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# Innovative Science Affordable Medicine



**Investor Presentation  
May 2013**

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?**

**Mission:** *“To be an integrated biotechnology enterprise of global distinction”*

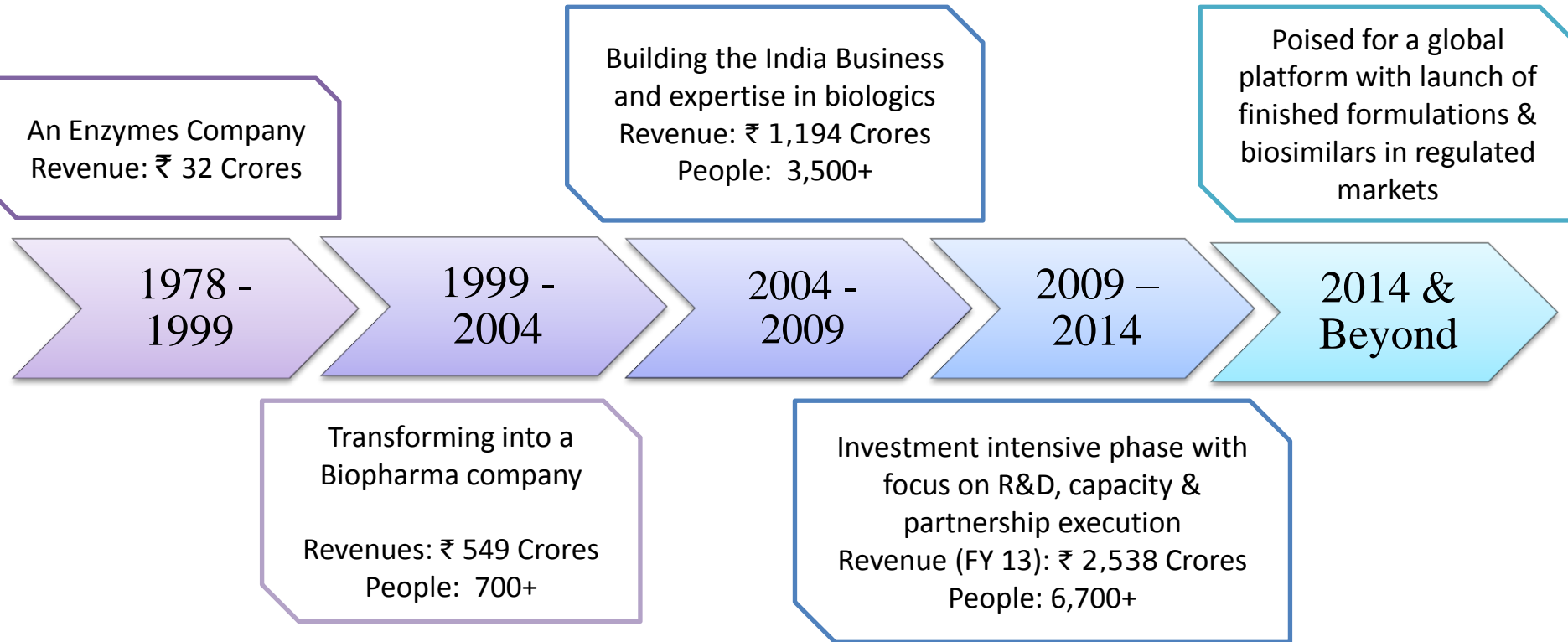
**Value Creation along 3 axes:**

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



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

### ***Novel Molecules***

- ❖ Entered into an option agreement with BMS for our novel asset, a prandial oral insulin: IN-105
- ❖ Itolizumab: Marketing Approval received from DCGI for plaque Psoriasis in India

### ***Biosimilars***

- ❖ Mylan expands existing partnership to encompass generic insulin analogs
- ❖ Part II of the EU Phase III trial for generic rh-Insulin completed. Part 1 of the trial successfully established the efficacy endpoint with comparable safety & efficacy with innovator products.
- ❖ Global Phase I trial for generic Insulin Glargine successfully completed.
- ❖ Global Phase III trial initiated for Biosimilar Trastuzumab post the successful completion of its Global Phase I
- ❖ Recruitment completed for India Phase III trial of Biosimilar Trastuzumab

## FY13 Highlights (2)

### **Other Milestones**

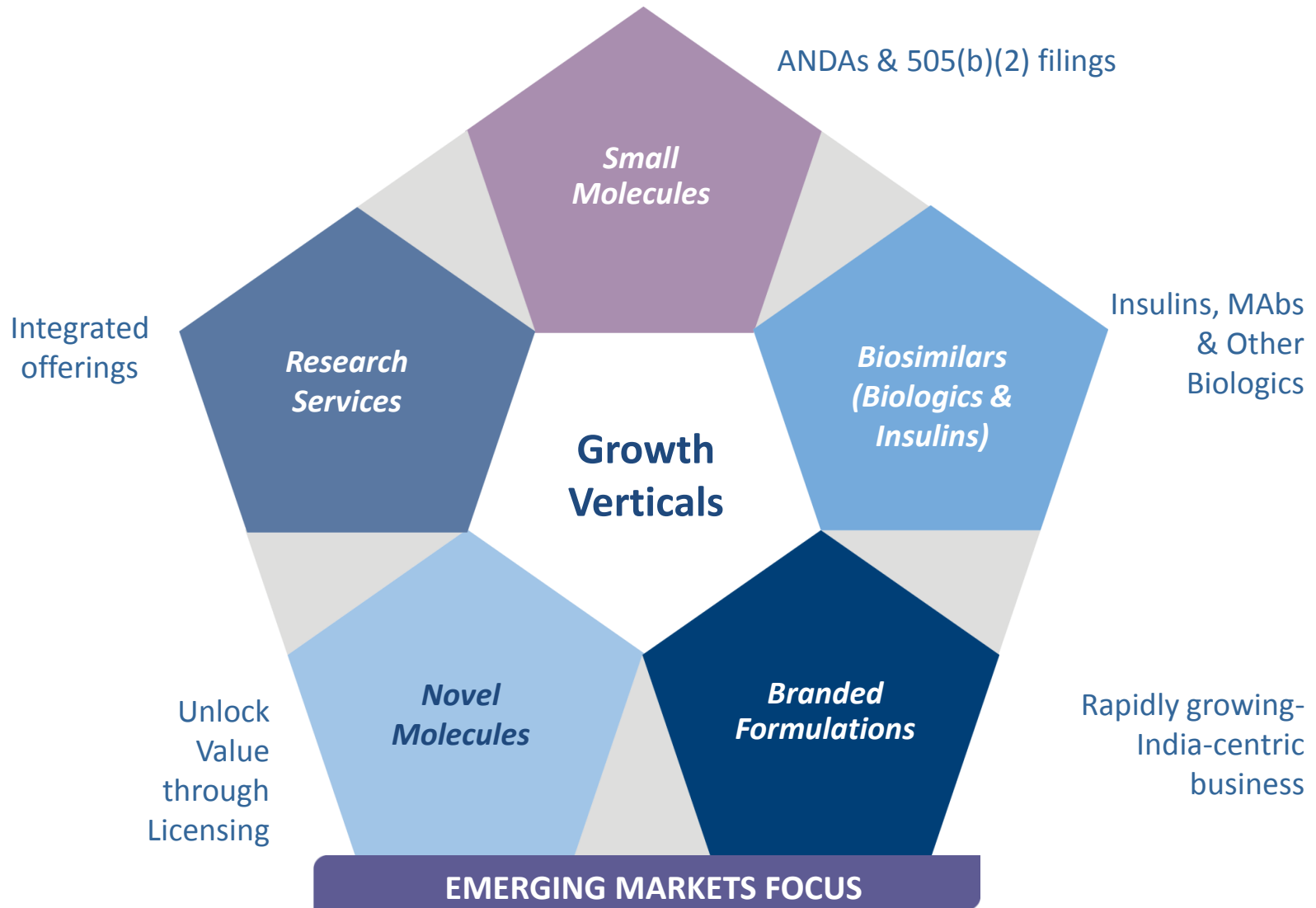
- ❖ GE Capital invests ₹125 Crores in Syngene for a 7.69% equity share
- ❖ Commencement of Abbott Nutrition Research & Development Centre
- ❖ Inauguration of Biocon Research Centre
- ❖ Becomes the only Asian Company to feature in Science magazine's global 'Top 20 Employers' in biotech & pharma.

### **FY13 Financial Performance**

- ❖ Group Revenue at ₹ 2,538 Crores (18% YoY growth)
- ❖ Growth\* across all verticals:
  - ❖ Biopharma – 10%
  - ❖ Branded Formulations - 34%
  - ❖ Research Services - 36%
- ❖ EBITDA at ₹ 596 Crores (EBITDA Margin: 23% )
- ❖ R&D Expense: 11% of Biopharma Revenue



# Growth Verticals: Aligned with Shifting Paradigms



# Aligning For Growth: Reorganizing for greater synergy

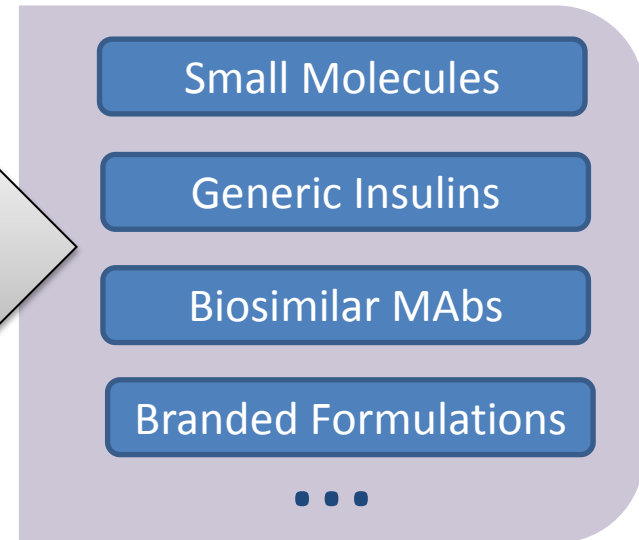
## Function Based Organization -----> Business Units

- ⚡ Sustaining the Entrepreneurial Spirit: Agility in decision making
- ⚡ Responsibility with Accountability
- ⚡ Greater Synergy amongst functions: Aligning people to the greater goal

### *Earlier Organization Structure*



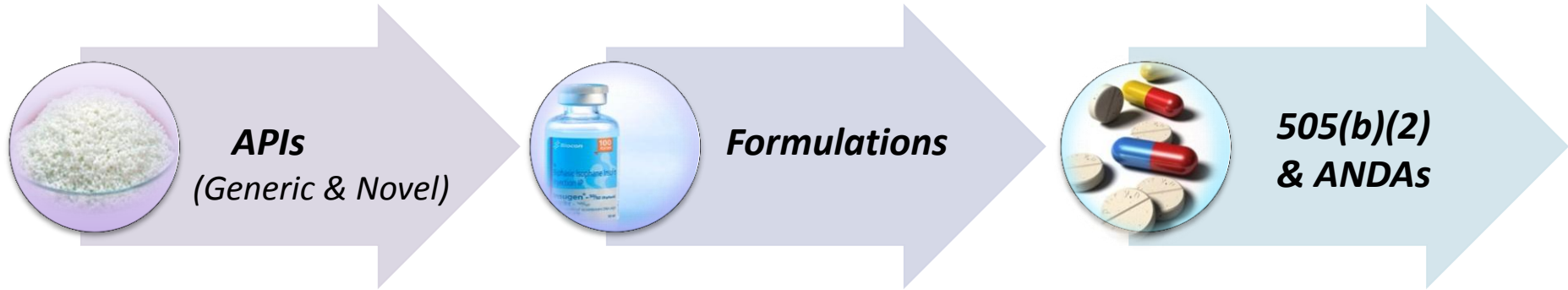
### *New Organization Structure*





**Growth Segments: Snapshot**

# Small Molecules



- ❖ 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

Current Portfolio	Constituents
Statins	Simvastatin, Atorvastatin, Lovastatin, Rosuvastatin, Fluvastatin & Pravastatin
Immuno suppressants	Tacrolimus, 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...**

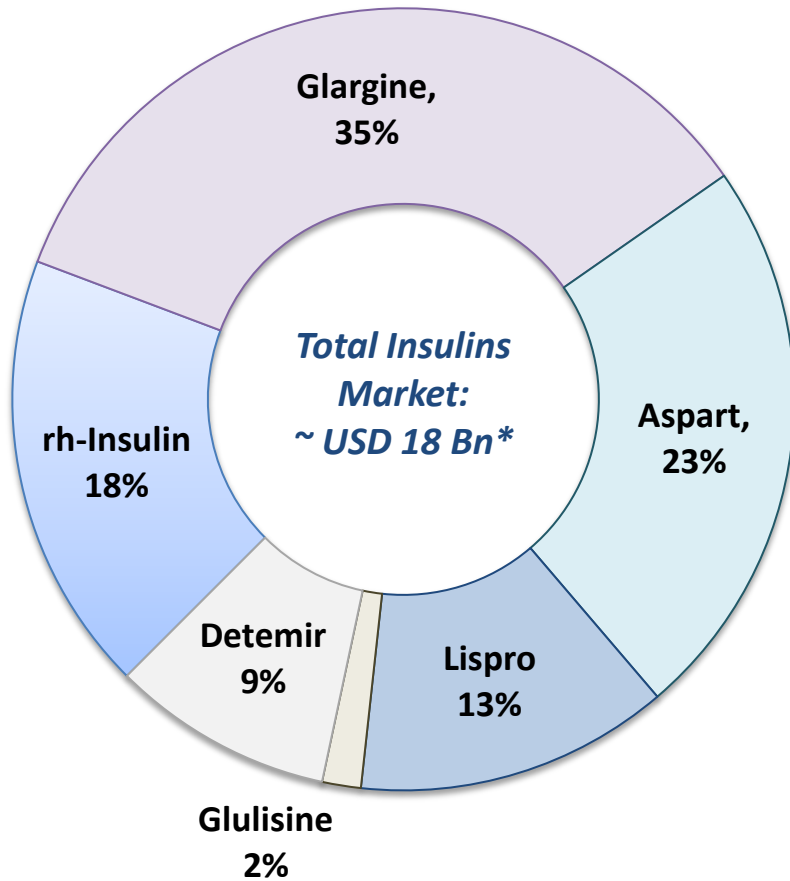
*Large Molecules (proteins): greater complexity  
Very difficult to make and demonstrate bio-similarity; Extensive development process  
Process development and Capacity constraints*

**Current Portfolio**

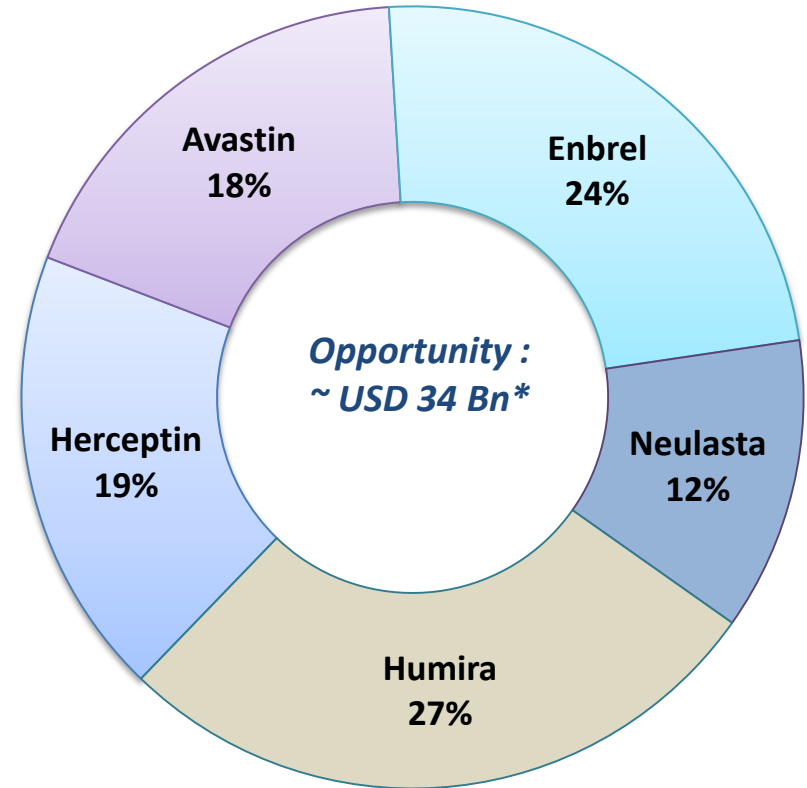
*Insulin & Insulin Analogs (4)  
Monoclonal Antibodies (3)  
Other Biologics (2)*

# Biosimilars: Opportunity

## The Insulin Pie

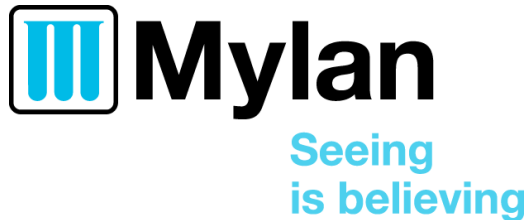


## Biosimilar MABs & Other Biologic



# 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*

	<b>Generic Insulin Analogs</b>	<b>Biosimilar MABs &amp; other Biologics</b>
<b>Global Market Size *</b>	<b>~ USD 13 Bn</b>	<b>~ USD 34 Bn</b>
<b>Portfolio Constituents</b>	Glargine, Lispro & Aspart	Trastuzumab, Bevacizumab, Adalimumab, Eterncept, Peg-filgrastim
<b>Mylan's <i>Exclusive Commercialization</i> Regions</b>	US, Canada, Europe, Australia & New Zealand	All regulated markets
<b>Upfront Received</b>	\$ 20 Mn	\$ 18 Mn

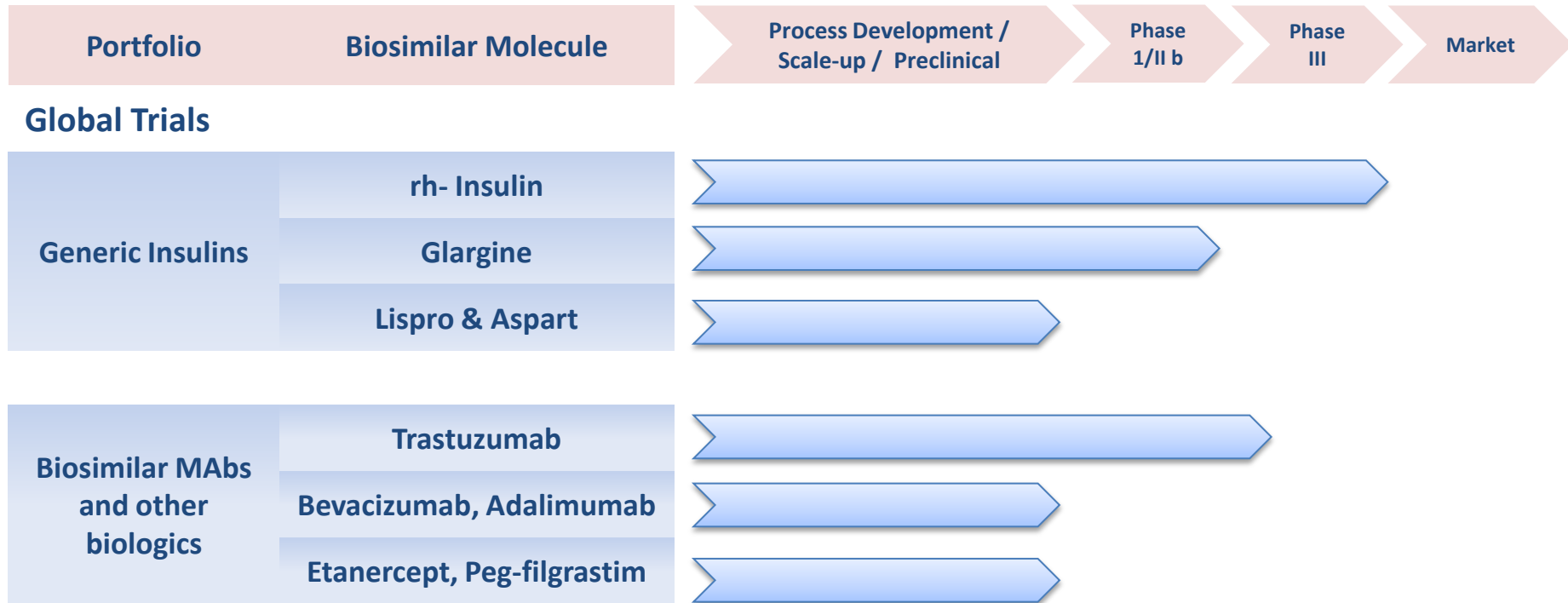
**Structure: Upfront Payment + Cost Sharing + Supplies + Profit Sharing<sup>#</sup>**

*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.*

# Biosimilars: Pipeline



- ⚡ **Emerging Markets First strategy** coupled with a **regional partnership** commercialization approach
- ⚡ Biosimilar Trastuzumab also undergoing an ROW focused, India Phase III trial.
- ⚡ Generic rh Insulin registered in 40+ countries; generic insulin glargine registered in 5+ nations



# Branded Formulations: Snapshot

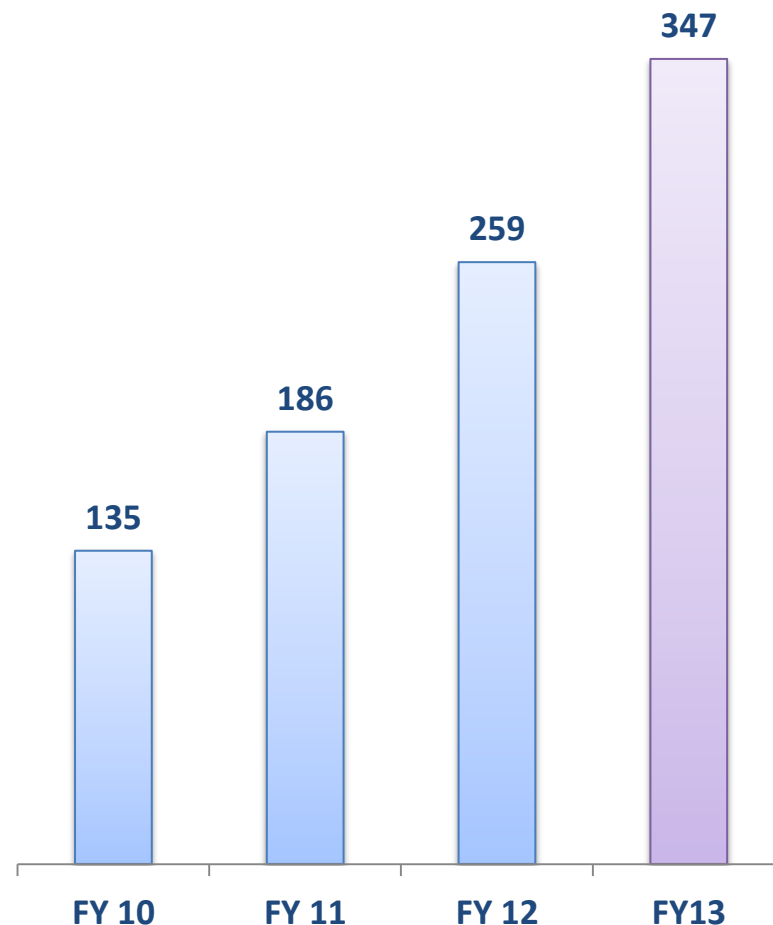
- An India Centric Business with Global Ambitions
- Front Ending of our vertically integrated API & Biologics pipeline
- Portfolio highlights:
  - Insugen & Basalog: India's largest selling generic insulin & analog
  - BioMAb EGFR: India's 1<sup>st</sup> indigenous novel MAb for head & neck cancer

## Branded Formulations: Sustained Growth

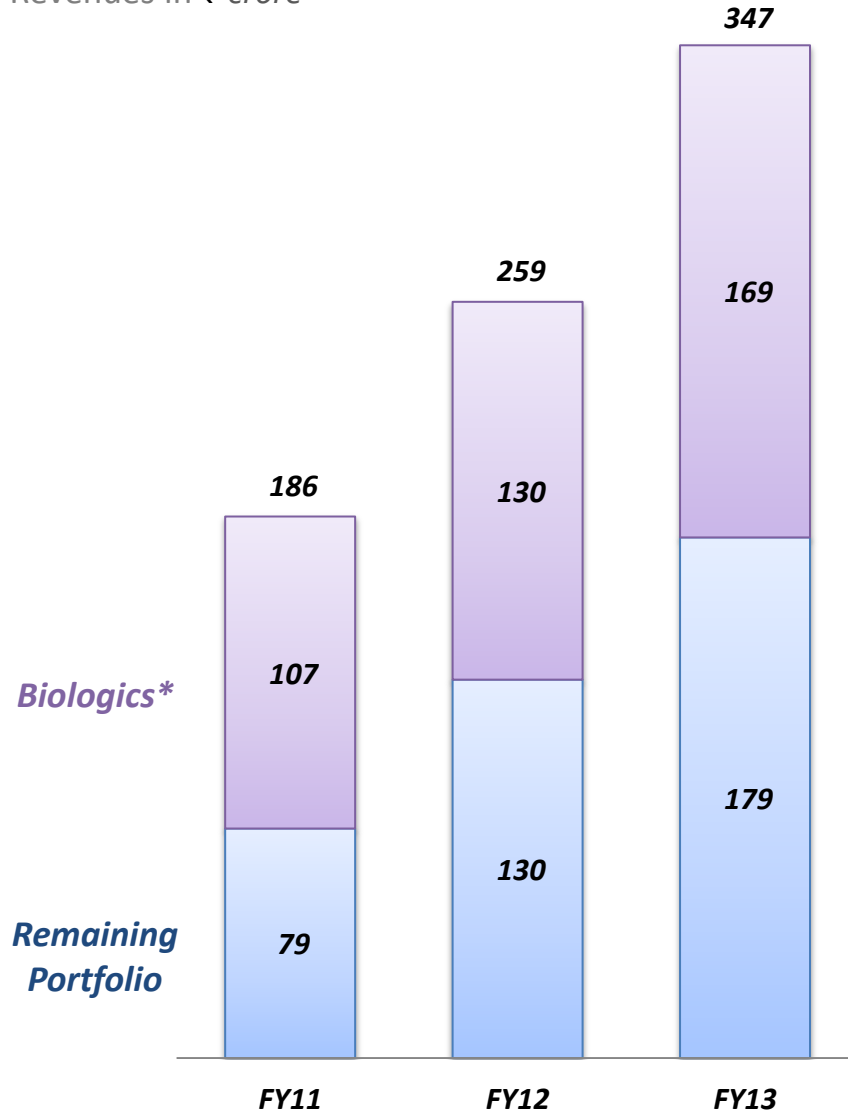
INDIA PRODUCT RANKINGS#	
Cardiology	
Clotide & Myokinase	2
Oncotherapeutics	
BioMAB EGFR	2
Abraxane	3
Evertor & Genxtor	2
Immunotherapy	
Calpsor C, Picon, Tbis	2
Nephrology	
Tacrograf	3
Bio-products	
Ivnex	2
Comprehensive Care	
Genpirome & Cegava TZ	2

Revenues in ₹ crore



# Branded Formulations

Revenues in ₹ crore



## India's Fastest growing Insulin company

- ❖ Biocon: 30% | Sanofi: 16% | Novo: 8%
- ❖ #4 in overall insulin market
- ❖ #3 in the 40 IU Insulin market
- ❖ #1 in the Glargine vial market

### Biocon's Volume Market share<sup>#</sup>

- ❖ 100 IU Insulin: 15%
- ❖ Glargine vials: 84%

## Market Share<sup>#</sup> of other flagship brands:

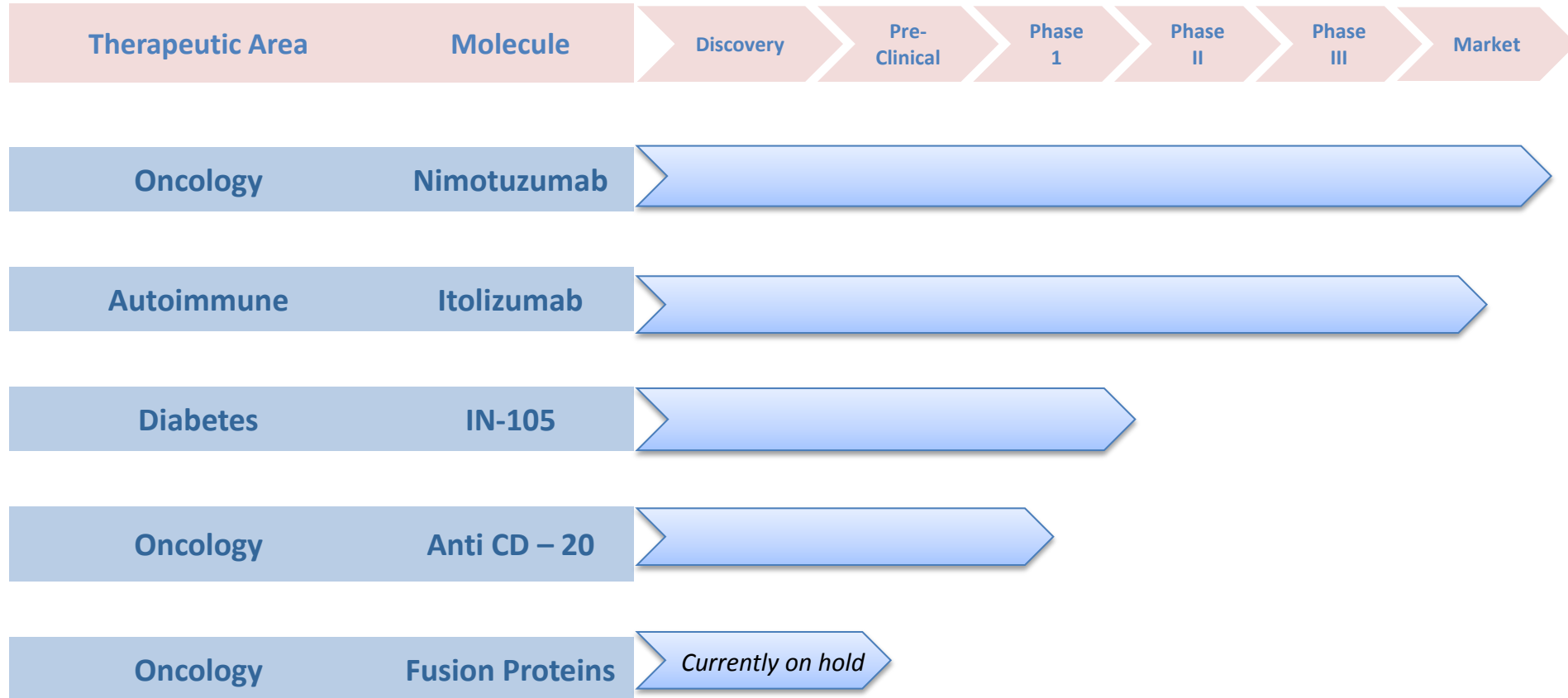
- ❖ BioMAb EGFR: 50%
- ❖ Evertor: 46%
- ❖ Picon: 34%
- ❖ Calpsor C: 33%

\* Includes biosimilars

# Market Share as per latest MAT reports, IPSOS, LASSCHN

# Novel Molecules: Pipeline

## India Trials



- ❖ **Itolizumab:** Marketing Authorization for Psoriasis approved by the Indian drug regulator
- ❖ **Anti CD 20** (BVx 20) has entered the clinic in India
- ❖ Multiple Global Trials planned for **Oral Insulin** in collaboration with BMS

## Novel Molecules: Collaboration

### 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*

---

## Novel Molecules: Product Profile

### Alzumab (Itolizumab- First-in-Class Anti CD6)

**Marketing Authorization for *Itolizumab* (IV delivery)** received from Indian Drug regulator for **Psoriasis**

**Alzumab** India launch in 2013

**2<sup>nd</sup> Novel Biologic** from Biocon's repertoire:  
**First Novel MAb** for Psoriasis developed in India

**US IND to be filed in 2013** to facilitate global clinical trials in Psoriasis, RA and other indications as Sub Q

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

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

Promising preclinical and clinical efficacy data in **other auto immune diseases** (RA, MS)

**Partnership discussions** initiated for **global development** of this **late stage** opportunity

Baseline



12 Weeks



28 Weeks





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

**2000**

**Today**

**India's largest CRO** with 1,500 + scientists, working with 16 of the Top 20 pharma companies in the world.  
Capital Investment of ~\$120 Mn

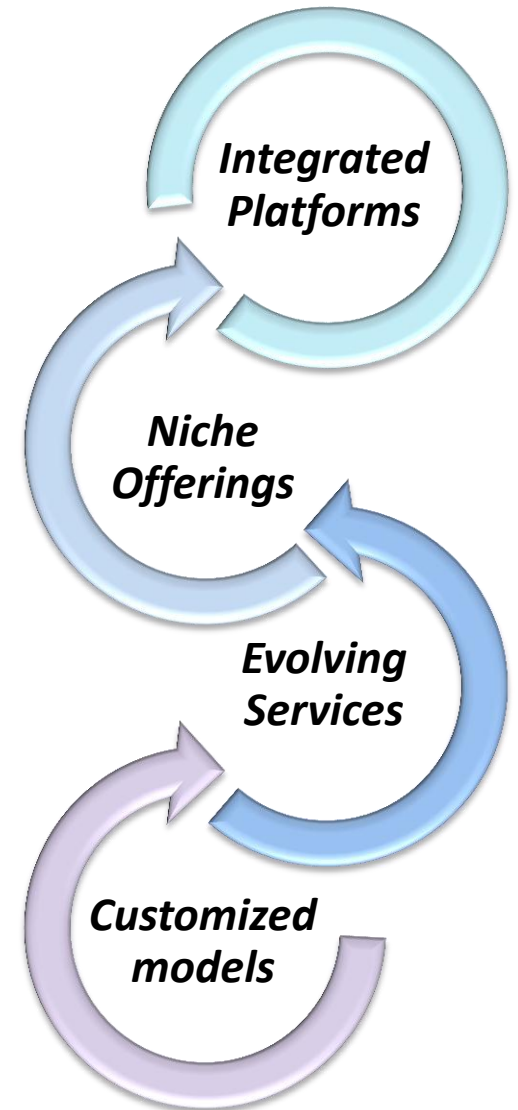
## Research Services: Capabilities & Collaboration Models

- 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



### Bristol-Myers Squibb

Together we can prevail.®

- Dedicated Infrastructure:  
***BMS Biocon Research Centre***
- BMS' largest research facility outside the US
- **7 years contract**, currently in its 4<sup>th</sup> year of operations
- **450+ FTEs** committed to integrated (end-to-end) research in a variety of therapeutic areas



### Abbott Nutrition

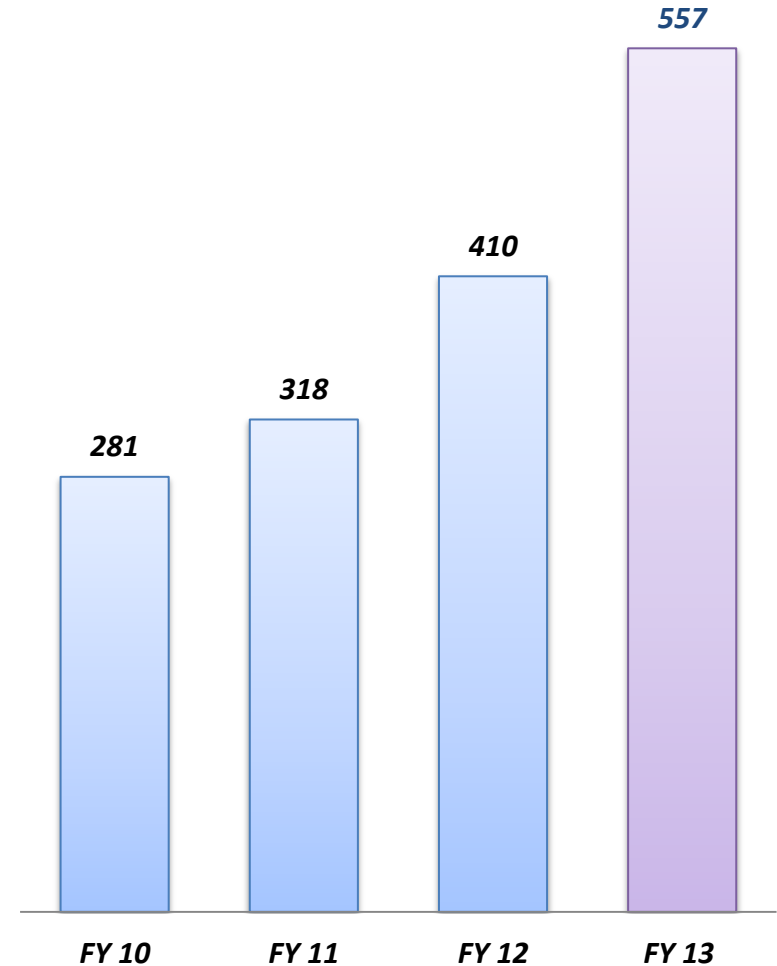
- Dedicated Infrastructure:  
***Abbott Nutrition and R&D Centre***
- ***India focused product development*** addressing local needs with customized offerings tailored to local taste & texture preferences
- **Long term contract for 50+ FTEs** focused on:
  - Maternal & Child Nutrition
  - Diabetes Care



## GE Capital

- PE Investment of ₹ 125 Crores for a 7.69% stake, assigning Syngene a **post money valuation of ₹1,625 Crores**
- 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

Revenues in ₹ crore





**Financials**

# Financial Performance



All Figures in ₹ Crore / USD Mn except EPS

	FY08		FY09		FY10		FY11		FY12	
<b>Revenue</b>	1,090	273	1,194	260	1,493	318	1,858	407	2,148	445
<b>R&amp;D Spend</b>	47	12	60	13	79	17	118	26	137	28
<b>EBITDA</b>	335	83	372	81	455	97	573	125	579	120
<b>Net profit*</b>	225	56	238	52	273	58	340	74	338	70
<b>EPS (FV: ₹5)</b>	11.2		11.9		13.6		17.0		16.9	

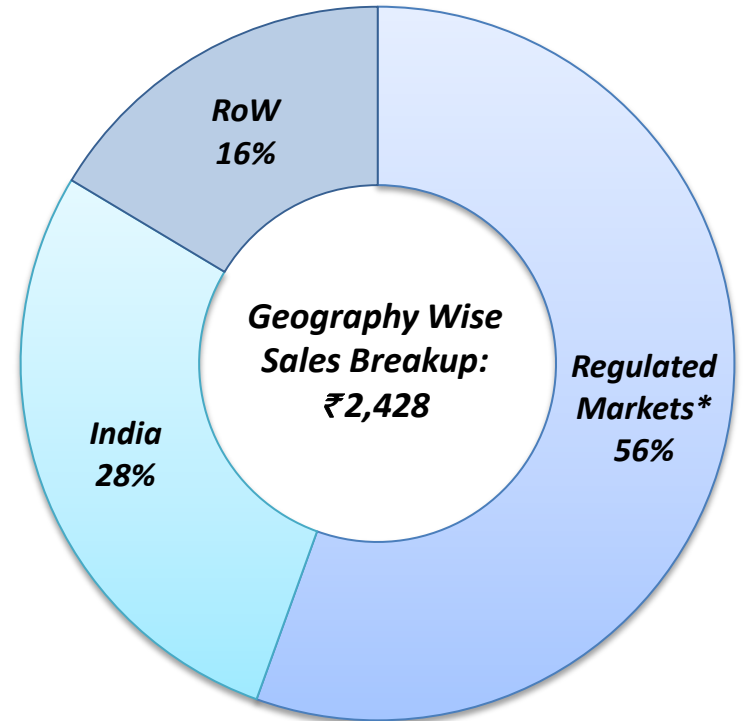
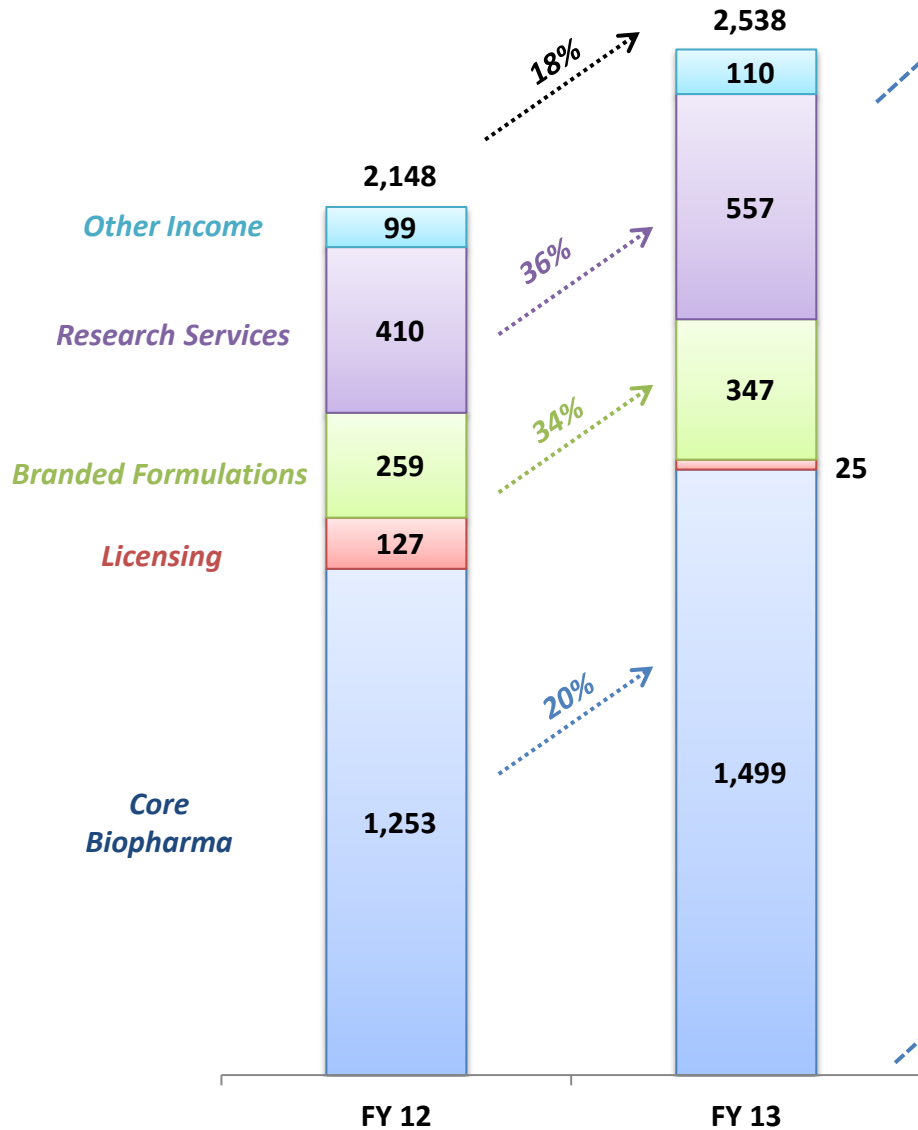
	Q4 FY13		Q4 FY12		FY13		FY12	
Revenue	649   120		622   123		2,538   467		2,148   446	
R&D Spends	43   8		53   10		164   30		137   28	
<i>% of Biopharma Sales #</i>	11%		13%		11%		10%	
EBITDA	124   23		156   31		596   110		579   120	
<i>EBITDA Margin</i>	19%		25%		23%		27%	
Net Profit	248   46		98   19		509   94		338   70	
<i>PAT Margin</i>	38%		16%		20%		16%	
EPS	12.4		4.9		25.4		16.9	

FY08-12: Avg.exch.rate in that fiscal : 4Q FY13: USD 1 = ₹ 54.12; 4Q FY12: USD 1 = ₹ 50.70 | FY13: USD 1 = ₹ 54.31; FY12: USD 1 = ₹ 48.13

# Biopharma Sales excluding branded Formulations; \* Net profit is pre-exceptional

# Revenue: Detailed

All Figures in ₹ crore unless otherwise specified



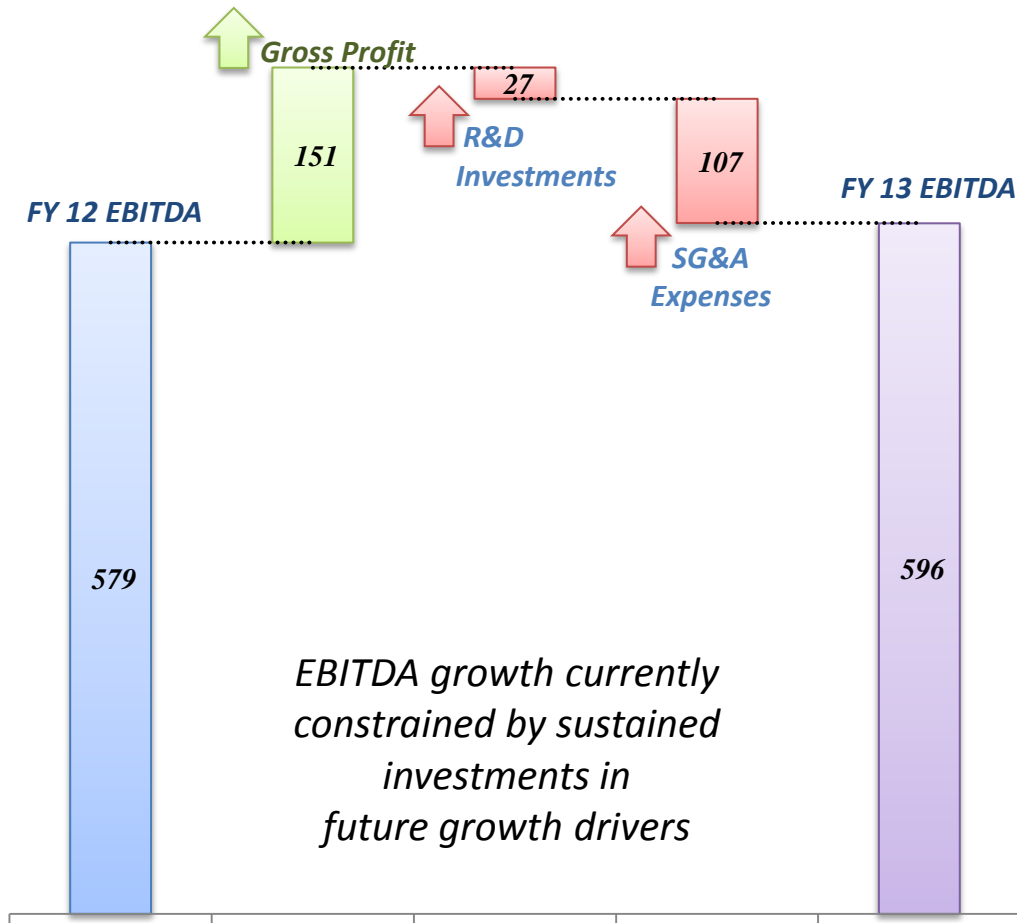
\*: Including Deemed Exports

# Other Key Parameters

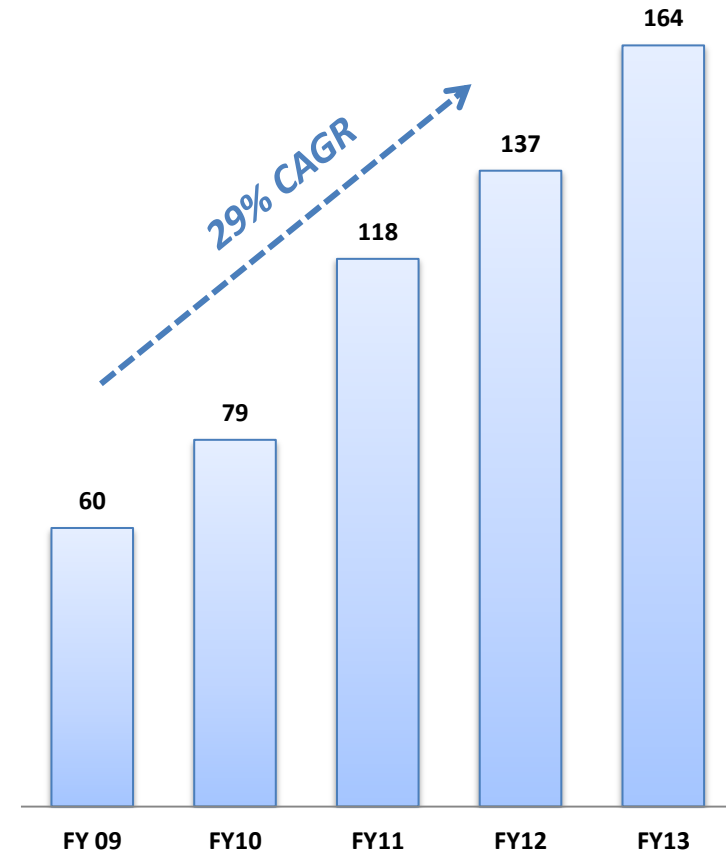


All Figures in ₹ crore unless otherwise specified

## EBITDA Growth: Summarized



## R&D Investments

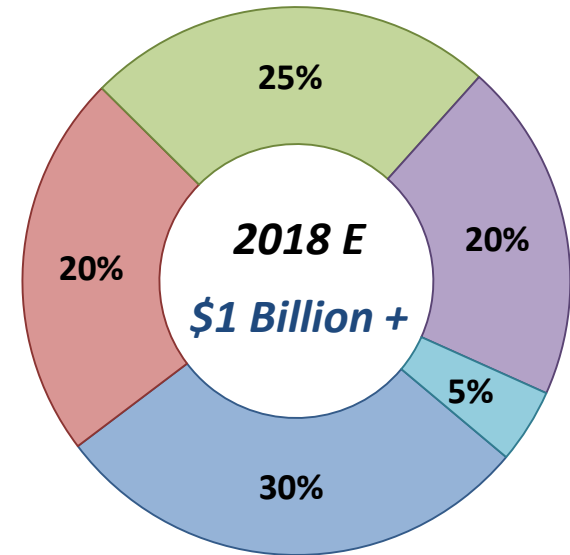
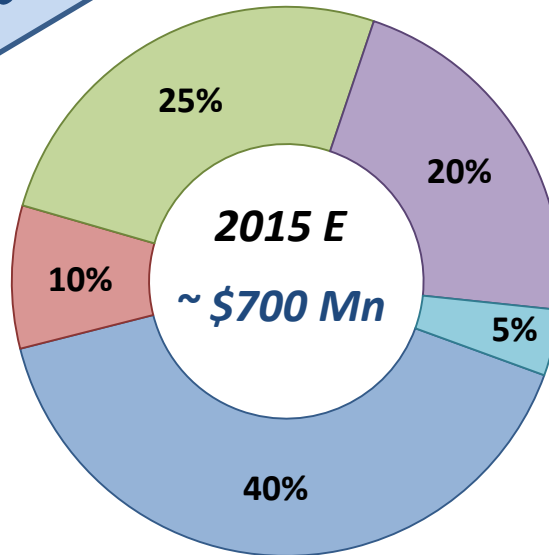
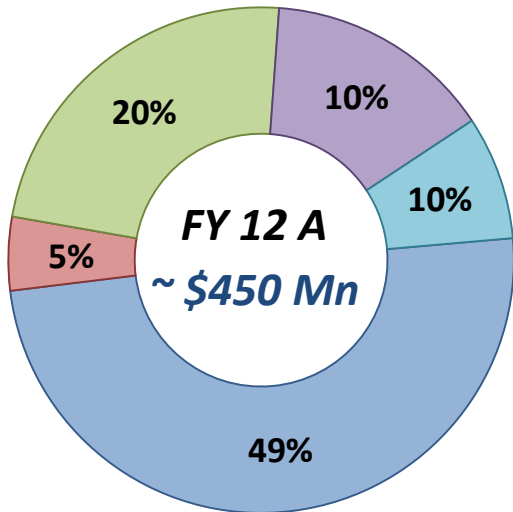









Outlook

# Targeting \$1 Bn Revenues in 5 Years

Estimated Growth CAGR: 18%



-  **Small Molecules**
-  **Biosimilars (Insulins + MAbs)**
-  **Research Services**
-  **Branded Formulation**
-  **Licensing & Other Income**



### Biosimilars: Global Development & Commercialization

- Commercialization of generic rh-Insulin in regulated markets (EU)
- Launch of generic insulin glargine in large semi-regulated markets
- Commercialization of biosimilar trastuzumab in India & other emerging markets
- Clinical development of generic rh-Insulin for US
- Preparation of launch of generic insulin glargine in regulated markets

### Capacity Enhancement

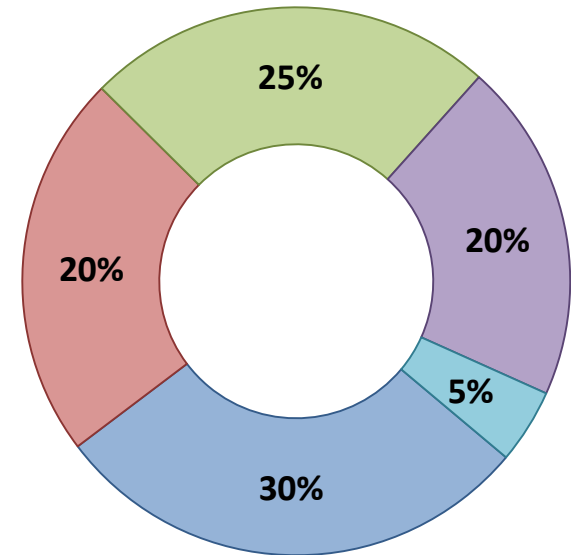
- Generic insulin plant in Malaysia comes on stream: augmenting capacity and cost advantage
- Research Services add further facilities & capabilities to catalyze the next growth wave

### Partnerships

- Development/Commercialization partnership in developed markets: generic rh-insulin, Itolizumab
- Emerging Market partnerships for small molecules & biosimilars

## Reaching \$1 Bn by 2018

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



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


## Biosimilars & Novel Molecules: Regulatory Clarity

- Continuous evolution of the biosimilar & therapeutic regulatory landscape in major regulated markets
- Regulatory approvals, Patient enrollment, R&D development, process refinement etc. determine the pace and quantum of the R&D activities

## R&D Outsourcing: Research Services

- Relationship management: New Contracts, Contract Renewal & Scope Expansion

## Partnership Management

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# Innovative Science Affordable Medicine



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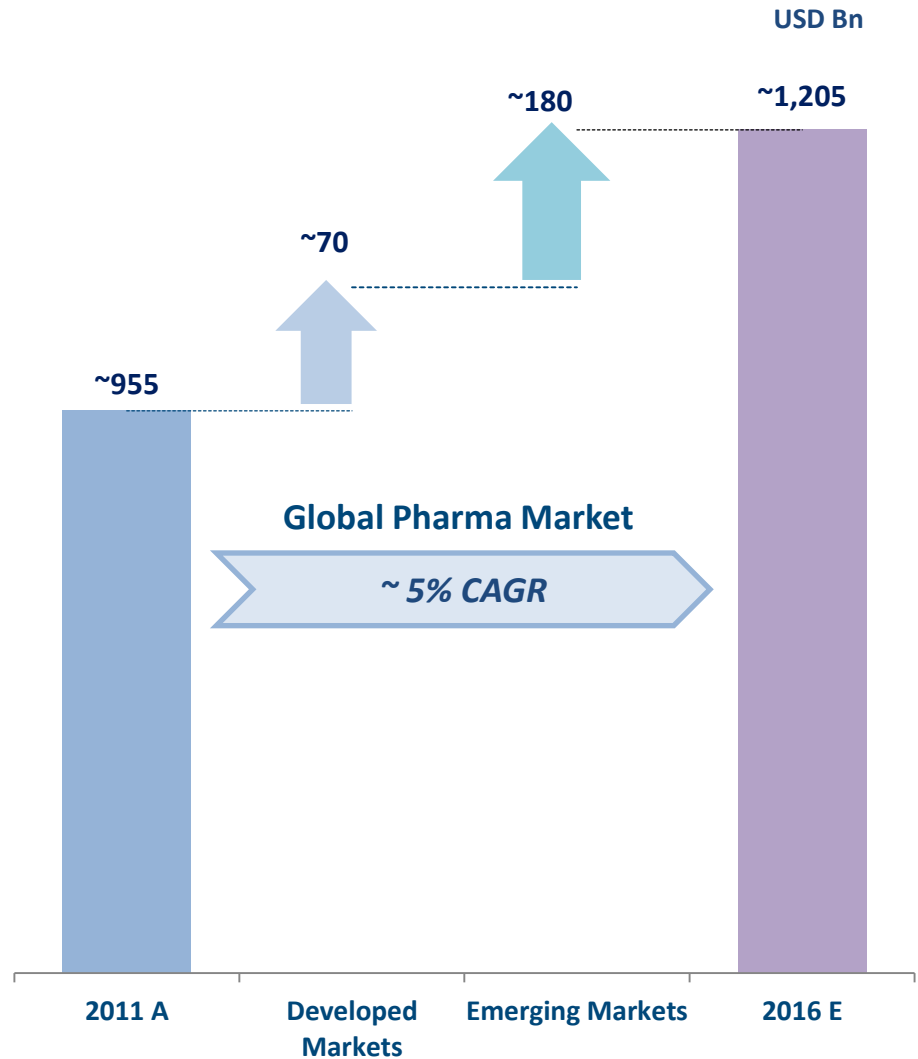
**Sweta Pachlangiya**  
[sweta.pachlangiya@biocon.com](mailto:sweta.pachlangiya@biocon.com)



# Global Pharma Growth Catalyst: Emerging Markets

Emerging Markets to contribute ~ 75% of the Total Pharma Growth by 2016

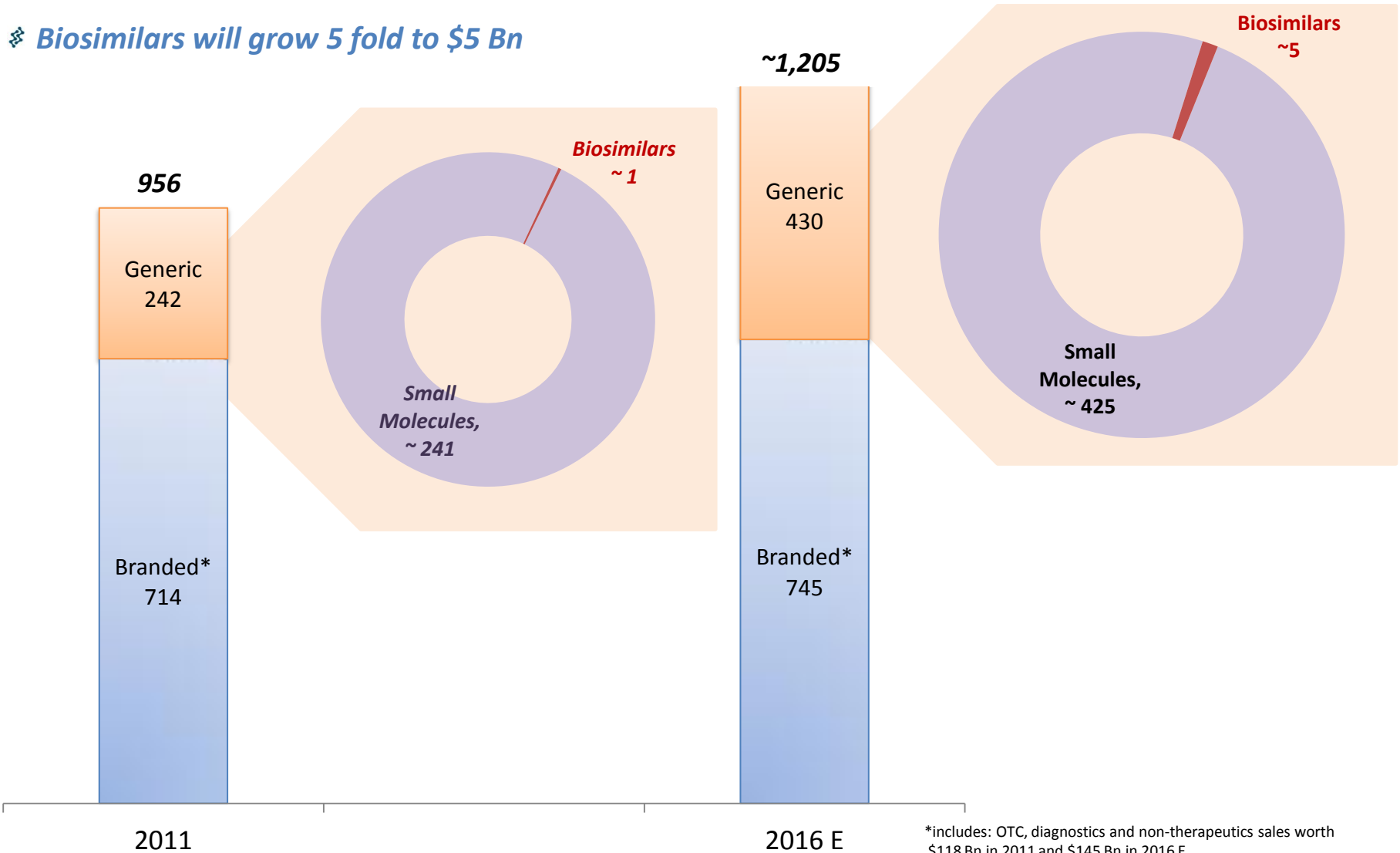
- ❖ Global Pharma Spending expected to cross **\$1.2 Trillion by 2016**
- ❖ Emerging Markets projected growth CAGR: **~10%**
- ❖ Developed Markets expected growth CAGR: **~2%**
- ❖ Emerging Markets growth driven by:
  - ❖ Increased Government Healthcare Spending
  - ❖ Growing Affluence



# Global Pharma Growth Catalyst: Generics & Biosimilars

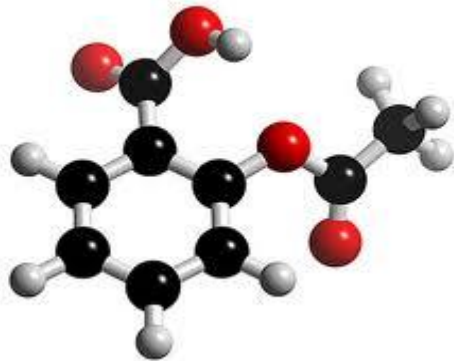
⚡ *Generic Spending to Increase by ~75% in the next 5 years vs. Branded drugs' growth of 9%* **USD Bn**

⚡ *Biosimilars will grow 5 fold to \$5 Bn*



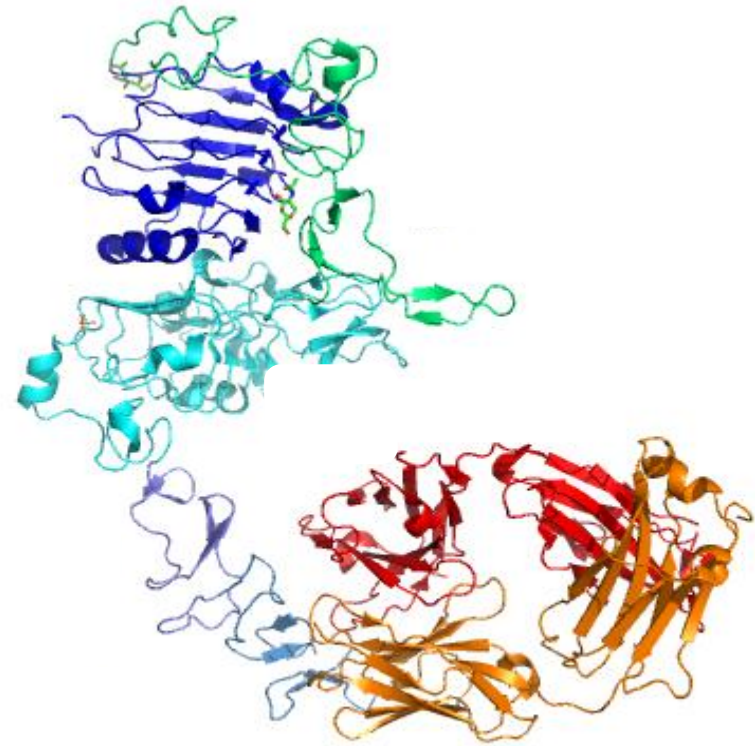
\*includes: OTC, diagnostics and non-therapeutics sales worth \$118 Bn in 2011 and \$145 Bn in 2016 E

## Small Molecules & Biosimilars: Comparison (1)



### ***Small Molecules***

Molecular Weight: Less than 700 Daltons  
Synthetic, Organic compounds  
[Chemistry based products]  
Well defined structure & relatively stable



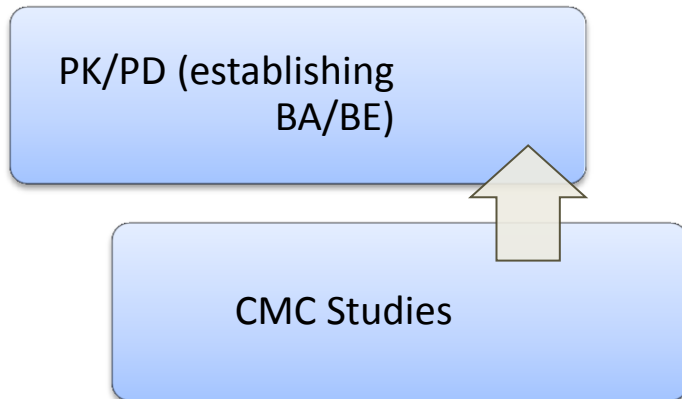
### ***Monoclonal Antibody***

Molecular Weight: ~150,000 Daltons (~250x in size)  
Biologics- prepared in living organisms  
[Proteins]  
Complex physiochemical characteristics & heat sensitive

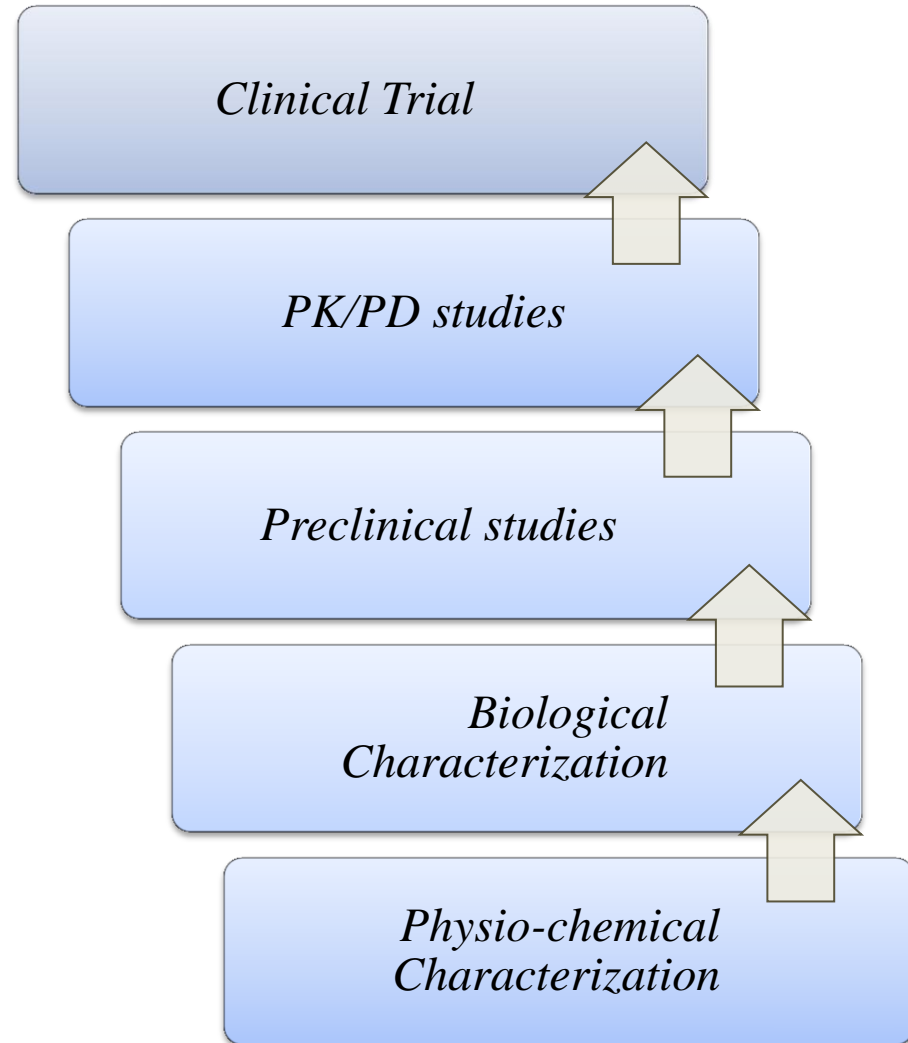


## Small Molecules & Biosimilars: Comparison (2)

### Regulatory Requirements



**Generics: Small Molecules**



**Biosimilars**

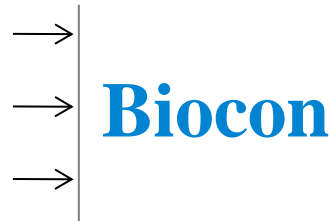
# Biosimilars: Regulatory Landscape



~61% | Promoters

~ 8 % | Employees & ESOP trust

~31 % | Public



## BIOPHARMA SUBSIDIARIES

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

Biocon Biopharmaceuticals | **100%**  
*MAbs and 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***