



**Investor Presentation July 2014** 

#### **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.



Biocon: Who are we?

# **Growth Segments**

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

**Financials** 

**Outlook** 





**Biocon: Who are We?** 

#### **Biocon: Global Ambitions with Indian Roots**



Mission: "To be an integrated biotechnology enterprise of global distinction"

#### Value Creation along 3 axes:

Reducing therapy costs of *chronic diseases*. (diabetes, cancer & auto-immune diseases)

Strategic Research and marketing *partnerships* that provide global access

Leveraging the India advantage to deliver *high value*, *licensable R&D assets* 

### **Evolving with the Times**



An Enzymes Company Revenue: ₹ 320 Million Building the India Business and expertise in biologics Revenue: ₹ 11,940 Million People: 3,500+ Poised for a global platform with launch of finished formulations & biosimilars in regulated markets

1978 -1999 1999 -2004

2004 **-** 2009

2009 – 2014 2014 & Beyond

Transforming into a Biopharma company

Revenues: ₹ 5,490 Million People: 700+ Investment intensive phase with focus on R&D, capacity enhancement & partnership execution

Revenue (FY 14): ₹ 29,332 Million

People: 7,000+

Unwavering focus through the years on Innovation & Difficult to make, niche products to create tangible differentiators for sustainable growth

### Q1 FY15 Highlights



# Financial Performance

- Group Revenue at ₹ 7,420 Million (3% YoY growth)
- YoY Growth\* across verticals:

<b>Business Vertical</b>	Absolute Growth (%)
Biopharma	(1)
Branded Formulations	10
Biopharmaceuticals	1
Research Services	12
Total Sales	3

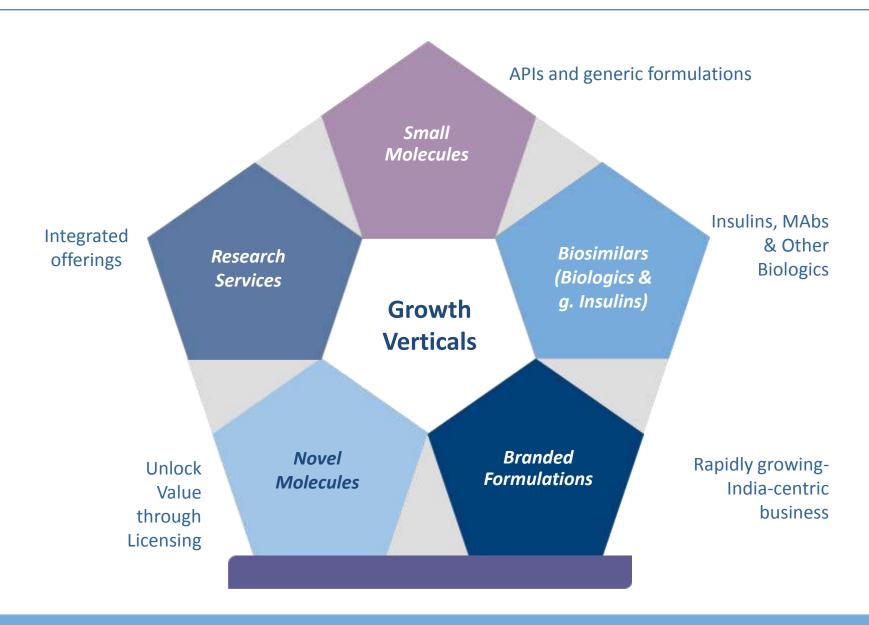
- EBITDA at ₹ 1,907 Million (EBITDA Margin: 26%)
- R&D Expense: ₹ 311 Million (6% of Biopharmaceuticals Revenue)
- PAT at ₹ 1,030 Million (PAT Margin: 14%)

# Corporate Milestone

Syngene and Bristol Myers Squibb extend research collaboration

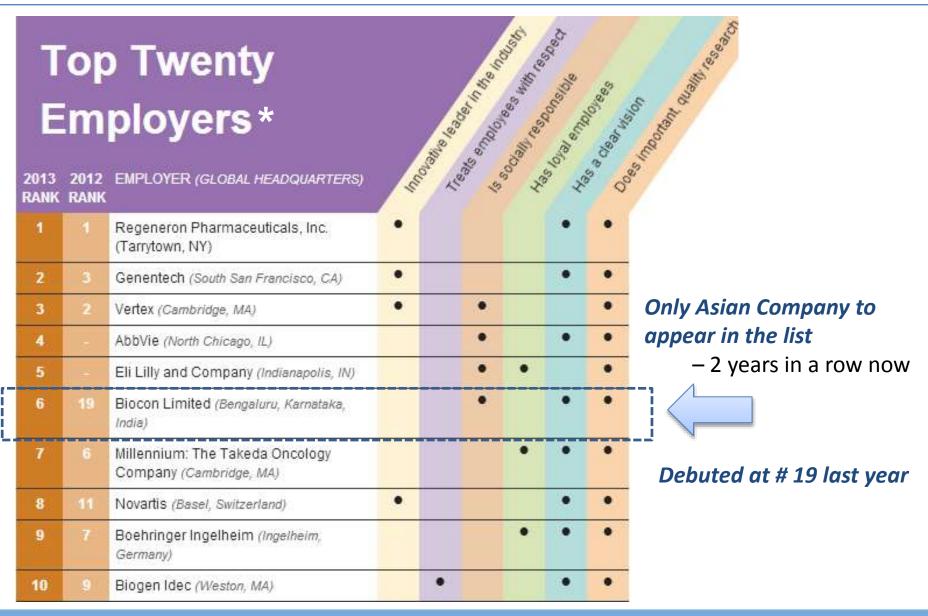
# **Growth Verticals: Aligned with Shifting Paradigms**





# Amongst the Top 20 Global Biotech Employers Worldwide





<sup>\*</sup> Partial List represented here | Source- http://sciencecareers.sciencemag.org/career\_magazine/previous\_issues/articles/2013\_10\_25/science.opms.r1300137



**Business Segments: Snapshot** 





- Product Portfolio which leverage our core fermentation capabilities and have a high degree of complexity.
- Early mover in niche products coupled with economies of scale.
- Portfolio based Approach.
- Making investments' to forward integrate from APIs to generic formulations, including ANDAs.

<b>Current Portfolio</b>	Constituents
Statins	Simvastatin, Atorvastatin, Lovastatin, Rosuvastatin, Fluvastatin & Pravastatin
Immuno suppressants	Tacrolimus, Sirolimus, MMF & MPA
Other Biopharma	Orlistat, Fidaxomicin, 50+ other molecules

### **Biosimilars: Demystifying**



A biosimilar is...

"a **biological product** that is **highly similar** to the reference product notwithstanding minor differences in clinically inactive components, and.. **no clinically meaningful differences against the reference product** in terms of the safety, purity and potency."

Unlike a small molecule...

Large Molecules (proteins): greater complexity

Extensive development process

Process development and Capacity constraints

**Current Portfolio** 

g. rh-Insulin & g. Insulin Analogs (insulin glargine, insulin lispro & insulin aspart)

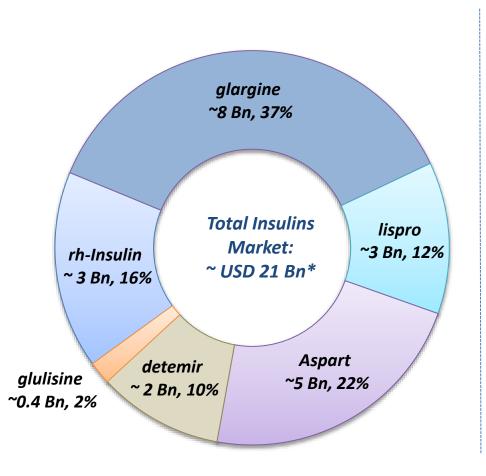
Monoclonal Antibodies (Trastuzumab, Bevacizumab, Adalimumab)

Other Biologics (Etanercept, Peg-filgrastim)

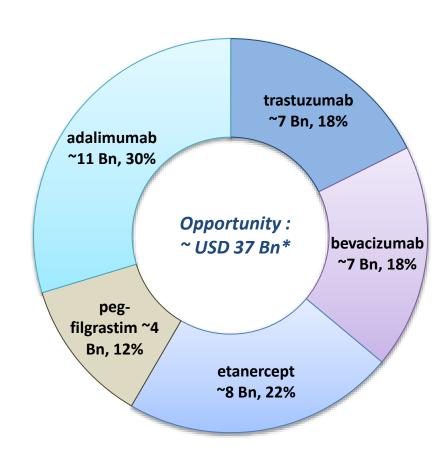
## **Biosimilars: Opportunity**



#### The Insulin Pie

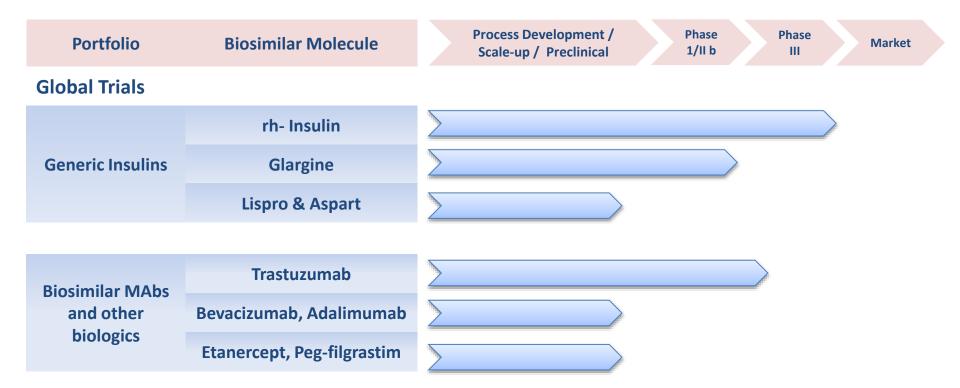


#### **Biosimilar MAbs & Other Biologics**



### **Biosimilars: Pipeline**



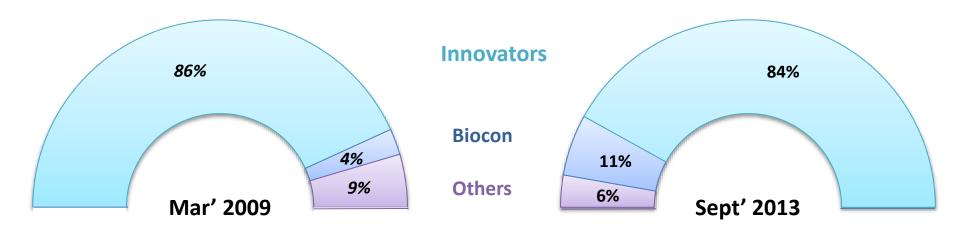


- Emerging Markets First strategy coupled with a regional partnership commercialization approach
- Launched the world's most affordable trastuzumab, CANMAb™ in India, in Q4 of fiscal 2014
- Generic rh Insulin registered in 55+ countries; generic insulin glargine registered in 10+ nations





#### rh-Insulin Volume Market Share: Evolution



2009 – 2013	Key Emerging Markets	Innovators	Biocon	Others
CAGR over 5 year	11%	10%	32%	-

#### **Biosimilars: Collaboration**



#### **Co-Development & Commercialization Partnership**



Combines Biocon's R&D and manufacturing prowess of biologics with Mylan's regulatory & commercialization capabilities in the US and Europe

	Generic Insulin Analogs	Biosimilar MAbs & other Biologics
Global Market Size *	~ USD 18 Bn	~ USD 37 Bn
Portfolio Constituents	Glargine, Lispro & Aspart	Trastuzumab, Bevacizumab, Adalimumab, Eternacept, Peg-filgrastim
Mylan's <i>Exclusive Commercialization</i> Regions	US, Canada, Europe, Australia & New Zealand	Developed markets
<b>Upfront</b> Received	\$ 20 Mn	\$ 18 Mn

Structure: Upfront Payment + Cost Sharing + Supplies + Profit Sharing#

Mylan and Biocon to share development and capital costs

#Profit Sharing Arrangement in regions where Mylan has exclusive commercialization rights

Biocon and Mylan have co-exclusive commercialization rights in other markets.

## **Malaysia Insulin Facility**



#### **Key Highlights**

Biocon's First Manufacturing expansion overseas: Iskandar, Johor

Asia's largest integrated Insulins manufacturing facility

Investment to the tune of ~\$ 200 Mn in the first phase

**Expected Commissioning: FY15** 





#### **Branded Formulations: Introduction**



- An India Centric Business with Global Ambitions
- Organized into 5 verticals around key therapy areas
- Portfolio highlights:
  - Insugen® & Basalog®: India's largest selling generic insulin & long acting analog
  - BioMAb EGFR®: India's 1st indigenous novel MAb for head & neck cancer
  - ♣ Alzumab™: India's 2<sup>nd</sup> indigenous novel MAb for Psoriasis
  - CANMAb™: World's most affordable trastuzumab to be commercialized
  - Cytosorb®: First-in-class Cytokine Filter











## **Branded Formulations: Key Brands**



**CV-Met** 





**Cancer Therapies** 





**Autoimmune** 



**Renal Therapies** 



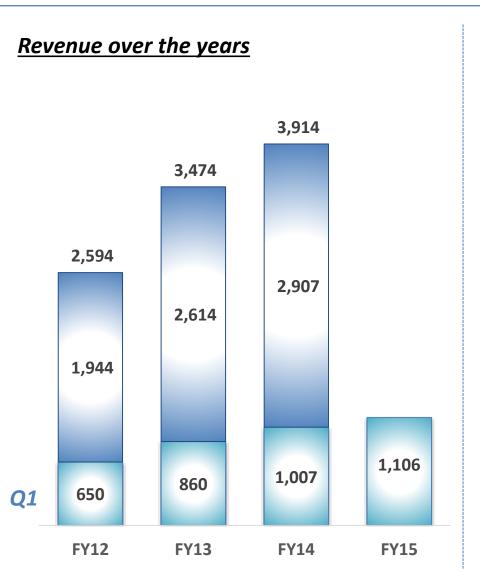


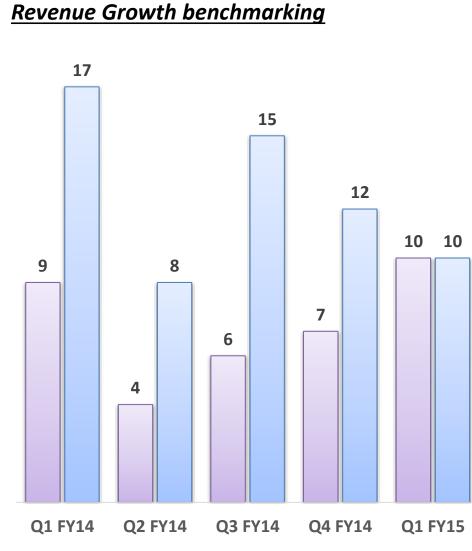
#### Hospital: Critical Care



#### **Branded Formulations: Sustained Growth**







Biocon

#### Branded Formulations: Alzumab™



#### **Key Differentiators**

First-in-Class Therapy : Novel MOA with an excellent safety profile

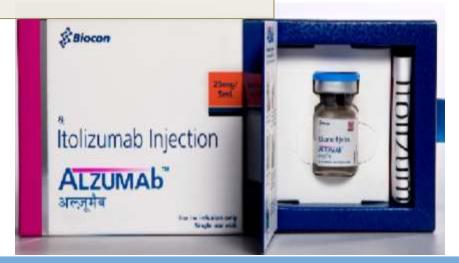
Excellent clinical remission & safety data in phase III for Psoriasis

**Very low Infection** rates vis-à-vis other approved therapies

**Modulates TH17 Pathway**: Frontrunner in the hot bed of research in auto immune space

**Commercialised in India** post a successful Phase III trial in Psoriasis (200+ patients);

Promising preclinical and clinical efficacy data in **other auto immune diseases** (Rheumatoid Arthritis, Psoriatic Arthritis etc)



#### Branded Formulations: CANMAb™



#### **Key Differentiators**

Approved after a Phase 3 (130 + patient) trial in India

Available in India from February 2014

C: Convenience -- Available in unique combination of multi-dose vial of 150 mg & 440 mg

**A: Affordability** 

- MRP Rs 57,500 for 440mg vial, Rs 19,500 for 150mg vial
- Availability of 150 mg multi-dose vial allows patients to save money by buying smaller quantities, and storing unused product for their next dose rather than wasting it

N: New from India-- World's most affordable trastuzumab to be commercialized



# **Novel Molecules: Pipeline**



Therapeutic Area	Molecule	Discovery Pre-Clinical Phase Phase III Market
Oncology	Nimotuzumab	Commercialized in India
Autoimmune	Itolizumab	Commercialized in India
Ophthalmology	QPI-1007	
Opininalinology	QF1-1007	
Oncology	ADXS-HPV	
Diabetes	IN-105	
Oncology	Anti CD – 20	
Oncology	Allei CD 20	
Oncology	<b>Fusion Proteins</b>	Currently on hold



#### **IN-105** Option Agreement: BMS (First-in-Class Oral Prandial Insulin)



Combines Biocon's novel asset and development experience with BMS' novel drug development, regulatory & commercialization capabilities.

Biocon will **continue global development** of the molecule through Phase II via redesigned trials.

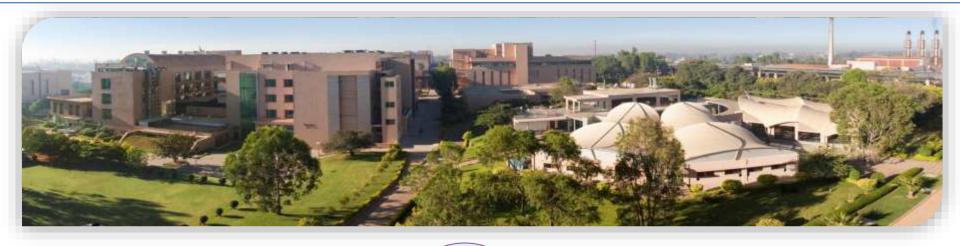
Partnership encompasses **Financial, Strategic and Clinical Support** throughout the development phase

BMS will have an **exclusive option post phase II** to further develop & commercialise the asset worldwide (excl. India)

Biocon will receive licensing fee in addition to potential regulatory & commercialization milestones, when BMS exercises its option

# **Research Services: Snapshot**





An investment of ~\$20 Mn supported by 100+ scientists focused on building a world class CRO

**2000** 



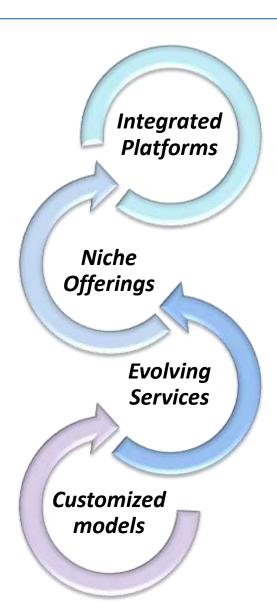
India's largest CRO with 2,000 + scientists, working with 16 of the Top 20 pharma companies in the world.

Capital Investment of ~\$130 Mn

# **Research Services: Capabilities & Collaboration Models**



- Integrated Drug Discovery and Development
- Biologics Discovery and Development
- Syngene- Clinigene axis
- Bioanalytical testing of small and large molecules
- Antibody Drug Conjugate (ADC) development
- Unique *In-Vivo* Models- Human tumour tissue Xenograft
- Early and rapid toxicology evaluation (Cardiomyocytes)
- Commercial scale production of NCEs
- High potency (cytotoxic) API manufacturing
- Formulation development
- Dedicated/customized infrastructure
- End-to-end services
- Risk sharing: Milestone based
- Incubation: IP sharing



### **Research Services: Key Customers**





Largest R&D Centre by a Big Pharma in Asia (started in 2009, contract extended to 2020)

Dedicated centre of research excellence with world class facilities

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

Integrated drug discovery & development across various therapeutic areas



Baxter's 1<sup>st</sup> research centre in India in partnership with Syngene (2014)

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

Engages a multidisciplinary team of over 100 scientists

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



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

Dedicated centre supporting development of nutrition products

Over 30 multi-disciplinary scientists engaged in product development lifecycle

Focus on maternal, paediatric, neonatal nutrition and diabetes care in line with emerging market needs

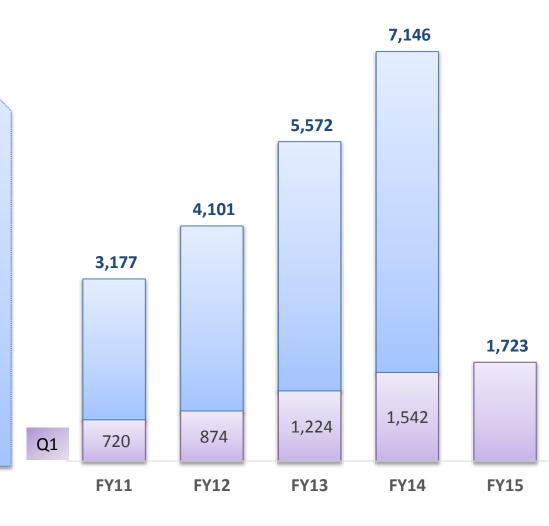
#### **Research Services: Performance**



Revenues in ₹ Million

GE Capital

- PE Investment of ₹ 1,250 Million for a 7.69% stake, assigning Syngene a post money valuation of ₹16,250 Million
- Investment earmarked for enhancing Syngene's service offerings, capacities & fund future growth
- GE brings in corporate best practices along with avenues for capability enhancement and new offerings





# **Financials**

# **Financial Performance**



All Figures in ₹ *Millions / USD Mn* except EPS

	FY10	FY11	FY12	FY13	FY14
Revenue	14,930   318	18,579   407	21,483   445	25,380 467	29,332 487
<b>R&amp;D Spend</b>	785 17	1,183 26	1,366 <b>2</b> 8	1,640 30	1,310 22
<b>EBITDA</b>	4,551 97	5,733 125	5,791 120	5,957 110	7,429 123
Net profit*	2,729 58	3,399 74	3,384 70	3,241 60	4,137 69
<b>EPS</b> ( <i>FV</i> : ₹ 5)	13.6	17.0	16.9	25.4	20.7

	Q1 FY15	Q1 FY14
Revenue	7,420   <b>124</b>	7,234   <b>129</b>
R&D Spends	311   <i>5</i>	431   <i>8</i>
% of Biopharmaceutical Sales #	6%	8%
EBITDA	1,907  <b>32</b>	1,753  <b>31</b>
EBITDA Margin	26%	24%
Net Profit	1,030  <b>17</b>	942  <b>17</b>
PAT Margin	14%	13%
EPS	5.2	4.7

FY10-14: Avg.exch.rate in that fiscal; Q1 FY14: USD 1 = ₹ 55.87; Q1 FY15: USD 1 = ₹ 59.88

# **Core Business Margins: Detailed**

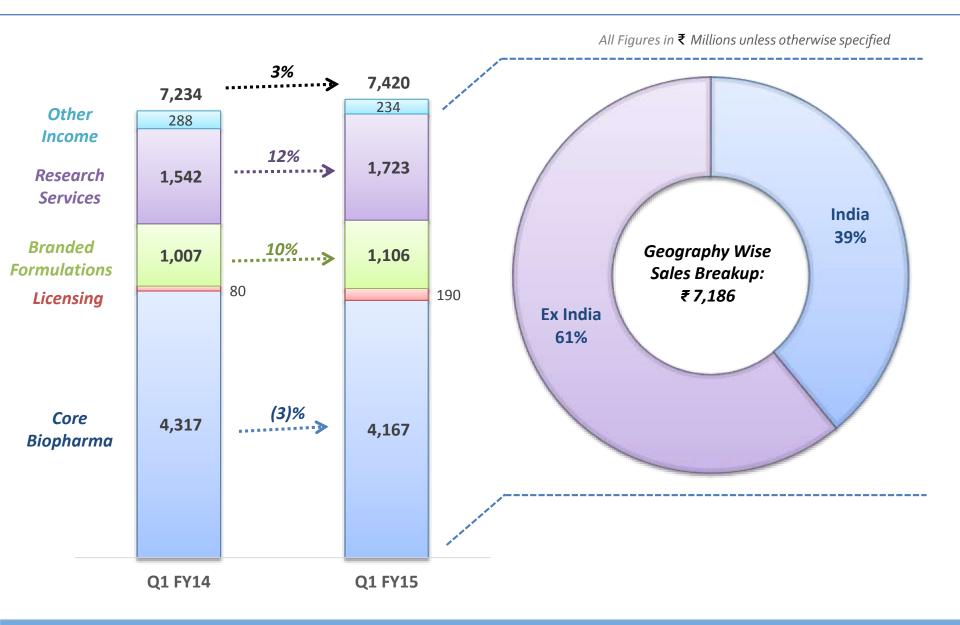


All Figures in ₹ Millions

	FY 10	FY 11	FY 12	FY 13	FY 14	Q1 FY15
Revenue	14,930	18,579	21,483	25,380	29,332	7,420
Less: Other Income	324	516	993	1,103	804	234
Less: Licensing Income	507	1,525	1,266	246	149	190
<b>Core Revenues</b>	14,099	16,538	19,224	24,031	28,379	6,996
EBITDA	4,551	5,733	5,791	5,957	7,429	1,907
Add: R&D Expense	785	1,183	1,366	1,640	1,310	311
Less: Other Income	324	516	993	1,103	804	234
Less: Licensing Income	507	1,525	1,266	246	149	190
Net EBITDA	4,505	4,875	4,899	6,248	7,786	1,794
Net EBITDA Margin	32%	29%	25%	26%	27%	26%

#### **Revenue: Detailed**









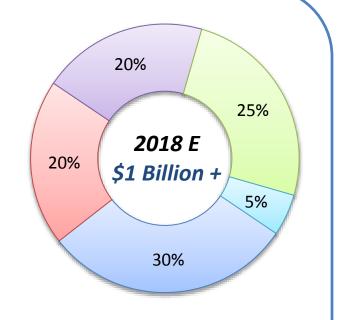
# Outlook

# **Aspiring for \$1 Billion in Revenues in 2018**



# **Key Focus Areas**

- Small Molecules Improved product Mix
- Biosimilars Geographical Expansion in semi regulated and regulated markets
- Branded Formulations Differentiated Value offerings
- Research Services Sustained Growth Momentum
- Novel Molecules Out-licensing and Global Development



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

# **Business Structure & Holdings**





#### **BIOPHARMA SUBSIDIARIES**

Biocon Research , India | 100% R&D- Novel Molecules & Biosimilars

Biocon Sdn. Bhd, Malaysia | **100%** Overseas subsidiary

Biocon SA, Switzerland | **100%** *Overseas subsidiary* 

NeoBiocon, UAE | **50%** *Overseas subsidiary* 

#### **RESEARCH SERVICES**

Syngene International, India | ~88% Custom research, drug discovery

Clinigene International, India | **100%** *Clinical development* 

Spanning the entire Value Chain with capabilities ranging from discovery to manufacturing

#### **Investor Contacts**



For updates and specific queries, please visit <u>www.biocon.com</u> or contact

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# **Appendix**



# **The Biologics Opportunity: Top Selling products 2013**

#	Drug Name	Nature	2013 Sales	<b>2009 Sales</b>	CAGR (%)
1	Humira	MAb	11.0	5.6	19
2	Enbrel	Recombinant product	8.8	6.5	8
3	Remicade	MAb	8.4	5.9	9
4	Advair	Small Molecules	8.3	8.0	1
5	Lantus	Recombinant product	7.6	4.3	15
6	Rituxan	MAb	7.5	5.6	7
7	Avastin	MAb	6.8	5.7	4
8	Herceptin	MAb	6.6	4.9	8
9	Januvia	Small Molecule	6.2	1.9	34
10	Crestor	Small Molecule	6.1	4.8	6

5/9 molecules in our biosimilar portfolio are part the global top-10 selling drugs list