



**November 2012** 

### **SAFE HARBOR**



Certain statements in this release concerning our future growth prospects are forwardlooking 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 currency changes, 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 our company, nor our directors, nor any of their respective 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**



**SNAPSHOT** PORTFOLIO SPREAD STRATEGIC ALLIANCES **RESEARCH & DEVELOPMENT** FINANCIAL HIGHLIGHTS





# **Snapshot**

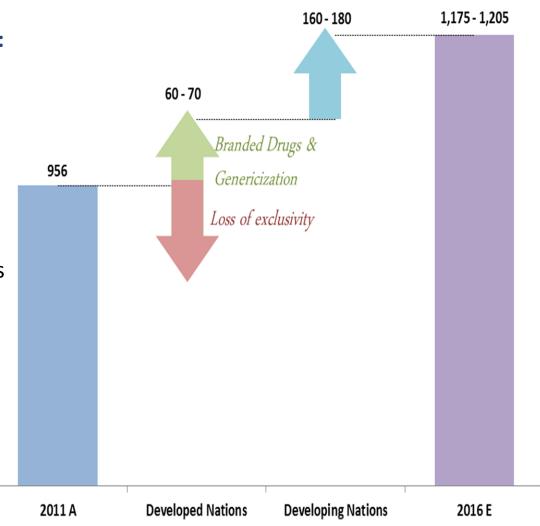
### THE EVOLVING PHARMA LANDSCAPE



# Emergence of a new paradigm for healthcare with shifting equations

### Growth Drivers for Global Pharma:

- Innovation enabling Affordability & Access
- Emerging Nations redefining unmet needs and industry landscape
- Healthcare Reforms with a focus on value based analysis
- Generics & Biosimilars restating industry dynamics
- Alliances to share costs and manage R&D risk



### **BIOCON: IN SYNC WITH SHIFTING PARADIGMS**



Biocon is **an emerging, global Bio-pharmaceutical** enterprise, focused on innovation to develop affordable products and services for patients, partners and healthcare systems across the world.

### **Biocon is committed towards:**

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* 

### YTD FY13 HIGHLIGHTS



# Financial Performance (H1 FY13)

- Group Revenue at ₹ 1,235 Crores (23% YoY growth)
- Growth across all verticals: Biopharma (15%), Branded Formulations (45%), Research Services (40%)
- EBITDA at ₹ 305 Crores (EBITDA Margin: 25%)

# **Research & Development**

- Entered into an option agreement with BMS for our novel asset, IN-105
- Itolizumab: Dossier filed with DCGI for marketing authorization in India for Psoriasis.
- Part 1 of EU Phase III trial for Biosimilar rh-Insulin successfully establishes comparable safety & efficacy with innovator products.
- Global Phase I trial for Biosimilar Insulin Glargine successfully completed.

# **Corporate Milestones**

- Inauguration of Biocon Research Centre
- Commencement of Abbott Nutrition Research & Development Centre
- GE Capital proposes Investment to the tune of ₹ 125 Crores in Syngene
- Becomes the only Asian Company to feature in Science magazine's global 'Top 20 Employers' in biotech & pharma.

### **BUSINESS STRUCTURE & HOLDINGS**





#### **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 | 99% Custom research, drug discovery



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

### MANAGING THE FUTURE









# **Portfolio Spread**

# **DIVERSIFIED OFFERINGS**



Statins	Insulins & Immuno	Other	Branded	Research	Biosimilars
	Suppressants	Biopharma	Formulations	Services	& Novels

Small Molecules: Base Business

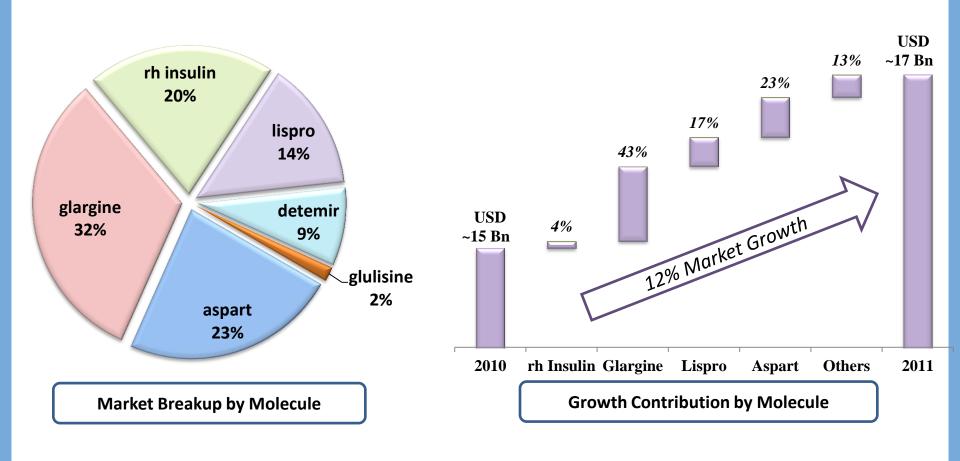
Moving up the Value Chain

Portfolio	Constituents
Statins	Simvastatin, Atorvastatin, Lovastatin, Rosuvastatin, Fluvastatin & Pravastatin
Insulins & Immuno suppressants	Insulin and analogs Tacrolimus, MMF & MPA
Other Biopharma	Orlistat, Fidaxomicin, 50+ other molecules
Branded Formulations	Diabetology, Cardiology, Nephrology, Oncology, Immunotherapy, Comprehensive Care
Research Services	Syngene (Custom Research) Clinigene (Clinical research)
Biosimilar Biologics	Insulin & Analogs; Biosimilar MAbs
Novel Molecules	IN-105, Itolizumab and others

# **INSULINS: GLOBAL OPPORTUNITY (1)**



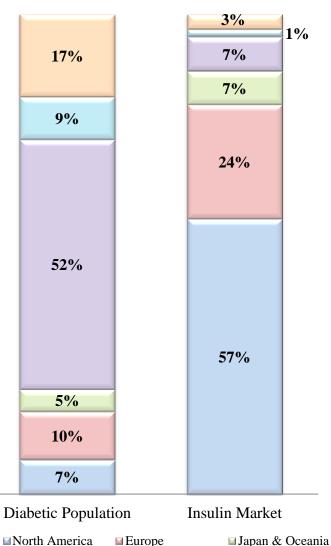
# Total 2011 Insulin Market: USD ~17 Bn



# **INSULINS: GLOBAL OPPORTUNITY (2)**







**■ MENA** 

**■**RoW

■ BRIC-TM

# The shift underway

- Total Diabetic Population 2011: 366 Mn
  - Developed Markets: 80 Mn
  - Emerging markets: 286 Mn
- Diabetes Population 2030E: 552 Mn
  - Developed Markets: 96 Mn
  - Emerging markets: 456 Mn
- Diabetes prevalence expected to go up from current levels of 8% to 10% in 2030.
- Diabetes prevalence expected to rapidly increase in Africa, MENA and Urban Areas of BRIC-TM
- More than half of the current diabetic population in emerging markets remains undiagnosed with limited access to affordable healthcare



# Committed to delivering affordable, quality insulin to global markets

- rh-Insulin
- Basal insulin analog
- Rapid acting insulin analogs

Portfolio



- 30+ registrations in Emerging markets
- Strong regional partners in major markets including Japan & China

Regional Partnerships



- rh-Insulin:
  - Commercialized in several geographies including India
- Glargine
  - Active US-IND
  - Commercialized in India

Molecule Status



# **Biosimilar Insulin & Analogs: Clinical Update**





# Biosimilar rh-Insulin

- EU Phase III Ongoing
- Part 1 of the study establishes the Efficacy endpoint (non inferiority to innovator product)
- Immunogenicity and safety at the 6 month time interval were also similar

# Biosimilar Insulin Glargine

- Global Phase I (PK-PD) study successfully completed
- Established equivalence between our biosimilar insulin glargine and the innovator product
- Global Phase III expected to commence in FY 14



### **BRANDED FORMULATIONS: THERAPEUTIC SEGMENTS**



























**STATIX®** 



Myokinase®





















PENMER®





### **BRANDED FORMULATIONS: CARVING A NICHE**



**Affordability Index\*** 

Basalog: 40%

Insugen: 13%

Bestor: 30%

**Statix: 25%** 

Advacan: 45%

Tacrograf: 30%

**Evertor: 60%** 

BioMAb EGFR: 54%

**Picon: 38%** 

Psorid: 28%

INDIA PRODUCT RANKINGS#			
Cardiology			
	Clotide	1	
	Myokinase	2	
Oncotherapeutics			
	BioMAb EGFR	2	
	Evertor	2	
	Abraxane	3	
Immunotherapy			
	Psorid	1	
	Picon	2	
	Tbis	2	
Nephrology			
	Tacrograf	2	
Comprehensive Care			
	Albubet	3	

<sup>\*:</sup> Compared to the top selling competitor brand; #: ORG IMS September MAT 2012

# **BRANDED FORMULATIONS: #1 Indian Insulin Company**



# Biocon's Volume Market share\*

100 IU Insulin: 14%

Glargine vials: 87%

# **Value Growth YoY\***

Fastest growing Insulin company

Biocon: 33%

Sanofi Aventis: 20%

**Novo Nordisk: 16%** 

# Biocon's ranking\*

#4 in overall insulin market

#3 in the 40 IU Insulin market

**#1** in the Glargine vial market

### INSUPen® ease

Reusable delivery device based on proprietary German technology, capable of delivering both Insugen<sup>TM</sup> & Basalog<sup>TM</sup> launched in India



### **RESEARCH SERVICES: FROM LABS TO CLINICS**



### **DISCOVERY SERVICES**

#### **CLIENTS**

Large & mid-size Pharma & Biotech Companies

On-going collaboration with over **60** companies worldwide

#### **SERVICES**

Biology R&D
Chemistry R&D
Custom Synthesis
Biologics Production
Pre-Clinical & Pharmacology
Pharmaceutical Development

Syngene

Clinigene

#### CLINICAL RESEARCH

#### **CLIENTS**

Large & mid-size Pharma & Biotech Companies

#### **SERVICES**

Clinical Operations & Development

Clinical Data Management

Central & Bioanalytical Research Lab

**Human Pharmacology Unit** 

**Regulatory Services** 

Integrated discovery model

Collaborative Partnerships Risk sharing projects

FTE based programs

Project based service

Fee based models

### **RESEARCH SERVICES: VALUE-BASED POSITIONING**

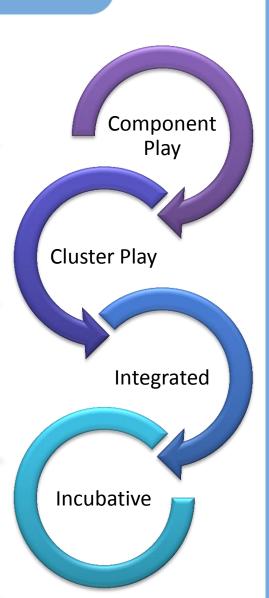


**Integrated Model** spanning discovery & early development to late stage clinical studies

Large Portfolio of Offerings combining Chemistry & Biologics expertise with cost advantage

**Custom partnership models** ranging from FTE based to risk-reward models

Clientele comprising of **100+ large and mid-size** pharma & biotech companies







# **Strategic Alliances**

# **STRATEGIC PARTNERSHIPS**



	BMS	Diabetology	Oral Insulin (IN-105)	
Discovery &	CIMAb	Oncology	BioMAb EGFR, Itolizumab	
Development	IATRICa	Oncology	Immuno-conjugated MAbs	
	Vaccinex	Oncology	Biobetter MAbs	
Commercialization	Optimer	First in Class Anti Infective	Fidaxomicin	
	Mylan	Oncology & Auto Immune	Biosimilar MABs & Biologics	
Research Services	BMS	Discovery to Commercialization	Integrated DD Services	
	Abbott	Nutrition R&D	Integrated discovery services	



# 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.

BMS to provide **developmental support** (financial, clinical & strategic)

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.

### FIDAXOMICIN PARTNERSHIP: OPTIMER



# First-in-class Anti-Infective



Combines Biocon's R&D and manufacturing prowess of novel biologics with Optimer's proprietary molecule technology

Collaboration for manufacture & supply of

Fidaxomicin API: DIFICID<sup>TM</sup> & DIFICLIR<sup>TM</sup> tablets

**Extension of prior relationship** where Biocon assisted Optimer with product development

Launched in US & select East European nations in first phase;

Alliances established for Japan & Brazil

### **BIOSIMILARS COMMERCIALIZATION PARTNERSHIP: MYLAN**



# **Monoclonal Antibodies (MAbs)**



Combines Biocon's R&D and manufacturing prowess of biologics with Mylan's regulatory & commercialization capabilities in the US and Europe

# Market Value of Portfolio in 2011: ~33 Bn USD

Exclusive collaboration for development and commercialization of complex biosimilars.

Basket of Products with patent expiries 2015 onward

(Trastuzumab, Peg-filgrastim, Bevacizumab, Adalimumab, Eternacept)

Mylan and Biocon to share development and capital costs.

Mylan will have exclusive commercialization rights in the **regulated markets**; **profits to be shared** 

Biocon and Mylan to have co-exclusive commercialization rights in other markets.

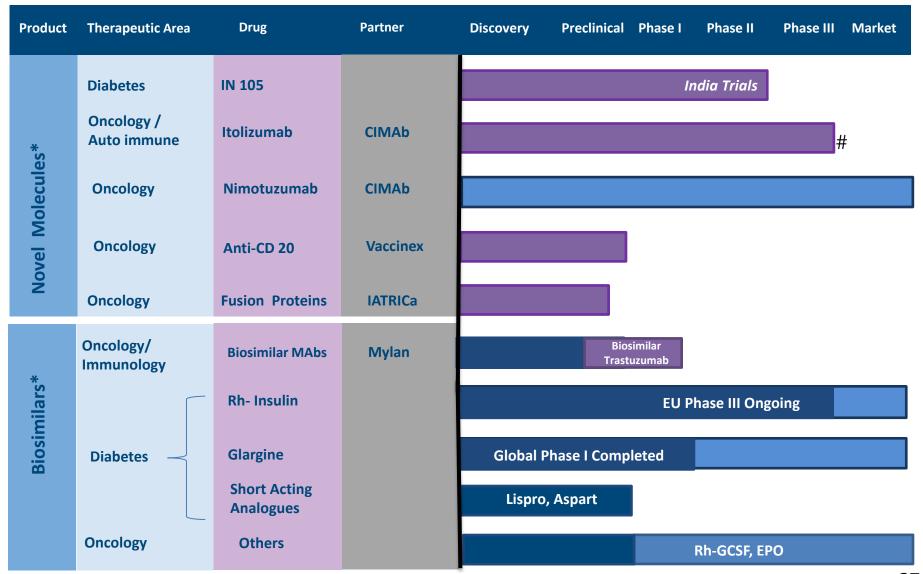




# **Research & Development**

### **RESEARCH PARTNERSHIPS: HIGH POTENTIAL PRODUCT PIPELINE**





<sup>\*</sup> Includes molecules from collaborative programs;

### **ANTI- CD6 MAB: ITOLIZUMAB**



# **Drug Highlights**

### **Targets CD6**

CD6 is a type 1 cell membrane glycoprotein belonging to the scavenger receptor cysteine-rich (SRCR) super family group B.

CD6 is predominantly expressed by T cells & a B cell subset.

CD6 binds ALCAM (activated leukocyte cell adhesion molecule) which is expressed on:

Activated T, cells, B cells & monocytes.

Skin fibroblasts, keratinocytes, rheumatoid arthritis synovium.

# **Molecule Update**

- Regulatory Filing Made with DCGI for Marketing Authorization in India for treatment of Psoriasis
- Indication Expansions being explored

# TREAT PLAQ STUDY: SUMMARY OF 28-WEEK INTERIM RESULTS



52-Week data confirms achievement of multiple, key primary and secondary end-points

### PRIMARY ENDPOINT

Result\*

Statistically significant patient cohort with ≥ PASI 75 Vs. placebo at 12 Weeks



### **SECONDARY ENDPOINTS**

Significant Proportion of subjects achieving PASI 50 and PASI 90



Safety & Tolerability



Improvement in PGA scores



Considerable Proportion of subjects with PGA score of "clear" or "minimal"



# TREAT PLAQ STUDY: EFFICACY RESULTS



Representative patient samples from each arm.



### **ORAL INSULIN: IN 105**



- Hepatic portal-vein-delivery
- Prime liver effect and benefit of "hepatic buffering"
- Physiological Benefits No sustained peripheral hyper-insulinemia
- **Emulates innate** insulin physiology

- Adequate post-prandial glucose control
- Reduces the risk of hypoglycaemia
- Weight neutral
- Action independent of pancreas functionality

# **Potential Therapeutic Use**

- Potential use across the diabetic treatment continuum
  - Concomitant use with OADs or monotherapy
  - "Bridge therapy" to intensive insulin therapy
  - Post-prandial control component with basal insulin therapy

# **IN-105 INDIA PHASE III RESULT SUMMARY**



IN-105 shows clear efficacy as a prandial insulin in lowering post-prandial glucose levels

Parameter	Result
SECONDARY END POINTS	
Efficacy – Secondary Endpoints Statistically significant reduction in PPG during STM	√
Significant reduction in SMBG post prandial glucose excursion	<b>√</b>
Safety – Secondary Endpoints  No clinically significant hypoglycemia	√
Very low immunogenicity	$\checkmark$
No neutralizing antibodies detected	<b>√</b>
No effect on liver enzymes	<b>√</b>
No effect on lipid profiles	$\checkmark$
No effect on renal function	1
Efficacy – Primary Endpoint  Change in Hb1Ac for IN-105 not statistically significant due to higher than anticipated placebo effect	X





# **Financial Highlights**

### **FINANCIAL PERFORMANCE**



₹ crore/USD mn

(	FYo8	FY09	FY10	FY11	FY12
Revenue	1,090   273	1,194   260	1,493   318	1,858   407	2,148   445
<b>EBITDA</b>	335 83	372 81	455 97	573 125	579 120
Net profit*	225 56	238 52	273 58	340 74	338 70

	H1 FY13	H1 FY12
Revenue	1,235   <b>225</b>	1,001   <b>219</b>
EBITDA	305   <b>55</b>	281  <i>61</i>
	25%	28%
PAT	169  <b>31</b>	156  <i>34</i>
	14%	16%
EPS	8.5	7.8

FY08-12: Avg.exch.rate in that fiscal;

H1 FY13: USD 1 = ₹ 54.55; H1 FY12: USD 1= ₹ 45.35

<sup>\*</sup> Net profit is pre-exceptional in table 1.No exceptional items in FY10, FY11 and FY12.

# **Leveraging Challenges for Sustained Growth**



