



#### For Immediate Release

Bangalore, India December 10, 2009

## BIOCON AND HCG GROUP OF HOSPITALS LTD. JOIN HANDS TO FIGHT AGAINST CERVICAL CANCER

Biocon and HCG group of hospitals today announced their partnership to conduct a study to evaluate the potential benefits of BIOMAb EGFR<sup>®</sup> in cervical cancer patients. This unique molecule would take healthcare for cervical cancer patients to a new threshold. BIOMAb EGFR<sup>®</sup> is Biocon's humanized monoclonal antibody which is approved for the treatment of head and neck cancers in India.

The study will be conducted for six years in various centers of HCG across the country, involving many eminent oncologists and will be in compliance to ICH-GCP guidelines. The participating centers are Bangalore, Mysore, Vijayavada, Ranchi, Cuttack and Nashik.

"This partnership is in light of the unmet need for an effective treatment option for the large number of cervical cancer patients in our country. I see this collaborative model of Biocon's unique humanized MAb and HCG's state of the art facilities as a big step towards developing India as a global destination for translational research and cutting edge clinical trials." said Kiran Mazumdar Shaw, MD, Biocon Ltd.

Ajai Kumar, Chairman and CEO of HCG group of hospitals said, "This HCG-led study will be conducted in a well controlled manner specifically keeping in mind the needs of the Indian patients which vary considerably from those of the West. Most treatment for this disease is currently based on data obtained from the western world. We chose BIOMAb EGFR<sup>®</sup> taking into account the safety profile this molecule has displayed in addition to results obtained in the other studies with this drug".

Cervical cancer is the most common cancer among women in India and is the primary cause of cancer-related deaths in developing countries. To an estimated annual global incidence of 500,000 cervical cancers, India contributes 100,000, i.e. 1/5 of the world burden. Cervical cancer is responsible for more than 280,000 deaths annually worldwide. In India the number of deaths due to cervical cancer is estimated to rise to 79,000 by the year 2010. The cancer mostly affects middle-aged women (between 40 and 55 years), especially those from the lower economic status. Chemo radiotherapy has been shown in several studies to be more effective in terms of overall survival and local control, than radiation therapy alone in the treatment of women with locally advanced carcinoma of the cervix. But still the 2 year progression free survival is around 67% and there is a need for further improvement.

BIOMAb EGFR<sup>®</sup> is being studied globally in various indications like Glioma, NSCLC, Pancreatic cancer, Gastric cancer, Cervical cancer etc. in addition to head and neck cancers. It is a boost to our division that a study headed by eminent oncologists, involving Indian patients is being initiated with this molecule. The results will clearly be of huge relevance to the Indian





subcontinent where cervical cancer is a true unmet need. Studies with BIOMAb EGFR<sup>®</sup> in NSCLC and Glioma are currently ongoing in India.

#### **About Biocon Limited**

Established in 1978, Biocon Limited is one of India's premier biotechnology companies. Together with its group companies, Biocon forms a fully integrated biotechnology enterprise, specializing in biopharmaceuticals, custom research and clinical research which deliver products and solutions to partners and customers across the globe. Biocon launched the world's first recombinant human insulin, INSUGEN<sup>®</sup> in November 2004 using Pichia expression and India's first indigenously produced monoclonal antibody BIOMAb-EGFR<sup>TM</sup>.

A leading US trade publication, Med Ad News, in its 2007/08 listings has ranked Biocon 20th amongst the leading biotechnology companies in the world and the 7<sup>th</sup> largest Biotech employer in the world. Biocon recently received the 2009 BioSingapore Asia Pacific Biotechnology Award for Best Listed Company.

Focusing on unmet medical needs in cancer, diabetes and inflammatory diseases, Biocon offers novel therapies on a platform of affordable innovation. Biocon's strategic licensing partnerships provide market penetration and global access to deliver breakthrough therapeutics to millions of patients the world over.

Visit us at www.biocon.com

#### About HCG

Established in 1989, HCG is now South Asia's largest cancer care network of 17 centers. It has gained repute for employing the latest and best technology to treat cancer patients. Some of the Hospitals of HCG are Bangalore Institute of Oncology, Bangalore,Bangalore Institute of Oncology Specialty Centre, Bangalore,Malnad Hospital & Institute Of Oncology, Shimoga, Karnataka,Bharat Hospital & Institute Of Oncology, Mysore,Gokula Curie Centre Of Oncology, Bangalore,Masalore,Panda Curie Cancer Hospital, Cuttack, Orissa,Curie Manavata Cancer Centre, Nashik, Maharashtra andCurie-Abdur Razzaque Ansari Cancer Institute, Ranchi, Jharkhand

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Press Release : 2

Bangalore, India

## Biocon Limited Announces Results for the Half-Year Ended September 30, 2009

#### Revenues rise to Rs 1,098 crores; EBITDA at Rs 236 crores; PAT at Rs 132 crores.

"Our numbers tell our compelling story. MTM losses are behind us. We have delivered strong earnings in the first half and are confident of sustaining this performance for the remainder of the year", said Chairman and Managing Director, Biocon Group, Ms. Kiran Mazumdar-Shaw.

#### **Performance Highlights**

For Half-Year ended September 30, 2009

Biocon Group including German Subsidiary AxiCorp

- Total Income at Rs 1098 crores. Up 50% YoY.
- EBITDA at Rs 236 crores. YoY growth was 40%.
- PAT at Rs 132 crores. YoY growth was 230% (up 32% YoY pre-exceptionals).
- Operating Margin at 22%.
- Earnings Per Share at Rs 6.82.

Biocon Group excluding German Subsidiary AxiCorp

- Total Income at Rs 696 crores. Up 17% YoY.
- EBITDA at at Rs 213 crores. YoY growth was 31%.
- PAT at Rs 121 crores. Up 218% YoY (up 24% YoY pre-exceptionals).
- Operating Margin at 31%.

#### For three months ended September 30, 2009

Biocon Group including German Subsidiary AxiCorp.

- Total Income at Rs 592 crores. Up 29% YoY.
- EBITDA at Rs 125 crores. YoY growth was 41%.
- PAT at Rs 74 crores. YoY growth was 192% (up 47% YoY pre-exceptionals).
- Operating Margin at 21%.
- Earnings Per Share at Rs 3.84.

#### Biocon Group excluding German Subsidiary AxiCorp

- Total Income at Rs 379 crores. YoY growth was 20%.
- EBITDA at Rs 114 crores. YoY growth was 37%.
- PAT at Rs 69 crores. YoY growth was 190%.
- Operating Margin at 30%.

#### **Discussion of Business Operations**

CMD, Biocon Group, Ms. Kiran Mazumdar-Shaw comments on -

• **Q2FY10 Syngene and Clinigene performance-** "Both Syngene and Clinigene have posted strong results and we believe that our investments are delivering good returns. The operations are strong and the investments made thus far assure good future profitability".



- **Biocon's agreement to acquire Hyderabad-based bulk manufacturer IDL Specialty** "We chose an inorganic path in preference to green field expansion, owing to significant advantages in time-to-market, shorter payback on investment and other commercials. The plan is to expand our chemical synthesis capabilities and manufacture
- advanced intermediates in this new facility. This additional capacity will enable us to address certain API opportunities in a timely manner."
- Biocon pact with California-based Amylin Pharmaceuticals for peptide therapeutics "Our partnership with Amylin is primarily synergy driven. Biocon will bring its recombinant DNA technology, large-scale manufacturing and low-cost pre-clinical and clinical development capabilities to the partnership while Amylin, a front-runner in peptide therapeutics will bring in its proprietary "phybrid" technology and other key development capabilities. The trend today in the Biotech business world is one of "profit together". Given that it takes a minimum of 5-7 years and approximately S1.2 bn to bring a drug into the market, collaborative co-development models are the new paradigms as it allows each partner to leverage each other's capabilities, share the risks as well as R&D costs and scale up quickly."
- **German subsidiary AxiCorp's performance** "AxiCorp continues to grow robustly. It is a profitable, revenue-driven business that is largely accretive to our top line as of now. AxiCorp is ranked amongst the fastest growing pharmaceutical companies in Germany. Biocon and AxiCorp are on track with the regulatory process for the registration of Recombinant Human Insulin with EMEA."
- Innovation progress "We have made significant progress in our R&D efforts and are pleased with the progress made. Our Oral Insulin program, IN 105, expects to complete patient enrollment in Q3 this fiscal. We expect to report Phase III data by the end of Q1 FY2011. T1h, our other leading research program, has shown promising Phase II data in Rheumatoid Arthritis (RA) as well as Psoriasis. We plan to commence Phase III trials for Psoriasis by the end of this calendar year and Phase III for RA in the next calendar year." On Biosimilars, she said, "Our recently announced partnership with Mylan for biosimilars is on track with both partners aiming to secure a market leader position in the biosimilar space. This partnership is based on complementary capabilities and shared costs wherein we expect paybacks to commence within three years starting with emerging markets. Much larger returns are expected post 2014 once the regulated markets open up."

#### **Business Outlook**

On the outlook for the remainder of this fiscal, Ms. Mazumdar-Shaw said, "We are very pleased that our company has posted such strong growth. Even more exciting is the progress of our research pipeline. We believe we can sustain the current trend across all our businesses and are confident of delivering a strong performance for the full year. With respect to our business strategy, Biocon will always look at moving up the innovation value chain which we firmly believe will deliver sustainable growth for us. We forecast strong organic growth going forward but will also remain open to inorganic growth opportunities when they present themselves at the right price".

Below are comments from Ms. Kiran Mazumdar-Shaw on

• Subsidiaries and Segments- "Syngene and Clinigene have posted a strong quarter on the back of stronger relationships with key customers. We believe that the propeller for this growth is Syngene's ability to run a program right from discovery all the way to pre-clinical development for both small and large molecules. There is also the opportunity to take this to the clinic seamlessly through our CRO, Clinigene. We believe that our research services business is well



differentiated in the market, given the end-to-end services we offer our growing customer base both in the development of small molecules as well as biologics. The Clinical Research Outsourcing space is enormous in terms of opportunities. Consultancy firm KPMG has estimated that this market is projected to hit US \$23 billion by 2011 and further that India will account for 15% of this (or roughly \$3.4 bn) by 2015. Importantly, these projections signify the growing interest of global pharma companies in conducting clinical trials in the emerging markets and also the value-per-dollar that these markets render vis-à-vis the developed world. Among these countries, India scores top of the list owing to its good IP track record and its highly-skilled scientific human capital with excellent communication skills."

• Innovation Plans - "Oral insulin is a global blockbuster market opportunity for Biocon. Based on the outcome of the Phase III trials, we will pursue a go-to-market strategy of launching in India first. We expect to realize a large licensing opportunity for Biocon with this molecule. T1h will shortly enter phase III trials for Psoriasis and we expect to initiate licensing discussions for this over the next 12 months. Phase III for Rheumatoid Arthritis will commence in the next calendar year. With respect to our immuno-conjugates program with IATRICa, we expect to file the IND by Q2 FY2011".

"Biocon has systematically built its bio-pharmaceutical business on a framework of generic and proprietary products and processes. We are steadily gaining global manufacturing scale and have increased our footprint in many world markets. Our demonstrated expertise in both small molecules and biologics has enabled us to build key partnerships across our businesses. Our bet on innovation is already delivering long-term value creation. We are now at a stage of post-gestational growth, which we expect will deliver sustained shareholder value for the foreseeable future" - CMD, Biocon Group, Ms. Kiran Mazumdar-Shaw.

#### **Corporate Developments**

**Biocon in pact to acquire Hyderabad firm IDL Specialty Chemicals Limited** - Biocon Limited announced on September 30 that it had signed a definitive agreement to acquire Hyderabad-based chemical synthesis unit IDL Specialty Chemicals Limited. Bulk manufacturer IDL is expected to add to Biocon's existing capacity as well as help augment its product offerings in the chemical synthesis segment. The acquisition is subject to closing conditions detailed in the agreement.

Biocon inks pact with Amylin for diabetic segment - Biocon announced on September 12 that it had inked an exclusive co-development and marketing pact with California-based Amylin Pharmaceuticals for peptide therapeutics. Specifically, this will be geared towards a peptide hybrid or "phybrid" which will combine the properties of two peptides into one small molecule to treat diabetes. "As opposed to using single properties on its own, this technology is likely to give a differentiated clinical outcome by enabling the interplay of two peptides with dual benefits like lower sugar level and weight loss", explained Biocon COO, Dr. Arun Chandavarkar. Amylin Pharmaceuticals has been a front-runner in the field of peptide therapeutics and is a leader in the diabetes market. For its part, Biocon will bring its recombinant DNA technology, large-scale manufacturing and low-cost pre-clinical and clinical development capabilities to this partnership. "Right now, the deal is a co-development deal which largely means that both Amylin and Biocon share the cost of development going forward. It is also a deal where we have marked out commercialization territory. Amylin would have the commercialization rights in North America, Biocon in most parts of Asia, and in the rest of the world, we will share the commercialization rights jointly," said Dr. Chandavarkar. The two companies will share the development costs, a significant portion of which will arise in the phase III trials. Even as Amylin will own the intellectual property (IP) rights to the molecule and the "phybrid" technology, Biocon will hold the IP for the manufacturing. "Going forward, after assessing the synergies that may accrue to the companies, we could also broaden our collaboration", he said.



**Biocon among 20 Indian companies in Forbes 'Best Under A Billion' list** - Biocon Ltd was included in the prestigious 'Best Under A Billion' list put out by Forbes this quarter. Only 20 Indian companies featured in the list this year. According to Forbes, the selected companies had grown sales and profits over the past 12 months or were forecast to do so in the coming quarters. This year's list was dominated by companies that had withstood challenges that threatened their survival and those that had demonstrated exemplary entrepreneurship.

#### **About Biocon**

Established in 1978, Biocon Limited (**BSE code:** 532523, **NSE Id:** BIOCON, **ISIN Id:** INE376G01013) is India's largest biotechnology company by revenue. The Group, promoted by Ms Kiran Mazumdar-Shaw, is a fully-integrated, innovation-driven healthcare enterprise with strategic focus on biopharmaceuticals and research services. Biocon's value chain traverses the entire length of discovery, development and commercialization of novel therapeutics. With successful initiatives in clinical development, bio-processing and global marketing, Biocon delivers products and solutions to partners and customers in approximately 75 countries across the globe. Many of these products have USFDA and EMEA acceptance. Biocon's robust product offering includes the world's first recombinant human insulin, INSUGEN® and India's first indigenously produced monoclonal antibody BIOMAb-EGFR(TM). For more information, visit www.biocon.com

#### **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 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, nor any of our 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.

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# Encl: Fact Sheet - Consolidated Income Statement and Balance Sheet (Indian GAAP) (All figures in Rs Crores, except EPS data)

**Note:** The discussions in this release reflect the financial performance of Biocon Limited and its subsidiaries based on Indian GAAP on a consolidated basis. Results for the German subsidiary are reported with a one-quarter lag.

## **BIOCON GROUP**

H1 FY 2010 vs H1 FY 2009 Q2 FY 2010 vs Q2 FY 2009

# **FACT SHEET**

### BIOCON LIMITED (CONSOLIDATED) UNAUDITED

PROFIT & LOSS STATEMENT							Full year	(Rs. Crores) Full year
Particulars	H1 WITH AXICORP FY 10	H1 WITH AXICORP FY 09	Variance	H1 WITHOUT AXICORP FY 10	H1 WITHOUT AXICORP FY 09	Variance	ended Mar 31, 2009 WITH AXICORP FY 2009	ended Mar 31, 2009 WITHOUT AXICORP FY 2009
INCOME								
Biopharmaceuticals	939	610	54%	539	471	14%	1,384	915
Contract research	137	96	43%	137	96	43%	225	225
Total Sales	1,076	706	52%	676	567	19%	1,609	1,139
Other income	22	28	-22%	20	27	-25%	65	54
Total Income / Revenues	1,098	734	50%	696	593	17%	1,673	1,194
<u>EXPENDITURE</u>								
Material & Power Costs	637	393	62%	313	279	12%	908	516
Staff costs	110	74	47%	77	64	20%	165	129
Research & Development	41	26	57%	41	26	57%	60	60
Forex Loss/ (gain)	8	10	-17%	8	10	-17%	11	11
Other Expenses	66	63	5%	43	52	-17%	141	107
Manufacturing, staff & other exps	862	566	52%	483	431	12%	1,285	822
PBDIT /EBIDTA	236	168	40%	213	162	31%	388	372
Interest and finance charges	11	8	38%	10	7	36%	18	15
PBDT	225	160	41%	204	155	31%	370	356
Depreciation	68	54	24%	65	52	26%	110	108
РВТ	158	106	49%	138	103	34%	260	248
Current taxes	19	8	131%	13	8	55%	12	10
Deferred taxes	4	(1)		4	(1)		0	0
Taxes	23	8	204%	17	8	121%	12	10
PROFIT FOR THE PERIOD	135	98	37%	121	96	27%	248	238
Add/(less): Minority interest / Share of Losses in Associates	(3)	2	-281%	-	2	0%	(8)	(5)
Profit before Exceptional Items	132	100	32%	121	98	24%	240	234
Exceptional Item (MTM Provision - Forex) - Net of tax	0	(60)	-100%	0	(60)	0%	(147)	(147)
NET PROFIT (PAT)	132	40	230%	121	38	218%	93	87
EPS on issued capital Rs. (before exceptional items)	7	5		6	5		12	12

Note: The figures are rounded off to nearest crores, percentages are based on absolute numbers

Biopharmaceutical sales includes licensing income of Rs 12.6 crores for H1 FY2010 and Rs 3 crores for H1 FY2009 (both with and without AxiCorp)

### BIOCON LIMITED (CONSOLIDATED) UNAUDITED

**PROFIT & LOSS STATEMENT** (Rs. Crores) Full year Full year ended ended Q2 Q2 Q2 Q2 Mar 31, 2009 Mar 31, 2009 Particulars WITHOUT WITH WITH WITHOUT WITHOUT WITH Variance Variance AXICORP AXICORP AXICORP **AXICORP** AXICORP AXICORP FY 10 FY 09 FY 10 FY 09 FY 2009 FY 2009 **INCOME** Biopharmaceuticals 507 389 294 1,384 915 30% 250 18% Contract research 73 225 225 73 53 37% 53 37% 442 303 1,609 1,139 Total Sales 580 31% 367 21% Other income 12 15 -19% 12 14 -14% 65 54 Total Income / Revenues 592 458 29% 379 317 20% 1,673 1,194 **EXPENDITURE** Material & Power Costs 348 257 35% 177 144 23% 908 516 Staff costs 57 43 32% 39 33 20% 165 129 Research & Development 21 15 36% 21 15 36% 60 60 Forex Loss/ (gain) (5) 12 -143% (6) 12 -146% 11 11 Other Expenses 47 41 14% 35 30 15% 141 107 Manufacturing, staff & other exps 369 266 234 1,285 822 467 27% 14% PBDIT /EBIDTA 126 89 41% 114 83 37% 388 372 5 4 Interest and finance charges 5 4 24% 34% 18 15 PBDT 120 85 42% 109 80 37% 370 356 Depreciation 35 29 21% 34 27 28% 110 108 PBT 85 56 53% 75 53 41% 260 248 27% 5 7 5 12 10 Current taxes 10 89% 0 0 Deferred taxes 1 (1) 1 (1) -220% 9 6 6 12 62% 6 5% 10 Taxes PROFIT FOR THE PERIOD 76 50 52% 69 47 45% 248 238 Add/(less): Minority interest / Share of Losses in Associates (2) 1 -383% 0 1 0% (8) (5) Profit before Exceptional Items 74 50 47% 69 49 41% 240 234 Exceptional Item (MTM Provision - Forex) - Net of tax 0 (25) -100% 0 (25) 0% (147) (147) NET PROFIT (PAT) 74 192% 69 24 190% 87 25 93 EPS on issued capital Rs.

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(before exceptional items)

Note: The figures are rounded off to nearest crores, percentages are based on absolute numbers

Biopharmaceuticals includes licensing income of Rs 10.6 crores in Q2 FY2010, Rs 3 crores in Q2 FY2009 (both with and without Axicorp);

BIOCON LIMITED (CONSOLIDATED) UNAUDITED						
ALANCE SHEET (Rs. C						
Particulars	As at	As at				
	30-Sep-09	31-Mar-09				
SOURCES OF FUNDS						
Share Capital	100	100				
Reserves & Surplus	1,545	1,411				
Total Shareholder's Funds	1,645	1,511				
Minority interest	28	25				
Deferred Tax Liability	51	47				
Secured Loans	298	396				
Unsecured Loans	131	128				
Total Loan Funds	429	524				
Total	2,153	2,106				
APPLICATION OF FUNDS						
Fixed Assets (Net)	1,199	1,221				
Intangible Assets	173	163				
Investments	318	368				
Inventories	375	319				
Sundry debtors	421	367				
Cash and bank balances	49	12				
Loans and advances	110	95				
Total Current Assets, Loans & Advances	954	792				
Less: Current liabilities and provisions	491	438				
Net Current assets	463	355				
Total	2,153	2,106				



Press Release : 3

Bangalore, India September 29, 2009

## Kiran Mazumdar Shaw in Financial Times 'Top 50 women in business' list

Kiran Mazumdar Shaw, CMD, Biocon Ltd, India's leading biotechnology major, has been included in the prestigious 'Top 50 women in business' listing by Financial Times, London. The report, compiled in collaboration with recruitment group Egon Zehnder International, celebrates women business leaders around the world and this year's list features three Indians.

FT used a range of factors to assess the candidates including biographical information, data on the size of the company (turnover and number of employees), its scope and complexity (operations in multiple countries or sectors) and the competitive landscape. Total shareholder return was also used to gauge corporate performance. This varied according to the country, sector and characteristics of the company. Women running companies with a multinational reach were likely to rank more highly than those in charge of nationally focused groups.

The number of women business leaders around the world remains miniscule. Just 3 per cent of Fortune 500 chief executives are women. Across Europe, only 10 per cent of board directors of the largest companies are female (quotas have made Norway the exception, with more than 40 per cent) and the numbers are even lower in Asia. There is substantial evidence that better gender balance has a positive impact on performance. Studies by Catalyst and McKinsey in the US and Europe have found a correlation between the number of women in a company's leadership and the company's profitability.

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