

# Innovative Science Affordable Medicine

Investor Presentation November 2014

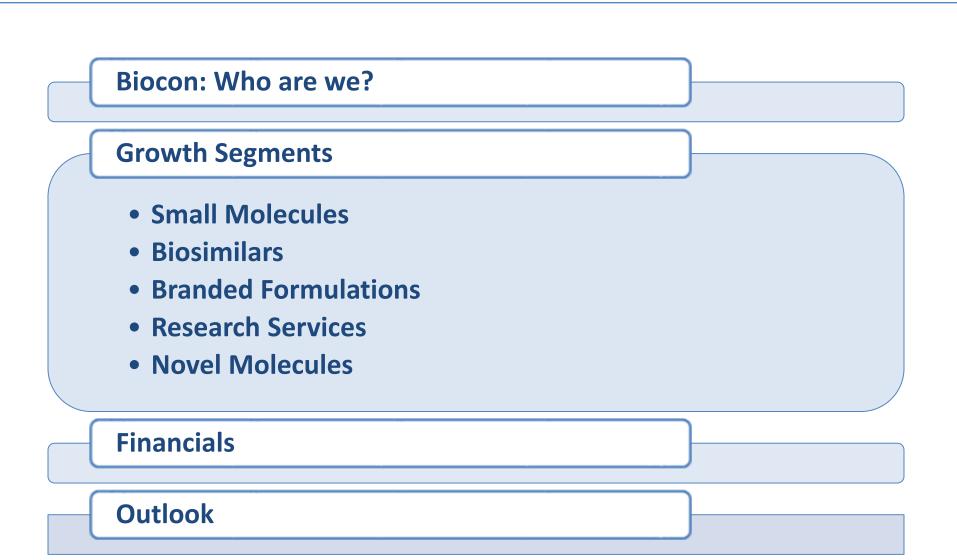
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Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated 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?**



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

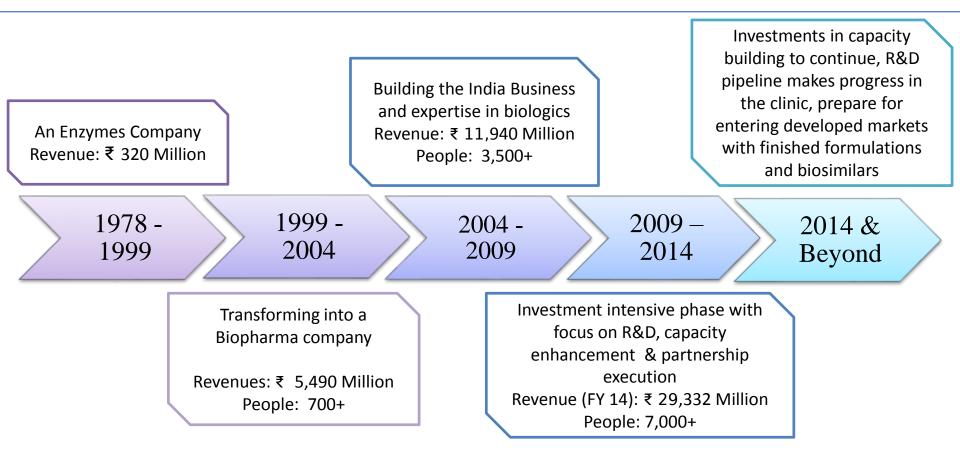
#### Value Creation along 3 axes:

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* 





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

## H1 FY15 Highlights



Financial Performance

**Events** 

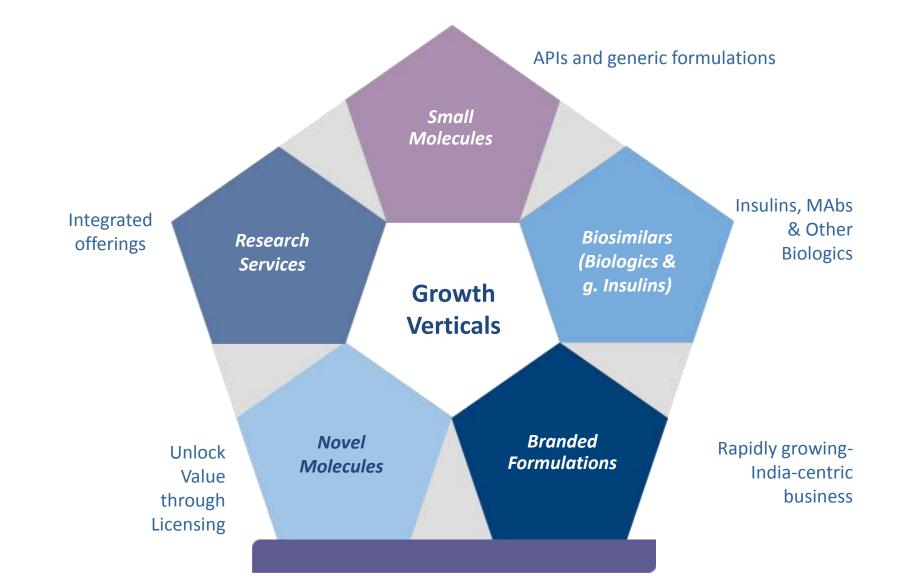
- Group Revenue at ₹ 15,146 Million (3% YoY growth)
- YoY Growth\* across verticals:

Business Vertical	Absolute Growth (%)
Biopharma	(1)
Branded Formulations	14
Biopharmaceuticals	2
Research Services	6
Total Sales	3

- EBITDA at ₹ 3,786 Million (EBITDA Margin: 25%)
- R&D Expense: ₹ 661 Million (6% of Biopharmaceuticals Revenue)
- PAT at ₹ 2,050 Million (PAT Margin: 14%)
- Biocon buys back GE Capital's 7.69% stake in Syngene
  - Silver Leaf Oak agrees to buy 10% stake in Syngene, valuing Syngene at ₹ 38,000 Million\*\*
    - Our partner Mylan initiates phase 3 trial of insulin glargine in US
    - Syngene and Bristol Myers Squibb extend research collaboration

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





## Amongst the Top 20 Global Biotech Employers Worldwide



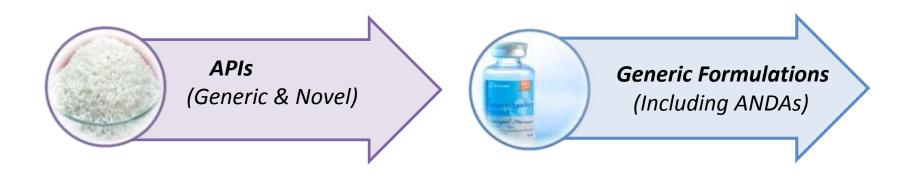
2013	m	<b>D Twenty</b> <b>ployers *</b> EMPLOYER (GLOBAL HEADQUARTERS)	and the second	Tra- Halle	to another man age ince	Hac dellines with feer	Ha entre perto	On Clean line	Sol - Contraction of the sol of t
1	1	Regeneron Pharmaceuticals, Inc. (Tarrytown, NY)	•				•	•	
2	3	Genentech (South San Francisco, CA)	•				•	٠	
3	2	Vertex (Cambridge, MA)	•		•			٠	Only Asian Company to
4	5	AbbVie (North Chicago, IL)			•		•	٠	appear in the list
5		Eli Lilly and Company (Indianapolis, IN)			•	•		٠	– 2 years in a row now
6	19	Biocon Limited (Bengaluru, Karnataka, India)			•		•	•	
7	6	Millennium: The Takeda Oncology Company <i>(Cambridge, MA)</i>				٠	•	•	Debuted at # 19 last year
8	11	Novartis (Basel, Switzerland)	•				•	٠	
9	7	Boehringer Ingelheim (Ingelheim, Germany)				•	•	•	
10	9	Biogen Idec (Weston, MA)		•			•	٠	

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



# **Business Segments: Snapshot**

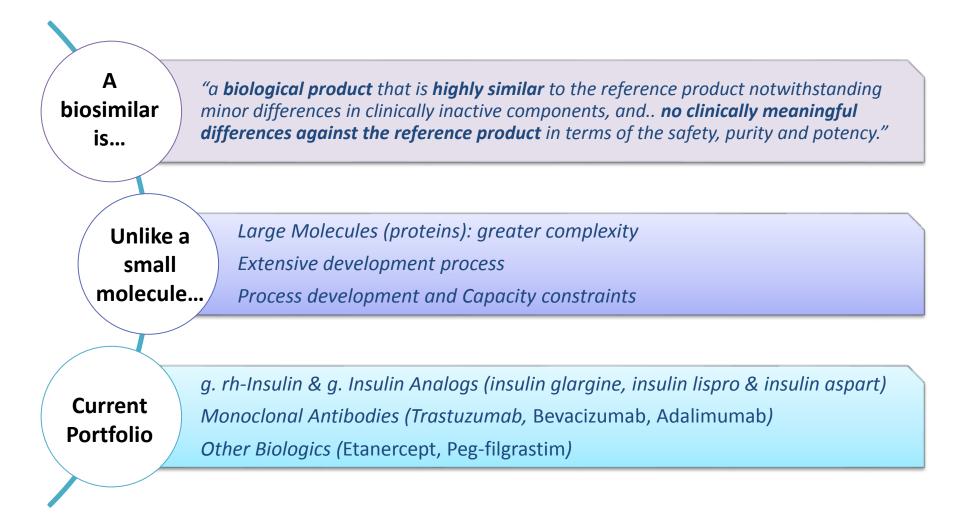




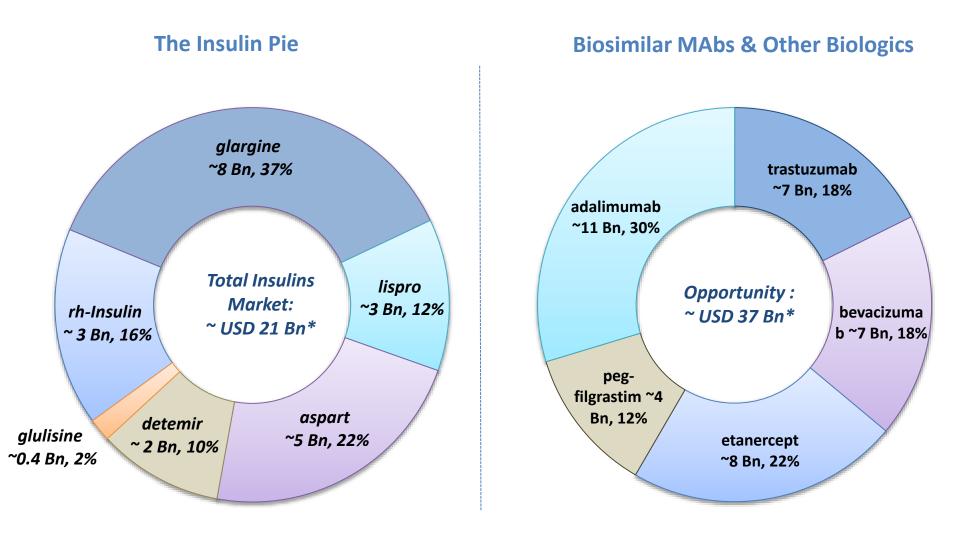
- Product Portfolio which leverage our core fermentation capabilities and have a high degree of complexity.
- Early mover in niche products coupled with economies of scale.
- Portfolio based Approach.
- Making investments' to forward integrate from APIs to generic formulations, including ANDAs.

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









\*Market Size of innovator products MAT March 2014, All figures rounded off to nearest USD Billion, %ages on absolute numbers

## **Biosimilars: Pipeline**



Portfolio	<b>Biosimilar Molecule</b>	Process Development / Scale-up / PreclinicalPhase 1/II bPhase IIIMarket
<b>Global Trials</b>		
	rh- Insulin	
Generic Insulins	Glargine	
	Lispro & Aspart	
Biosimilar MAbs	Trastuzumab	
and other	Bevacizumab, Adalimumab	
biologics	Etanercept, Peg-filgrastim	

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



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

Structure: Upfront Payment + Cost Sharing + Supplies + Profit Sharing<sup>#</sup>

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.



**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<sup>®</sup> & Basalog<sup>®</sup>: India's largest selling generic insulin & long acting analog
  - BioMAb EGFR<sup>®</sup>: India's 1<sup>st</sup> indigenous novel MAb for head & neck cancer
  - Alzumab<sup>™</sup>: India's 2<sup>nd</sup> indigenous novel MAb for Psoriasis
  - ★ CANMAb<sup>™</sup>: World's most affordable trastuzumab to be commercialized
  - Cytosorb<sup>®</sup>: First-in-class Cytokine Filter





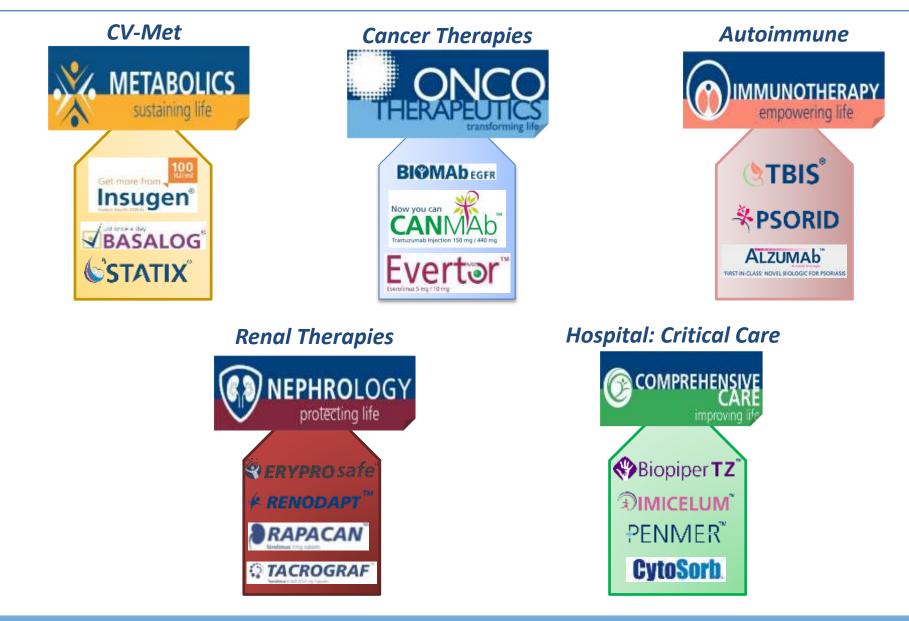






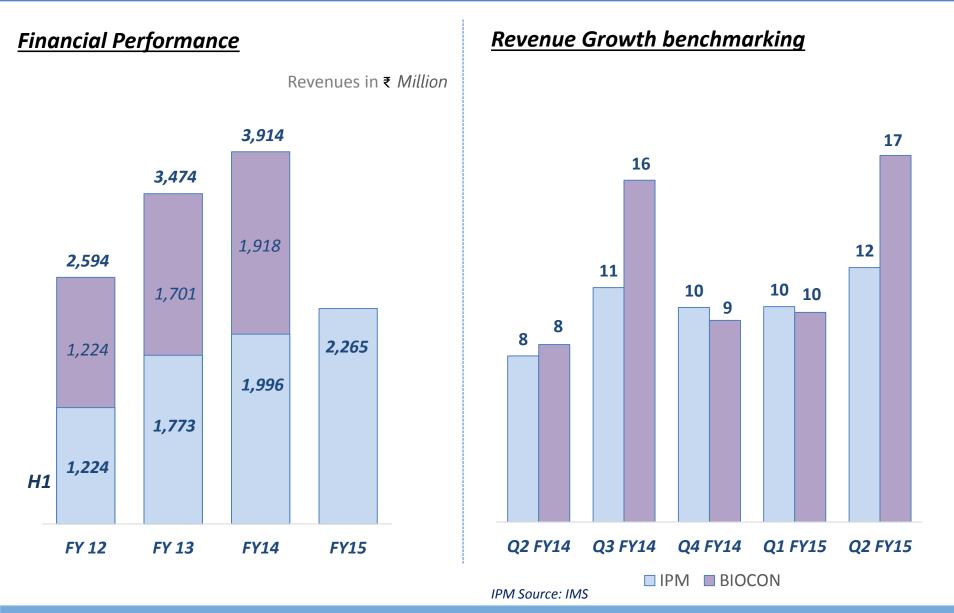
## **Branded Formulations: Key Brands**





## **Branded Formulations: Sustained Growth**







#### **Key Differentiators**

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

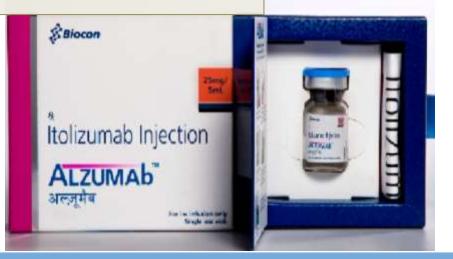
Excellent clinical remission & safety data in phase III for Psoriasis

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

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

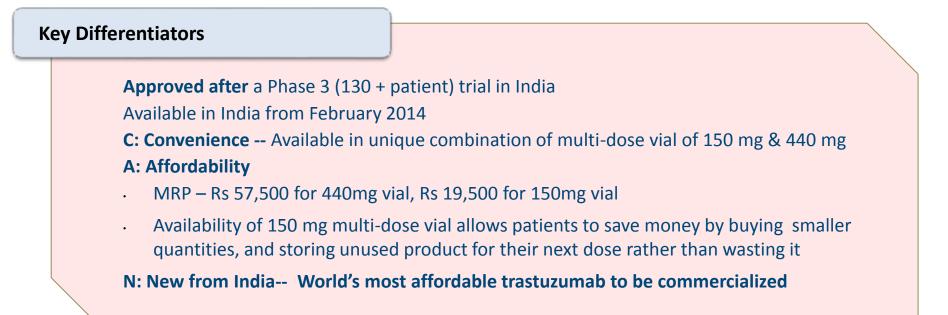
**Commercialised in India** post a successful Phase III trial in Psoriasis (200+ patients);

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



## **Branded Formulations: CANMAb**<sup>™</sup>







# **Novel Molecules: Pipeline**



Therapeutic Area	Molecule	Discovery Pre- Clinical 1 II III Market	
Oncology	Nimotuzumab	Commercialized in India	8
Autoimmune	Itolizumab	Commercialized in India	1
Ophthalmology	QPI-1007		
Oncology	ADXS-HPV		
Diabetes	IN-105		
Oncology	Anti CD – 20		
Oncology	Fusion Proteins	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

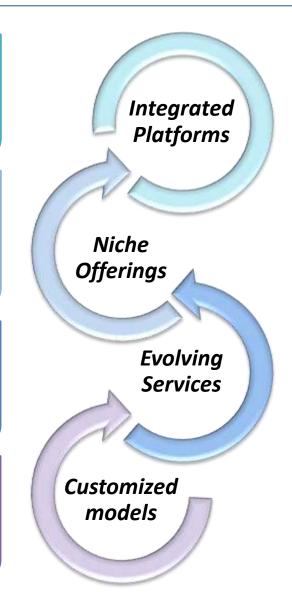


India's largest CRO with 2,000 + scientists, working with 16 of the Top 20 pharma companies in the world. Capital Investment of ~\$130 Mn



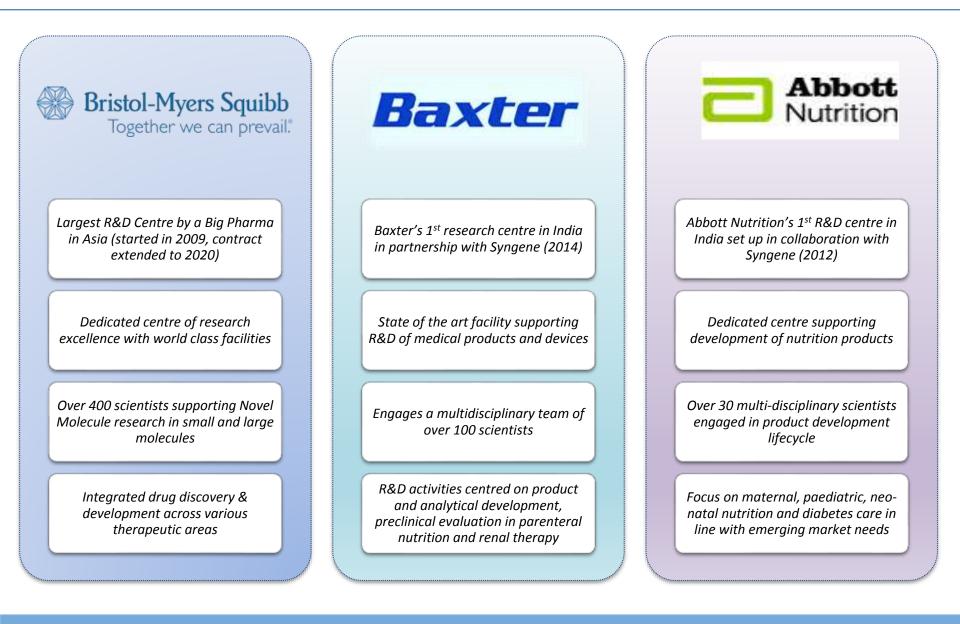


- Integrated Drug Discovery and Development
- Biologics Discovery and Development
- Syngene- Clinigene axis
- Bioanalytical testing of small and large molecules
- Antibody Drug Conjugate (ADC) development
- Unique *In-Vivo* Models- Human tumour tissue Xenograft
- Early and rapid toxicology evaluation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



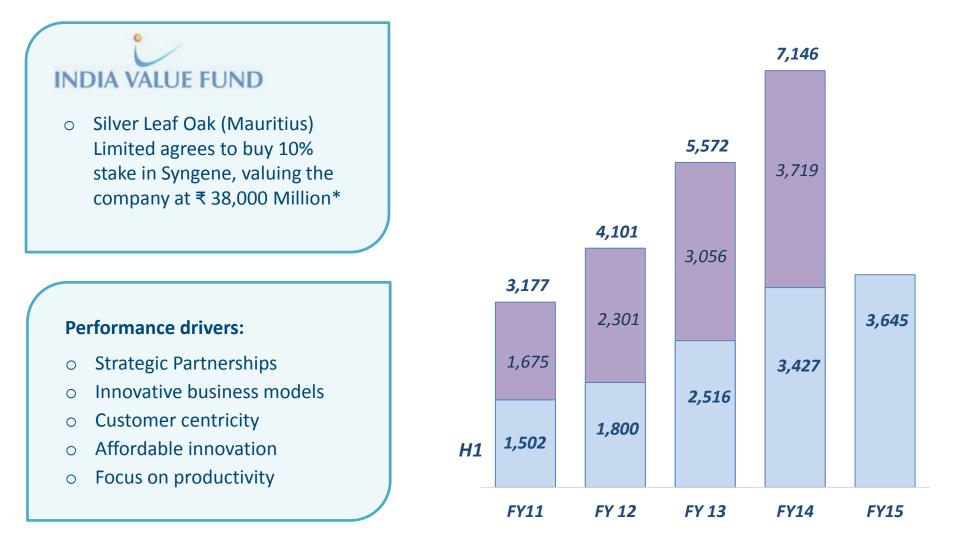
## **Research Services: Key Customers**







Revenues in ₹ *Million* 









	All Figures in ₹ <i>Millions / USD Mn</i> except EPS									
(	FYı	-0	FY	<b>11</b>	FY:	12	F`	Y13	F	(14
Revenue	14,930	318	18,579	407	21,483	445	25,380	467	29,332	487
R&D Spend	785	17	1,183	26	1,366	28	1,640	30	1,310	22
EBITDA	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
EPS (FV: ₹ 5)	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 <sup>#</sup>	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

*# Biopharmaceutical Sales including Branded Formulations |\* Net Profit Pre exceptional items* 

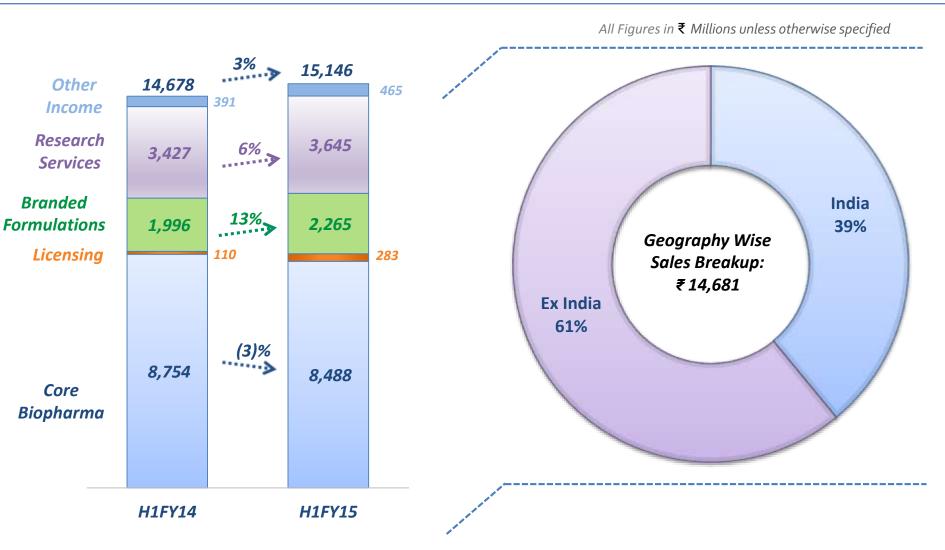


All Figures in ₹ *Millions* 

	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%

## **Revenue: Detailed**





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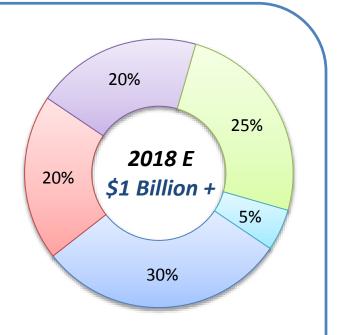




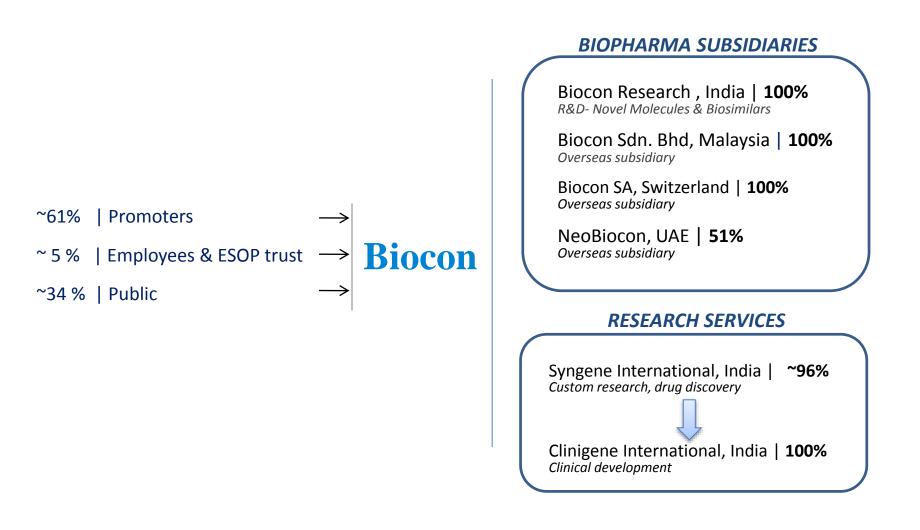
# **Key Focus Areas**

- 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)







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



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

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## The Biologics Opportunity: Top Selling products 2013

#	Drug Name	Nature	2013 Sales	2009 Sales	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