

### Biocon Ltd.

# **EQUITY REPORT**

### August 8, 2013

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Biocon Limited (Biocon), a fully integrated healthcare company incorporated in the year 1978 as a joint venture between Biocon Biochemicals Limited of Ireland and an Indian entrepreneur, Kiran Mazumdar-Shaw. Being the largest biotech company of India, Biocon is committed to reduce therapy costs of chronic diseases like diabetes, cancer and autoimmune diseases by leveraging India's cost advantage to deliver affordable healthcare solutions to patients, partners and healthcare systems across the globe.

### Investor's Rationale

Biocon witnessed robust growth of 18.6% YoY in its consolidated net profit at ₹0.9 bn during Q1FY'14,led by strong performance in the biopharma segment (24%). Further, at ₹7.2 bn, consolidated revenue also grew by 22% YoY. Looking ahead, the company, with inherent strength in product portfolio, is expecting the Insulin business (currently with 34% market share in India) to drive growth in FY14E.

With a cash reserve of ~₹7 bn, the company aims to achieve USD 700 mn revenue in 2015 and to become USD 1bn company in terms of revenue by 2018 from USD 457 mn in FY13, through commercialization of rh-insulin in regulated markets, ramp-up in contract research business, sustained growth in branded formulations business while low growth in statins (~8-10% range) would be a drag on Biopharma growth rates.

The company's strategic partnership with Mylan for manufacture and marketing of insulin analog products will aid the firm strengthen its presence worldwide in generic insulin analogs, thereby, providing access to affordable therapy options.

Biocon expects its research services business to grow at ~25% on the back of new contracts as well as execution of ongoing business. We expect R&D spend to increase, as Biocon continues to pursue biosimilars and other innovative R&D programs, but with the launch of world-class therapies in the Indian market, the margins continue to remain protective at around current levels in the coming year.

### Key risk

**Regulatory approvals:** The government's approval delay for new products or withdrawal of approval for old products, any stringent rule or severe penalties imposed by regulatory authorities is the biggest cause of concern for pharma companies. New drug price also remains a major concern.

Market Data	
Rating	BUY
CMP (₹)	336
Target (₹)	380
Potential Upside	~13.0%
Duration	Long Term
Face Value (₹)	5
52 week H/L (₹)	340/238
Adj. all time High (₹)	473
Decline from 52WH (%)	1.2
Rise from 52WL (%)	41.2
Beta	0.4
Mkt. Cap (₹bn)	72.0
Price to Book Value	2.5

Fiscal Year Ended				
Y/E	FY12A	FY13A	FY14E	FY15E
Revenue (₹bn)	21.5	25.4	30.3	35.1
EBITDA (₹bn)	3.4	5.1	3.7	4.2
Net Profit (₹bn)	1.0	1.0	1.0	1.0
Adj EPS (₹)	16.9	25.4	18.6	21.1
P/E (x)	19.9	13.2	18.1	15.9
P/BV (x)	3.0	2.5	2.3	2.1
EV/EBITDA (x)	10.6	10.1	8.5	7.3
ROCE (%)	12.2	16.6	12.5	13.0
ROE (%)	14.9	18.9	12.7	13.0

# One year Price Chart 140 100 Nov-12 100 Nov-12 100 Nov-13 Nay-13 Nay-13 Netry Biocon Netry Biocon

Shareholding Pattern	Jun'13	Mar'13	Diff.
Promoters	60.96	60.96	0
FII	10.02	8.08	(0.2)
DII	7.97	8.96	0.6
Others	21.05	22.00	(0.4)



Biocon recognized as largest Indian Insulins company has several innovations to its credit including world's first Pichia based recombinant human Insulin, INSUGEN®, insulin analogue Glargine, BASALOG® and India's first indigenously produced monoclonal antibody BioMAb-EGFR®, for head & neck cancer.

### Biocon: an integrated biotechnology company of global distinction

Incorporated in 1978, Biocon Ltd., a fully integrated biopharma company, delivering innovative solutions, across discovery, development and commercialization of biopharmaceuticals value chain, leveraging the cutting edgescience, cost-effective drug development capabilities and global scale manufacturing capacities by serving its partners and customers in over 75 countries. The company has shaped its business into five key growth verticals - small molecules (APIs), biosimilars, branded formulations, novel molecules and research services, with the aim to deliver sustainable long term value for patients, partners and healthcare systems across the globe.

Leveraging India's globally competitive cost base, the company is advancing its in-house R&D programs by providing integrated research services to leading global pharmaceutical and biotechnology companies through Syngene and Clinigene. Biocon recognized as largest Indian Insulin company has several innovations to its credit including world's first Pichia based recombinant human Insulin, INSUGEN®, insulin analogue Glargine, BASALOG® and India's first indigenously produced monoclonal antibody BioMAb-EGFR®, for head & neck cancer. It has also developed another Novel Biologic, Itolizumab for Chronic Psoriasis, which is to be introduced in India shortly much ahead of its global launch. With the successful commercial launch of its first anti-cancer drug and several promising discovery partnerships in the clinic, the company remains confident to scale new heights in frontier science and achieving new milestones in affordable medicine.

With an aspiration to become a US \$ 1 billion company by FY'18E, we expect Biocon to become leading global player in insulin, immunosuppressant, statins and branded formulations.

### **Evolving with the times**

An Enzymes Company Revenue: ₹0.32 bn. Building the India Business and expertise in biologics Revenue: ₹11.9 bn

People: 3,500+

Poised for a global platform with launch of finished formulations & biosimilars in regulated markets

1978 - 1999

1999 - 2004

2004 - 2009

2009 - 2014

2014 & Beyond

Transforming into a Biopharma company

Revenues: ₹5.49 bn People: 700+ Investment intensive phase with focus on R&D, capacity & partnership execution
Revenue (FY 13): ₹25.4 bn

People: 6.700+

Unwavering focus through the years on Innovation & Difficult to make, niche products to create tangible differentiators for sustainable growth



The newly carved SBUs will have greater autonomy and greater accountability for the financial performance of their respective businesses.

# Change in organization structure to create an optimal matrix for greater synergy

Biocon has decided to move from a function-led to a business-led structure by carving out Strategic Business Units (SBUs), where businesses own core functions and share support functions. The newly carved SBUs will have greater autonomy and greater accountability for the financial performance of their respective businesses. The SBUs will be supported by teams from R&D, Quality, Regulatory, Human Resources, Procurement & Supply Chain, Finance, Legal, Corporate Communications and General Administration. Research Services comprising Syngene and Clinigene platforms, has been a standalone integrated business from its inception and has already evolved its independent support functions.

This paradigm changes will help it to create an optimal matrix, where business heads will have greater clarity on business needs and a better understanding of deliverables to responsed quickly and make faster decision, by enabling better execution of strategy.

Shifting paradigm from function based organization to strategic business units

# Marketing Finance Manufacturing R&D New organization structure Small Molecules Generic Insulins Biosimilar MAbs Branded Formulations

New drug Pricing Policy 2013 raised concern for the pharma companies that are expecting a lower profitability and margins on the announced news.

### New drug pricing policy is key concern for the company

The government has recently announced the new drug Pricing Policy 2013 under which the costs of 348 medicines in the National List of Essential Medicines have been brought under price control. This declaration might bring cheer on customers face but put all the pharma companies in a wait and watch mode. It has raised concern for the pharma companies that are expecting a lower profitability and margins on the announced news.

IMS estimates that the contribution from these 348 medicines (aggregating sales of  $\overline{1}$ 30.0 bn) to the retail Indian Pharmaceutical market ( $\overline{7}$ 27.6 bn) is approximately 18%.

Biocon, being the largest player in Asia bestowed with differentiated product portfolio (earned ₹3.3 bn revenue from branded formulation in FY13) coupled with huge exposure to the foreign market will not be impacted significantly by the new drug policy. Albeit, it has shown some concern on overall industry growth that is realizing a decline from last 5 years and perhaps get reeled further on government's policy. Therefore, the need of the hour is to provide certainty and clearness from government's side to shore up the growth.

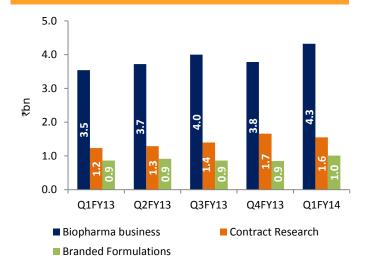


## Strong traction in Biopharm business continued to deliver stellar performance

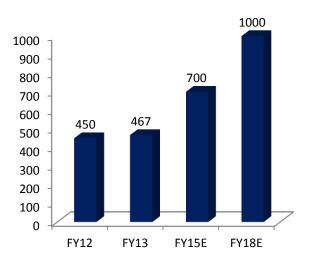
Biocon reported a better-than-expected set of Q1FY14 numbers. Revenues grew 22% YoY and 10% QoQ to ₹7.0 bn, mainly on account of a surprisingly strong performance from its biopharma business and contract research. EBITDA margins improved 40 bps to 21.7%, on the back of decline in the R&D cost and other expenditure. The net profit grew 19% to ₹0.9 bn on account of better product mix and forex gain, despite higher taxation.

Revenue from its biopharma sub-segment (excluding licensing fees and branded formulation) grew ~21% YoY and 16% QoQ to ₹4.4 bn, driven by higher growth in Fidaxomicin and Orlistat APIs. During Q1FY14, the insulin plant in Bangalore was re-commissioned after expansion shut down. The company has registered rhinsulin in more than 45 countries and is also in the process of registering the same in another 20 countries. Branded formulations business grew 17% to ₹1.0 bn, higher than the industry growth of 7% driven by growth in anti-diabetics, oncology and nephrology. With strong performance across all segment, we expect that the company to grow at an estimated CAGR of 18% from FY12 to FY18E

### Q1FY14 Revenue growth drive across each verticals



### Aim to cross US\$ 1,000 mn revenue by FY18E



### R&D services to build further growth momentum on new client addition

In order to streamline the integrated service offerings of its research services, Biocon board has given an in-principle approval for the merger of Clinigene with its parent company, Syngene. The research services subsidiary Syngene and the clinical research arm Clinigene together crossed the US\$100-million revenue mark in FY13, growing 36% over the previous fiscal. Syngene, in which GE Capital last year bought a 7.69% stake for ₹1.25 bn, is looking at going public in FY15E. During Q1FY14, the R&D services business of the company continues to witness strong growth of 26% to ₹1.5 bn on the back of new client addition and improvement in existing clients servicing. The company has added 50 new clients in the last two or three years. Through a strategic alliance with Bristol-Myers Squibb, Biocon will continue to conduct clinical studies to further characterize IN-105, an oral insulin drug's clinical profile through Phase II. With the inauguration of the Abbott Nutrition and R&D centre, the company encouraged to supply a growing number for partners who have products in late Phase II and Phase III programs. With the increasing demand for its contract research services in allied areas such as agrochemicals, petrochemicals, and even electronics, we expect the company's R&D services to build further growth momentum and deliver a strong growth in FY14E.

Biocon is targeting research services growth to 25% by FY15. The company has framed strategic capex investments in R&D in biosimilars programs (R&D investment during FY13 stood at ₹1.2 bn with 44% increase) to encompass clinical research activity worldwide.



### Small Molecules business continued to gain traction through niche products and cost advantage

Current Portfolio	Constituents
Statins	Simvastatin, Atorvastatin, Lovastatin, Rosuvastatin, Fluvastatin & Pravastatin
Immuno suppressants	ExploTacrolimus, MMF & MPA
Other Biopharma	Orlistat, Fidaxomicin, 50+ other molecules

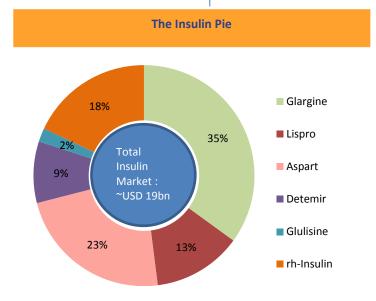
Biocon has strong presence in fermentation based APIs such as Statins & Immunosuppressants. The company believes that statin APIs with ~25% of total sales currently, are likely to register modest growth going forward. Biocon's customers for atorvastatin APIs are expected to receive ANDA approvals in FY14. Two of Biocon's customers for atorvastatin APIs are expected to receive ANDA approvals in FY14.

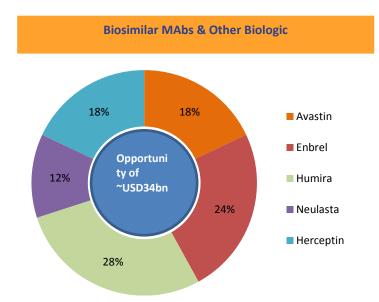
Other API products – immunosuppressants, which account 10% of sales currently, fidaxomicin, or listat and ophthalmics (travoprost, latanoprost) – are expected to drive growth for the segment going forward. The company reiterated its plans to forward integrate its niche API portfolio through 505(b)2 and ANDA filings in the next 24 months. Currently, the company has 20 ANDA products under development and it expect ANDA filling to commence in FY15E.

### Biosimilars to provide the next wave of growth for the company

Biocon is upbeat about its biosimilars. The leading biopharmaceutical company expects the sales revenue from this segment to treble by FY15. It hopes the patent expiry of eight of the top 10 biotech products by 2018 will boost the Indian generics market. Biosimilars contributed about five per cent of Biocon's \$450 million sales in FY12. The contribution of this segment is expected to grow to over 10% in FY15 when the company is projected to achieve total sales of \$700 million. The company sees an increasing shift towards generics and biosimilars. However, there are steep entry barriers in the US and Europe for biosimilars. Despite this, biosimilars will inevitably provide the next big bolus of growth in the generics market.

Biosimilar trastuzumab (Herceptin) is currently undergoing phase III trials in India; launch expected in FY15.







The company is growing much faster than other Insulin players with 11% market share. The company is eyeing to make Insugen, its generic rh- insulin, a ₹1.0 bn brand.

The company's biosimilar business offers a promising portfolio of recombinant human insulin and insulin analogs. It is developing more complex biosimilar biologics, including monoclonal antibodies (MAbs), for the global market. The company has also entered into an agreement with US-based Mylan for the global development and commercialization of three biosimilar insulin analog products. At present, the company is manufacturing and commercializing generic rh-Insulin and generic Insulin glargine (a long-acting insulin analog) in the emerging markets. The company reiterated its plan to file for biosimilar rh-insulin in Europe in FY14E. Filing and approval for biosimilar insulin glargine are expected in FY15 and FY16, respectively. Global phase III trials for biosimilar trastuzumab initiated and expected to be launch in FY15E. One more MAb expected to enter clinics in FY14E.

### Branded formulation verticals to grow by ~20% in FY15E

The company differentiated itself as a biologics-led healthcare company and has thereby created a premium niche in a crowded Indian pharma market. Biocon's India-centric Branded Formulations business has a portfolio of over 80 brands across seven therapy segments. During Q1FY14, the company recorded 17% YoY growth from its branded formulations vertical, outpacing the industry growth of 8% YoY. But, with the changes in regulations, phased roll-out of NPPA pricing protocols and widespread de-stocking have impeded the growth momentum. However, the company expect this vertical to grow by 20% in FY15E.

India trials of Novel Molecules pipeline					
Therapeutic Area	Molecule	Discovery Pre-Clinical Phase - Phase - Market			
Oncology	Nimotuzumab				
Autoimmune	Itolizumab				
/ latelli marie	resilearnas				
Diabetes	IN-105				
Oncology	Anti CD – 20				
Oncology	Fusion Proteins	Currently on			

Biocon's novel biologics pipeline received a significant boost in FY13, to capitalize on Biocon's inhouse expertise and talent to create innovative therapies in diabetes, oncology and autoimmune diseases. The company's Oncotherapeutics division was created on a strong foundation of innovation and differentiation with the launch of Nimotuzumab, the first novel biologic from its R&D pipeline to treat of head and neck cancers. In 2013, Biocon signed an agreement with US firm Bristol-Myers Squibb (BMS) allowing the latter an optional agreement to acquire worldwide marketing rights to Biocon's oral insulin candidate.

With the regulatory approval of ALZUMAbTM, partnering of IN-105 (Oral Insulin), and first-in-human clinical studies for BVx 20, this unit is at the cusp of unlocking significant value from these molecules for patients as well as other stakeholders. Currently, the company geared towards the launch of its 2nd novel biologic, Alzumab(TM) in the Indian market in Q2 FY14. It is a novel, first-in-class therapy with a differentiated mechanism of action indicated for Psoriasis.



### **Balance Sheet (Consolidated)**

Y/E (₹mn)	FY12A	FY13A	FY14E	FY15E
Share Capital	1,000	1,000	1,000	1,000
Reserve and surplus	21,724	25,946	28,398	31,391
Net Worth	22,724	26,946	29,398	32,391
Minority Interest	38	653	653	653
Loans	2,571	2,488	2,986	3,881
Long term provision	2,115	2,505	2,806	3,142
Current Liability	6,170	6,920	7,958	9,152
Deferred tax liability	-78	412	412	412
Other liability	5,832	4,237	3,729	3,281
Capital Employed	39,372	44,161	47,941	52,912
Fixed Asset	16,600	18,228	20,415	23,647
Investment	5,563	5,866	6,042	6,223
Long term loans &adv.	2,620	3,297	3,854	4,510
Current Assets	14,302	16,365	17,183	18,042
Other Assets	287	405	446	490
Capital Deployed	39,372	44,161	47,941	52,912

### **Key Ratios (Consolidated)**

Y/E	FY12A	FY13A	FY14E	FY15E
EBITDA Margin (%)	27.0	23.5	23.0	22.9
EBIT Margin (%)	18.8	24.4	16.5	16.2
NPM (%)	15.8	20.1	12.3	12.0
ROCE (%)	12.2	16.6	12.5	13.0
ROE (%)	14.9	18.9	12.7	13.0
EPS (₹)	16.9	25.4	18.6	21.1
P/E (x)	19.9	13.2	18.1	15.9
BVPS(₹)	113.6	134.7	147.0	162.0
P/BVPS (x)	3.0	2.5	2.3	2.1
EV/Operating Income (x)	2.9	2.4	2.0	1.7
EV/EBITDA (x)	10.6	10.1	8.5	7.3

### Profit & Loss Account (Consolidated)

Y/E (₹mn)	FY12A	FY13A	FY14E	FY15E
Total Income	21,483	25,380	30,279	35,089
Operating Expense	15,692	19,423	23,308	27,037
EBITDA	5,791	5,957	6,971	8,052
Depreciation	1,744	1,793	1,972	2,367
Exceptional Items	0	2,019	0	0
EBIT	4,047	6,183	4,999	5,685
Interest	122	81	97	126
Profit Before Tax	3,925	6,102	4,902	5,559
Tax	541	975	1,127	1,279
Share of asso.	0	(38)	(46)	(59)
Net Profit	3,384	5,089	3,729	4,221

### Valuation and view

In order to sustain its growth momentum by optimizing its small molecules portfolio, the comapny is expanding its insulin footprint in emerging markets, and continue to deliver robust growth in Branded Formulations and Research Services.. Further, with the introduction of a series of new products, global partnerships, investment in R&D services, potential foreign direct investment and opportunity in clinical trial outsourcing market will build further momentum to deliver a strong growth in the coming two years.

At a current CMP of ₹336, BIOCON is attractively placed at P/E and P/BVPS of ~15.9x and 2.1x for FY15E. Considering the above aspects, we rate the stock as 'BUY' with a potential upside of 13.0% for the coming 12 months.





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