



# Exclusively **inclusive**



## **Investor Presentation**

September 2015

# 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?

Growth Segments

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

Financials

Outlook



**Biocon: Who are we?**

# Biocon: We have a differentiated business vision

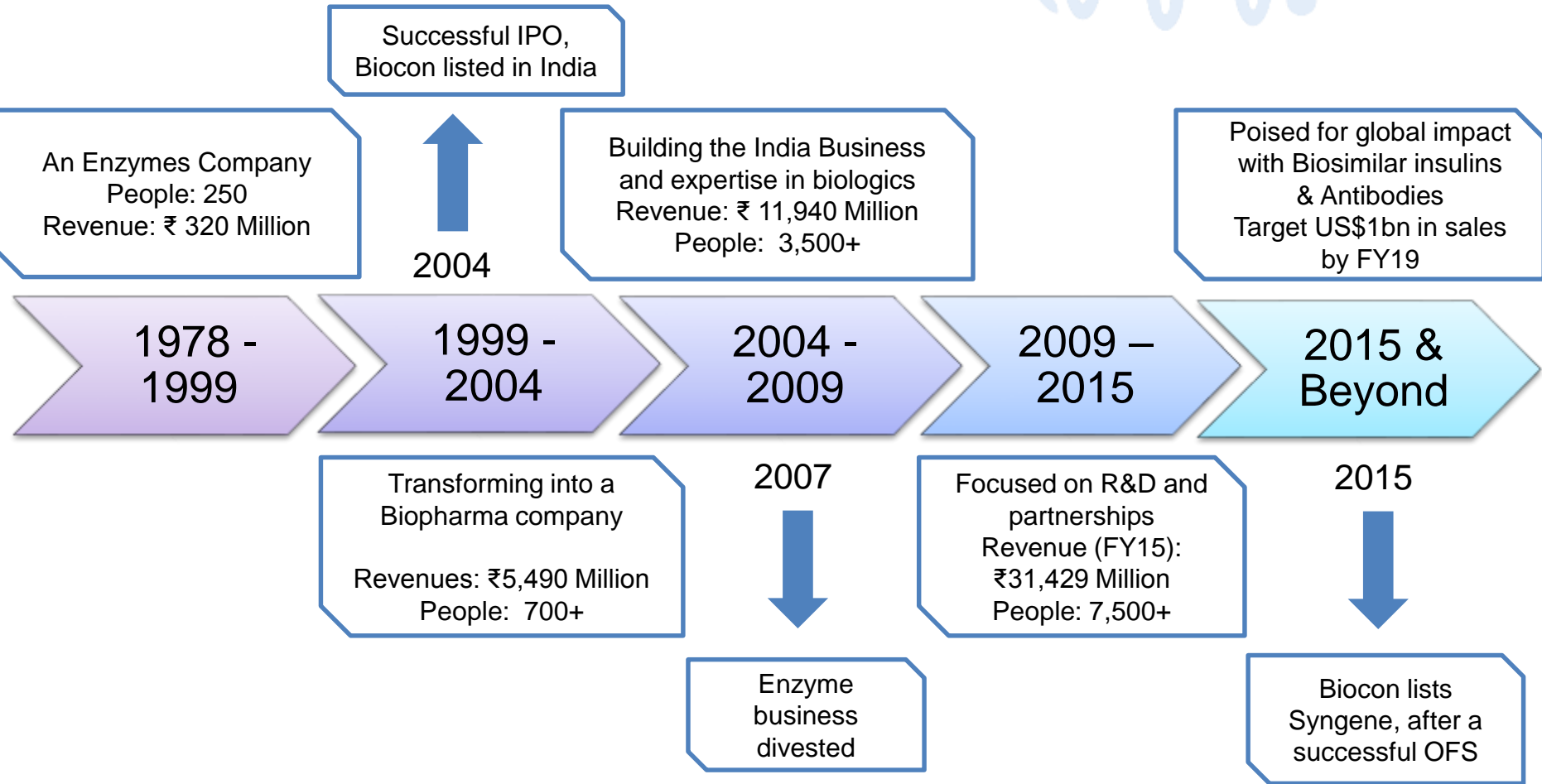
*To enhance global healthcare through a balance of innovative & cost-efficient R&D, i.e. high science at a lower cost*

An innovative portfolio: Monoclonal antibodies and recombinant insulins

Collaborative partnership model

Strong core capabilities and scale

# 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

# YTD Highlights

## Q1 FY16 Results

- ❖ Group Revenue at ₹ 8,565\* Million
- ❖ EBITDA at ₹ 2,357 Million (*EBITDA Margin: 28%*)
- ❖ R&D Expense: ₹ 499 Million (8% of Biopharmaceuticals Revenue)
- ❖ PAT at ₹ 1,263 Million (*PAT Margin: 15%*)
- ❖ YoY Growth# across verticals:

Business Vertical	Absolute Growth (%)
Biopharmaceuticals	10%
- Biopharma	12%
- Branded Formulations	1%
Research Services	30%
Total Sales	15%

\*Includes one time capacity reservation fee of INR 446 million

# YoY comparison of Q1FY16 Sales vs. Q1 FY15 Sales

# YTD Highlights (2)

- ❖ **Biocon successfully lists Syngene, its Biocon's Research Services subsidiary**
  - ❖ IPO oversubscribed 31 times, market capitalization\* of INR 64.8 bn
  - ❖ Listed on NSE and BSE on August 11, 2015
- ❖ **Biosimilar programs accelerating through the clinic**
  - ❖ Glargine, Trastuzumab, Adalimumab, Pegfilgrastim in global phase III
  - ❖ 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**

\* Per closing price on NSE, 15<sup>th</sup> Sep 2015

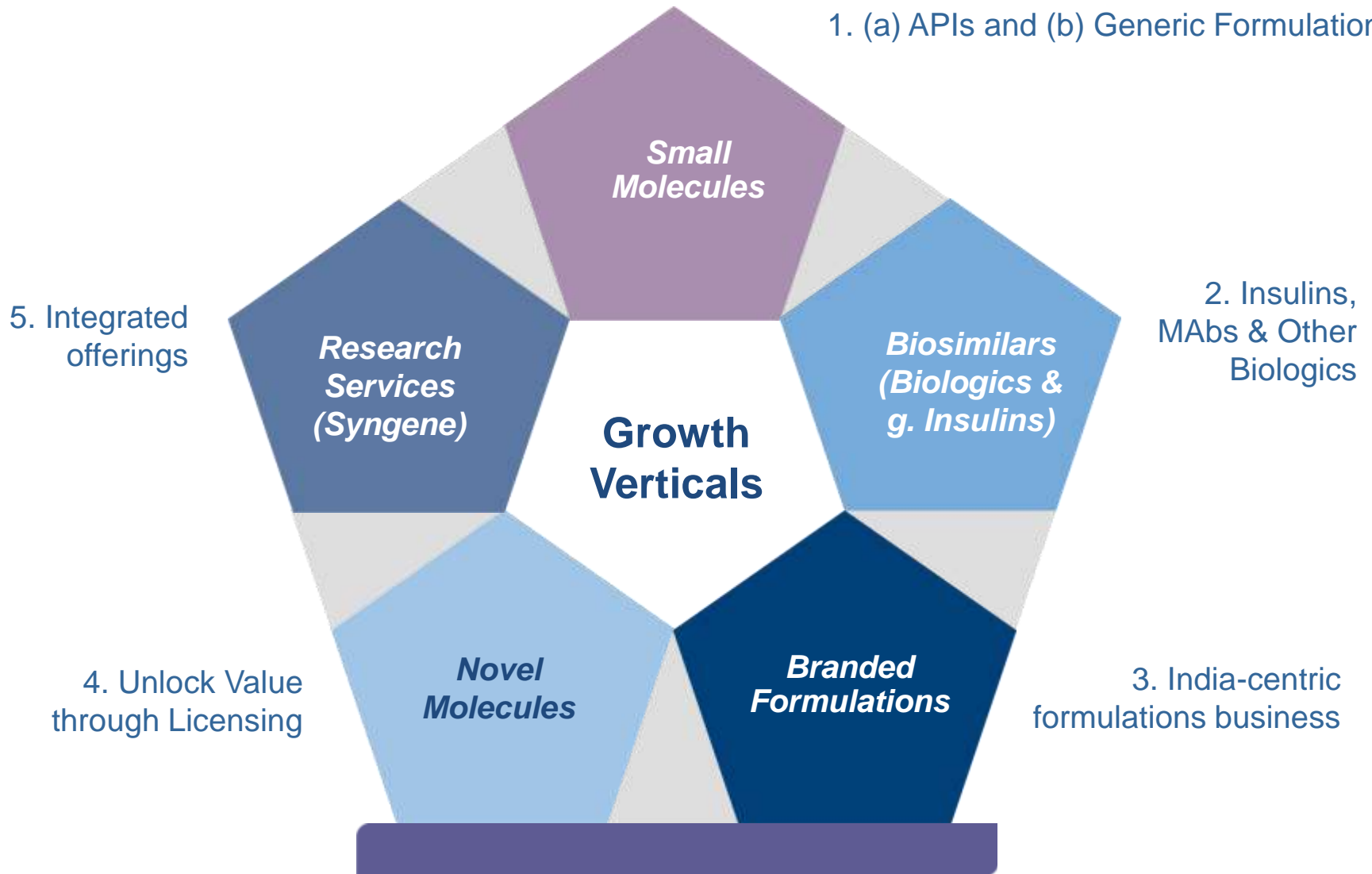




## Business Segments

# 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.

<b>Current Portfolio</b>	<b>Constituents</b>
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.
- ❖ Strong scientific and technical capabilities and manufacturing expertise to address global opportunities.
- ❖ Four molecules in advanced Global Phase III studies positioning Biocon amongst the early wave of entrants in the developed markets.
- ❖ 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 strong biologic capability and know how are targeted at the global biosimilar opportunity

# 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 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.
- ❖ Plant has been commissioned.
- ❖ Emerging market filings planned for FY17.

- ❖ Expansion of drug product facility in Bangalore initiated. Expected completion in FY18.
- ❖ Disposable insulins pen line in Bangalore starts commercial production.
- ❖ MAbs capacity to be augmented in line with market entry requirements.

Biocon over the years have built global scale and cost competitive, complex manufacturing capabilities to address patient needs the world over.



# 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
Upfront Received	US\$20 Mn	US\$18 Mn
Market Opportunity*	~US\$20 Bn	~US\$40 Bn

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

### 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

### Oral Insulin

First-in-Class Oral Prandial Insulin

Partnered with BMS

- Multiple sets of studies completed. Additional studies planned
- Sizeable global opportunity

### Itolizumab

Novel, humanized antibody directed at CD6

In – house program

- Commercialized in India for Psoriasis.
- Understanding path forward in autoimmune disorders
- 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

### ADXS-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

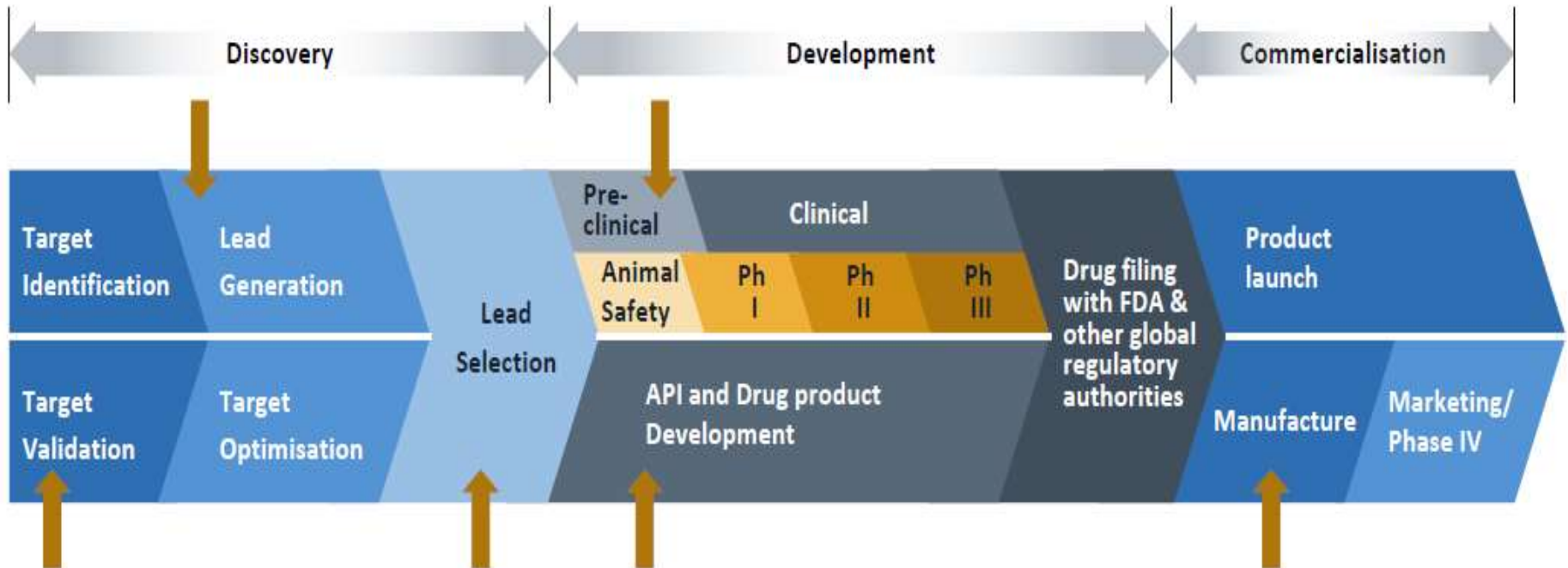
- Highly successful track-record in molecule development
- Client base includes 8 of the top 10 global pharma company by 2014 sales<sup>(3)</sup>
- 8 of our top 10 clients have been associated for more than 5 years illustrating their longstanding and extensive relationship
- Total clients increased from 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: Integrated Platform with multiple entry points

Entry points create opportunity for customer engagement expansion



# Syngene: Long Term Relationships – Dedicated Research Centres



Largest R&D Centre in Asia for BMA (2009). Contract extended to 2020

Dedicated centre for research excellence with world class facilities

Over 400 scientists supporting Novel Molecule research in small and large molecules.

Produced nine drug candidates for further study and advanced new compounds for first-in-human studies.

## ***Baxter***

Dedicated research centre in India for Baxter (2013).

State of the art facility supporting R&D of medical products and devices worldwide.

Engages a multidisciplinary team of ~150 scientists.

R&D activities centred on product and analytical development, preclinical evaluation in parenteral nutrition and renal therapy.



Abbott Nutrition's 1st R&D centre in India set up in collaboration with Syngene(2012).

Dedicated research centre supporting development of affordable, nutrition products.

~30 multi-disciplinary scientists engaged in product development lifecycle.

Focus on maternal, paediatric, neo-natal nutrition and diabetes care in line with emerging market needs.



## Consolidated 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%**



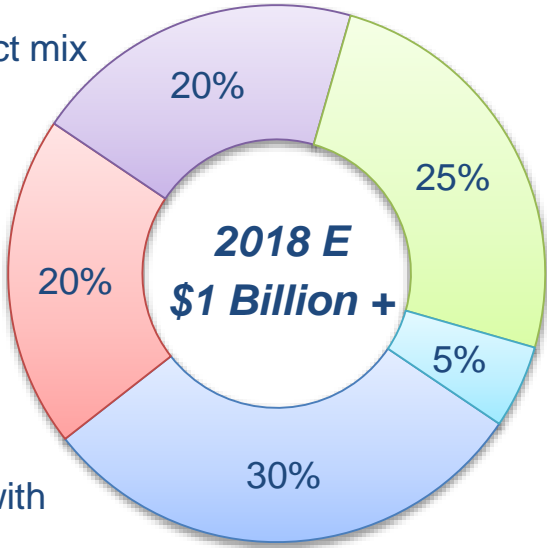


## Outlook

# Aspiring for \$1 Billion in Revenues in 2018

## 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
- **Research Services** - Sustained growth momentum with increase in clients & services, moving from CRO to CRAMS with commercial manufacturing
- **Novel Molecules** - Out-licensing and Global Development



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

# Business Structure & Holdings



~61% | Promoters →  
~ 4% | Employees & ESOP trust → **Biocon**  
~35% | Public →

## 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*



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

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