

# Innovative Science Affordable Medicine



**JP MORGAN HEALTHCARE CONFERENCE**

**January 7, 2013**

[www.biocon.com](http://www.biocon.com)

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.

**Global Pharma : Catalysts**

**Biocon: Aligned With Trends**

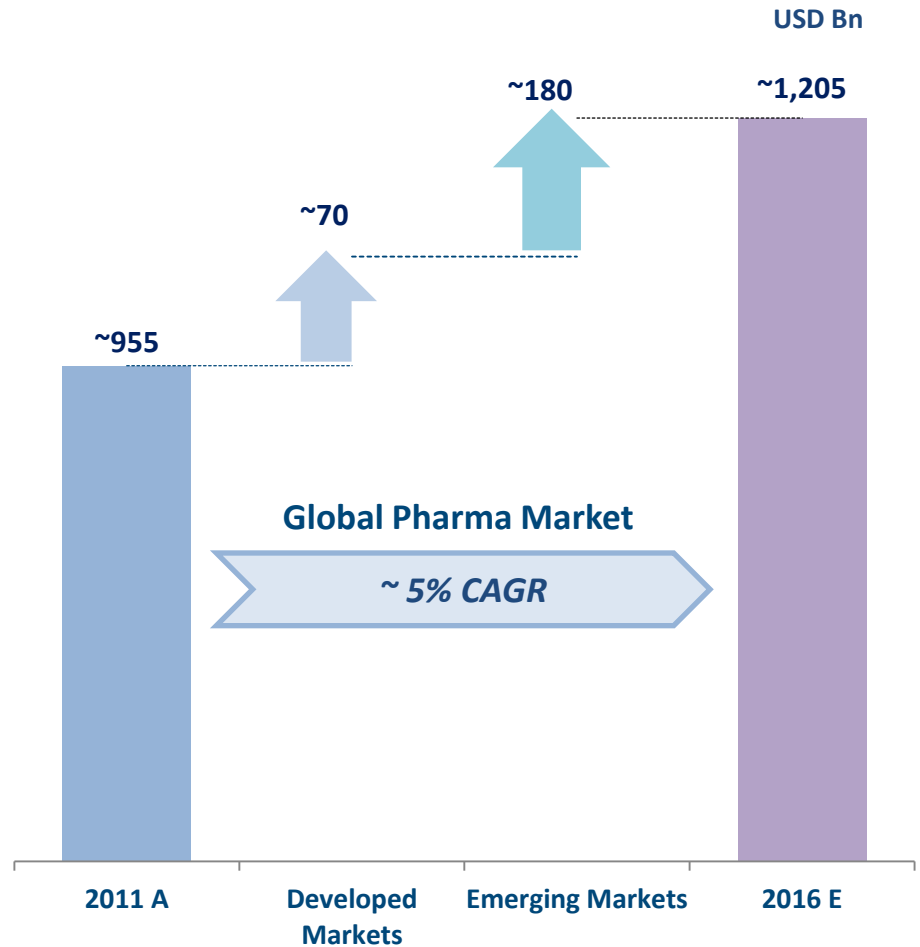
**Growth Segments: Snapshot**

**Financial Highlights**

# Global Pharma Catalysts: Emerging Markets

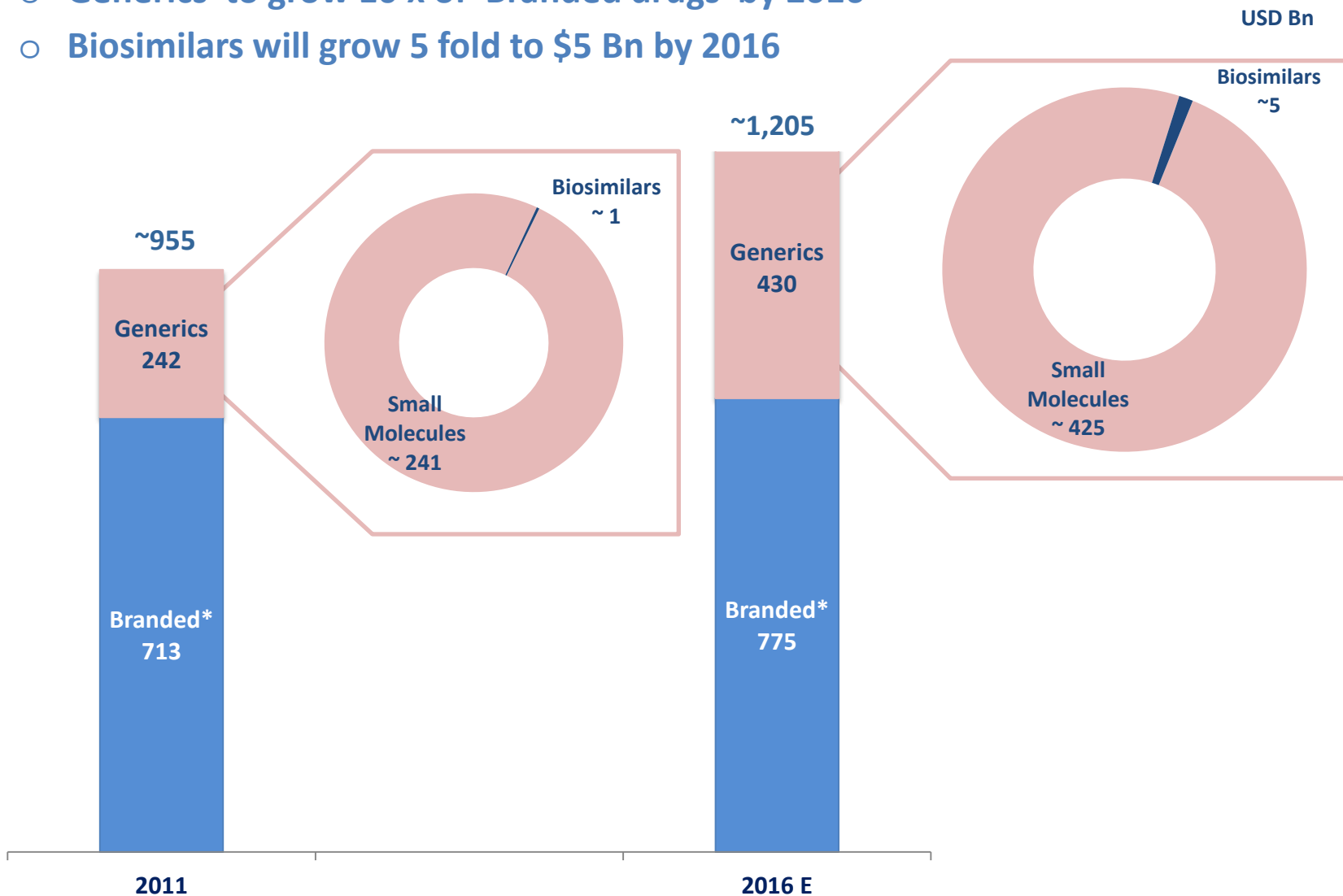
Emerging Markets to contribute ~ 75% of the Total Pharma Growth by 2016

- Global Pharma Spending expected to cross **\$1.2 Trillion by 2016**
- Emerging Markets to grow > double of Developed Markets
- Emerging Markets growth driven by:
  - Increased Government Healthcare Spending
  - Growing Affluence

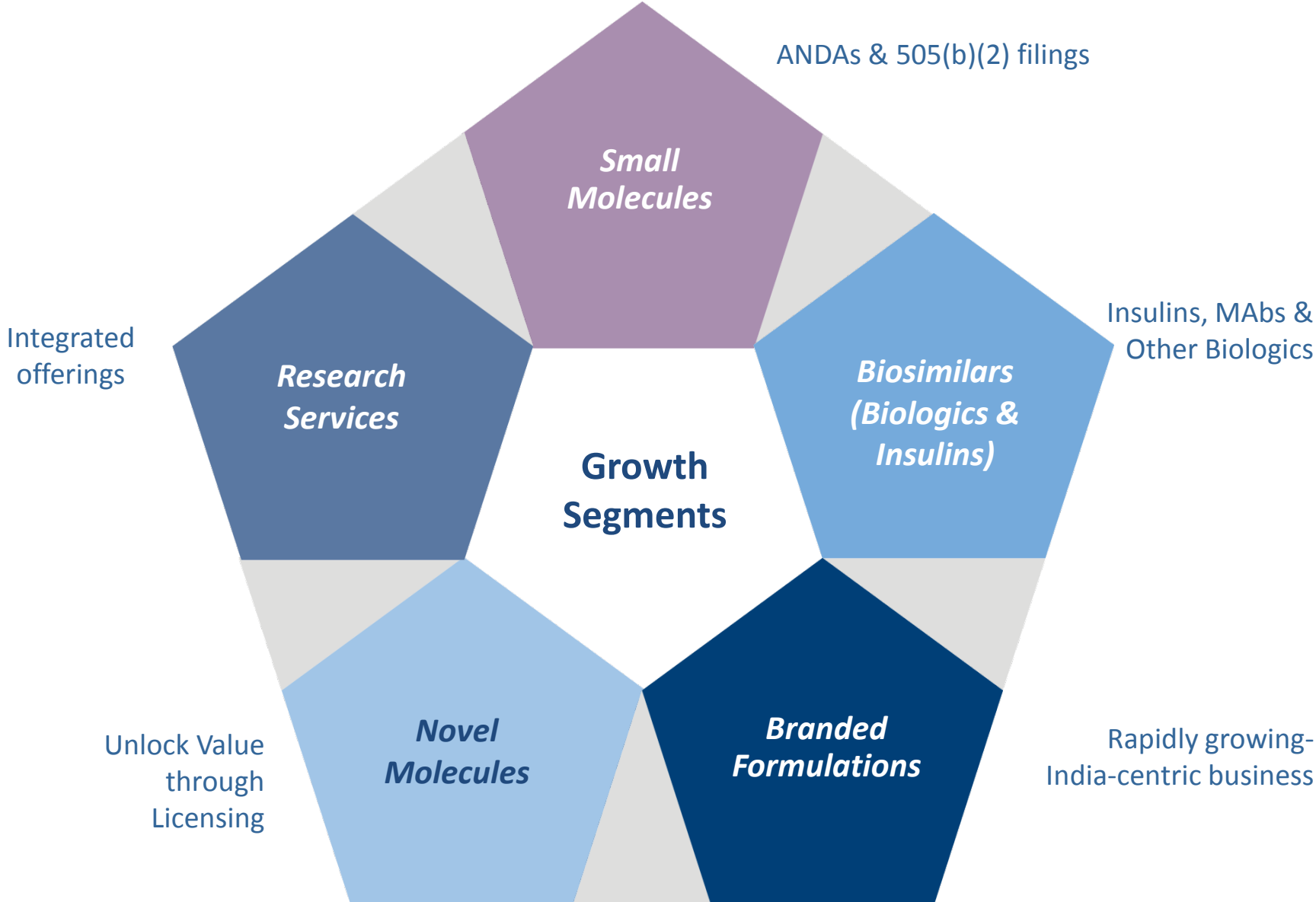


# Global Pharma Catalysts: Generics & Biosimilars

- Generics to grow 10 x of Branded drugs by 2016
- Biosimilars will grow 5 fold to \$5 Bn by 2016



# Biocon: Aligned With Trends - Growth Segments

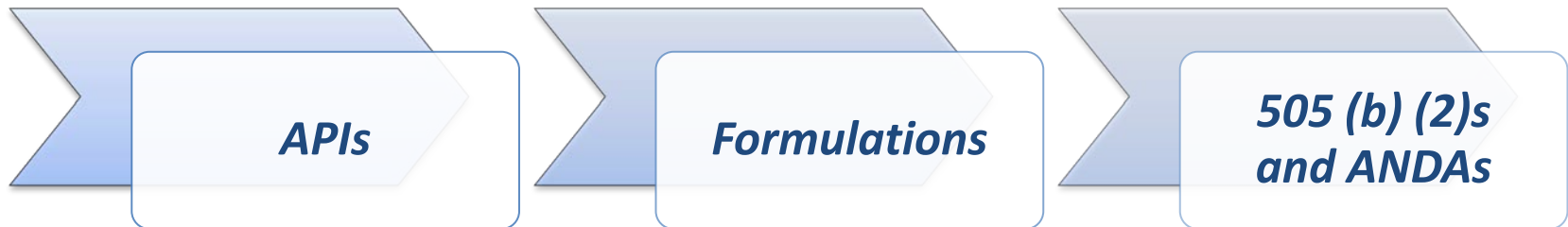


**EMERGING MARKETS FOCUS**



**Growth Segments: Snapshot**

## Growth Segment: Small Molecules

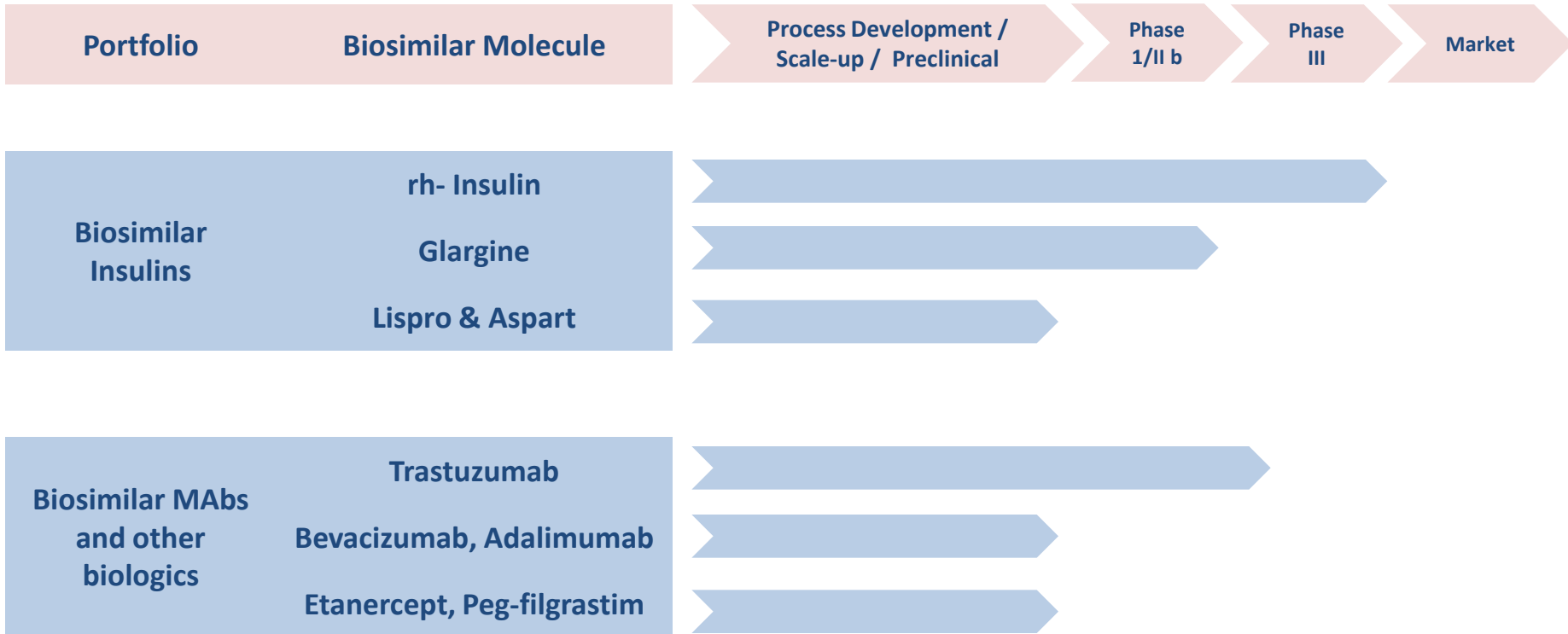


- Leveraging existing APIs capabilities to forward integrate into:
  - Branded Formulations for Emerging Markets
  - Generic Finished Dosages for Developed Markets
- Differentiated ANDA strategy encompassing our fermentation capabilities and molecular complexity
- 25 molecules identified for ANDAs addressing a market opportunity of ~\$30 Bn
- ANDA Filing to commence in 2013



# Growth Segment: Biosimilars

## Biosimilars Pipeline



- Emerging Markets focus through Regional Partnerships
- Portfolio Opportunity Size\*
  - Biosimilar Insulins: \$ 17 Bn
  - Biosimilar MABs & Other biologics: \$ 33 Bn

\*Market size of innovator products

# Growth Segment: Biosimilars

## Biosimilar Insulin & Analogs

- Multiple regional partnerships inked post Pfizer
- Partnership discussions in progress for US & Europe
- Registrations:
  - rh-Insulin: 40+ countries
  - Gargine: 5+ countries
- Greenfield expansion of ~ \$200 Mn in Malaysia is on track
- World class Delivery Device: INSUPen launched in Emerging Markets



# Growth Segment: Biosimilars

## Biosimilar Insulin & Analogs- Clinical Update

### Biosimilar rh-Insulin

- EU Phase III completed
- Results from Part 1 of the study establishes the Efficacy end-point (*non inferiority to innovator product*)
- Immunogenicity and safety at the 6 month time interval also similar to innovator; 12 months data awaited
- Market Authorization for EU to be filed in FY 14

### Biosimilar Insulin Glargine

- Global Phase I (PK-PD) study successfully completed
- Established equivalence between biosimilar insulin glargine and the innovator product
- Global Phase III to commence in 2013
- Market Authorization to be filed in 2015



# Growth Segment: Biosimilars

Biosimilar MAb & other Biologics: Program partnered with Mylan



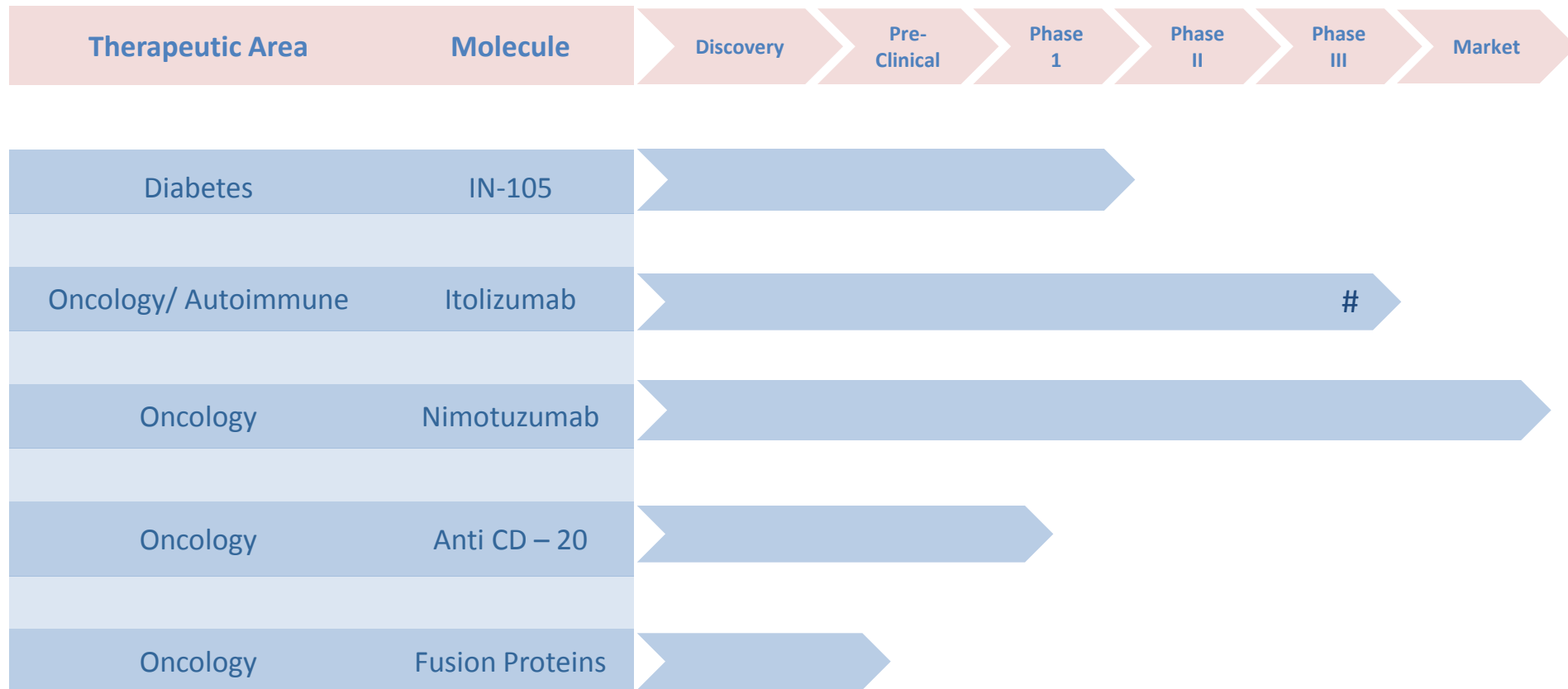
Combines Biocon's biologics R&D and manufacturing  
with  
Mylan's regulatory & commercialization capabilities

## Program Update

- Biosimilar Trastuzumab
  - Global Phase III trial for developed markets initiated
  - ROW Focused, Phase III trial underway in India
  - First Filing in Emerging Markets expected in FY14
- Other Molecules
  - Several Programs expected to enter the clinic in FY14

# Growth Segment: Novel Molecules

## Novel Pipeline



- **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

### IN-105 (First-in-class Prandial Insulin) Option Agreement with



**Bristol-Myers Squibb**  
Together we can prevail.®

- Redesigned Phase II trials under US IND for **Global development**
- BMS will have an **exclusive option post phase II** to further develop & commercialise the asset worldwide
- Biocon to receive **licensing fee** in addition to regulatory & commercialization milestones

# Growth Segment: Novel Molecules

## 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

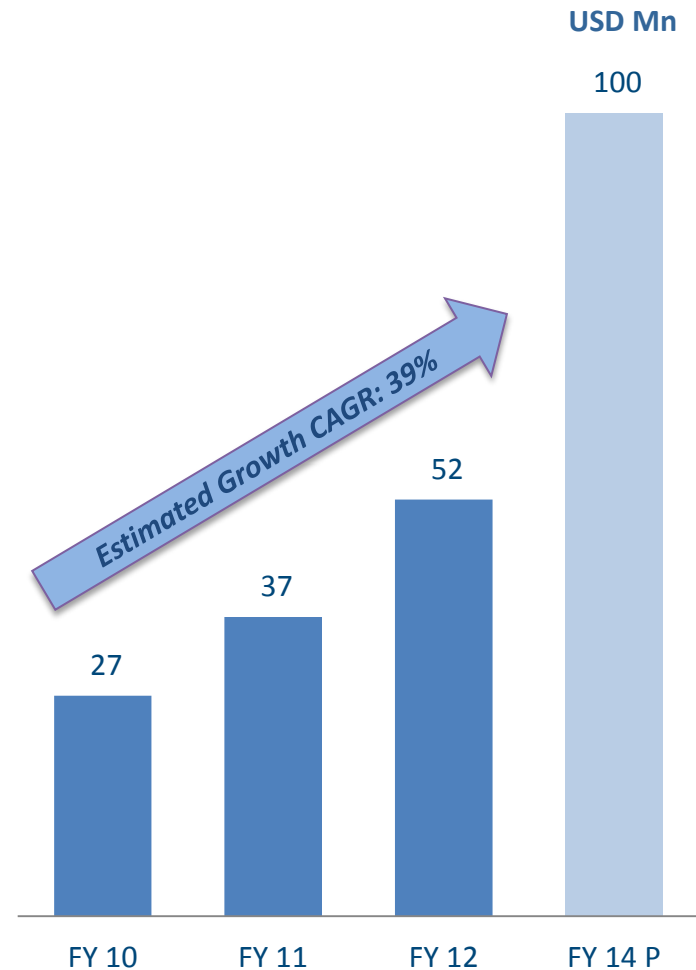
28 Weeks



Treatment Arm

# Growth Segment: Branded Formulations

- **Portfolio of 80 brands across 7 therapy segments**
- **Focus on patient convenience, product differentiation & personalized medical support**
- **Several Biocon Brands in the Top 3**
- **Unique Product Offerings:**
  - **BioMAb EGFR: India’s first indigenously developed novel biologic**
  - **Insugen: #1 Indian Insulin Brand**





# Growth Segment: Branded Formulations

## Differentiated Portfolio

- Unique Mix of Novels, Biosimilars and Branded generics

## Consistent Growth

- Fastest growing Insulins Company in India at 33% YoY Growth
- CAGR in excess of 30% vis-à-vis an industry average of 15% over 4 years
- Recognized as a leading Oncology company in India

## Moving Ahead

- Portfolio Expansion with Novels & Differentiated generics
- Growing beyond India: Geographical Expansion into Emerging Markets

## Integrated Platforms

- Integrated Drug Discovery and Development
- Biologics Discovery and Development
- Syngene- Clinigene axis

## Niche Services

- Bioanalytical testing of small and large molecules
- Antibody Drug Conjugate (ADC) development
- Unique *In-Vivo* Models- Human tumor tissue Xenograft
- Early and rapid toxicology evaluation (Cardiomyocytes )

## Evolution of Services

- Commercial scale production of NCEs
- High potency (cytotoxic) API manufacturing
- Formulation development

## Differentiated Business Models

- Dedicated/customized infrastructure
- End-to-end services
- Risk sharing: Milestone based
- Incubation: IP sharing



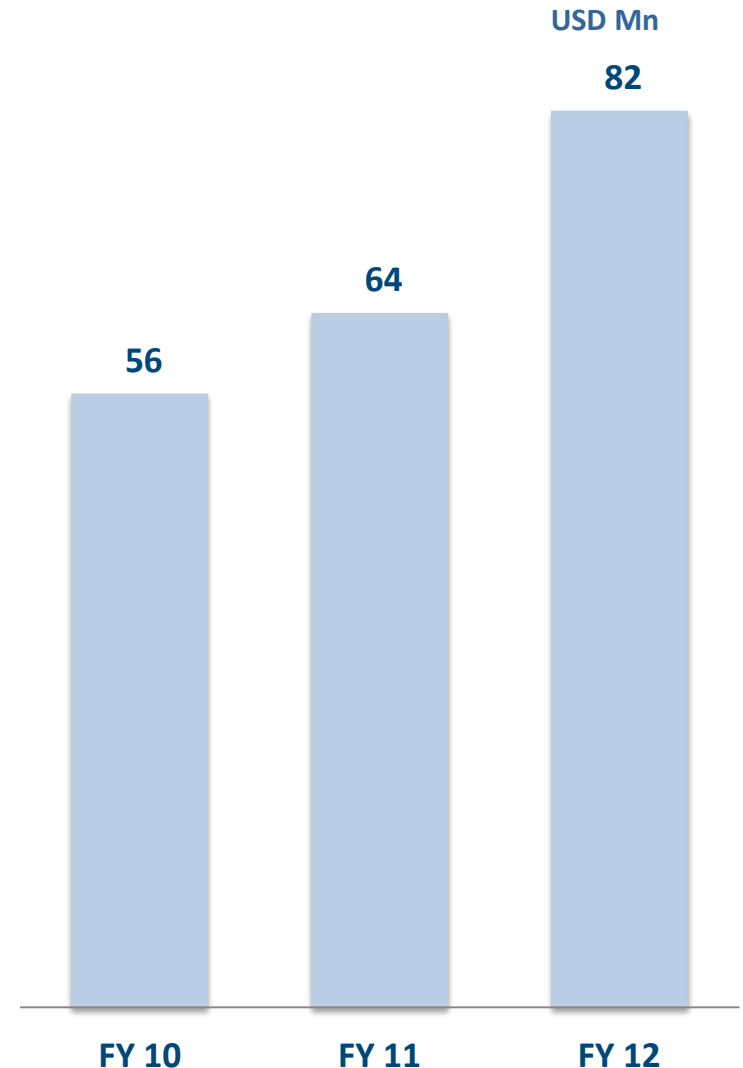
## GE Capital

- PE Investment of \$ 25 Mn for a 7.7% stake, valuing Syngene at \$ 325 Mn
- Investment aimed at enhancing Syngene's service offerings & fund future growth



## Abbott Nutrition

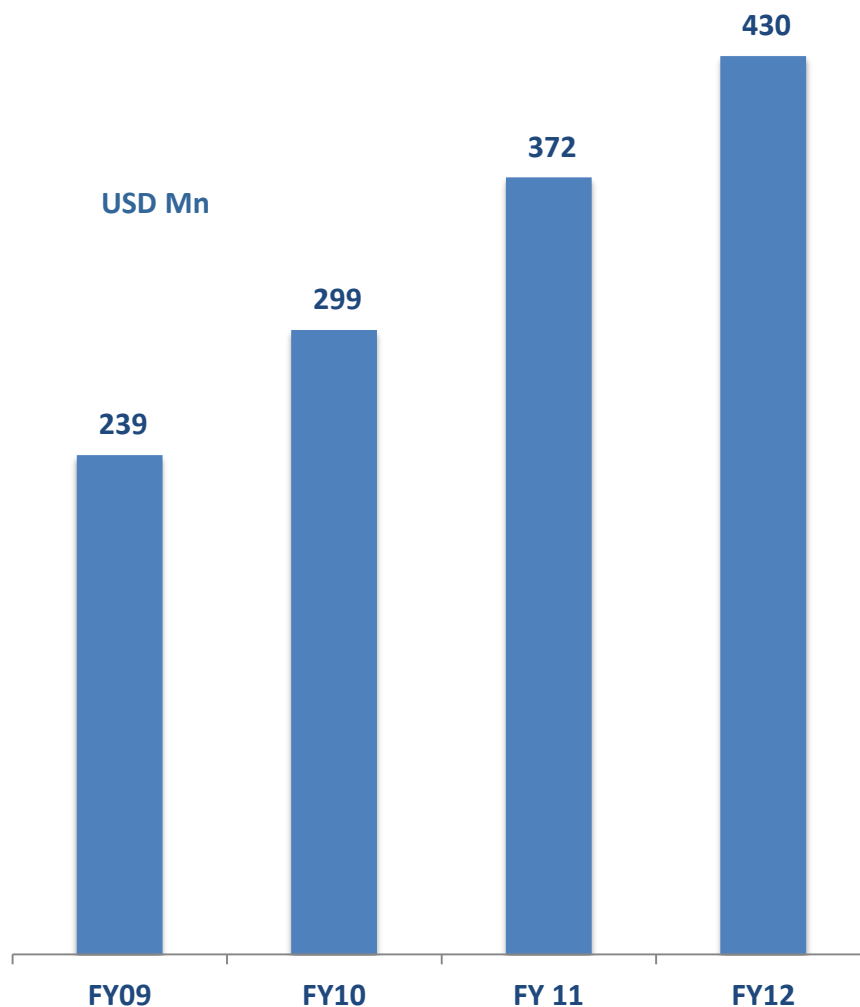
- Dedicated, India-centric nutrition R&D Centre
- Focused on:
  - Maternal & Child Nutrition
  - Diabetes Care





## Financial Highlights

# Revenue FY 09 - FY12



**Strong Top Line Growth**

○ 3 year CAGR :22%

# Financial Performance : H1 FY13

USD Mn

	H1 FY13	H1 FY12
Revenue	247	200
R&D Expenses	16	10
	7%	5%
EBITDA	61	56
	25%	28%
PAT	34	31
	14%	16%
EPS	8.5	7.8

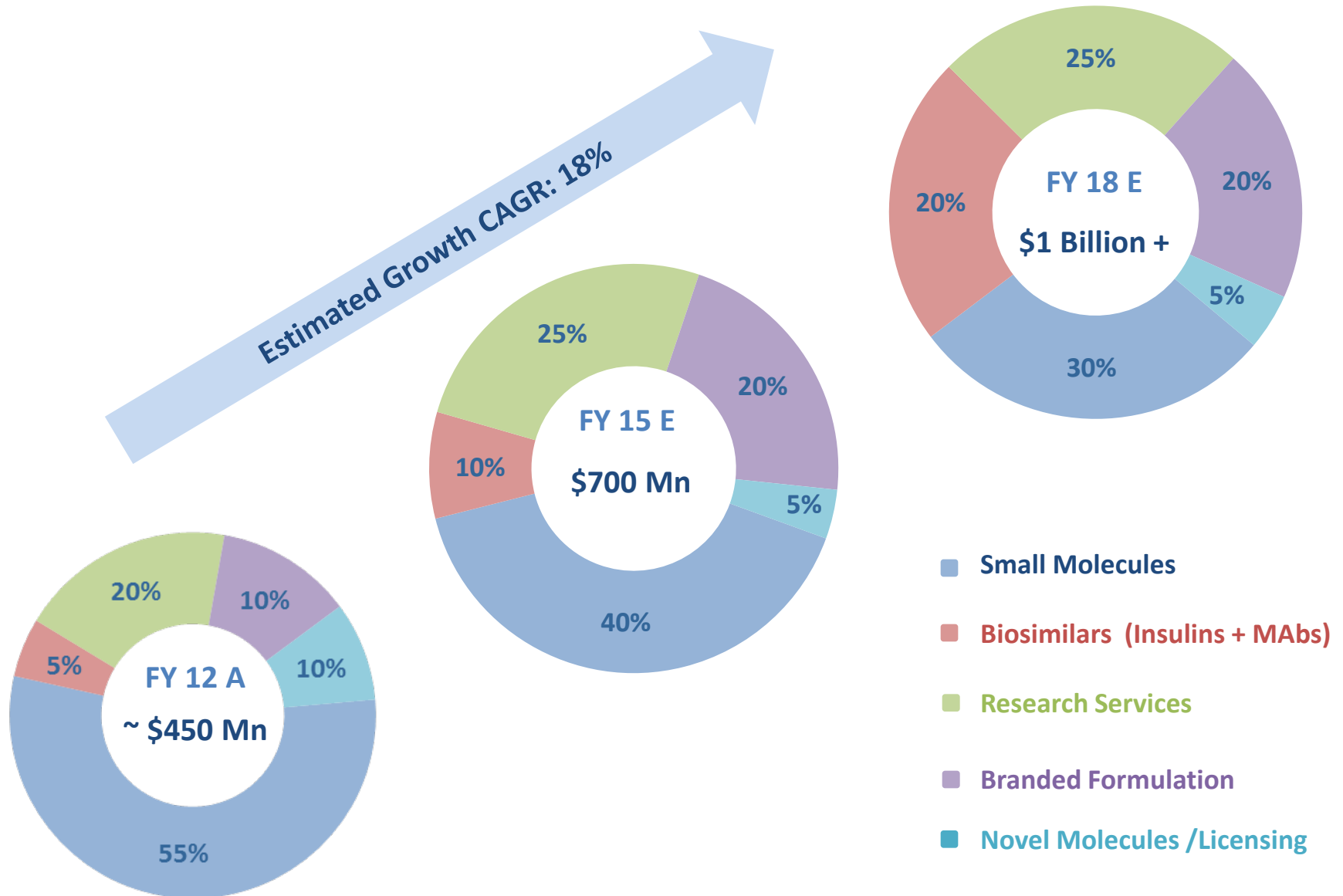
## Growth Drivers in H1 - FY13\*

- APIs & Biosimilar Insulins: 21%
- Branded Formulations: 45%
- Research Services: 40%

## Strong Balance Sheet

- Shareholder Funds: \$490Mn
- Net Cash Position: \$125 Mn

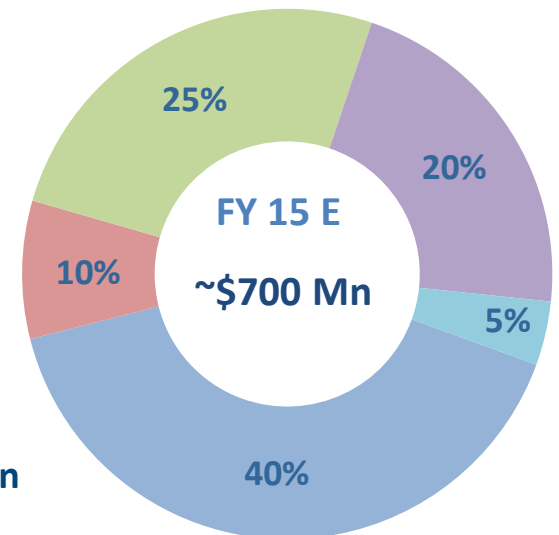
# Leveraging Challenges for Sustained Growth




# Looking Ahead

## Reaching \$700 Mn by 2015

- **Small Molecules** - Improved product Mix: **\$280 Mn**
- **Research Services** - Sustained Growth Momentum : **\$175 Mn**
- **Branded Formulations** - Differentiated Value offerings :**\$140 Mn**
- **Biosimilars** - Geographical Expansion :**\$70 Mn**
- **Novel Molecules** - Out-licensing and Global Development :**\$35 Mn**





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# Innovative Science Affordable Medicine



## Thank You



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