

# SCALING NEW HEIGHTS IN FRONTIER SCIENCE

29<sup>th</sup> ANNUAL GENERAL MEETING July 18 2007



#### 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, 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.



#### **AFFORDABLE MEDICINE**

Biocon is developing affordable therapeutics for the world's most debilitating diseases - cancer, diabetes, inflammatory and auto-immune diseases.

We have commercialized INSUGEN®, a Recombinant Human Insulin in 2004 & a proprietary cancer targeting monoclonal antibody, BIOMAb-EGFR<sup>™</sup> in 2006.



### **MILESTONE 1: BIOCON PARK**

- O Dr. A P J Abdul Kalam, President of India, inaugurated India's largest integrated biotech hub, "Biocon Park".
- o India's first SEZ in biotechnology.
- o Largest investment in biotechnology: Rs. 750 crores.
- o Incorporates state-of-the-art research laboratories, USFDA qualified fermentation based manufacturing plants and India's first antibody manufacturing facility.
- Facilities inspected by USFDA and certified to be in compliance to international regulatory standards.
- o Incorporates tax efficiency.



**BIOCON PARK** 



### MILESTONE 2: BIOMAb EGFR – Best-in-Class Drug

# Affordable antibody for Indian cancer patients



**Biocon's firSt onco-therapeutic** 

# **TARGETED THERAPIES TAKE CENTER STAGE**

 The monoclonal antibodies market is expected to almost triple in value over the next six years from \$10.3 billion in 2004 to \$30.3 billion.

o A wave of fully humanized antibodies is expected to be launched from 2007 onwards, accounting for 12 of the 20 launches between 2007 and 2010.

o Combination of new molecular diagnostic technologies and targeted therapies are predicted to revolutionize cancer treatment.



#### BIOMAb EGFR TM – Best-in-Class Drug

 o Very successful launch and acceptance in India of Biocon's novel monoclonal antibody, BIOMAb-EGFR™.

o 1<sup>st</sup> humanized anti-EGFR monoclonal antibody commercialized anywhere in the world.

o Approved for use in SCCHN (head & neck cancer) and being evaluated in global clinical trials for colorectal, lung, brain (glioma) and pancreatic cancers.

o Global consortium of Biocon partners include Germany, Japan, Canada, Austria, Italy, Cuba.



#### BIOMAb EGFR TM – Best-in-Class Drug

o 1<sup>st</sup> Monoclonal Antibody produced and validated by clinicians in India.

o Indigenous clinical development and manufacture enables affordable treatment in relation to global equivalents.

o Manufacturing facility in partnership with CIMAB, Cuba.

o Will target market expansion into SAARC and GCC region in future.

o Most successful drug launch in India.



# **B.E.S.T** -

#### **Significant Efficacy in Head & Neck Cancer Patients**

Response	h-R3 +CT+RT (n=20)		CT+RT (n=20)		p- value
	Number	%	Number	%	
CR	18	90	14	70	0.375
PR	2	10	0	0	0.489
SD			-	-	
PD	0	0	6 (*2 DIED)	30	0.033
OR	20	100.00	14	70	0.020

Legend: CR:Complete Response, PR:Partial response, SD:Stable Disease, PD:Progressive Disease, OR: Objective response (OR = CR+PR). Patients who died did not show PD but have been included here 1 patient in each arm showing PD in lymph node attained CR after Salvage surgery



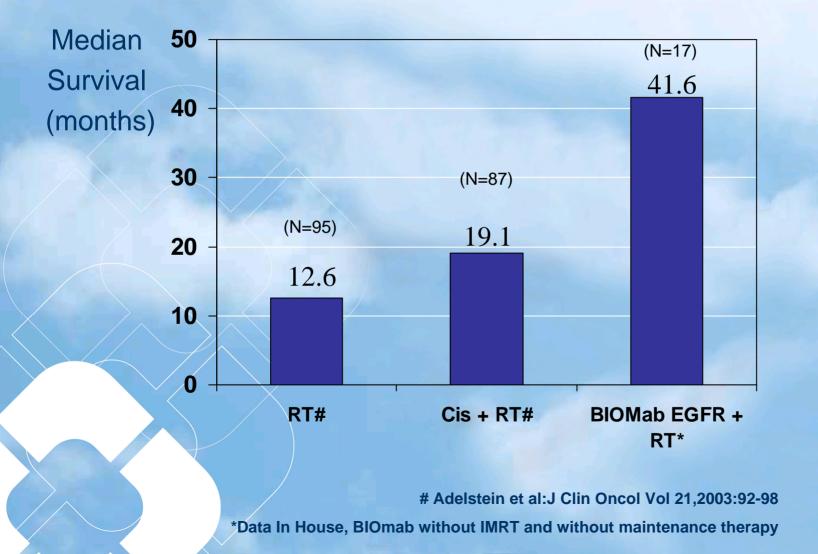
#### **BIOMAb EGFR**<sup>™</sup> – **Best-in-Class Drug**

## **Best Safety profile in EGFR Class of MAbs**

Severe Adverse Events	Other MAb	<b>BIOMAb EGFR</b>	
Skin Rash	88%	0%	
Oral Mucositis Gd 3/4	56%	0%	
Hypomagnesemia	50%	NR	
Gd 3-4 Infusion reaction	3%	0%	



# **BIOMab EGFR<sup>TM</sup>** : Better than standard of care



#### **MILESTONE 3**: ONCOTHERAPEUTICS & NEPHROLOGY DIVISIONS

o Best oncology product specialists in the country.

 Market Penetration in all Tier I and Tier II cities in India.

 Biocon's new Nephrology Division offers a comprehensive portfolio of renal therapy products.

o Immunosuppressants are powerful inhibitors of the body's immune system and are used to prevent allograft rejection.

o Biocon is the largest vertically integrated manufacturer of immunosuppressants in India with US-FDA approved API facilities.



#### **NEPHROLOGY DIVISION**

- RENPODAPT, CYCLOPHIL ME, TACROGRAF are immuno suppressants for Nephrotic syndrome and kidney transplant.
- o RAPACAN- for chronic allograft nephropathy.
- o ERYPRO for anaemia management in renally impaired patients.



#### MILESTONE 4: SYNGENE & BRISTOL MYERS SQUIBB

Biocon

- Long term research services partnership to help advance Bristol-Myers Squibb's discovery and early drug development.
- o Focus on integrated capabilities in medicinal chemistry, biology, drug metabolism and pharmaceutical development.
- Leveraging the current global demand for bio partnering, this alliance aims to provide BMS cost-effective growth and access to top scientific talent in India.
- o Dedicated 150,000 sft. facility to house more than 400 scientists.



#### **SYNGENE & BRISTOL MYERS SQUIBB**





#### MILESTONE 5: CLINIGENE AT SEMICON PARK

o Four-fold expansion: 65,000 sft.

o New state-of-the-art facility at Semicon Park in Electronic City Phase II.

o Clinigene at the forefront of clinical research.



### CLINIGENE HOUSE AT SEMICON PARK





## **MILESTONE 6: LICENSING INNOVATION**

o Licensing agreement with Bayer HealthCare (BHC) for the exclusive marketing and trademark rights for INSUGEN® for the Chinese market.

o Licensing of INSUGEN® to a leading international pharmaceutical company for the US market.

 Biocon grants exclusive license to Ferozsons
Laboratories Limited for marketing BIOMAb EGFR™ in Pakistan.





 Agreement to divest Enzymes business for USD 115 million to NOVOZYMES signed today.

• Biocon's enzyme business will be integrated into Novozymes South Asia Pvt. Ltd. a fully owned affiliate of Novozymes A/S.

 Biocon will concentrate its activities on its bio-pharma business verticals that include APIs, biologicals and proprietary molecules both commercialized and under development.

 O Production and formulation will continue at the Biocon site under lease and service agreements with Novozymes.

o A postal shareholder ballot will be conducted shortly.



### **RESEARCH PIPELINE**

o Strong focus on developing high value Intellectual Property.

- o Oral insulin (IN 105) completes 'Proof of Concept' Phase I Human Clinical trials, on track to enter Phase II trials later this year.
- o T1h, a novel anti-CD6 monoclonal antibody for the treatment of Rheumatoid Arthritis research underway.
- o BVX 10, BVX 20 and oral BNP (BN 054) for the treatment of acute Congestive Heart Failure expected to enter pre-clinical development later this year.
- Other R&D programs on bio-similar products viz. Streptokinase, GCSF, Glargine, Reteplase, HGH, etc., moving up the development path.



#### **FINANCIAL PERFORMANCE**

 Revenues from Research & Licensing Fees grew 60 % to Rs. 163 crores from Rs.102 crores contributing 17% to operating revenues in FY 2007.

 Revenues from biopharmaceuticals and enzymes business grew 20% to Rs. 823 crores from Rs. 687 crores, contributing 83% to operating revenues in FY 2007.

Healthy 29% operating margin for the Financial Year
2006-07 despite a fiercely competitive environment.

# Thank you