

Bangalore, India July 21, 2011

BIOCON LIMITED ANNOUNCES EARNINGS FOR THE FIRST QUARTER ENDED JUNE 30, 2011.

#### BIOCON DELIVERS STRONG PERFORMANCE IN ITS CORE BUSINESSESS IN THE FIRST QUARTER

# Revenues at Rs 454 crores; EBITDA at Rs 133 crores; PAT at Rs 70 crores

Commenting on the results, Chairman and Managing Director Kiran Mazumdar-Shaw stated,

"Biocon's consolidated financials for Q1 FY12 has delivered a PAT of Rs 70 crores with a robust increase in profits derived from its core Manufacturing and Services businesses. There has been lower licensing income recognition this quarter. This is as per plan and is expected to ramp up in the quarters ahead. Inherent variability in licensing income linked to development and regulatory timelines requires this to be viewed on an annualized basis.

Our Services businesses led by Syngene and Clinigene had a particularly strong quarter signaling the success of our integrated business model that offers end- to-end services.

On the licensing front, we have initiated several partnering discussions for Oral Insulin and Itolizumab (Anti CD6 MAb) which we will endeavor to realize during this fiscal.

We are making steady progress on the Biosimilar Insulins front with a number of registration processes initiated in emerging markets. We expect to commence supplies of Insulin and Glargine to Pfizer for their India market launch in this quarter. We also plan to launch our Insulin pen, INSUPEN® shortly.

We expect to end the year on a note of strong performance."

# **Biocon Group (consolidated) (excluding Axicorp)**

### For three months ended June 30, 2011

- Total Income at Rs 454 crores. Up 11% YoY.
- EBITDA at Rs 133 crores. YoY growth of 12%.
- PAT at Rs 70 crores. YoY growth of 7%.
- Operating Margin at 29%.
- Earnings Per Share at Rs 3.5
- Headcount at 5,400+ employees.

Mr. Murali Krishnan, President, Group Finance, Biocon Group, commented "Licensing income from our partnered programs will see a high degree of variability given the inherent nature of licensing



recognition that is linked to development and regulatory timelines. In FY11, licensing income varied from Rs 21 crores to Rs 77 crores across quarters. Therefore, it is prudent to view licensing on an annualized basis."

# **Business Performance and Outlook**

### **Biopharmaceuticals**

The Biopharma business posted a 8% YoY increase in revenues in the first quarter of this fiscal on the back of growth in the sales of immunosuppressant and the branded formulations segments.

Statins continue to remain buoyant with Atorvastatin and Fluvastatin leading the sales in this segment.

Sales of Fidaxomicin API to Optimer began in June 2011. Biocon is the sole supplier of the drug substance for global markets. Fidaxomicin is used for the treatment of CDI – Clostridium difficile Infection, which is a major threat in hospitals across the world. Optimer received FDA approval for Fidaxomicin on May 28th 2011 and has just launched the product in the US market and expects to launch in Europe (through its licensee, Astellas) by the end of this year.

<u>Biosimilar Insulins</u> - Licensing income from the Pfizer partnership will continue to accrue in the remainder of the year based on certain development and regulatory milestones. Our co-marketing partner, Pfizer, is expected to launch Insulin and Glargine in India this coming quarter. We expect to launch our re-usable Insulin pen, *Insupen®*, by the end of next quarter.

Our biopharmaceuticals project in Malaysia is making good progress and we plan for ground breaking in the coming quarter. In June 2011, the Prime Minister of Malaysia announced the inclusion of our project in the Economic Transformation Programme (ETP) initiative of the Malaysian Government. Performance Management and Delivery Unit (PEMANDU), a division under the Prime Minister's Office, provides special focus and assistance to projects covered under ETP.

<u>Domestic Branded Formulations</u> – The six verticals in branded formulations, namely, Diabetology, Oncotherapeutics, Nephrology, Cardiology, Dermatology and Comprehensive Care, have posted a combined YoY growth of 28% for Q1FY12.

❖ Diabetology — Biocon ranks #3 in the Insulin's space, with a growth rate of 35% that outpaces the market's 19% growth (source: April 2011 MAT). The division's growth plans for the next three quarters are fuelled by the launch of Insulin pens, which is slated to change the way the 51 million diabetics in India get their daily Insulin dose. The existing product portfolio is led by Insugen 100, launched in Q3FY11 and it has garnered strong support from doctors. Brand Basalog is now the largest brand by volume sales in the Glargine vials market. This year, the Orals segment will be led by the launch of "Volicose" (Voglibose) and "Metadoze V" (Metformin+Voglibose combination).



- ❖ Comprehensive care This division, which was launched in August 2010 with an objective of providing affordable and quality medicines in the Critical Care segment, has met with great success and wide acceptance of its brands in various hospitals and nursing homes across India. In the first quarter of this fiscal, the flagship brands Celrim TZ, Entavar, Biopiper and Penmer have posted excellent growth. With scientific marketing initiatives, the Comprehensive Care division is planning to post an aggressive growth this fiscal.
- ❖ Nephrology The first quarter of this fiscal saw the Nephrology division deliver a strong growth driven by brands Tacrograf, Renodapt, the Erypro Group and Cyclophil ME. The division supported a symposium on Organ Transplantation in Hyderabad, with Prof Dr. Francis L. Delmonico, President elect of The Transplantation Society (TTS), an international society of transplantation. The objective of this symposium was to increase awareness and promote organ donation in the country.

The Nephrology division has started to conduct academically enriching activities for Nephrologists. For example, the 'Women in Nephrology' program was successfully held in Bangalore on July 16, 2011 in conjunction with the Indian Society of Nephrology.

- ❖ Oncology A best-in-class taxane launched in India in 2008, Abraxane®, used in the treatment of metastatic breast cancer, is ranked 3<sup>rd</sup> in the hypercompetitive taxanes market. On the heels of the BIOMAb EGFR® & Abraxane® success story, Biocon's Oncotherapeutics division has added another frontline anti-cancer drug Evertor® to its portfolio. Evertor® (Everolimus) was launched in January 2011 (ahead of competition) in the domestic market and has gained significant mileage since then. Three more significant Oncotherapeutics launches expected shortly are Atsure® (Gemcitabine), Xtide® (Oxaliplatin) and Adnexa® (Epirubicin) for cancer chemotherapy.
- ❖ Immunotherapy According to ORG data, brand TBIS is now among the top 5 brands in Tacrolimus in all the major cities as of June 2011, within nine months of its launch. PICON (Pimecrolimus) is expected to be the largest brand of Pimecrolimus in India by end of this financial year. In Q2 FY12, Biocon is planning to launch two more brands for the treatment of Immuno-dermatological disorders. Biocon's Immunotherapy division is looking at garnering a leadership position in the Immuno-dermatology market in India with the launch of a basket of differentiated and unique molecules this fiscal.
- Cardiology With key brands like Bestor, Actiblok-IPR, Telmisat and Myokinase posting strong growth, the year has started off on a promising note to deliver high growth for this segment. The launch of BESTOR-FN (Rosuvastatin + Nanonized Fenofibrate) in May 2011 has enabled us to augment our statins portfolio. Our brand is one of the few brands in the market to have Nanonized Fenofibrate with Rosuvastatin as a fixed dose combination therapy for the high-risk diabetic dyslipidemics.

Mr. Rakesh Bamzai, President, Marketing, Biocon Group, stated "Our healthcare division is a strong driver of growth both in terms of earnings and brand value creation. We are committed to building market leadership in our chosen segments through a carefully orchestrated strategy of product differentiation and personalized medical support through e-enabled platforms. Many of our brands are amongst the top 5 in an overly crowded market indicating our growing brand presence."



## **Research Services**

<u>Syngene</u> – Syngene has delivered a strong first quarter, with sales growing 21% YoY. Growth was delivered through a number of drivers - expansion by existing clients, the addition of new clients, an evolution of our business mix towards higher value and more integrated services and an accelerating contribution from the Biologics platform. The Syngene collaboration with BMS has now grown to over 400 FTEs and represents the largest integrated Discovery and Development CRO collaboration in India.

Commenting on this performance Peter Bains, Director, Syngene International, said, "We are pleased to report a very solid start to the year at Syngene. Our robust top line growth, building on recent investments in strengthening and expanding our capability platform, is also delivering improved margins. The shift in our business mix towards higher end and integrated services is an encouraging and positive signal of our ability to add a stronger value proposition towards our client's R&D objectives"

Clinigene - Clinigene has made significant strides in evolving its business model from a generic operational service provider to an integrated service partner over the last 12 months. With a state-of-the art immunoanalytical laboratory and strong operations capabilities in early and late stage studies, Clinigene is well poised to grab a significant share of the growing novel biologic and biosimilar clinical services market globally. The investment in a state of the art LIMS and Meso Scale Discovery Platform will make it the only CRO in India to offer these high end services at a GLP compliant immunoanalytical laboratory. In the wake of the recent press reports on regulatory challenges faced by certain CROs, Clinigene would like to re-emphasize its strong commitment to following all the GCP and Schedule Y requirements while conducting clinical studies.

# **Research Pipeline**

<u>IN-105</u> - IN-105 is an oral Insulin program that potentially addresses 300 million diabetes patients worldwide. A Phase I study in patients with type I diabetes mellitus, to test the pharmacokinetics and pharmacodynamics of IN-105 under US IND, is currently ongoing. Biocon is currently in talks with several potential partners, for the global development and commercialization of IN-105.

<u>Itolizumab</u> – The data lock for the Phase 2/3 clinical trial in Psoriasis has been done and data analysis is on-going. A Phase 2/3 clinical trial planned for Rheumatoid Arthritis is expected to begin at the end of 2011.

**BVX20** – Biocon has recently received DCGI approval to begin a Phase 1 clinical trial.



### **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 EMA acceptance. Biocon's robust product offering includes the world's first Pichia-based recombinant human Insulin, INSUGEN® and India's first indigenously produced monoclonal antibody BIOMAb-EGFR<sup>(TM)</sup>.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 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, 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.

# **Earnings Call**

The company will conduct an hour long call at 12:30 pm IST on July 21, 2011 where the senior management will discuss the company's performance and answer questions from participants. To participate in this conference call, please dial the numbers provided below five to ten minutes ahead of the scheduled start time. The dial-in numbers for the call are 1800 425 4061 / 1800 425 4250 / 1800 22 4061 / 1800 425 1300 (India Toll Free numbers are accessible through all mobiles and landline services). Other toll numbers are listed in the conference call invite which is posted on the company website <a href="https://www.biocon.com">www.biocon.com</a>. The operator will provide instructions on asking questions before the start of the call. A replay of this call will also be available from July 21, 2011 – July 28, 2011 on the same dial-in numbers provided above. The transcript of the conference call will be posted on the company website.

# **BIOCON GROUP** FACT SHEET June 2011 Q1 FY 2012 vs. Q1 FY 2011

BIOCON LIMITED (CONSOLIDATED) UNAUDITED BALANCE SHEET		(Rs. Crores	
	June-11	March-11	
SOURCES OF FUNDS			
Share Capital	100	100	
Reserves & Surplus	2,019	1,939	
Total Shareholder's Funds	2,119	2,039	
Deferred Tax Liability	45	50	
Secured Loans	145	204	
Unsecured Loans	113	118	
Total Loan Funds	258	322	
TOTAL	2,422	2,411	
APPLICATION OF FUNDS			
Fixed Assets (Net)	1,436	1,349	
Intangible Assets	224	229	
Intangible Assets Investments - Liquid Funds	224 379	229 400	
Investments - Liquid Funds	379	400	
Investments - Liquid Funds Investments - Others	379 62	400 61	
Investments - Liquid Funds Investments - Others Inventories	379 62 309	<b>400 61</b> 291	
Investments - Liquid Funds Investments - Others Inventories Sundry debtors	379 62 309 444	400 61 291 489	
Investments - Liquid Funds Investments - Others Inventories Sundry debtors Cash and bank balances	379 62 309 444 426	400 61 291 489 403	
Investments - Liquid Funds Investments - Others Inventories Sundry debtors Cash and bank balances Loans and advances	379 62 309 444 426 157	400 61 291 489 403 122	
Investments - Liquid Funds Investments - Others Inventories Sundry debtors Cash and bank balances Loans and advances Total Current Assets	379 62 309 444 426 157 1,336	400 61 291 489 403 122 1,305	

# BIOCON LIMITED (CONSOLIDATED) UNAUDITED PROFIT & LOSS STATEMENT

(Rs. Crores)

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Particulars	Q1 FY 12	Q1 FY 11	Variance	
INCOME				
Biopharmaceuticals	354	329	8%	
Contract research	88	72	22%	
Total Sales	442	401	10%	
Other income	12	8		
Total Income / Revenues	454	409	11%	
<u>EXPENDITURE</u>				
Material & Power Costs	214	192	11%	
Staff costs	64	51	27%	
Research & Development	20	21	-4%	
Other Expenses	23	27	-14%	
Manufacturing, staff & other expenses	321	291	10%	
PBDIT /EBITDA	133	118	12%	
Interest and finance charges	6	7	-13%	
Depreciation & Amortisation	45	36	24%	
PBT	82	75	9%	
Taxes	12	10	19%	
NET PROFIT (PAT) WITHOUT AXICORP	70	65	7%	
Profit from discontinued (AxiCorp) Operations, net	-	12		
NET PROFIT FOR THE PERIOD	70	77	-9%	
EPS Rs.	3.5	3.8		

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

Biopharmaceuticals Income includes Licensing development fees of Rs 14 crores in Q1 FY 2012 vs. Licensing Income of

Rs.21 crores in Q1 FY 2011.