



**October 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

### **Q2 FY15 Highlights**



# Financial Performance

- Group Revenue at ₹ 7,726 Million (3% YoY growth)
- YoY Growth\* across verticals:

Business Vertical	Absolute Growth (%)
Biopharma	(1)
Branded Formulations	17
Biopharmaceuticals	2
Research Services	2
Total Sales	2

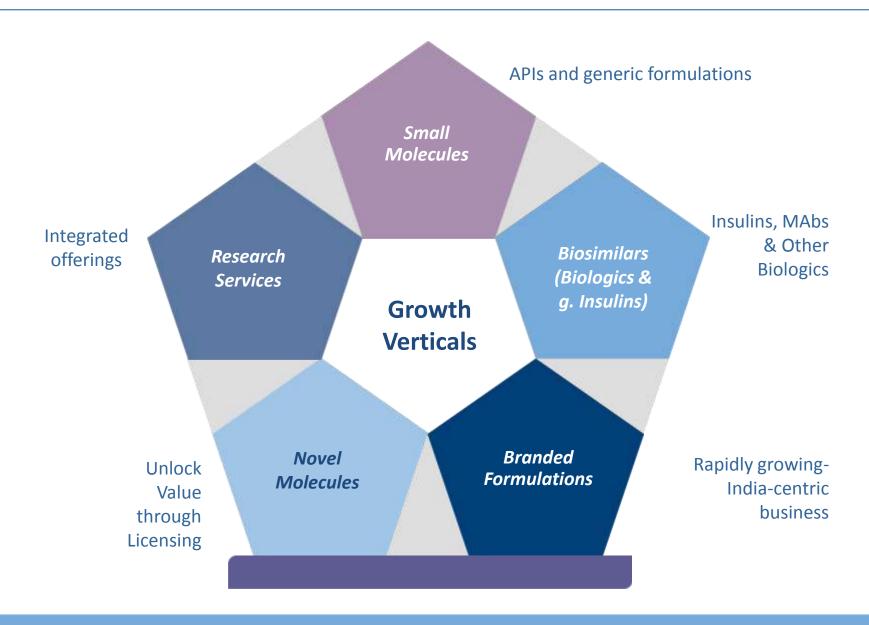
- EBITDA at ₹ 1,879 Million (EBITDA Margin: 24%)
- R&D Expense: ₹ 350 Million (6% of Biopharmaceuticals Revenue)
- PAT at ₹ 1,020 Million (PAT Margin: 13%)

#### **Events**

- Biocon buys back GE Capital's 7.69% stake in Syngene
- Our partner Mylan initiates phase 3 trial of insulin glargine in US

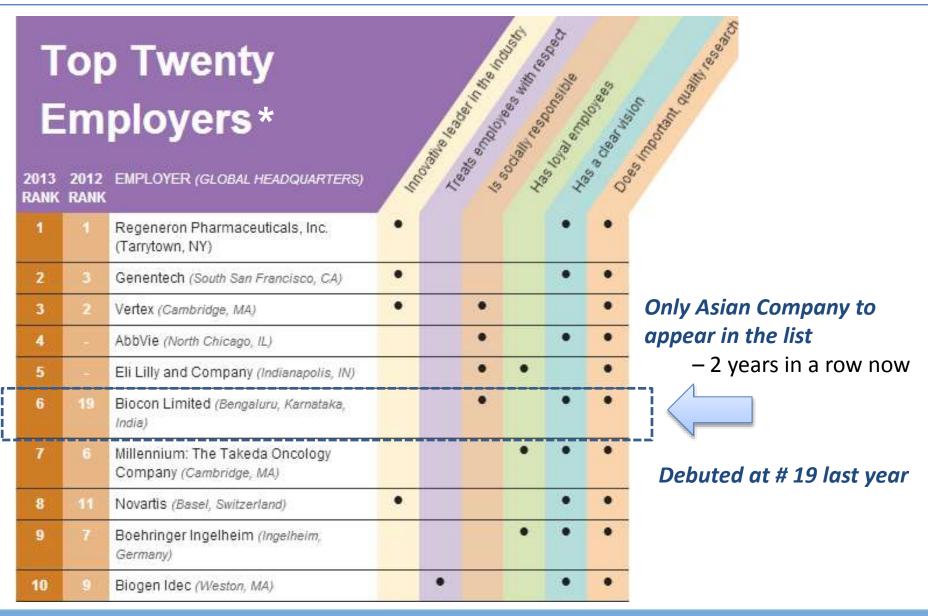
# **Growth Verticals: Aligned with Shifting Paradigms**





# 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)

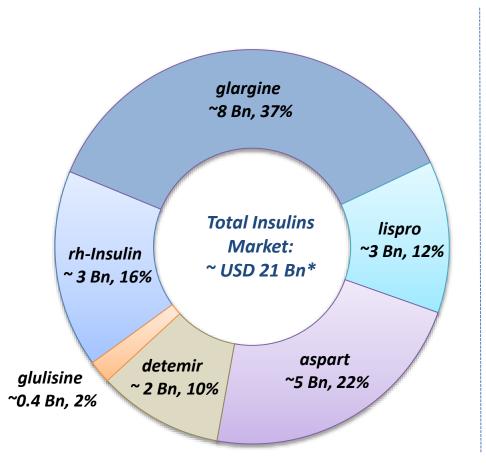
Monoclonal Antibodies (Trastuzumab, Bevacizumab, Adalimumab)

Other Biologics (Etanercept, Peg-filgrastim)

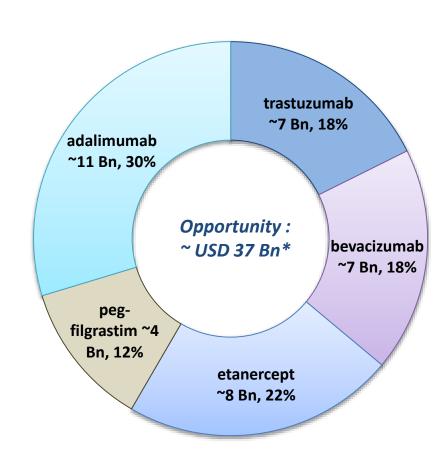
# **Biosimilars: Opportunity**



#### The Insulin Pie

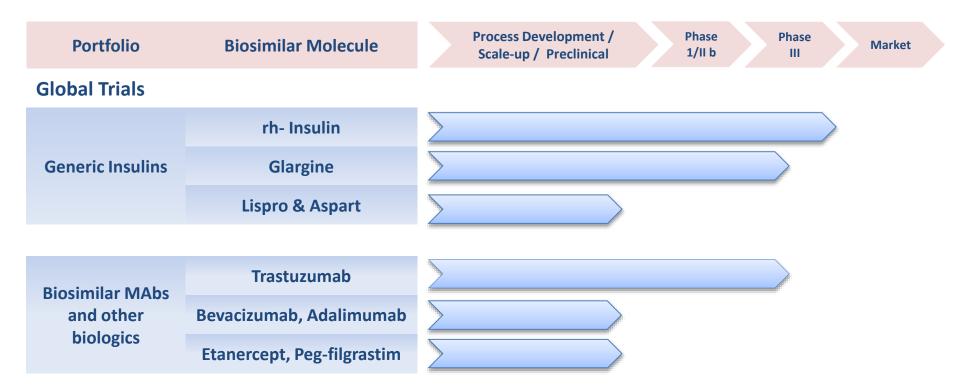


#### **Biosimilar MAbs & Other Biologics**



### **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

#### **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

Capital Investment of ~\$ 200 Mn in the first phase

**Expected Commissioning: FY15** 

Plant Qualification, Product Stability Testing: To start in FY16





#### **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** 





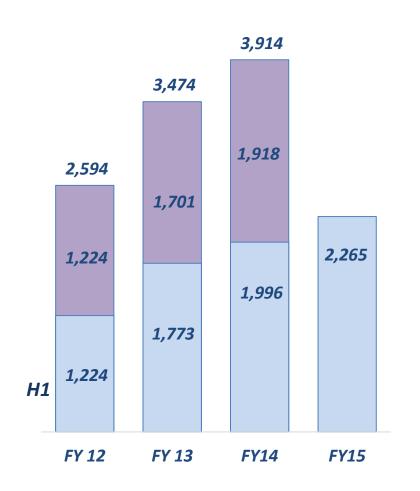
#### Hospital: Critical Care



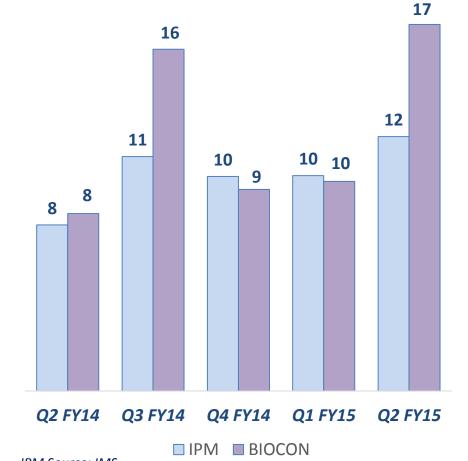




# **Financial Performance**



# Revenue Growth benchmarking



Revenues in ₹ Million

IPM Source: IMS

#### Branded Formulations: Alzumab™



#### **Key Differentiators**

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

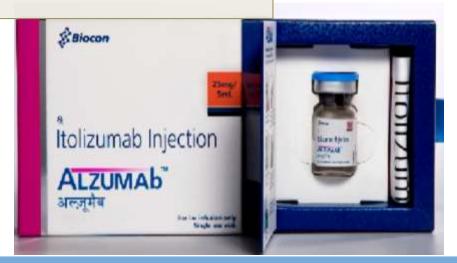
Excellent clinical remission & safety data in phase III for Psoriasis

**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	
	Opininamiology	Q11-1007	
	Oncology	ADXS-HPV	
	Diabetes	IN-105	
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	Oncology	Anti CD – 20	
	050.057	7	
	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.

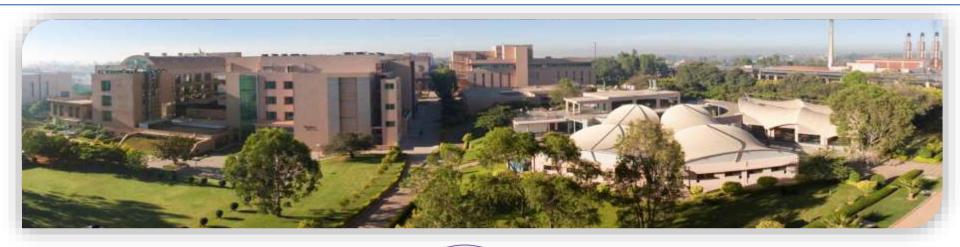
Partnership encompasses **Financial, Strategic and Clinical Support** throughout the development phase

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



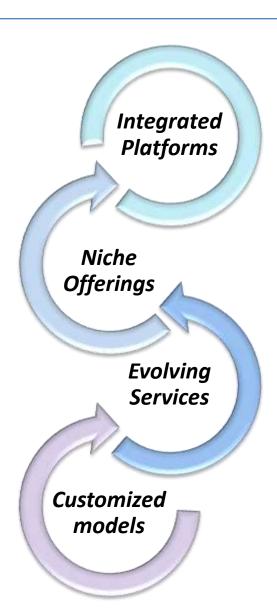
India's largest CRO with 2,000 + scientists, working with 16 of the Top 20 pharma companies in the world.

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

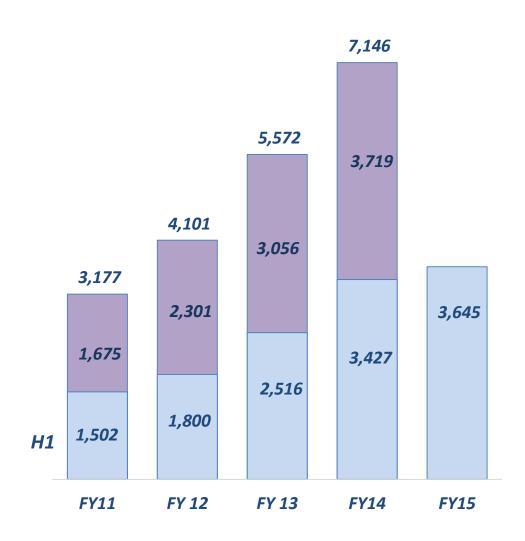
#### **Research Services: Performance**



Revenues in ₹ Million

#### **Performance drivers:**

- Strategic Partnerships
- Innovative business models
- Customer centricity
- Affordable innovation
- Focus on productivity





# **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
R&D Spend	785 17	1,183 26	<b>1,366 28</b>	1,640 <mark>30</mark>	1,310 22
EBITDA	4,551 97	5,733 <mark>125</mark>	5,791 120	5,957 <b>110</b>	7,429 <b>123</b>
Net profit*	2,729 58	3,399 <sub>74</sub>	3,384 70	3,241 60	4,137 69
EPS <i>(FV: ₹5)</i>	13.6	17.0	16.9	25.4	20.7

	H1 FY15	H1 FY14	
Revenue	15,146   252	14,678   248	
R&D Spends	661   11	816   14	
% of Biopharmaceutical Sales #	6%	8%	
EBITDA	3,786   63	3,622   61	
EBITDA Margin	25%	25%	
Net Profit	2,050   34	1,958   33	
PAT Margin	14%	13%	
EPS	10.3	9.8	

FY10-14: Avg.exch.rate in that fiscal ; H1 FY14: USD 1 = ₹ 59.11; H1 FY15: USD 1= ₹ 60.19

# **Core Business Margins: Detailed**

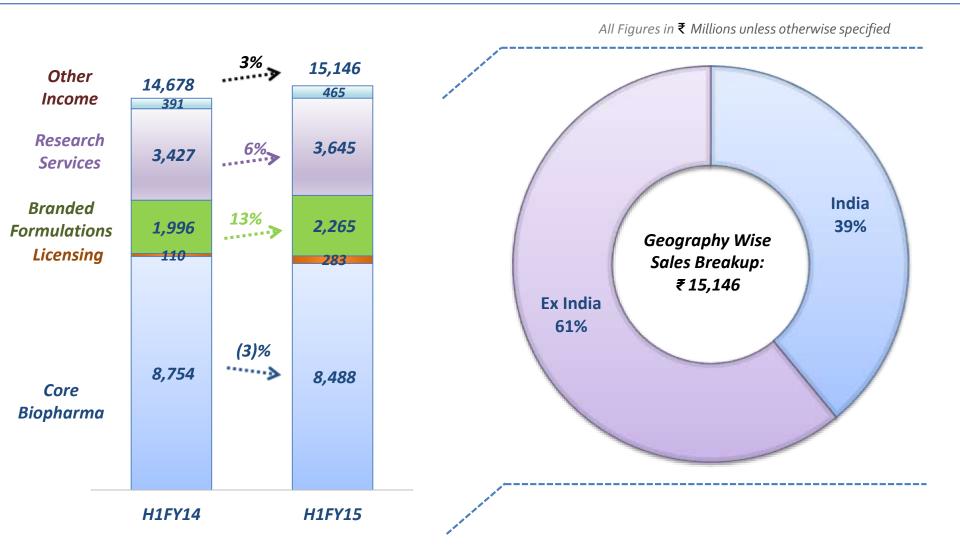


All Figures in ₹ *Millions* 

	FY 10	FY 11	FY 12	FY 13	FY 14	H1 FY15
Revenue	14,930	18,579	21,483	25,380	29,332	15,146
Less: Other Income	324	516	993	1,103	804	465
Less: Licensing Income	507	1,525	1,266	246	149	283
Core Revenues	14,099	16,538	19,224	24,031	28,379	14,398
EBITDA	4,551	5,733	5,791	5,957	7,429	3,786
Add: R&D Expense	785	1,183	1,366	1,640	1,310	661
Less: Other Income	324	516	993	1,103	804	465
Less: Licensing Income	507	1,525	1,266	246	149	283
Net EBITDA	4,505	4,875	4,899	6,248	7,786	3,699
Net EBITDA Margin	32%	29%	25%	26%	27%	26%











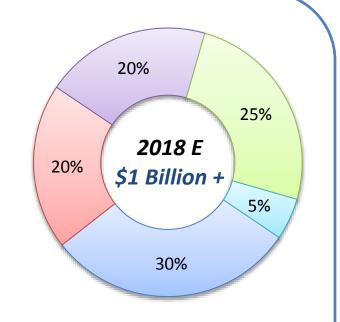
# Outlook

# **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 | **51%** *Overseas subsidiary* 

#### **RESEARCH SERVICES**

Syngene International, India | ~96% 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	<b>2013</b> 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