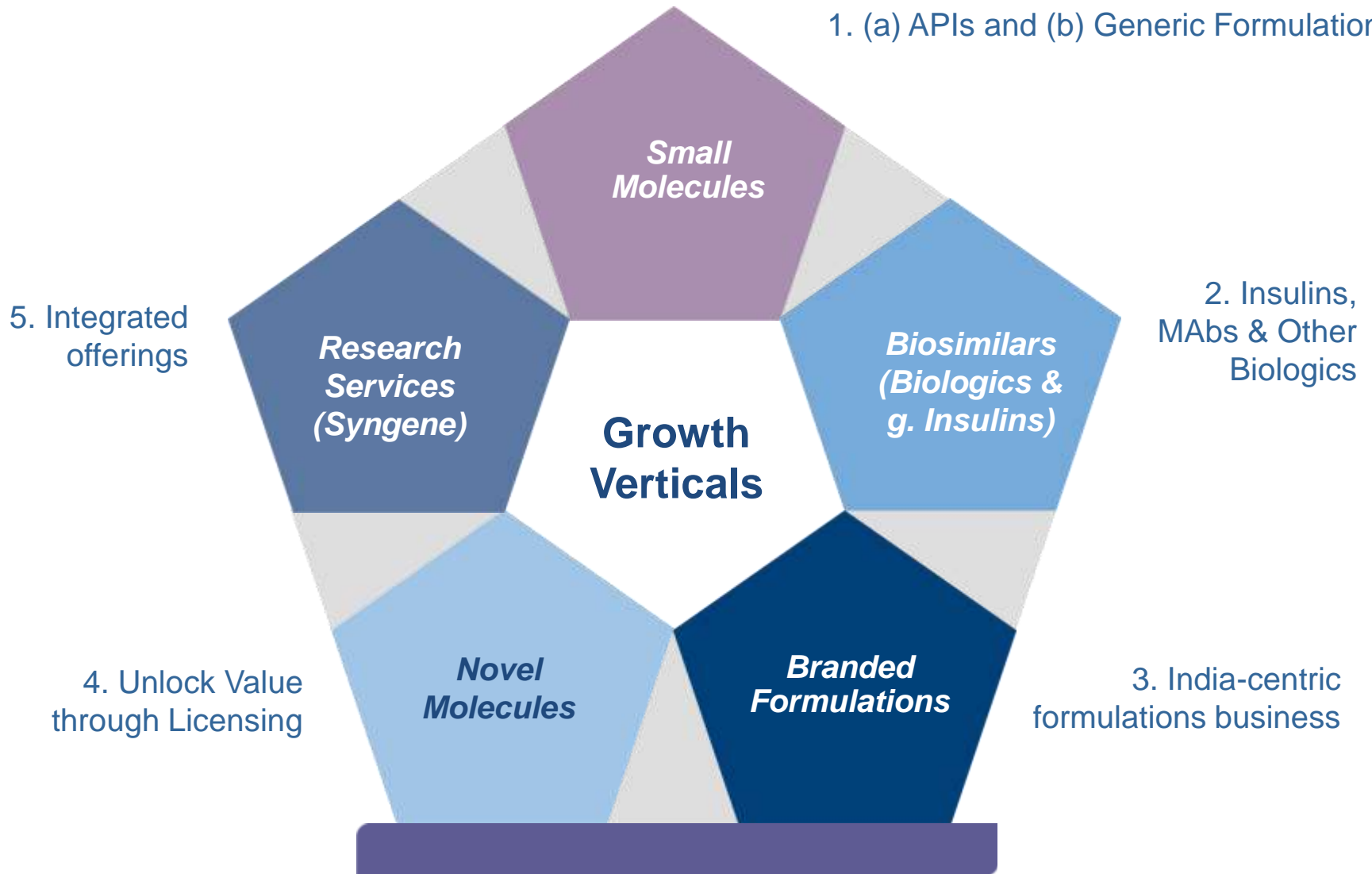
\* H1 Biopharma sales includes one time capacity reservation fee of INR 446 million



## Business Segments

# Growth Verticals: Aligned with Shifting Paradigms

1. (a) APIs and (b) Generic Formulations



# 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 ~25-30 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.
- ❖ **Four molecules in advanced Global Phase III studies. To file for regulatory approvals in US and Europe, in FY17.**
- ❖ Human insulin and Glargine registered in 60 and 20 emerging markets, respectively.
- ❖ Biocon's Trastuzumab launched in India in Feb-14, the first biosimilar Trastuzumab to be commercialized globally.
- ❖ 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 MAb's 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 MAb's & other Biologics
Mylan's Exclusive Commercialization Regions	US, Canada, Europe, Australia & New Zealand	Developed markets
Market Opportunity*	~US\$20 Bn	~US\$40 Bn

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

# Biosimilars: Insulins Pipeline

<b>Molecule</b>	<b>Type</b>	<b>Status</b>	<b>Market Size* (US\$ bn)</b>
Rh Insulin	Recombinant Human Insulin	EU Phase III complete	3.4
Glargine	Long Acting Basal Insulin	Global Phase III	8.4
Aspart	Rapid Acting Insulin Analog	Preclinical/Scale Up	4.9
Lispro	Rapid Acting Insulin Analog	Preclinical/Scale Up	2.8
<b>Total Market Size (rounded off)</b>			<b>19.5</b>

\*Market Size of innovator products in the current portfolio: Innovator Sales CY 2014

# Biosimilars: MAbs & Biologics Pipeline

Molecule	Indication	Status	Market Size* (US\$ bn)
Trastuzumab	mBreast Cancer	Global Phase III	6.9
Bevacizumab	mColorectal Cancer	EU Phase 1, RoW Phase III	7.0
Adalimumab	Chronic Plaque Psoriasis	Global Phase III	12.5
Pegfilgrastim	Chemo-induced Neutropenia	Global Phase III	4.6
Etanercept	Auto-immune	Preclinical/Scale Up	8.5
<b>Total Market Size (rounded off)</b>			<b>39.5</b>

\*Market Size of innovator products in the current portfolio: Innovator Sales CY 2014

# Biosimilars: Biocon well placed in the Competitive Landscape

Top 10 Biologics <sup>1</sup>	Company	Patent Term – US	2014 Sales (US\$ bn)	Biosimilar Development Pipeline*		
				Pre-Clinical	Phase I	Phase III/Filed
Humira (adalimumab)	AbbVie	2016	11.8		Dr.Reddy's  EPIRUS	
Lantus (insulin glargine)	Sanofi	2015	10.3			
Enbrel (etanercept)	Amgen/Pfizer	2028	8.7			
Remicade (infliximab)	Merck/J&J	2018	8.1			
Rituxan(rituximab)	Roche/Biogen	2013	6.6		Dr.Reddy's	
Avastin (bevacizumab)	Roche	2019	6.1			
Herceptin (trastuzumab)	Roche	2019	5.6			
Novolog (insulin aspart)	Novo Nordisk	2014	4.7			
Neulasta (pegfilgrastim)	Amgen	2015	4.6		Dr.Reddy's	
Lucentis (ranibizumab)	Roche/Novartis	2020	4.4			

(1) Ranking based on 2014 Sales, IMS Health MIDAS, December 2014

\* Biosimilar Development Pipeline details may not be exhaustive, Source: 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.
- ❖ 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

### 3. Branded Formulations: Introduction

- Presently an India focused Specialty Business with Regional Ambitions
- Organized into 5 key divisions around chronic therapy areas
- Strategy focused around biologics and differentiated products as anchor brands.
- **Portfolio highlights:**
  - **Insugen® & Basalog®:** Dominant position in generic insulin & insulin Glargine. Complete portfolio spanning vials, cartridges and disposable pens.
  - **CANMAb™:** World's first biosimilar Trastuzumab commercialized in Feb-14.
  - **BIOMAb EGFR®:** First indigenous novel Mab, for head & neck cancer.
  - **Abraxane:** Novel nab paclitaxel, launched in Sep-06.
  - **Alzumab™:**Indigenously developed first in class novel MAb, for Psoriasis
  - **Cytosorb®:** Cytokine Filter, first-in-class therapy for Sepsis.



## 4. Novel Molecules

### Insulin Tregopil

First-in-Class Oral Prandial Insulin

Partnered with BMS

- Multiple sets of studies completed to establish Post Prandial glycemic control.
- Sizeable global opportunity

### Itolizumab

Novel, humanized antibody directed at CD6

In – house program

- Commercialized in India for Psoriasis.
- Studies to be conducted across multiple indications (Rare and Common diseases)

### SiRNA platform

QPI- 1007 for Rare Diseases

Partnered with Quark Pharma

- QPI-1007 has entered Pivotal trial in NAION (Rare ophthalmic disease)

### Fusion Proteins

In – house program

- Differentiated class of Fusion Antibody platform in Immuno-Oncology

### Anti-CD 20

In – house program

- Oncology asset currently in Phase I of development

### ADX5-HPV

Partnered with Advaxis

- Developed for cervical cancer Currently in Phase II study



## 5. Syngene (Research Services Business)

### Global High Growth CRO Company

- One of the leading India-based contract research organizations (CRO)
- Integrated discovery and development
- Over 200 clients across multiple sectors
- 95%<sup>(1)</sup> of revenues from outside India
- Over 2,100<sup>(2)</sup> 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)
- Listed on Indian stock exchanges, BSE & NSE on August 11, 2015.

### 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>(3)</sup>
- 8 of our 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 200 in FY15
- 71% of FY15 revenue from top 10 customers compared to 79% in FY12
- Clients across sectors – Pharma, Biotech, Agrichem, Nutrition

(1) For fiscal ended March 31, 2015 ; (2) As of May 31, 2015

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

# Syngene: Value unlocking through a successful IPO

- **Subscription:** IPO Oversubscribed 31x
- **Allotment Price:** INR 250 (Implied market cap US\$770mn)
- **Listing Price:** INR 295
- **Closing on Listing Day (August 11, 2015):** INR 310 (25% premium)
- **Price Range since listing:** INR.295-386
- **Current Market Cap:** US\$1.14bn
- **Biocon owns 73.5% of Syngene**



## Five Year Financials

# Consolidated Financial Performance (FY11-15)

All Figures in ₹ Million except EPS

Business Segment	FY11	FY12	FY13	FY14	FY15
<b>Biopharmaceuticals</b>	<b>14,866</b>	<b>16,764</b>	<b>18,705</b>	<b>21,382</b>	<b>22,367</b>
- Biopharma	13,023	14,170	15,231	17,468	18,071
- Branded Formulations	1,863	2,594	3,474	3,914	4,296
<b>Contract Research</b>	<b>3,177</b>	<b>4,101</b>	<b>5,572</b>	<b>7,146</b>	<b>8,225</b>
<b>Total Sales</b>	<b>18,063</b>	<b>20,865</b>	<b>24,227</b>	<b>28,528</b>	<b>30,592</b>
Other Income	516	618	1,103	804	837
<b>Total Revenue</b>	<b>18,579</b>	<b>21,483</b>	<b>25,380</b>	<b>29,332</b>	<b>31,429</b>
EBITDA	5,733	5,792	5,957	7,429	7,489
EBITDA Margin (%)	31%	27%	23%	25%	24%
<b>Net Profit*</b>	<b>3,399</b>	<b>3,384</b>	<b>3,241</b>	<b>4,137</b>	<b>4,022</b>
Net Profit Margin	18%	16%	13%	14%	13%
<b>EPS</b>	<b>18.4</b>	<b>16.9</b>	<b>25.4</b>	<b>20.7</b>	<b>24.8</b>
R&D Spends (in P&L)	1,183	1,566	1,640	1,310	1,688
R&D (as % of Biopharmaceuticals Sales)	7.9%	9.3%	8.8%	6.1%	7.5%

\*Net Profit is pre-exceptional

**Revenue mix (FY15): Ex-India 65%:India 35%**

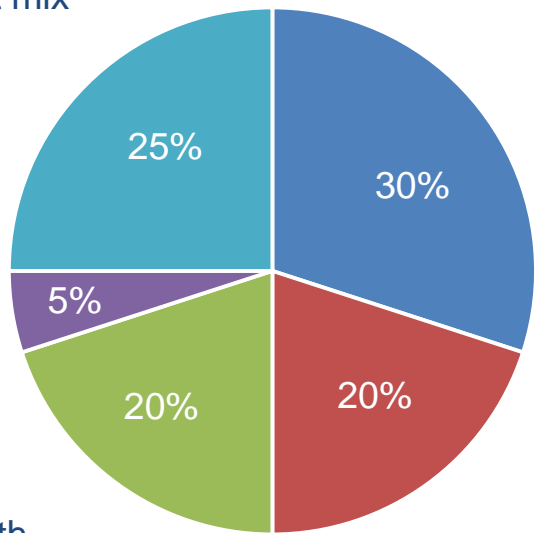


## Appendix

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

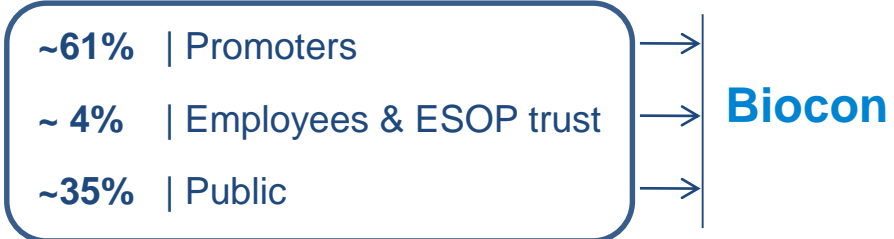
## Key Focus Areas

- **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)**

# Shareholding Pattern & Business Holdings\*



## BIOPHARMA SUBSIDIARIES

- Biocon Research, India | **100%**  
*R&D- Novel Molecules & Biosimilars*
- Biocon Pharma, India | **100%**  
*Manufacturing - Generic Formulations*
- Biocon Pharma Inc., USA | **100%**  
*Step Down Subsidiary*
- Biocon Sdn. Bhd, Malaysia | **100%**  
*Overseas subsidiary*
- Biocon SA, Switzerland | **100%**  
*Overseas subsidiary*
- NeoBiocon, UAE | **51%**  
*Overseas subsidiary*
- Biocon FZ LLC, UAE | **100%**  
*Overseas subsidiary*

## RESEARCH SERVICES

- Syngene International, India | **73.5%**  
*Leading Indian CRO*

\* As on 30<sup>th</sup> Sep 2015





For more information, please visit  
[www.biocon.com](http://www.biocon.com)

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