



# Corporate Presentation

December 2009



DRIVING INNOVATION



Delivering Affordability

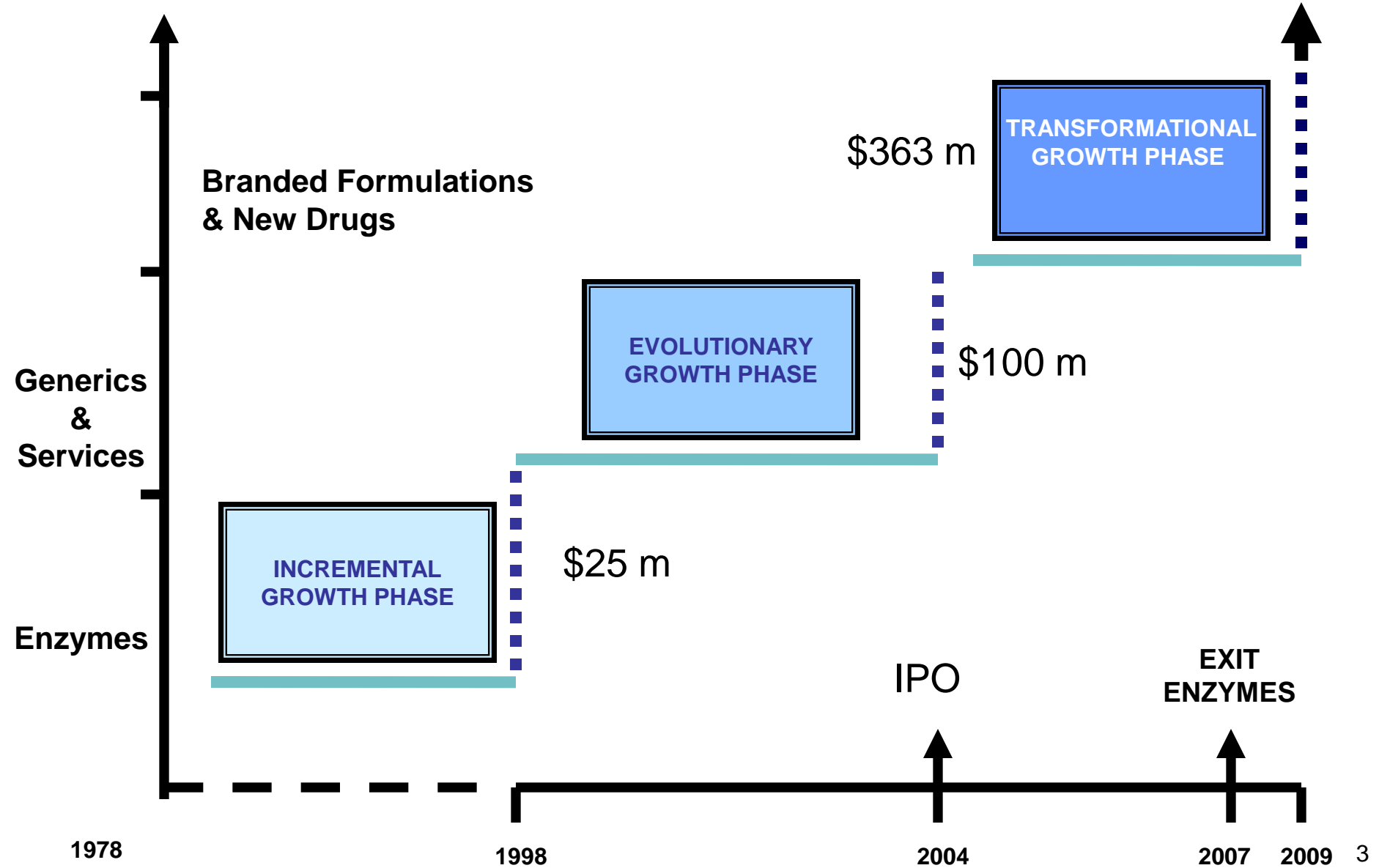




*Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements. Important factors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

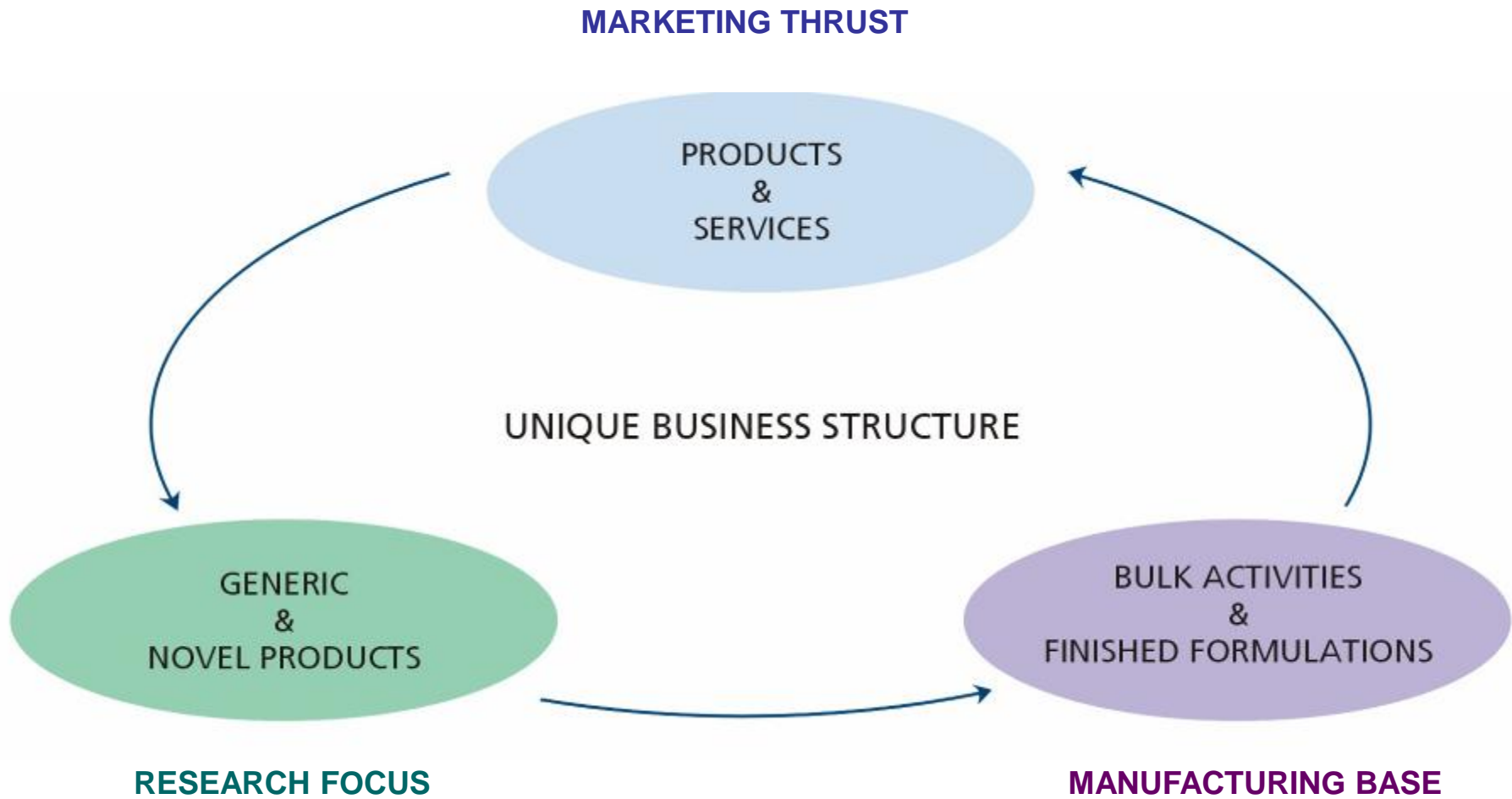


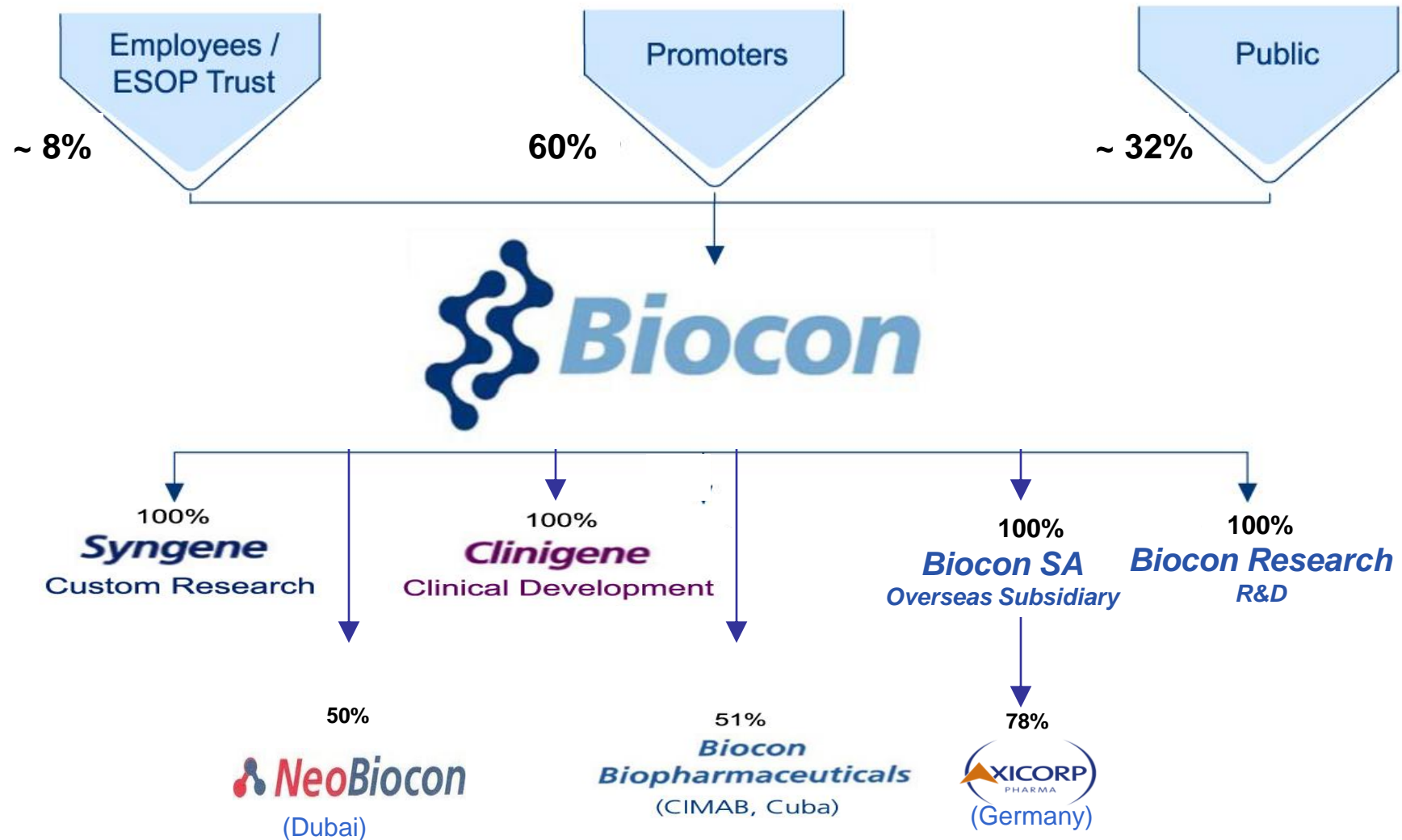
# From Enzymes to Bio-Pharma





# Risk-Balanced Business Model









# Integrated Drug Development Capabilities



## ACROSS THE VALUE CHAIN

### *Syngene*

#### PRE-CLINICAL DISCOVERY

- **Chemistry**
  - Medicinal Chemistry
  - Process R&D
  - Analytical Services
  - Combinatorial Chemistry
  - Custom Manufacturing
  - Polymer Chemistry
- **Biology**
  - Molecular Biology
  - Protein Sciences
  - Cell Line Services
  - Assay Services
  - eADMET & PK Studies
  - Bioanalytical Services
  - Biologics

### *Clinigene*

#### CLINICAL DEVELOPMENT

- Clinical Operations
- Clinical Development
- Clinical Data Management and Biostatistics
- Regulatory Services
- Human Pharmacology Unit
- Bioanalytical Research Laboratory
- Central Laboratory



#### COMMERCIALIZATION

- Research Collaboration
- Product Development
- Process Development
- Manufacturing
- Regulatory filing
- Marketing
- Custom Manufacturing
- Licensing





- **POSITIONING:** Leading producer of generics & bio-similars and a frontline biopharmaceutical innovator.
- **STRATEGY:** Investing in new drug development and penetrating global markets for bio-similars through partnerships.
- **RISK MITIGATION:** Selection of *New Drugs* based on validated targets (BVX 20), novel delivery systems (IN105 Oral Insulin), Phase II Human clinical data (T1h, BIOMAb EGFR) and novel targeting technologies (IATRICa).



## **AFFORDABLE INNOVATION**

- ✓ **Develop and offer the world's most affordable Diabetes Therapies**
- ✓ **Innovate and deliver the most affordable biologics for cancer and auto-immune diseases**
- ✓ **Forge strategic partnerships that create global market access**
- ✓ **Commercialize novel biologics with a “Made in India” label**





# Research & Development



## Diabetes, Oncology & Auto-immune Diseases



ANTI EGFR MAb  
ANTI CD6 MAb (T1h)  
BVX20 MAb (Anti-CD20)  
CONJUGATED ANTIBODIES

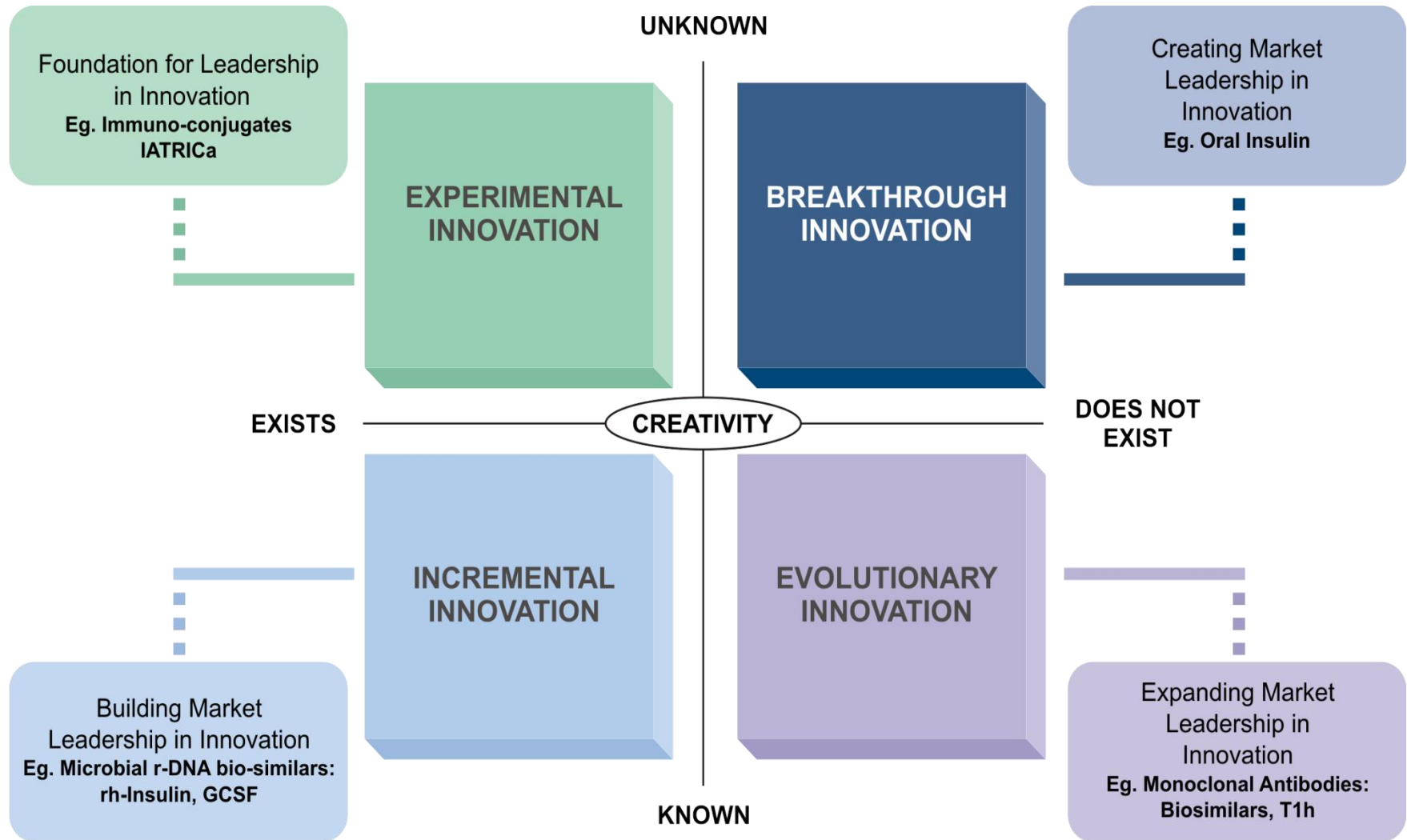
IN105 (Oral Insulin)

### GENERIC BIOLOGICS

rh-INSULIN  
INSULIN ANALOGS

TRASTUZUMAB  
BEVACIZUMAB







- **Business model: Leverage our strong financial position to develop novel drugs for licensing and co-promoting with multiple marketing partners in various global markets**
  
- **Research programs in advanced stages**
  - ❖ **Oral Insulin or IN-105 and**
  - ❖ **T1h or Anti-CD6 Monoclonal antibody**

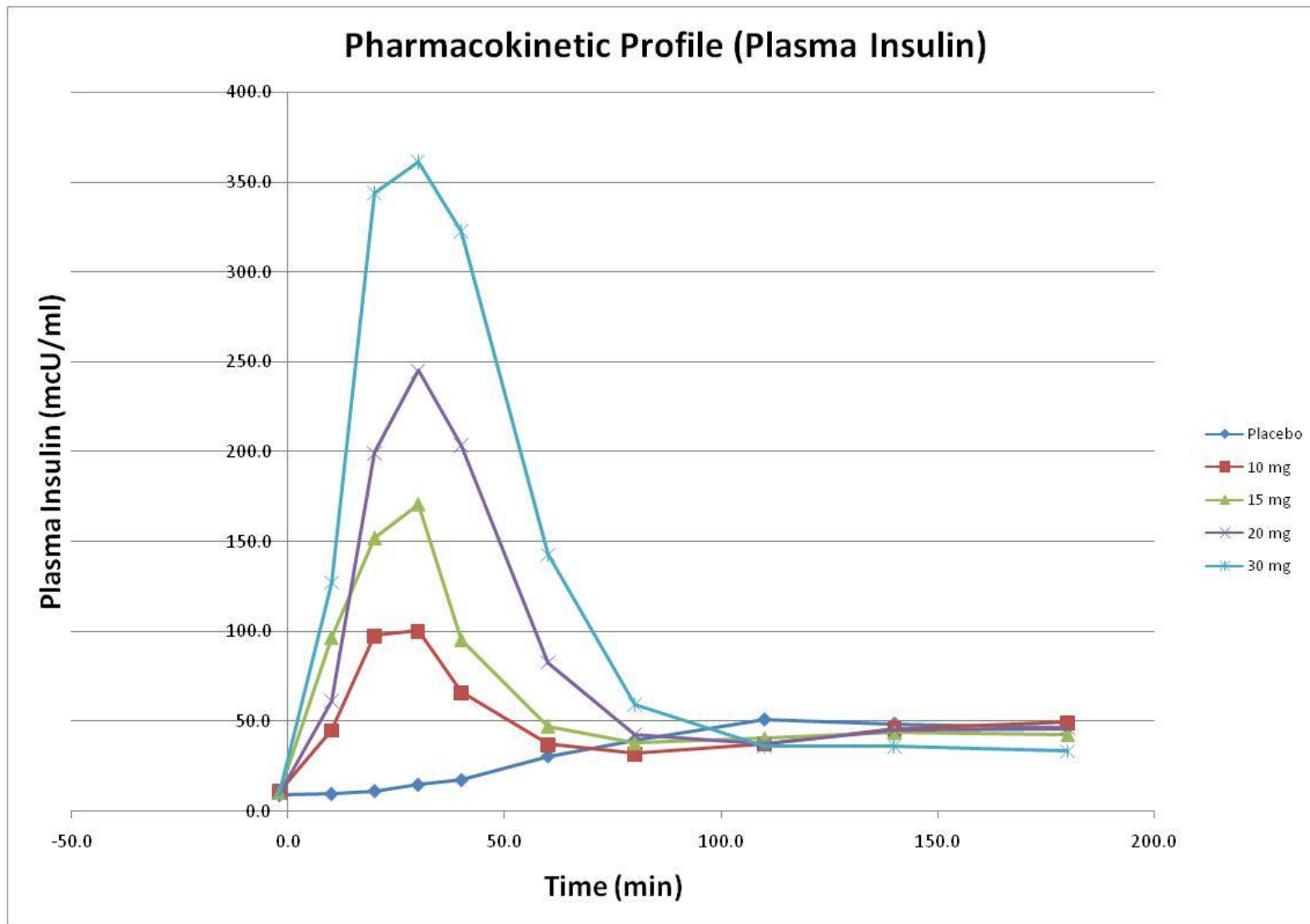


- **Phase III: Completed initial dose range finding studies. Currently in the middle of a long-term efficacy and safety study (CTRI/2008/091/000276) in Indian patients with Type II diabetes.**
- **Presented a paper on IN105 at the session on Novel Therapies during the European Association for Study of Diabetes (EASD) meet held in Rome in September 2008.**
- **Presented a poster at the American Diabetes Association in New Orleans in June 2009.**





# Phase 2a findings - Absorption is proportional to dose







- **Psoriasis Phase II – Treatment phase is complete. Final report to be submitted to regulators by Nov 2009.**
- **Double-blind Placebo-controlled Phase III study (TREATPLAQ) in Psoriasis to be initiated in Q1CY2010.**
- **RA Phase II report to be submitted to the regulators in Q4 FY2010.**
- **Data on the mechanism of action of T1h was presented at the Fourth Asian Congress on Autoimmunity in September 2009 in Singapore.**

**0.4mg/kg once every 4 weeks**

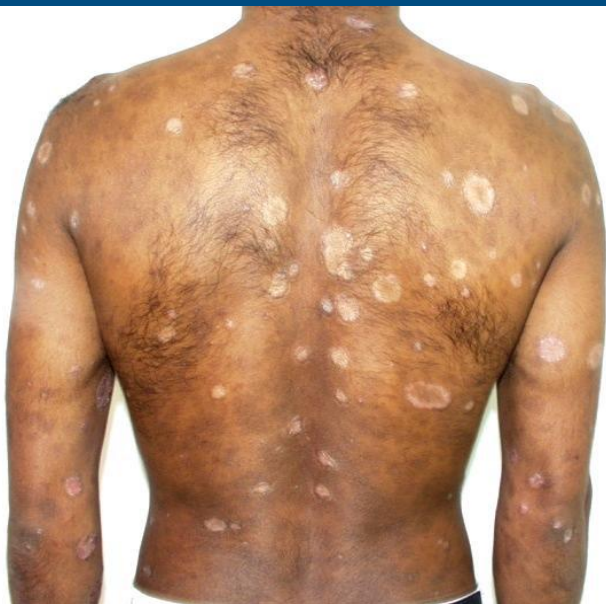
**Day 1**



**Day 29**



**0.8 mg/kg once every 4 weeks**



**Day 1**



**Day 29**



**Day 57**





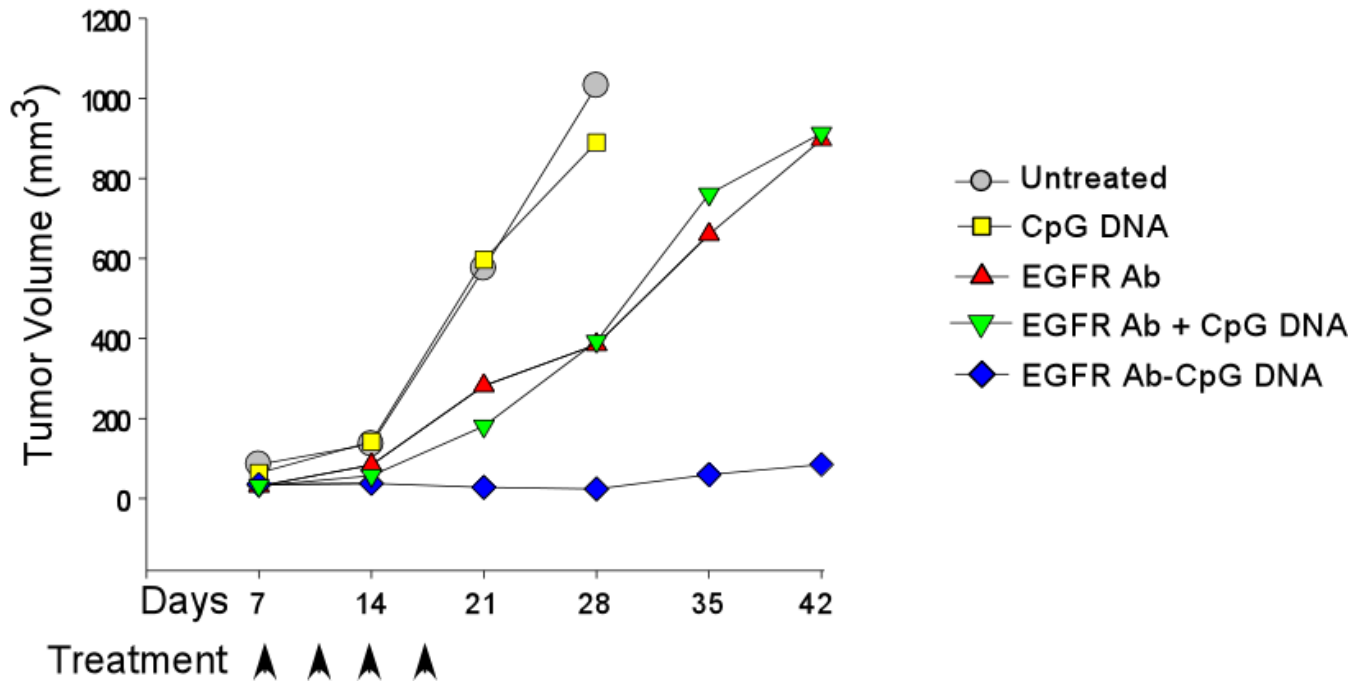
# STRATEGIC ALLIANCES



- ❑ Invested in IATRICa in 2008, a US-based start-up Biotech firm
- ❑ To co-develop novel, anti-cancer molecules based on a proprietary immuno-conjugation technology licensed from Johns Hopkins University, USA.
- ❑ Bio-hybrid molecules for targeted immunotherapy are considered to be the next generation drugs: Biocon is at the cutting edge.
- ❑ The first molecule: Conjugated-*Trastuzumab* for Breast Cancer.



# EGFR Antibody-CpG DNA (Active antibody) – More effective and durable inhibition of colon cancer







- An exclusive collaboration for the development, manufacturing and commercialization of complex biogenerics / biosimilars, especially MAbs.**
- Biocon is well positioned in both novel biologics and biogenerics owing to its early investments in R&D and manufacturing.**
- Mylan brings in regulatory and commercialization capabilities.**
- Biocon & Mylan will share the development and capital costs.**
- Mylan will have exclusive commercialization rights in the regulated markets through a profit-sharing arrangement.**
- Biocon & Mylan will have co-exclusive commercialization rights in other markets.**



- An exclusive agreement to jointly develop, commercialize and manufacture a novel peptide therapeutic.**
- Partnership is specific to Diabetes segment.**
- Amylin brings in its knowledge on peptide therapeutics.**
- Biocon brings in its recombinant DNA technology, large-scale manufacturing and low-cost pre-clinical and clinical development capabilities.**
- A co-development deal where both will share cost of development.**
- Commercialization territory marked out for each partner.**



# Products & Markets



**Global presence: ~ 75 countries**

**Europe, USA, Latin America,  
South East Asia and the Middle East.**

# Therapeutic Segments

## DIABETOLOGY

sustaining life

**Biocon** WINNING with Diabetes<sup>®</sup>



**INSUGEN<sup>®</sup>**

## ONCO THERAPEUTICS

transforming life



**NUFILsafe<sup>™</sup>**  
Filgrastim 300 mcg

**BIOMAb EGFR<sup>™</sup>**  
Nimotuzumab 200 mg

**Abraxane<sup>®</sup>**  
Albumin bound Paclitaxel 100 mg

## NEPHROLOGY

protecting life



**RENODAPT**

## CARDIOLOGY

enhancing life



**STATIX<sup>®</sup>**



**Myokinase<sup>®</sup>**





# Research Services

***Clinigene***

 A Biocon company

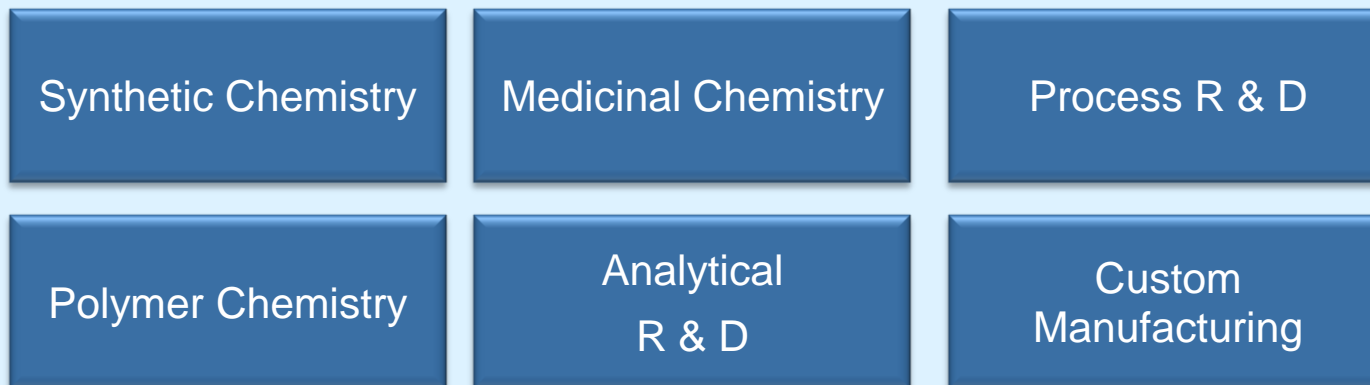
***Syngene***

 A Biocon company

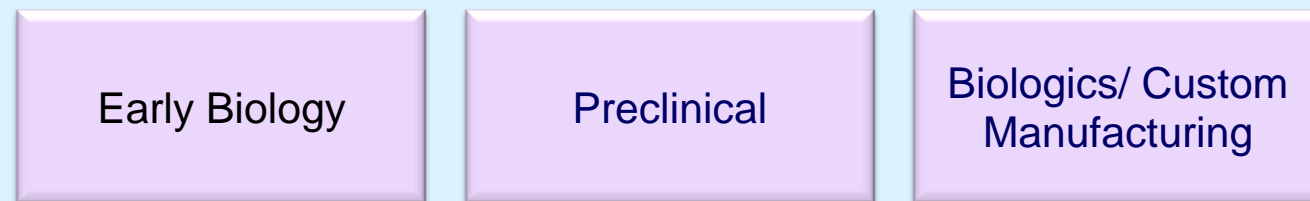




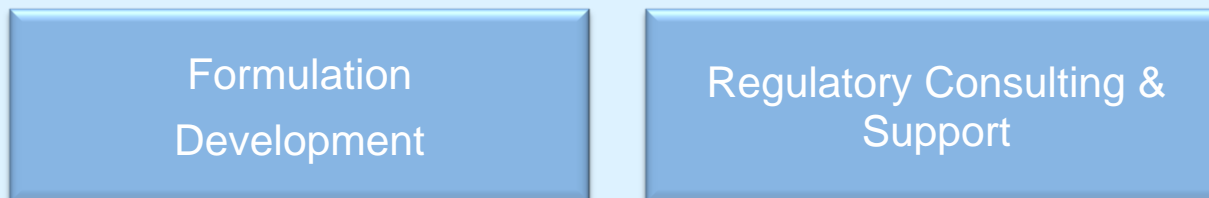
## Chemistry Services

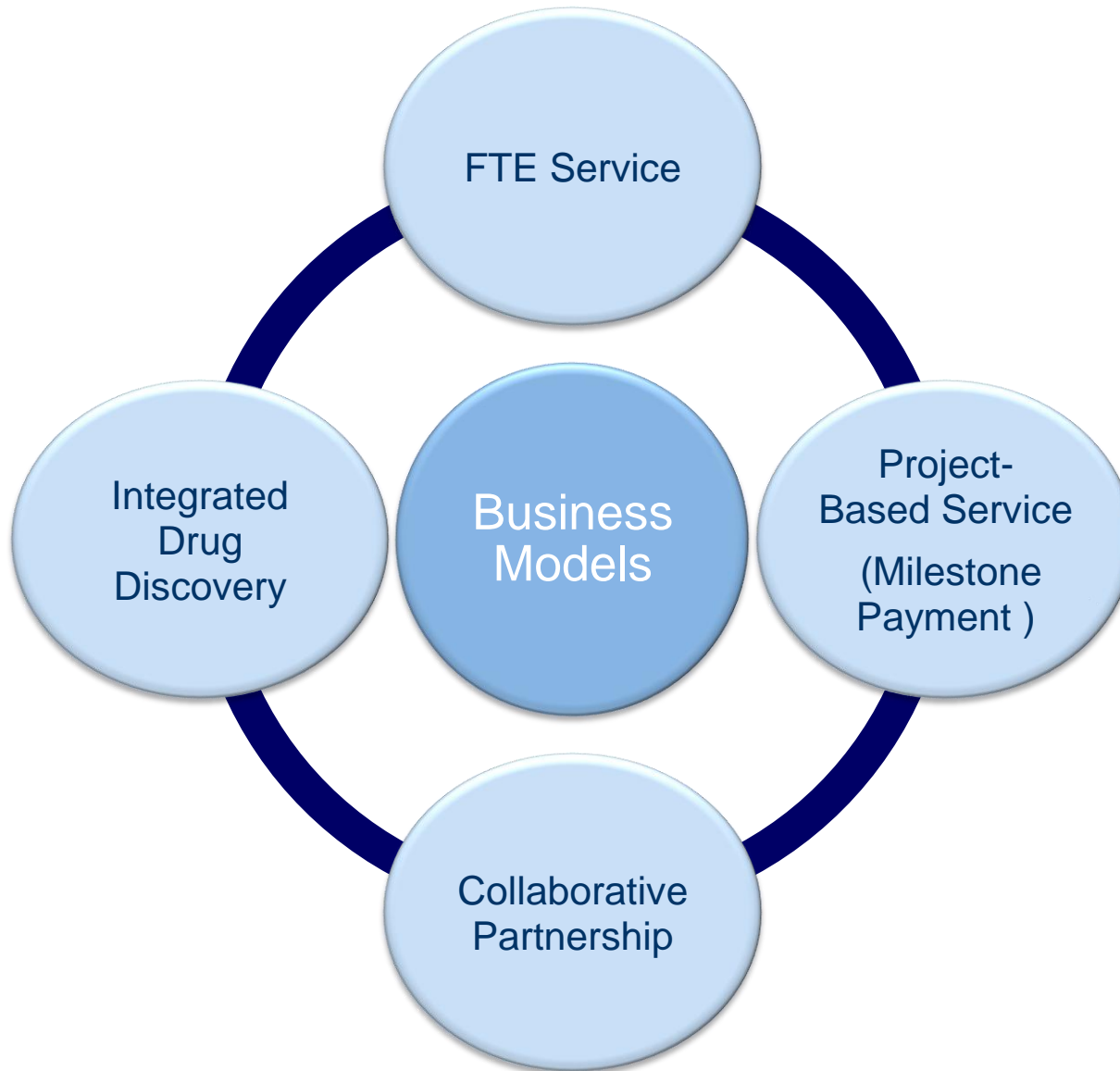


## Biology & Biologics Services



## Pharmaceutical Services







# Growth Trajectory: 2000 - 2009

**2000**

**2009**

<b>Area</b>	20,000 Sq Ft Facility	1,000,000 Sq Ft Facility
<b>Chemical Hoods</b>	~60	800+
<b>Biology Capabilities</b>	Simple Biology laboratory	Includes Biochemical and Cell-based assay (automated liquid handling systems)
<b>R&amp;D Scope</b>	Early stage molecular biology, scaffold synthesis scale up <5 Kgs	<ul style="list-style-type: none"><li>▪ ADME-T, hERG channel assays</li><li>▪ Focused Libraries, Design Input</li><li>▪ Purification including SFC</li><li>▪ PRD with Hazard Analysis, (Rc1e, DSC)</li><li>▪ cGMP production facilities (first in human material)</li><li>▪ GLP TOX studies</li><li>▪ AAALAC Accredited Animal Facilities; Rodent Disease Models</li><li>▪ Formulation Development Center</li></ul>
<b>Total Investment</b>	\$ 5 M	\$ 100 M



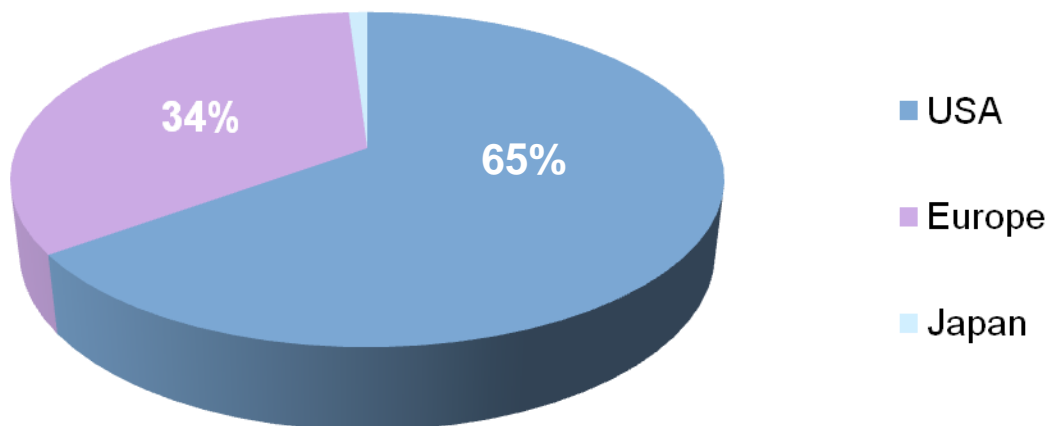
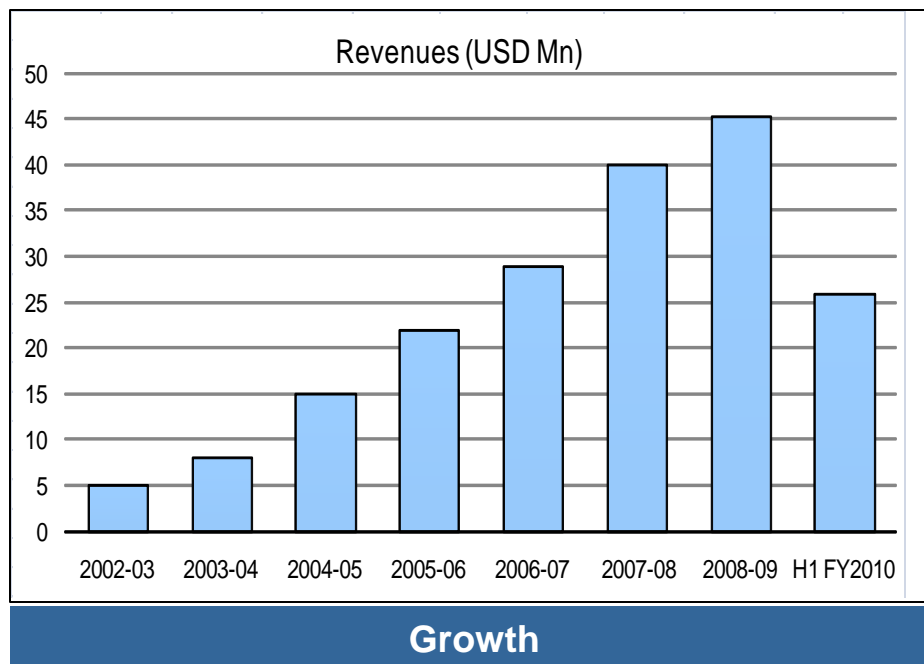
# Broad Customer Base

CAGR ~ 25%

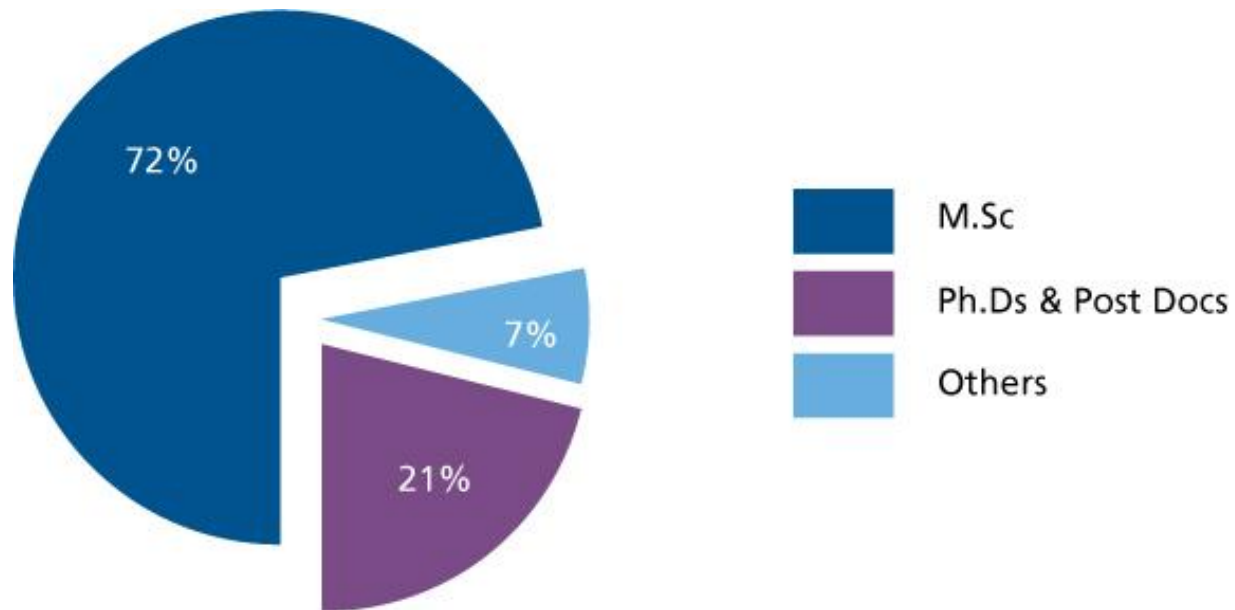
On going collaborations with ~ 60 companies worldwide currently

Collaboration with seven of top ten "BIG" Pharmaceutical Companies

Broad & Extensive Customer Base



## SCIENTIFIC TALENT POOL



**Strong team of 1200+ Scientists**



# Milestones

2000

Establishment

2002

CAP accreditation for Central Laboratory

2003

- NABL accreditation for Central Laboratory
- Started Clinical Trial Operations with Phase III trial for Biocon

2004

Established Human Pharmacology Unit & Bioanalytical Research Lab

2005

Started offering Clinical Research services to global clients

2007

Scale-up of infrastructure to a dedicated 65,000 sq. ft. area facility

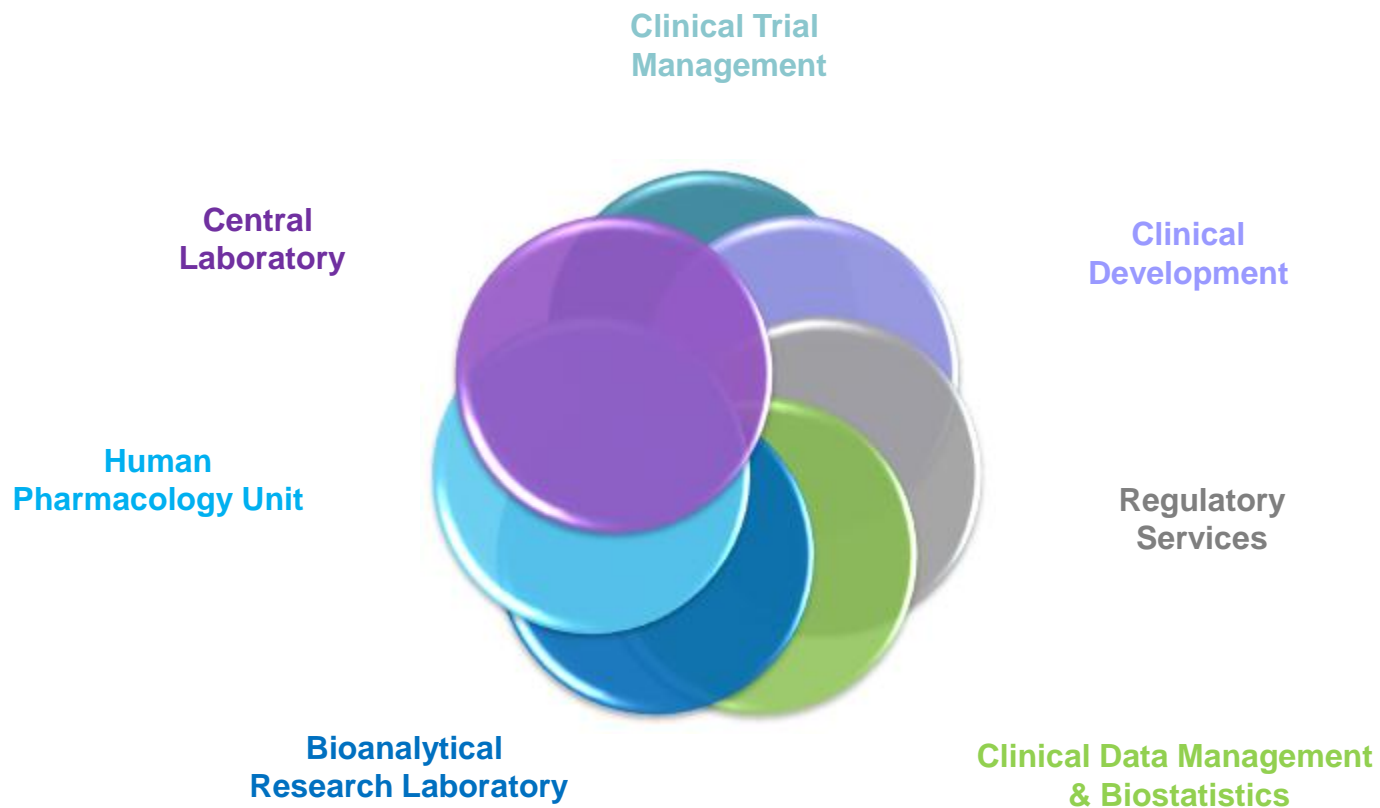




# Comprehensive Services

**Clinigene**

A **Biocon** company





## Therapeutic Areas

- Oncology
- Diabetology
- Metabolic disorders
- Rheumatology
- Dermatology
- Cardiovascular
- Gastroenterology
- Nephrology
- Immunology
- Infectious Diseases
- Neuropsychiatry

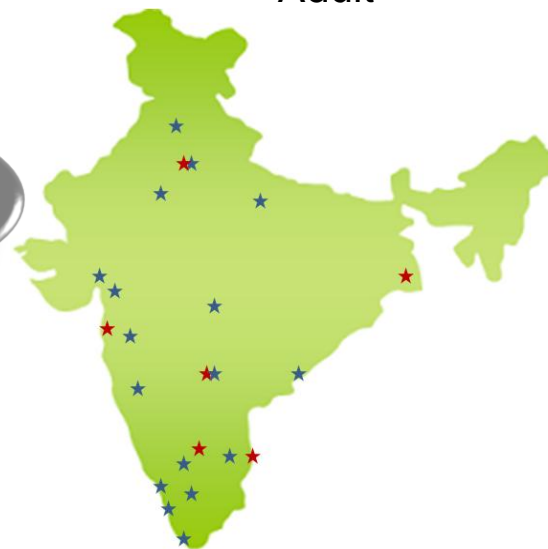
## Products

- Small Molecules
- Biologics
- Vaccines
- Devices

## Patient Population

- Neonatal
- Pediatric
- Adult

Spread of our clinical project sites in India

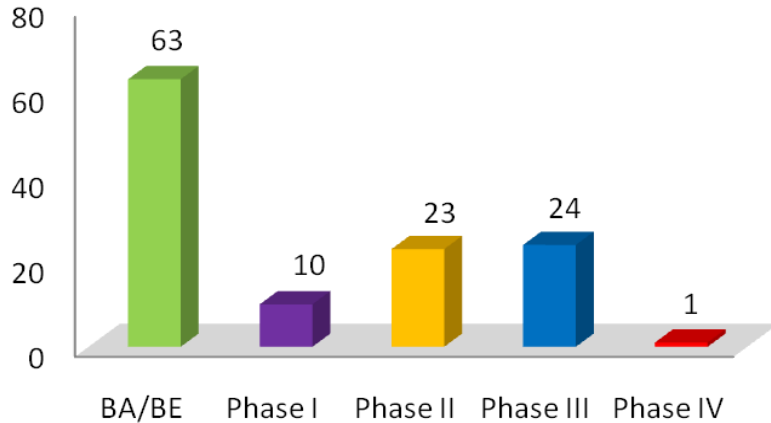


**A comprehensive database of investigators & investigation sites provides speed & efficiency in clinical trials**

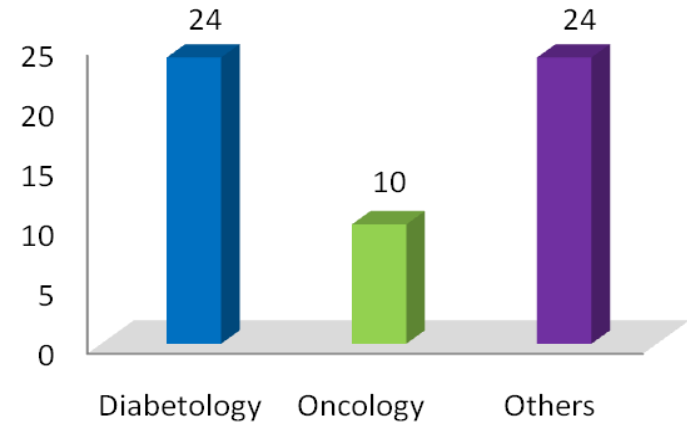


# Clinical Research Experience

### Phase-wise

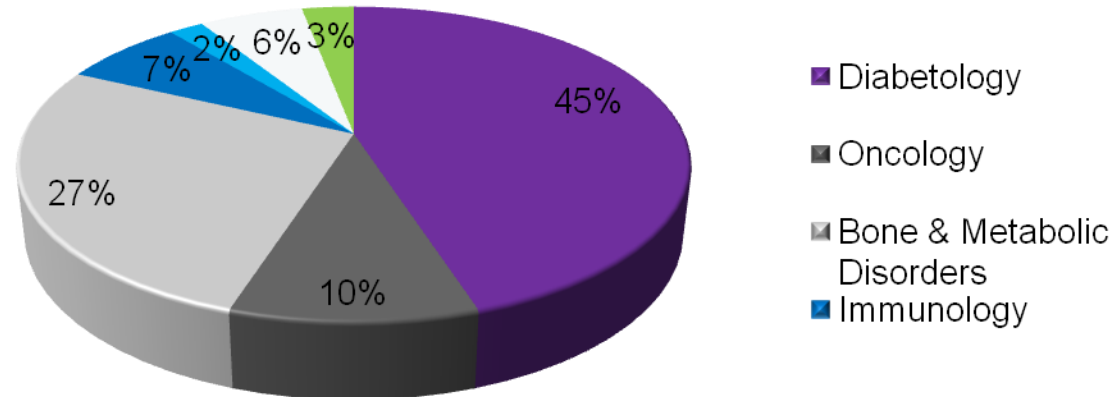


### Therapeutic Area-wise (Phase I-IV)



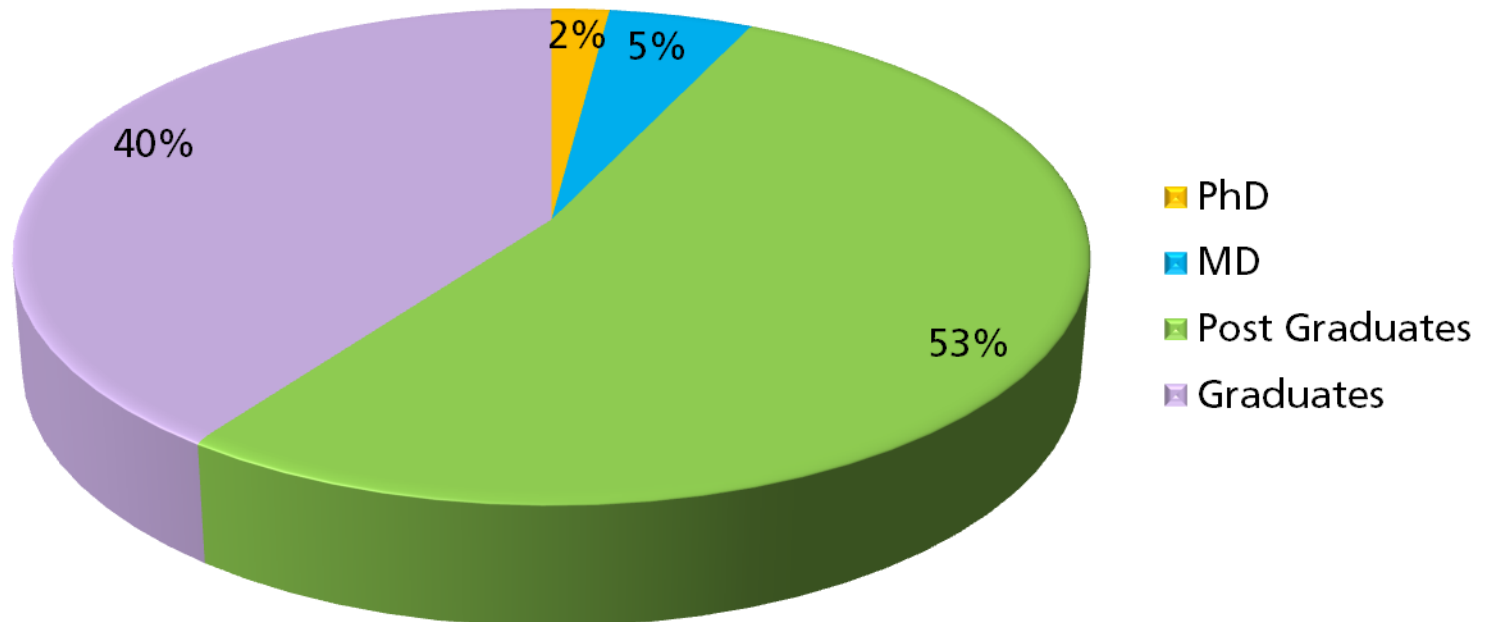
### Break-up of Patients by Therapeutic areas

More than 5000 patients have participated



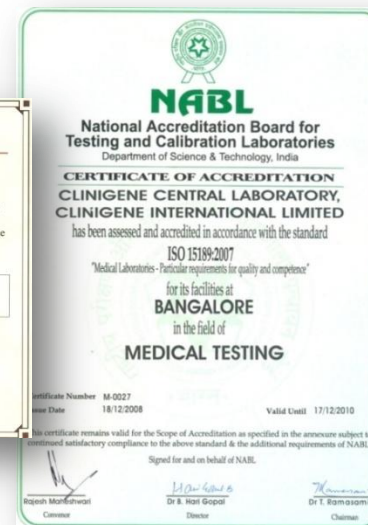
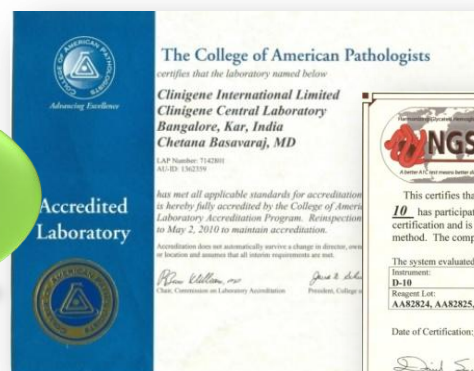


Clinigene is a rapidly growing organization with over 150 highly skilled and experienced professionals





# The Clinigene Advantage



- ❑ Have conducted some large studies involving up to 1500 subjects
- ❑ Vast experience in *Oncology, Diabetes & Osteoporosis* segments
- ❑ Secured 100% approval from regulators with Clinical Trial Applications
- ❑ Flexibility offered –
  - Services customized to each sponsor
  - Types Of Contracts
    - Fee for Service (Time & Materials)
    - Fixed-Fee
    - FTE-based

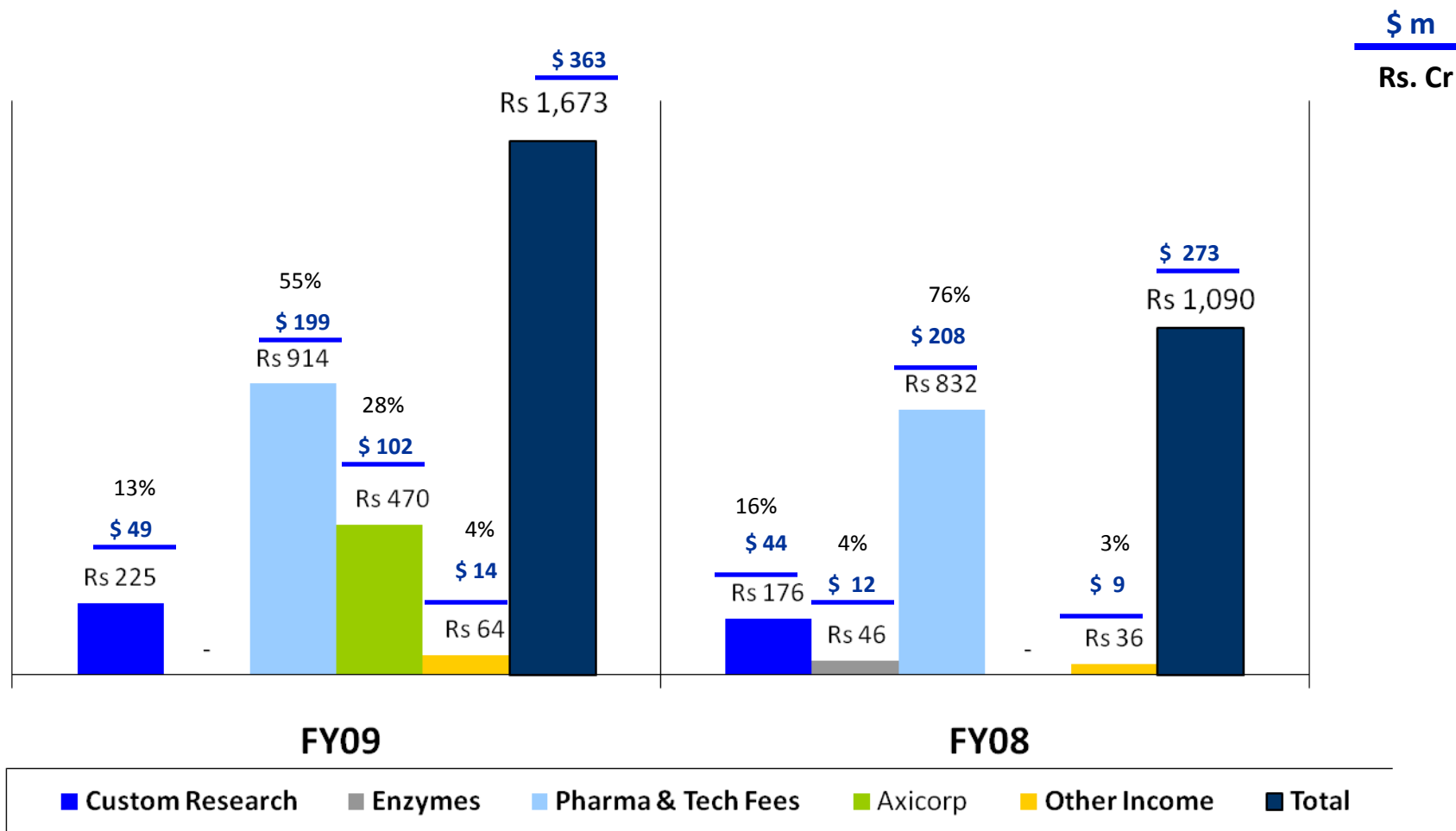
**FOCUS** : Time, Cost, Quality and Confidentiality



# FINANCIAL PERFORMANCE



# Revenues FY 09 vs. FY 08







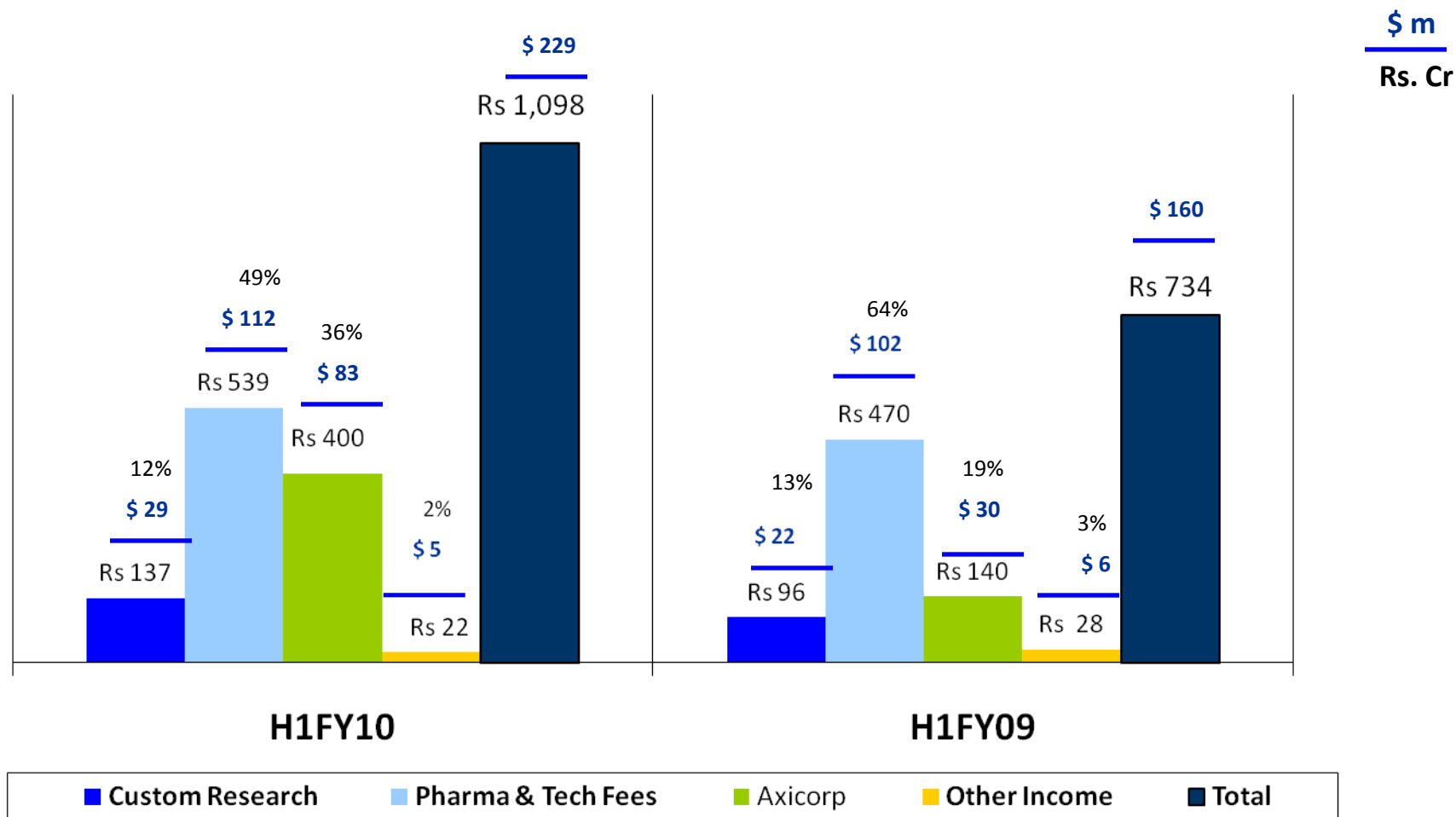
# P & L FY 09 vs. FY 08

Particulars	FY 09 Rs. Cr / \$ m	% on Rev	FY08 Rs. Cr / \$ m	% on Rev
Revenues	1,673 / 363		1,090 / 273	
EBIDTA	387 / 84	23%	342 / 86	31%
PBT	260 / 57	16%	231 / 58	21%
Tax	12 / 3		13 / 3	
PAT #	240 / 52	14%	225 / 56	21%
Exceptional Item	(147) / 32		240 / 60	

FY 09 \$ 46 Rs.  
FY 08 \$ 40 Rs.



# Revenues H1 FY 10 vs. H1 FY 09



Particulars	H1 FY10		% on Rev	H1 FY09		% on Rev
	Rs. Cr	/ \$ m		Rs. Cr	/ \$ m	
Revenues	1,098	/ 228		734	/ 159	
EBIDTA	236	/ 49	21	168	/ 36	22
PBT	158	/ 32	14	106	/ 23	14
Tax	23	/ 4	2	8	/ 2	1
PAT	132	/ 27	12	100	/ 21	13
Exceptional Item	-			(60)	/ (13)	

H1 FY 10 \$ 48 Rs.  
H1 FY 09 \$ 46 Rs.



Thank You

