

# Innovative Science Affordable Medicine



**Investor Presentation  
April 2014**

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

An Enzymes Company  
Revenue: ₹ 320 Million

1978 -  
1999

Building the India Business  
and expertise in biologics  
Revenue: ₹ 11,940 Million  
People: 3,500+

1999 -  
2004

2004 -  
2009

Poised for a global  
platform with launch of  
finished formulations &  
biosimilars in regulated  
markets

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*

## Financial Performance

- Group Revenue at ₹ 29,332 Million (16% YoY growth)
- YoY Growth\* across verticals: 18%

Business Vertical	Absolute Growth (%)
Biopharma	15
Branded Formulations	13
Biopharmaceuticals	14
Research Services	28
Total Sales	18

- EBITDA at ₹ 7,429 Million (*EBITDA Margin: 25%*)
- R&D Expense: ₹ 1,310 Million (6% of Biopharmaceuticals Revenue)
- PAT at ₹ 4,137 Million (*PAT Margin: 14%*)

### **Corporate Milestones**

- ❖ Commercial Launch:
  - Alzumab™, our indigenously developed first-in-class anti-CD6 indicated for Psoriasis
  - CANMAB™, World's most affordable trastuzumab to be commercialized
- ❖ Strategic Tie ups with:
  - Cytosorbents: Cytosorb for sepsis management
  - Quark Pharma : siRNA based novel therapeutics
  - Advaxis Inc: Novel cancer immunotherapy
- ❖ Syngene :
  - successfully cleared the first US FDA audit of its quality systems
  - Inauguration of the Baxter Global Research Centre
- ❖ Ranked #6 in the Top 20 global biotech employer list (2013) by the Science Magazine

### **R&D Milestone**

- ❖ Initiated trials for IN-105 (oral insulin program) in US



# Growth Verticals: Aligned with Shifting Paradigms



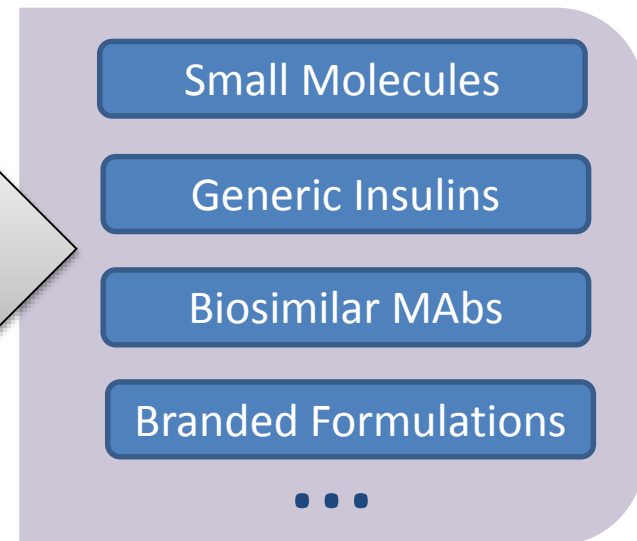
## Function Based Organization -----> Business Units

- ❖ 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*



# Amongst the Top 20 Global Biotech Employers Worldwide

## Top Twenty Employers\*

2013 RANK    2012 RANK    EMPLOYER (GLOBAL HEADQUARTERS)

2013 RANK	2012 RANK	EMPLOYER (GLOBAL HEADQUARTERS)	Innovative leader in the industry	Treats employees with respect	Is socially responsible	Has loyal employees	Has a clear vision	Does important, quality research
1	1	Regeneron Pharmaceuticals, Inc. (Tarrytown, NY)	•			•	•	
2	3	Genentech (South San Francisco, CA)	•			•	•	
3	2	Vertex (Cambridge, MA)	•	•		•	•	
4	-	AbbVie (North Chicago, IL)		•		•	•	
5	-	Eli Lilly and Company (Indianapolis, IN)		•	•	•	•	
6	19	Biocon Limited (Bengaluru, Karnataka, India)		•	•	•	•	
7	6	Millennium: The Takeda Oncology Company (Cambridge, MA)			•	•	•	
8	11	Novartis (Basel, Switzerland)	•			•	•	
9	7	Boehringer Ingelheim (Ingelheim, Germany)			•	•	•	
10	9	Biogen Idec (Weston, MA)	•			•	•	

**Only Asian Company to appear in the list**

– 2 years in a row now



**Debuted at # 19 last year**



## Business Segments: Snapshot

## Small Molecules: APIs & Generics



- ❖ 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, 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...**

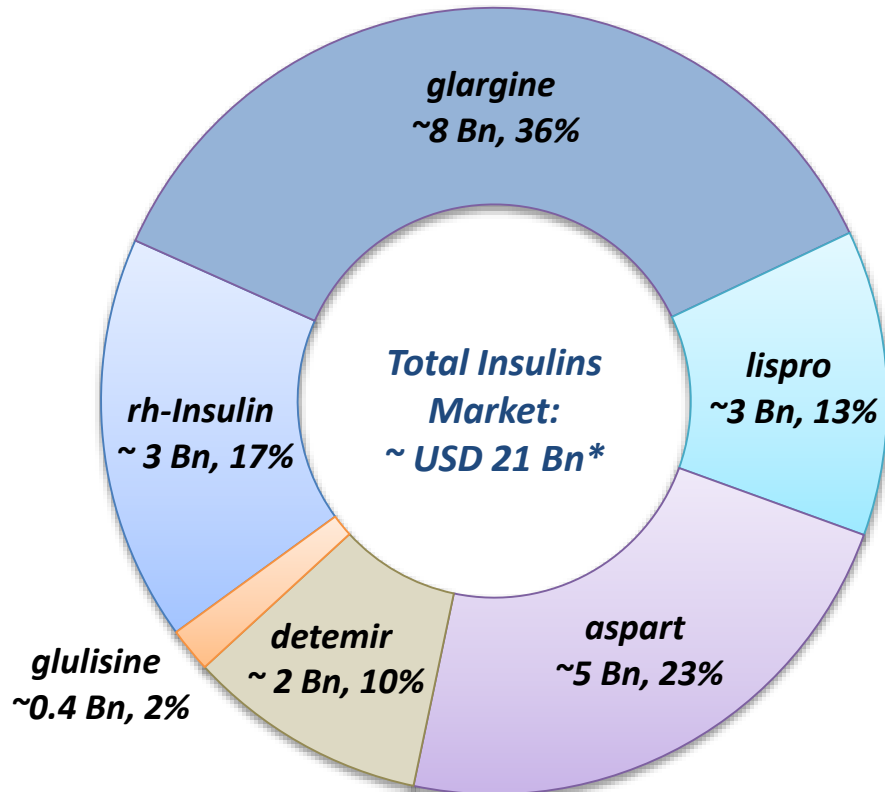
*Large Molecules (proteins): greater complexity  
Extensive development process  
Process development and Capacity constraints*

**Current  
Portfolio**

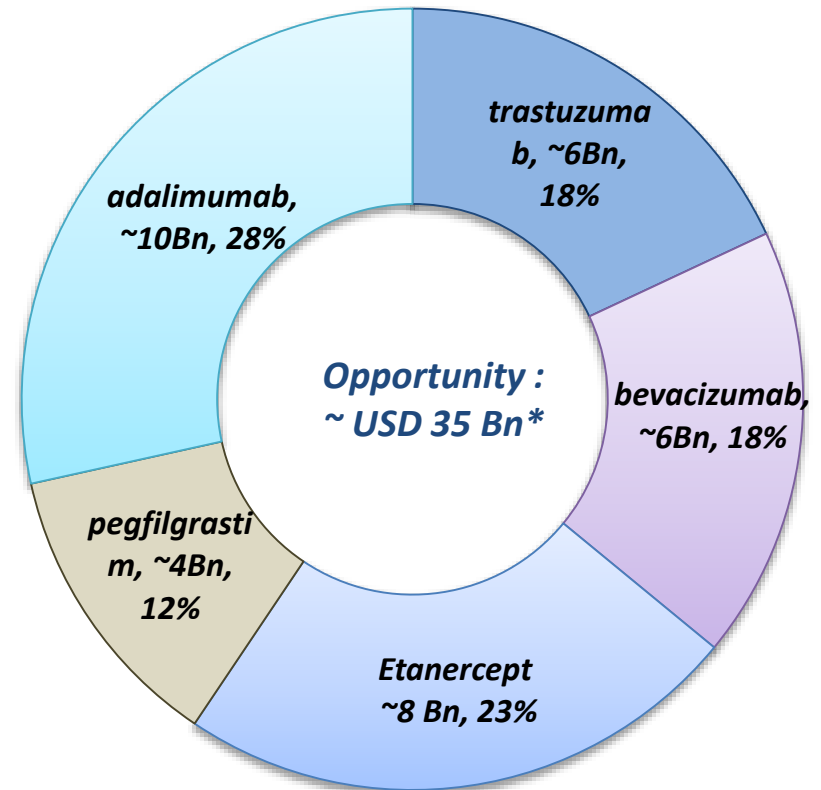
*g. rh-Insulin & g. Insulin Analogs (insulin glargine, insulin lispro & insulin aspart)  
Monoclonal Antibodies (Trastuzumab, Bevacizumab, Adalimumab)  
Other Biologics (Etanercept, Peg-filgrastim)*

# Biosimilars: Opportunity

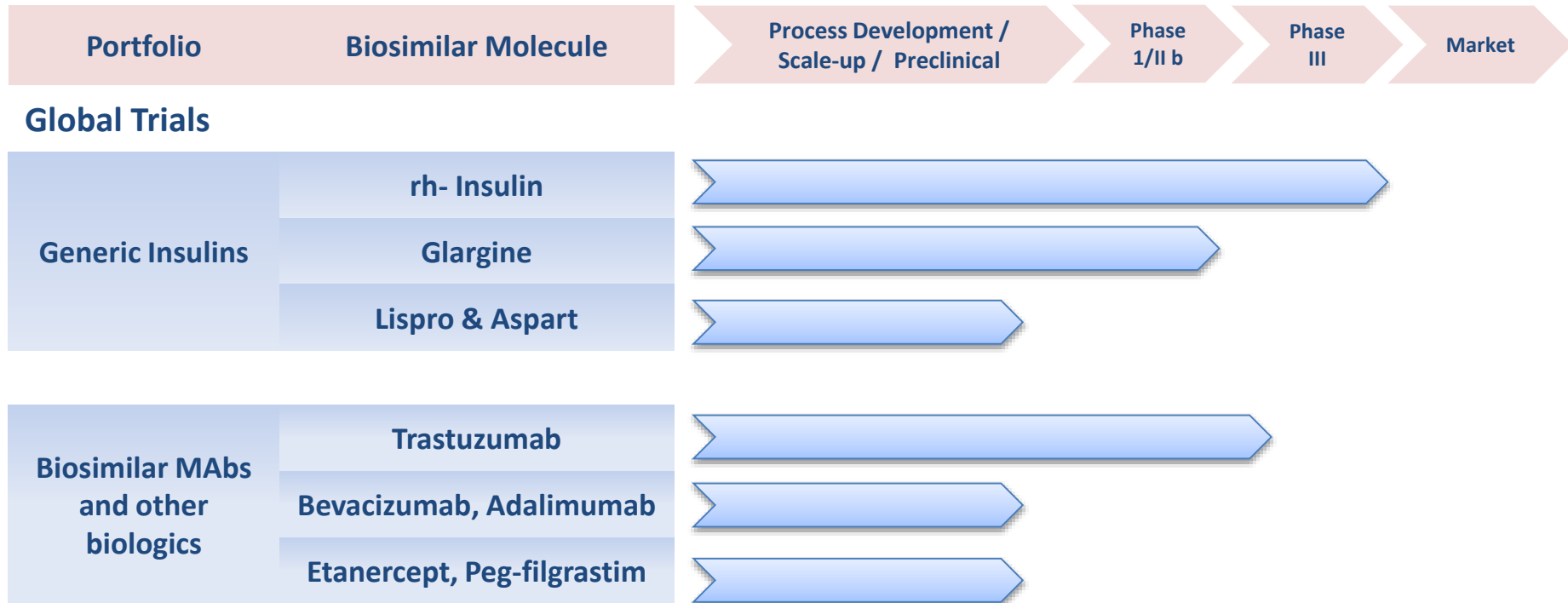
## The Insulin Pie



## Biosimilar MABs & Other Biologic



# Biosimilars: Pipeline

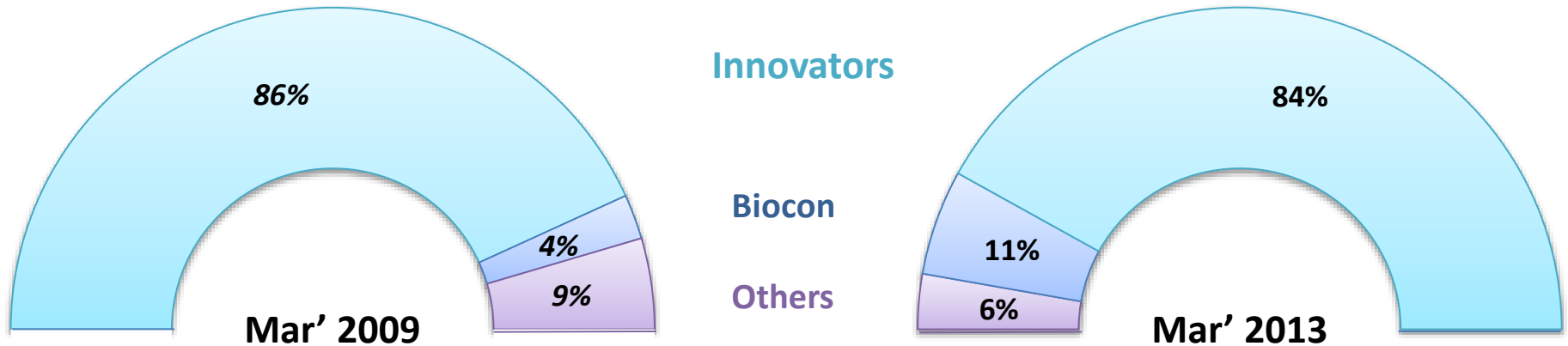


- ❖ **Emerging Markets First strategy** coupled with a **regional partnership** commercialization approach
- ❖ Launched the world’s most affordable trastuzumab, CANMAB™ in India, in Q4 of fiscal 2014
- ❖ Generic rh Insulin registered in 55 countries; generic insulin glargine registered in 10+ nations



# Biosimilars: Key Emerging Market Footprint

## rh-Insulin Volume Market Share: Evolution



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

\*IMS MAT for respective years in Key emerging markets where we have a presence

# 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 18 Bn</b>	<b>~ USD 35 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	Developed 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.*

# 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 ~\$ 180 Mn in the first phase**

Development on-going at full steam

Expected Commissioning: FY15



## Branded Formulations: Snapshot

- An India Centric Business with Global Ambitions

- **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

- **Alzumab™**: India's 2<sup>nd</sup> indigenous novel MAb for Psoriasis

- **CANMab™**: World's most affordable trastuzumab to be commercialized

# Branded Formulations: Sustained Growth

## India's Fastest growing Insulin company

- ⌘ Biocon: 41% | Sanofi: 19% | Novo: 20%
- ⌘ #4 in overall insulin market
- ⌘ #3 in the 40 IU Insulin market
- ⌘ #1 in the Glargine vial market

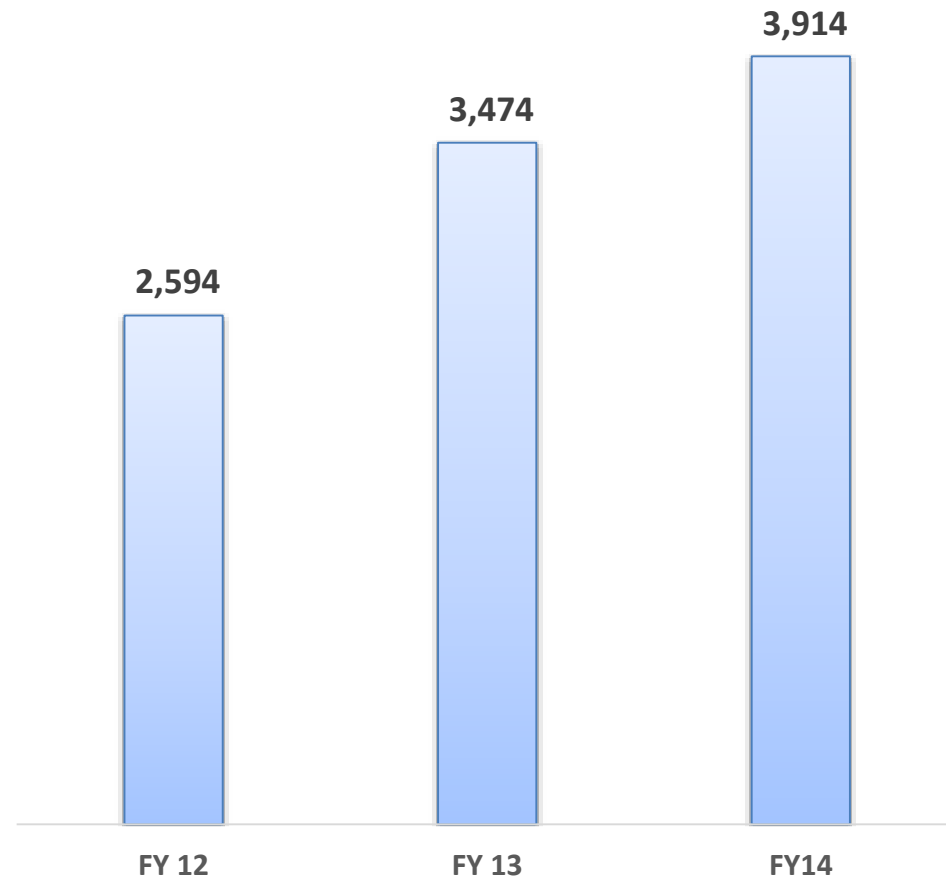
## Biocon's Volume Market share#

- ⌘ rh-Insulin Pen/Cartridges: 14%
- ⌘ 100 IU Insulin: 11%
- ⌘ Glargine vials: 91%

## Market Share # of other flagship brands:

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

Revenues in ₹ Million



# 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)



## 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**

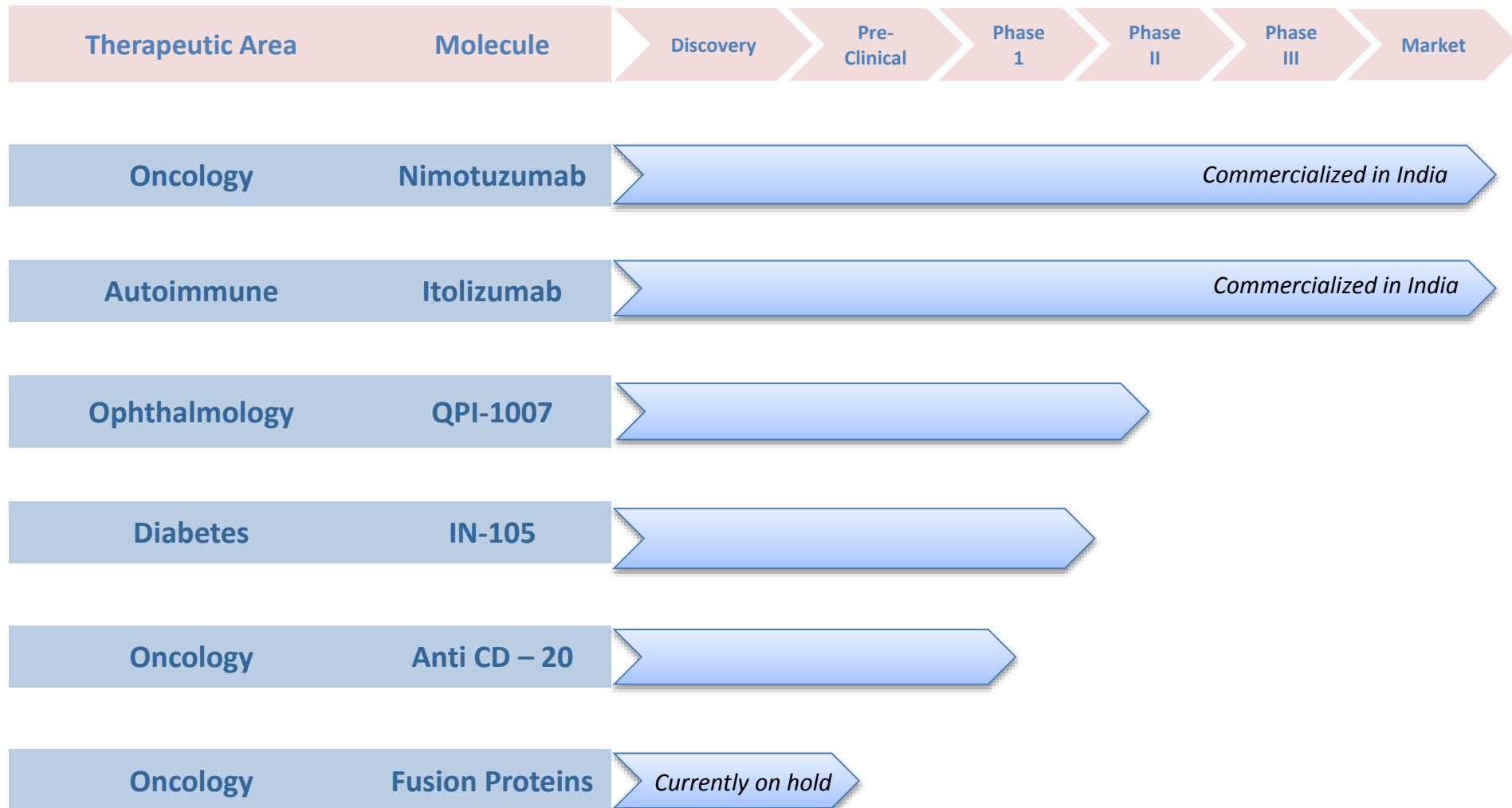
- MRP – Rs 57,500 for 440mg vial, Rs 19,500 for 150mg vial
- Availability of 150 mg multi-dose vial allows patients to save money by buying smaller quantities, and storing unused product for their next dose rather than wasting it

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





# Novel Molecules: Pipeline





## 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.*

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

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

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

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

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*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

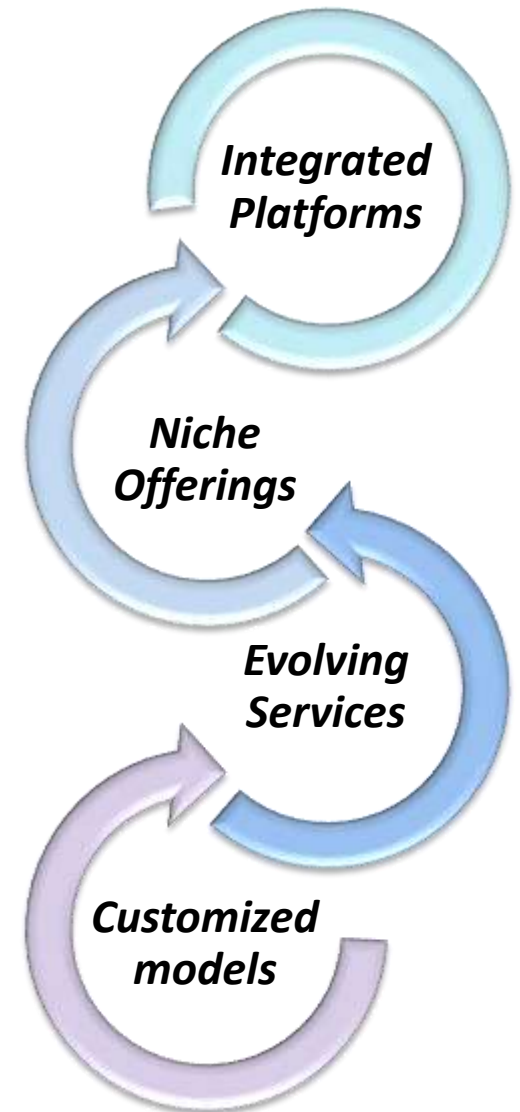
## Research Services: Capabilities & Collaboration Models

- 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



*Largest R&D Centre by a Big Pharma in Asia (2009)*

*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**

*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*

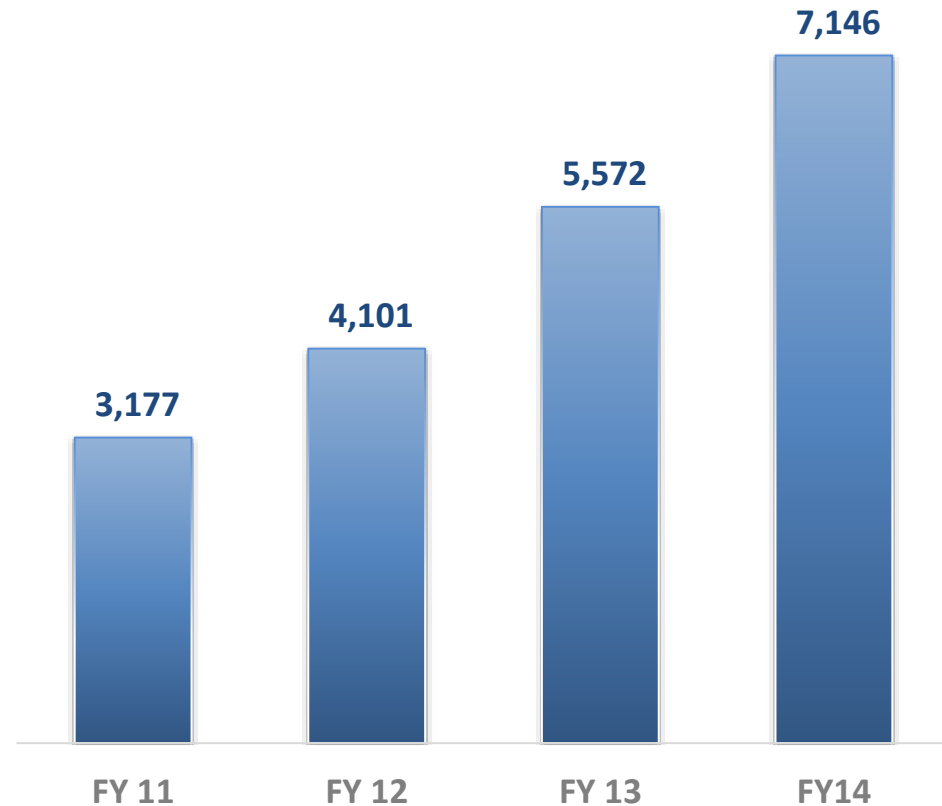
*Over 30 multi-disciplinary scientists engaged in product development lifecycle*

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



## 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

	FY09		FY10		FY11		FY12		FY13	
<b>Revenue</b>	11,937	260	14,930	318	18,579	407	21,483	445	25,380	467
<b>R&amp;D Spend</b>	598	13	785	17	1,183	26	1,366	28	1,640	30
<b>EBITDA</b>	3,715	81	4,551	97	5,733	125	5,791	120	5,957	110
<b>Net profit*</b>	2,338	52	2,729	58	3,399	74	3,384	70	3,241	60
<b>EPS (FV: ₹ 5)</b>	11.9		13.6		17.0		16.9		25.4	

	FY14	FY13
Revenue	29,332   487	25,380   467
R&D Spends	1,310   22	1,640   30
<i>% of Biopharmaceutical Sales #</i>	6%	9%
EBITDA	7,429   123	5,957   110
<i>EBITDA Margin</i>	25%	23%
Net Profit	4,137   69	3,241   60
<i>PAT Margin</i>	14%	13%
EPS	20.7	25.4

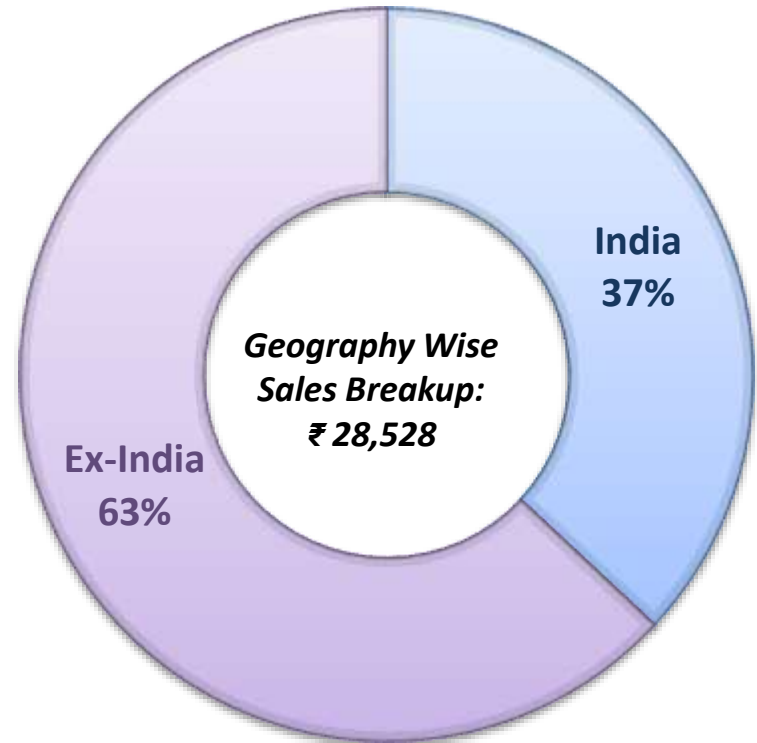
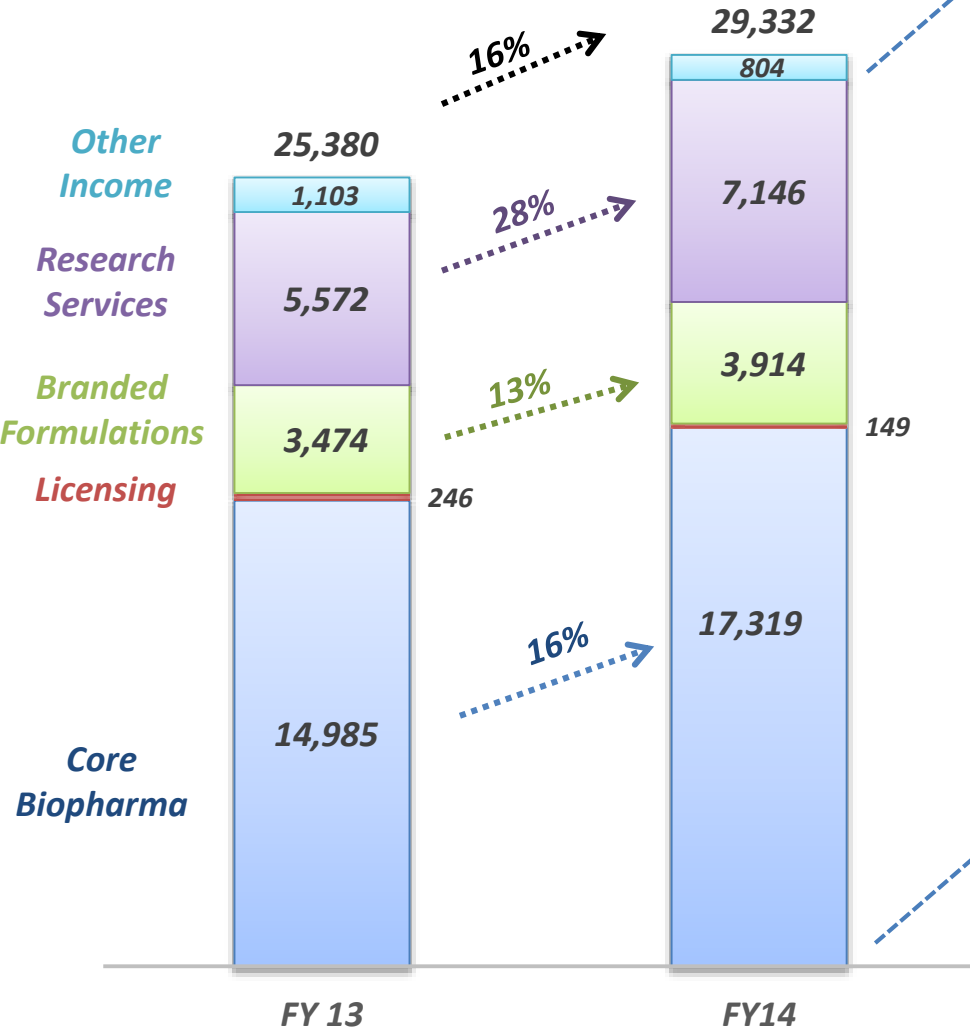
FY09-13: Avg.exch.rate in that fiscal ; FY13: USD 1 = ₹ 54.35; FY14: USD 1 = ₹ 60.28

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



# Revenue: Detailed

All Figures in ₹ Millions unless otherwise specified





## Core Business Margins: Detailed

All Figures in ₹ Millions

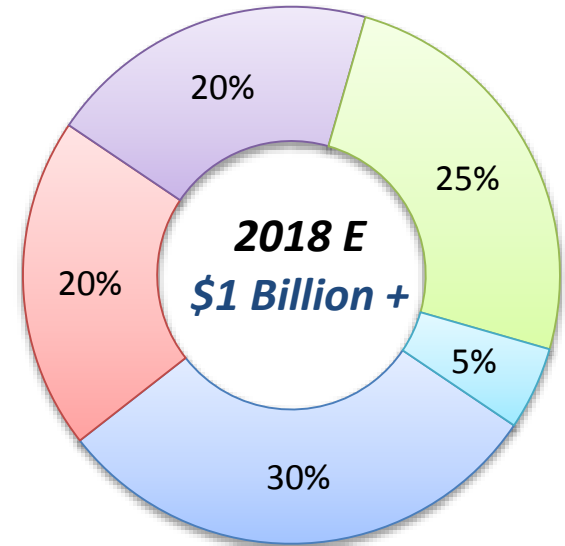
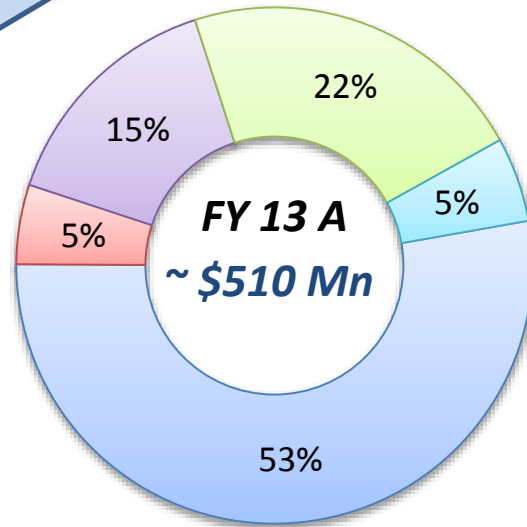
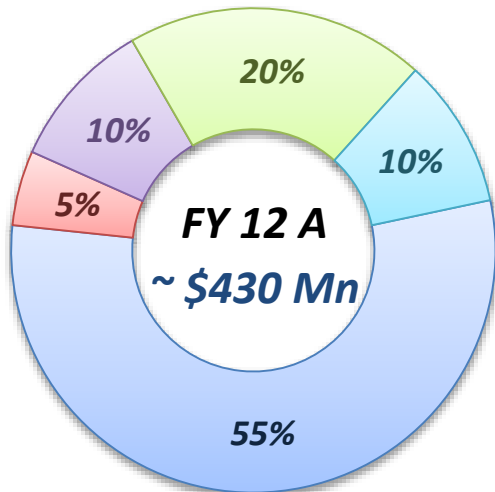
	<b>FY 09</b>	<b>FY 10</b>	<b>FY 11</b>	<b>FY 12</b>	<b>FY 13</b>	<b>FY14</b>
Revenue	11,937	14,930	18,579	21,483	25,380	29,332
Less: Other Income	544	324	516	993	1,103	804
Less: Licensing Income	123	507	1,525	1,266	246	149
<b>Core Revenues</b>	<b>11,270</b>	<b>14,099</b>	<b>16,538</b>	<b>19,224</b>	<b>24,031</b>	<b>28,379</b>
EBITDA	3,715	4,551	5,733	5,791	5,957	7,429
Add: R&D Expense	598	785	1,183	1,366	1,640	1,310
Less: Other Income	544	324	516	993	1,103	804
Less: Licensing Income	123	507	1,525	1,266	246	149
<b>Net EBITDA</b>	<b>3,646</b>	<b>4,505</b>	<b>4,875</b>	<b>4,899</b>	<b>6,248</b>	<b>7,786</b>
<b>Net EBITDA Margin</b>	<b>32%</b>	<b>32%</b>	<b>29%</b>	<b>25%</b>	<b>26%</b>	<b>27%</b>








**Outlook**

# Revenue Growth Trajectory

Estimated Growth CAGR: 18%

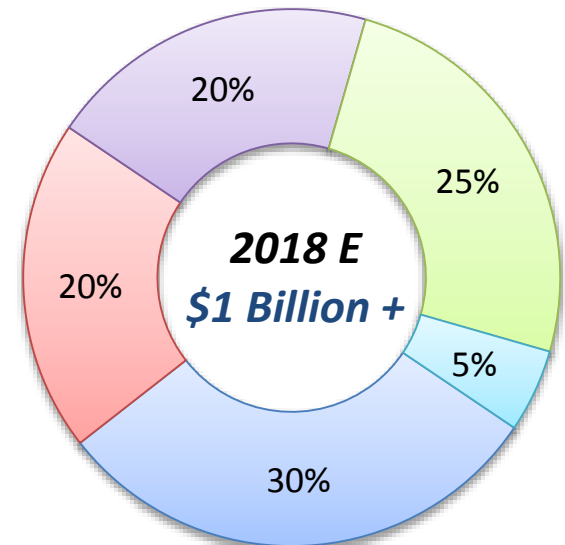


-  **Small Molecules**
-  **Biosimilars (Insulins + MABs)**
-  **Branded Formulation**
-  **Research Services**
-  **Licensing & Other Income**

## 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)*



## Biosimilars: Global Development & Commercialization

- Increased global footprint for our generic insulin's portfolio led by
  - Accelerated commercialization of generic rh-Insulin across regulated and semi-regulated markets
  - Launch of generic insulin glargine in large semi-regulated markets; clinical development for regulated markets
- Commercialization of trastuzumab in India & other emerging markets

## Capacity Enhancement

- Augmenting capacities for biosimilars (Malaysia, India)
- Capacity and capability additions in Research Services to deliver end to end development and manufacturing services

## Partnerships

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

## 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

For updates and specific queries, please visit [www.biocon.com](http://www.biocon.com)  
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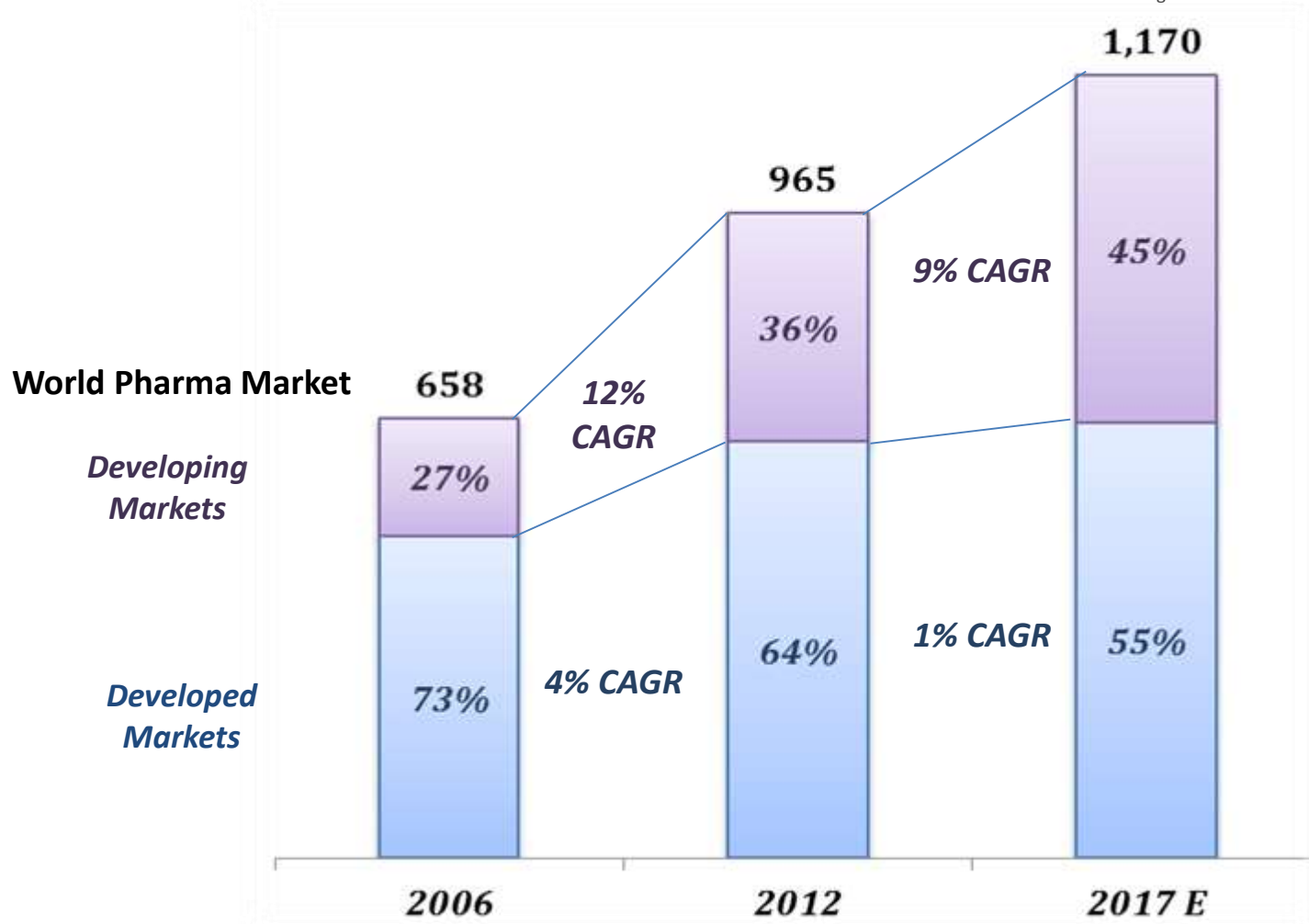
[sweta.pachlangiya@syngeneintl.com](mailto:sweta.pachlangiya@syngeneintl.com)





# Key Trends: *Developing markets driving growth*

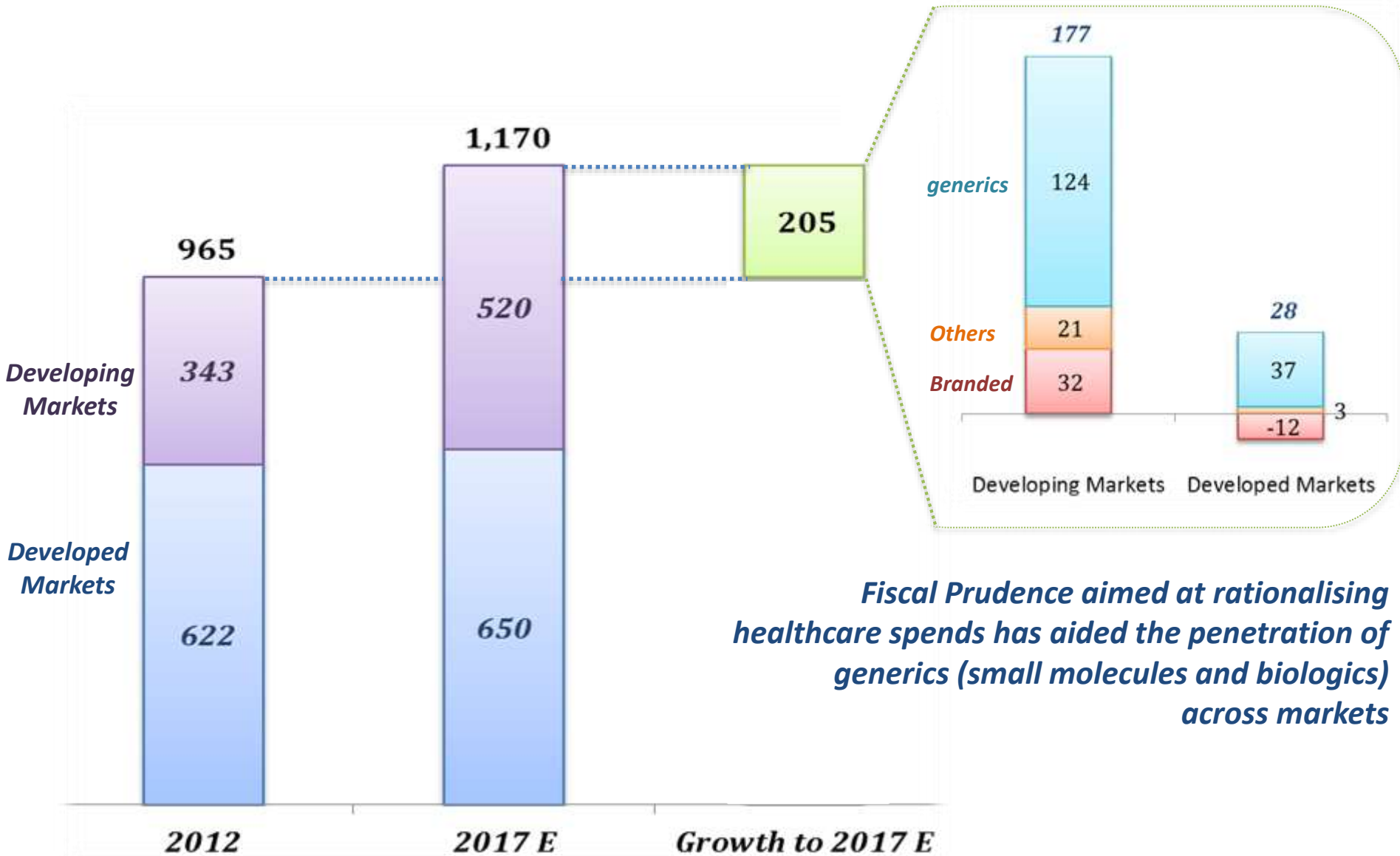
All figures in USD Bn unless otherwise specified



***Pharma Growth in Developing markets has significantly outpaced the developed markets***  
***Trend expected to continue***

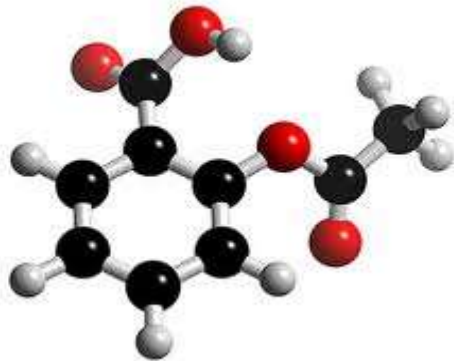
# Key Trends: *Affordability is the focus across markets*

All figures in USD Bn unless otherwise specified



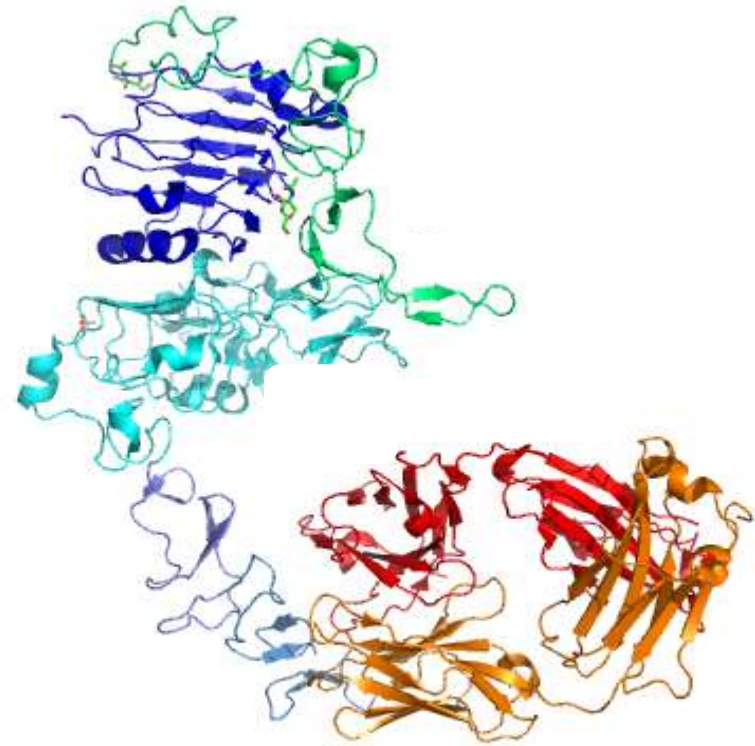
*Fiscal Prudence aimed at rationalising healthcare spends has aided the penetration of generics (small molecules and biologics) across markets*

# Small Molecules & Biosimilars: *Comparison (1)*



## ***Small Molecules***

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

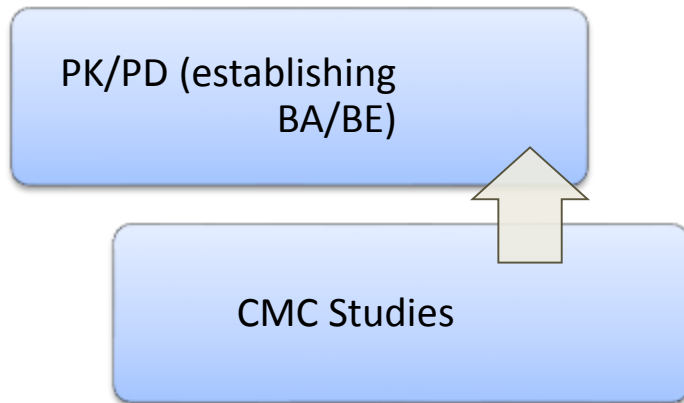


## ***Monoclonal Antibody***

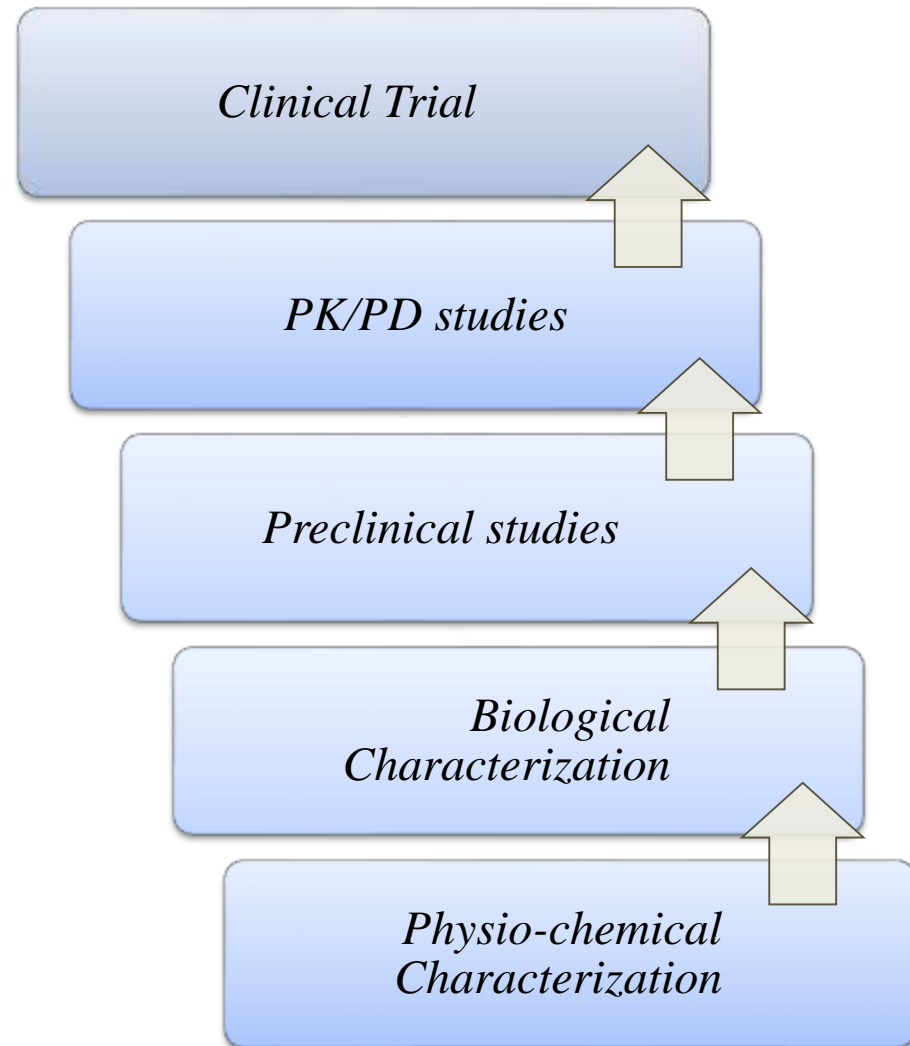
Molecular Weight: ~150,000 Daltons (~250x in size)  
Biologics- prepared in living organisms  
[Proteins]  
Complex physiochemical characteristics & heat sensitive

# Small Molecules & Biosimilars: *Comparison (2)*

## Regulatory Requirements

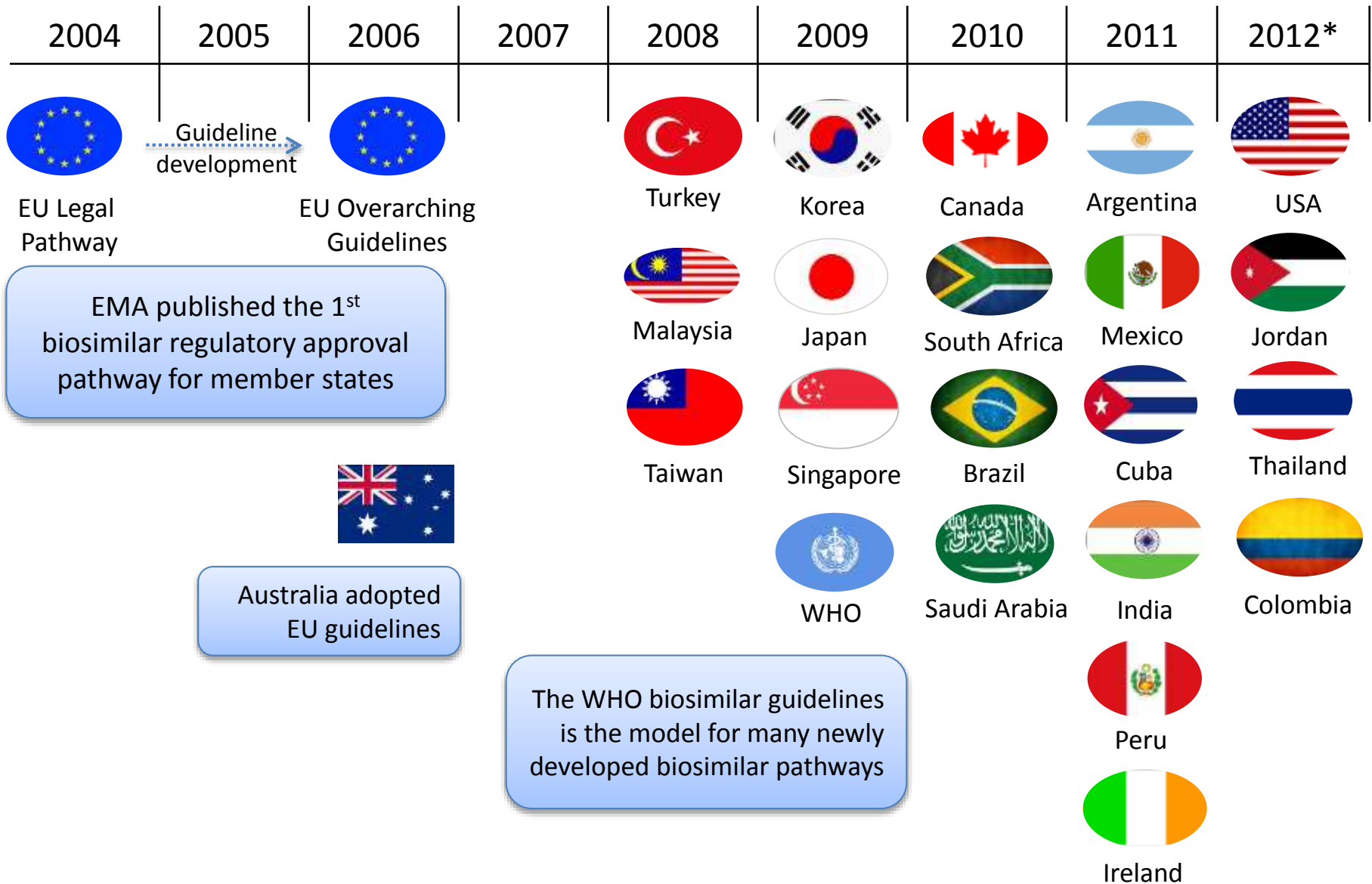


*Generics: Small Molecules*



*Biosimilars*

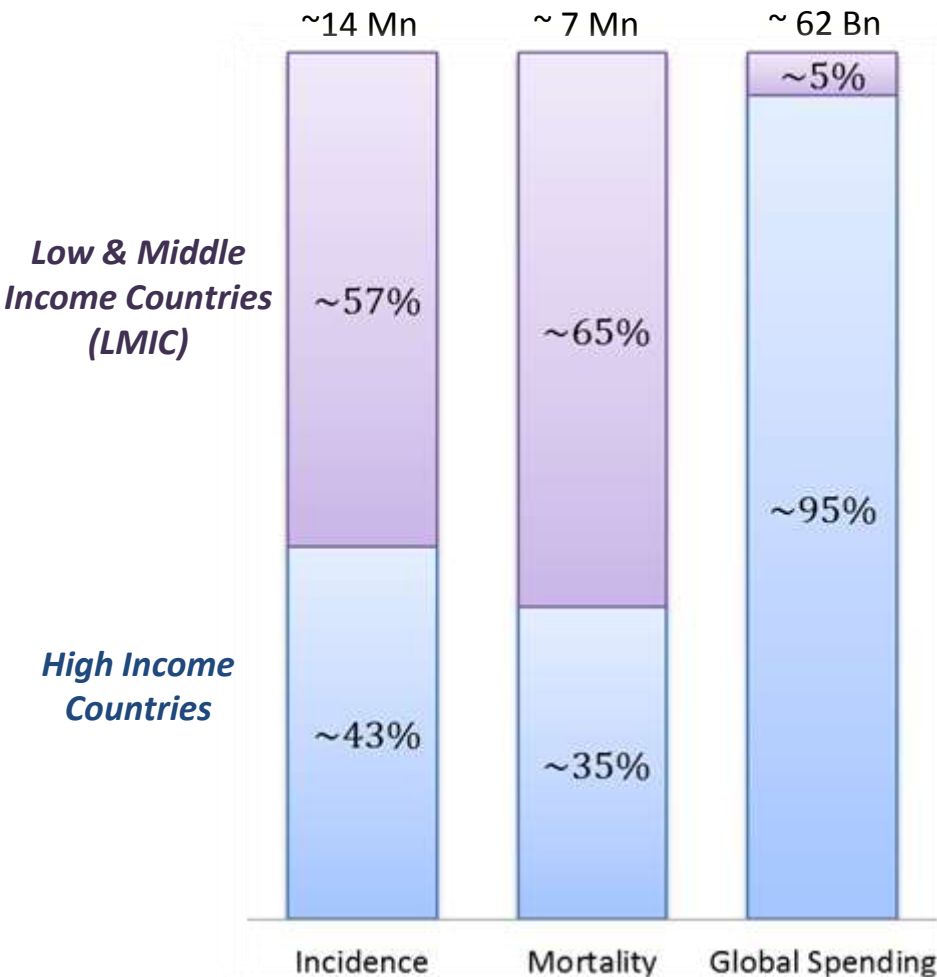
# Biosimilars: *Regulatory Guidelines*



# Developing Markets: *Cancer landscape*

## Low and Middle Income countries face the 5/80 cancer disequilibrium:

*5% of global spending vs. ~ 80% of the global cancer burden in terms of years of life lost to cancer*



- ~30% of deaths in LMIC due to cancer are preventable
- Key Challenges:
  - Detection and diagnosis
  - Access to medication and adjuvant therapies
  - High cost of therapy despite differential pricing by innovators

In South East Asia (per capita Income ~ 3,000 USD), treatment cost for leukemia (chemo + transfusions) is \$20,000

# Breast Cancer: *Overview*



Most common cancer in the world with ~2 Mn new cases every year

- More than 50% of these cases occur in less developed markets (150K new cases detected in India alone every year)
- Most common cause of cancer death in women: India has highest number of women dying every year, from breast cancer, in the world
- More than a third of these deaths could have been prevented with early detection
- Only 3 out of 10 HER 2 positive breast cancer patients in India is currently able to afford the medication

*# of days of wages to purchase the innovator's HER2 positive treatment course for a month*

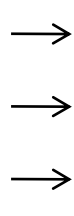


# Business Structure & Holdings

~61% | Promoters

~ 8 % | Employees & ESOP trust

~31 % | Public



**Biocon**

## 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***