



AGM Presentation July 2004

#### Disclaimer

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, our directors, any member of the syndicate 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.

### **Vision of Leadership and Excellence**





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#### LEADERSHIP & EXCELLENCE

1978 BIOTECHNOLOGY

 India's first & No 1 Biotech company with a global Biotech ranking of 16\*

1979 ENZYMES

- Global leadership in specialty enzymes

1989 FERMENTATION

Globally unique fermentation profile - Solid State,
 Submerged & Mammalian Cell Culture

1994 CUSTOM RESEARCH

- SYNGENE: India's first & No 1 Contract Research Company. Global market share of 2%

### **Vision of Leadership and Excellence**





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#### LEADERSHIP & EXCELLENCE

1998 STATINS

 India's largest and only USFDA qualified producer and exporter of Statins

2000 CLINICAL RESEARCH

 CLINIGENE: India's first CAP accredited Clinical Laboratory

2002 INSULIN

- The most clinically validated r-human Insulin in India
- India's first and Asia's largest Insulin plant
- Global supply arrangement with BMS

2003 ANTIBODIES & CANCER VACCINES

- India's first and Asia's largest Antibody Facility
- Unique platform of proprietary products in Antibodies & Vaccines

#### **Milestones**





Billion Dollar market cap on first day of listing

Biocon in **Top 20 Global Biotech Companies**\*

Biocon in India's Top 5 Life Science Companies\*

# **Biocon in Top 20 Global Biotech Companies\*\***

Rank	Company	Revenues (\$mln) 2003	Net Income (\$mln) 2003	Market Capitalization*
1	Amgen Inc	8,356	2,260	67,800
2	Genentech	3,300	563	55,306
3	Serono	2,019	390	9,776
4	Chiron Corporation	1,766	227	8,125
5	Applied BioSystems	1,683	183	4,168
6	Genzyme Corporation	1,580	104	10,506
7	MedImmune	1,054	192	5,632
8	Novozymes	981	123	3,460
9	Gilead Sciences	868	(72)	14,096
10	Biovail Corp	824	(27)	2,937
11	Biogen Idec Inc	679	(875)	21,153
12	Millennium Pharmaceuticals	434	(484)	3,755
13	Genencor International	383	16	908
14	Sepracor	344	(136)	4,276
15	Affymetrix	301	14	1,858
16	Biocon	124	31	1,159
17	Netkar	106	(47)	1,562
18	Celera Genomics	88	(82)	791
19	ImClone Systems Inc	81	(113)	6,032
20	Exelixis Inc	51	(96)	600

# **Biocon in India's Top 5 Life Science Companies\***

### **Pharmaceutical Industry Comparison**

Company	Current Price	Rsm Mc	cap USDm
Ranbaxy	963	178,753	3,909
Cipla	227	68,040	1,488
Sun	353	65,466	1,432
Dr Reddy	746	57,053	1,248
Biocon	530	53,010	1,109
Nicholas Piramal	754	28,654	625
Wockhardt	265	28,848	631
Cadila	423	26,564	581

# **Strategic Vision**





- 1. Building strong fermentation technology platforms
- 2. Leveraging technology for **product differentiation**
- 3. Creating long term value through **quality & innovation**
- 4. Charting an integrated development pathway for **proprietary products**

### **Delivering on a long term vision of proprietary products**



New drug discovery & development

- Clinical data mining for novel bio-makers
- Alliances for new molecules (e.g. MAb)
- Development of NDDS\*

Generic Biopharmaceuticals

- Products with large global markets
- Near term patent expiry
- Fermentation derived molecules
- High technology barriers
- High regulatory barriers

Funding long term discovery research through a short term generic strategy

### **Leveraging Fermentation Technologies**





#### **Biologicals**

r-human Insulin Streptokinase **GCSF** 

#### **Small Molecules**

**Statins Immunosuppressants** 

#### **Proprietary Molecules**

#### **Antibodies**

h-R3 (anti-EGFR) Anti-CD6 & Anti-CD 3

**Cancer Vaccines** 

EGF, TGFα, HER<sub>1</sub>



Research Clinical Development Process Development Commercialization





#### **Statins**





- Statins (anti-cholesterol) are the largest selling drugs in the world with global sales in excess of US\$ 20bn
- The global generic market for Lovastatin, Pravastatin & Simvastatin is estimated at US\$ 7bn in 2007
- Biocon is the only USFDA approved producer of Lovastatin, Pravastatin & Simvastatin in India
- Biocon has leadership position in USA & Europe for Lovastatin & Simvastatin in APIs



#### **Statins**





- + Biocon's leadership position in this segment is supported by
  - USFDA & EDQM approvals
  - Patented / non infringing processes
  - Global-scale manufacturing facilities
  - Significant market share in key markets where the products have gone off patent
  - Tie-ups with a large number of Generic Companies



#### **Recombinant Human Insulin**



- Global Sales of US\$ 5 bn dominated by few players
- Demand for Insulin expected to grow exponentially post approval of pulmonary Insulin (Pfizer's Exubera)
- The USFDA has stated that products like Insulin and Human growth hormone whose science has progressed far enough for FDA to be able to assess "similarity" may be accepted under the 505 (b)(2) process
- This should open up a significant generic opportunity in the near term



#### **Recombinant Human Insulin**





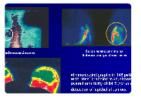
- Biocon is well poised to access this opportunity based on the following:
  - Long term supply agreement with Bristol-Myers Squibb
  - World class and Asia's largest Insulin facility
  - Alliances with Generic Companies







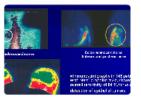
- The market for monoclonal antibodies is expected to grow from US\$ 4 bn in 2003 to US\$ 13 bn by 2010
- Biocon is setting up Asia's largest Monoclonal Antibody facility
- The facility will manufacture hR3, an anti-EGF receptor antibody targeted against head & neck cancer as its first product followed by other antibodies & cancer vaccines







- The product has completed Phase II Clinical Trials in Canada and Phase II B Clinical Trials in India are expected to commence in Q2 FY 2004-05
- Proof of concept studies have indicated potential application in treatment of other cancers including brain cancer, lung cancer and breast cancer



### **Capital Outlay**



- Biocon has committed to invest approximately Rs 650 crores to establish the following:
  - A new research facility for Syngene to double its current scientific strength
  - A large fermentation and synthesis facility that will quadruple existing Statins capacity
  - A Biologicals facility to undertake large scale Mammalian Cell Culture

### **Managing the Future**





#### **Competitive Environment**

Price pressure on Statins

Commoditizing of Generics

Potential competition in Insulin space

#### **Biocon's Competitive Edge**



Technology Regulatory Compliance Global Scale Capacities



Strong Product Pipeline that addresses a sequential flow of new fermentation based generics

**Proprietary Molecules** 



Technology Global Alliances (BMS) Regulatory Compliance New Insulins

# **Managing the Future**





#### **Competitive Environment**

#### **Biocon's Competitive Edge**

Pace and Race for Drug Discovery is frenzied



Monoclonal Antibodies and Cancer Vaccines are the most promising front runners in the approval pipeline

Increasing Costs of Drug Development



Integrated Model provides speed and cost advantage

# Financial Analysis FY 2003-04

### **Key Financial Highlights FY 2003-04**



- → Revenues crosses Rs. 5 billion (Rs. 5.493 billion), (94% ↑)
- + Profits crosses Rs. 1 billion (Rs. 1.386 billion), (219% ↑)
- PAT Margins increase to 25%, (10% ↑)
- + EPS (Post IPO Capital) @ Rs. 13.86 /share
- Maiden dividend of 20% recommended by Board
- Exports surge to 63%, (15 % 1)
- Statins and Custom Research Services drives export revenues

### **Other Highlights**



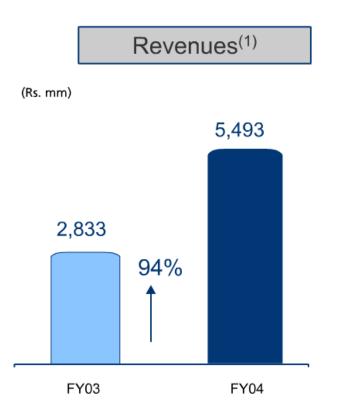
- → Biocon signs agreement for supply of recombinant human insulin with BMS.
- Biocon files DMF with USFDA for recombinant human insulin
- Biocon launches branded formulations in the domestic market for cardio diabetes
- U.S. FDA acceptance for Biocon's statins and pioglitazone manufacturing facilities
- Human Pharmacology Unit launched by Clinigene
- Biocon files 88 Patent/PCT applications in FY 2004.
- Expansion program on track:

Syngene Facility: Q3 2004 Statins Facility: Q1 2005

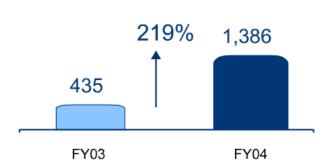
### FY 2003 - 04 Overview







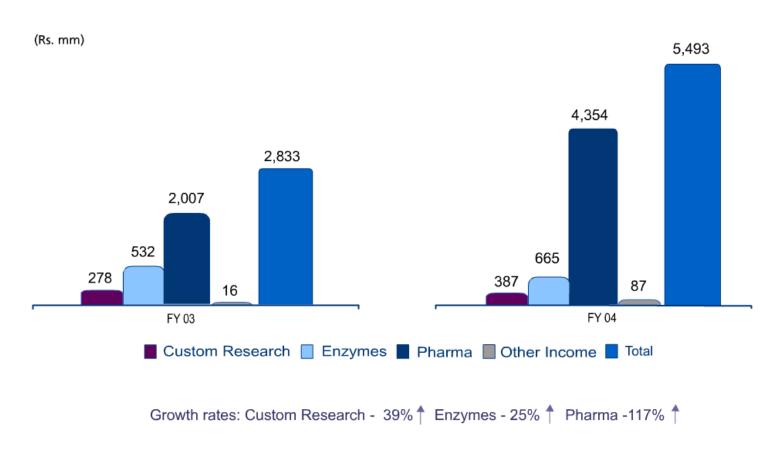
Profit After Tax<sup>(1)</sup>



# **Revenue Break-up**





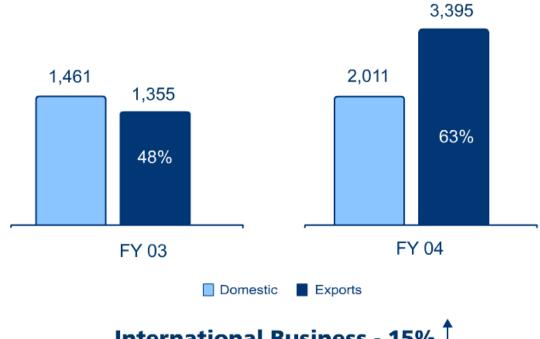


### **Markets**





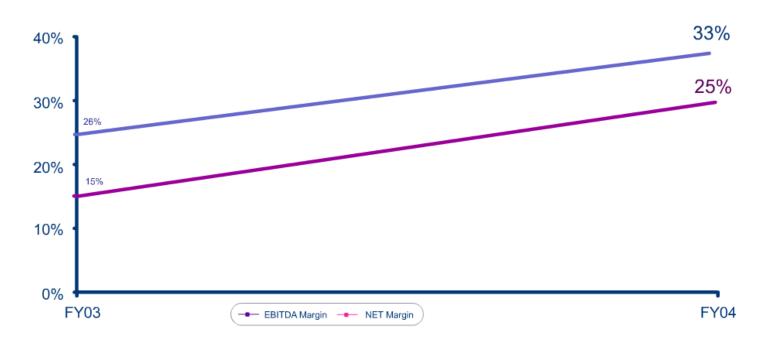
(Rs. mm)



International Business - 15%

# **Gross Margins**





#### EBITDA and net margins have improved substantially due to

- Increased sales to regulated markets
- Process improvements

# Financial Analysis Q1 2004-05

### **Key Growth Drivers in Q1 2004-05**





- Successful market entry of Pravastatin in Europe post patent expiry in key markets in Europe
- Increased supply of Lovastatin to US post USFDA approval of additional statin facilities
- Increase in Syngene's research services

#### **Key Developments in Q1 2004-05**

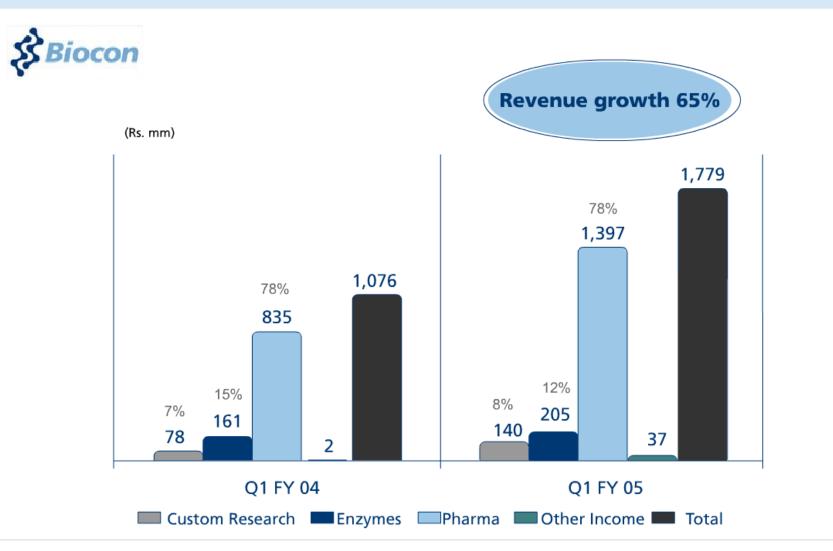




- Product portfolio of BBPL expanded to include the following products:
  - h-T1, a humanized anti-CD6 targeting immuno-suppressive monoclonal antibody for T-cell Lymphoma, Rheumatoid Arthritis and Psoriasis.
  - 2. q-T3, a chimeric anti-CD3 targeting immuno-suppressive monoclonal antibody for organ transplant.
  - 3. EGF Cancer Vaccine
  - 4. TGFα Cancer Vaccine
  - 5. HER 1 Cancer Vaccine
  - Insulin clinical trials completed & awaiting final approval for market launch
  - Syngene's new facilities housing 150 scientists to be commissioned shortly

# **Revenue Break-up**





# **Revenue Growth**



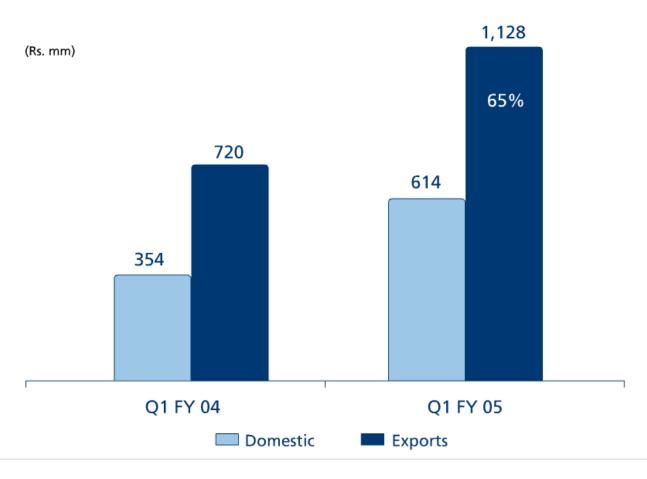
# **Dynamics**

Custom research	80 %	■ Significant expansion of revenues from both existing & new customers
E nzymes	27 %	■ Speciality Enzymes continue to generate significant interest in US & Europe
Pharma Others	46 %	<ul><li>☐ Introduction of Tacrolimus</li><li>☐ Commencement of supply of Domestic Formulations</li></ul>
Pharma S tatins	79 %	<ul> <li>■ Backlog supply of Lovastatin to US Markets</li> <li>■ Significant gains from supply of Pravastatin to Europe</li> <li>■ Consolidation of Simvaststin in Europe</li> </ul>

# **Markets**







# **Profit**





(Rs. mm)

	Q1 FY 04	% to Revenues	Q1 FY 05	% to Revenues	
Revenues	1,076		1,779		
EBDITA	352	33	573	32	- Improved Yields & Sales Mix - Growth in Personnel & Salary Increment - Exchange Loss & Increase in SG&A Exps
PBT	305	28	520	29	
PAT	229	21	486	27	- Profits from 100% EOUs not taxable

Profit Growth - 112%



# **Thank You**