

October 22, 2018 06:21 AM GMT

## Biocon Ltd | Asia Pacific

Four Out of Four in Europe;  
Maintain OW

Stock Rating  
Overweight

Industry View  
In-Line

Price Target  
Rs785.00

Of the four planned biosimilars for EU, Biocon, in partnership with Mylan, has launched Hulio (adalimumab); received approval for Semglee (glargine) with likely launch in Q4 2018, and received +ve CHMP for Fulphila (pegfil) and Ogivri (trastu).

**What's New? 1) Hulio launch** - Biocon/MYL has initiated commercial launch of Hulio (bHumira, adalimumab) across major markets in Europe. To recall, Mylan (and Biocon) partnered with Fujifilm in Apr'18 for this product and, subsequent to this, it received European Commission (EC) approval in Sep'18. The EU market opened on October 16, 2018; and the drug seems to have 4-5 biosim entrants, including Amgen (Amgevita), Biogen (Imraldi) and Sandoz (Hyrmoz). Boehringer has received approval (Cyltezo).

**Product economics** - Humira EU market is roughly US\$4.3bn in brand sales (July MAT). Assuming 60-70% price drop (given multiple entrants and largely tender-driven sales) and a market share of 10-15% (overall biosim penetration of 60-70%), this could be a US\$120-240mn sales opportunity. Of this, Biocon should have ~17% profit share, equivalent to US\$14-25mn.

**2) Ogivri +ve CHMP** - Biocon (and partner Mylan) announced that it has received a positive CHMP opinion (European Medicines Agency's Committee for Medicinal Products for Human Use) for Ogivri (bHerceptin, trastuzumab). This will now be considered by the European Commission (EC) for approval and a decision is expected by end 2018. The branded market for Herceptin is ~US\$1.9bn in EU. Assuming a 70% price drop and 15% market share, this could be a US\$80-100mn sales opportunity for Biocon/MLN, of which, Biocon should receive a 33% profit share.

**Overall EU Progress** - In Sep'18, Biocon received a positive CHMP opinion recommending EU approval for Fulphila, bNeulasta; European Commission approval is expected by Nov '18. Given the EC approval for both, Ogivri and Fulphila are expected by end 2018, the launches are likely to be in 1H19; (manufacturing facility is EU GMP-certified). In addition, Insulin glargine was approved in Mar'18 and launch is expected by Q4 2018, per management. **So, by mid-2019, we expect Biocon to benefit from commercialization of its entire advanced pipeline in EU markets.**

MORGAN STANLEY INDIA COMPANY PRIVATE LIMITED+

Sameer Baisiwal, CFA

EQUITY ANALYST

Sameer.Baisiwal@morganstanley.com

+91 22 6118-2214

Pooja Bhatia

RESEARCH ASSOCIATE

Pooja.Bhatia@morganstanley.com

+91 22 6118-2217

## Biocon Ltd ( BION.NS, BIOS IN )

India Healthcare / India

Stock Rating	Overweight
Industry View	In-Line
Price target	Rs785.00
Up/downside to price target (%)	19
Shr price, close (Oct 19, 2018)	Rs661.05
52-Week Range	Rs718.00-343.55
Sh out, dil, curr (mn)	600
Mkt cap, curr (mn)	Rs396,630
EV, curr (mn)	Rs399,968
Avg daily trading value (mn)	Rs1,783

Fiscal Year Ending	03/18	03/19e	03/20e	03/21e
ModelWare EPS (Rs)	6.22	9.41	19.62	25.67
Prior ModelWare EPS (Rs)	-	-	-	-
Consensus EPS (Rs)\$	6.80	10.25	17.56	23.97
Revenue, net (Rs mn)	41,524	51,794	67,003	79,331
EBITDA (Rs mn)	8,508	12,609	21,106	24,868
ModelWare net inc (Rs mn)	3,732	5,643	11,774	15,399
P/E	95.5	70.3	33.7	25.8
P/BV	6.9	7.3	6.3	5.5
RNOA (%)	5.8	9.6	21.5	23.7
ROE (%)	7.7	10.9	21.7	24.4
EV/EBITDA	42.3	31.1	18.4	15.5
Div yld (%)	0.8	0.8	0.8	1.7
FCF yld ratio (%)	0.1	2.3	1.2	1.8
Leverage (EOP) (%)	(2.6)	(16.7)	(20.4)	(21.6)

Unless otherwise noted, all metrics are based on Morgan Stanley ModelWare framework

\$ = Consensus data is provided by Thomson Reuters Estimates

e = Morgan Stanley Research estimates

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## Valuation Methodology & Risks

### BION.NS

Our price target of Rs785 is our base case scenario value. We derive it by applying a target P/E multiple of 40x to our EPS estimate of Rs19.62 for the 12 months ending March 2020.

Our target P/E multiple of 40x is at a 10% premium to the stock's two-year average (which we view as a relevant time period given significant improvement in fundamentals since 2016). It is a 50-60% premium to Indian pharmaceutical industry multiples (not strictly comparable, since this is the only pure play on global biosimilars). To note, Asian biosimilar stocks are commanding much higher multiples (60-80x one-year forward consensus earnings).

Our F20 EPS estimate is 14% higher than consensus, because we believe that the global biosimilar monetization story for 2019-2021 is getting clearer as regulatory, legal, and market uncertainties are being addressed.

Biocon's rich pipeline (partnered with Mylan) has four lead biosimilars in advanced stages of approval in various markets (US, EU, EMs). It includes Trastu, recently approved by the US FDA and pegfil, recently launched in the US, which should result in significant monetization in 2019 and onwards.

We also reflect improving visibility of the second wave of the company's five biosimilar assets, steady base business fundamentals, prospects of global biosimilar opportunities coming to fruition in the coming years (through 2020), and commercialization of its greenfield Malaysian facility (US\$200mn capex).

### Key risks to our price target:

- Regulatory risks include delay in product approvals, indication extrapolation, clinical trial design.
- Legal risks include at-risk launches, delay in market entry (180 days, patent dance), 30m NDA stay.
- Asset monetization risks include innovator defence (flexible pricing, reformulation, patents) marketing challenges, slower biosimilar update from physicians.
- Other risks include a slowdown in base business due to factors such as capacity constraints or a sluggish domestic market; risk pertaining to Syngene business – late-stage client molecules may not culminate in business; and delays in scale-up or regulatory filings from the Malaysian facility.

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(as of September 30, 2018)

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STOCK RATING CATEGORY	COVERAGE UNIVERSE		INVESTMENT BANKING CLIENTS (IBC)			OTHER MATERIAL INVESTMENT SERVICES CLIENTS (MISC)	
	COUNT	% OF TOTAL	COUNT	% OF TOTAL IBC	% OF RATING CATEGORY	COUNT	% OF TOTAL OTHER MSC
Overweight/Buy	1178	37%	308	42%	26%	562	40%
Equal-weight/Hold	1378	44%	343	46%	25%	625	44%
Not-Rated/Hold	49	2%	5	1%	10%	7	0%
Underweight/Sell	554	18%	83	11%	15%	224	16%
<b>TOTAL</b>	<b>3,159</b>		<b>739</b>			<b>1418</b>	

Data include common stock and ADRs currently assigned ratings. Investment Banking Clients are companies from whom Morgan Stanley received investment banking compensation in the last 12 months. Due to rounding off of decimals, the percentages provided in the "% of total" column may not add up to exactly 100 percent.

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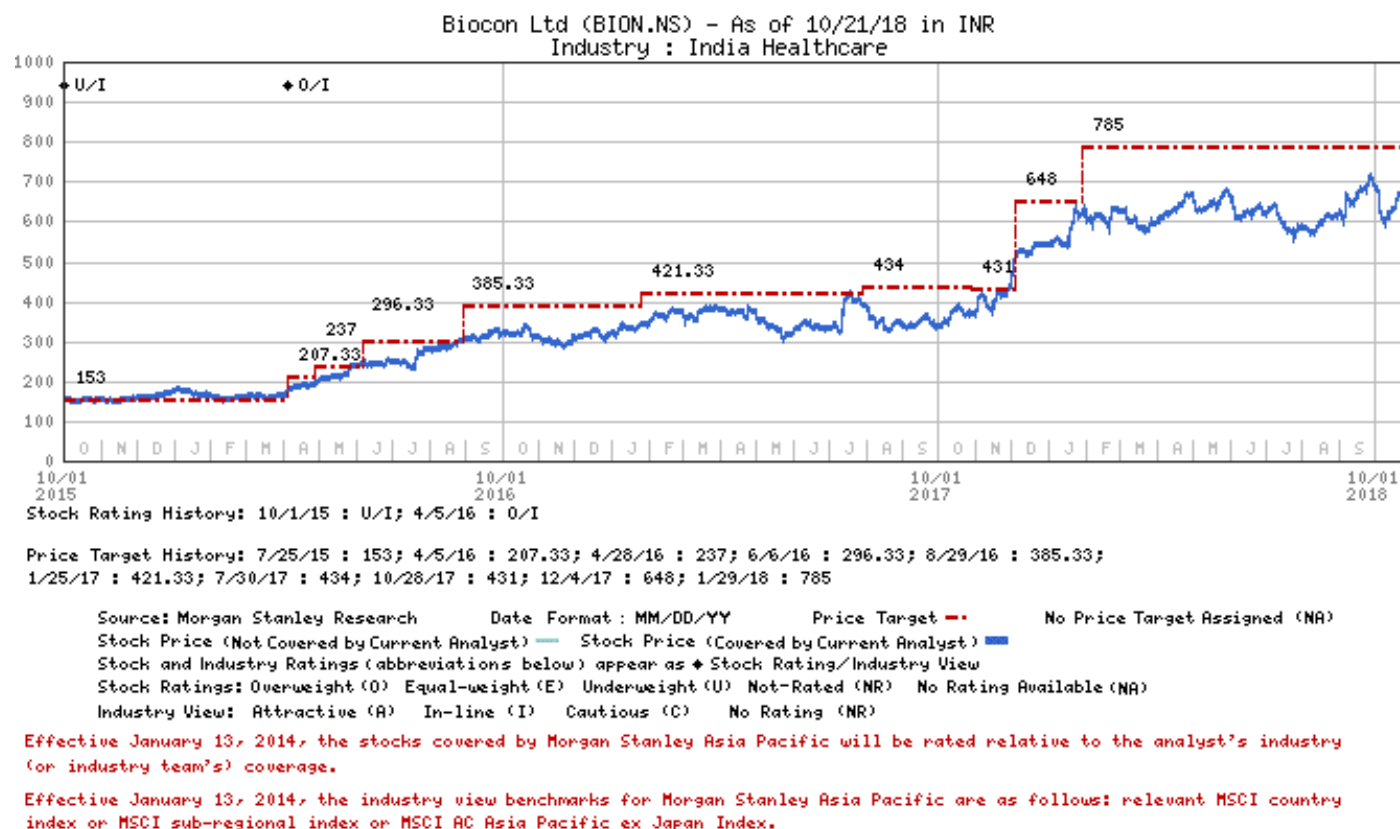
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## INDUSTRY COVERAGE: India Healthcare

COMPANY (TICKER)	RATING (AS OF)	PRICE* (10/19/2018)
<b>Sameer Baisiwala, CFA</b>		
Apollo Hospitals Enterprise Ltd. (APLH.NS)	O (04/27/2017)	Rs1,121.45
Biocon Ltd (BION.NS)	O (04/05/2016)	Rs661.05
Cadila Healthcare Ltd. (CADI.NS)	O (01/29/2016)	Rs371.75
Cipla Ltd. (CIPL.NS)	O (02/08/2018)	Rs633.80
Dr. Lal PathLabs Ltd (DLPAN.S)	U (04/19/2017)	Rs929.30
Dr. Reddys Lab (REDY.NS)	O (09/21/2017)	Rs2,552.35
GlaxoSmithKline Pharma (GLAX.NS)	U (02/28/2013)	Rs1,416.55
Glenmark Pharmaceuticals (GLEN.NS)	E (05/24/2017)	Rs599.00
IPCA Laboratories (IPCANS)	O (02/09/2018)	Rs668.35
Lupin Ltd. (LUPN.NS)	E (11/08/2017)	Rs880.25
Narayana Hrudayalaya Ltd (NARY.NS)	E (04/27/2017)	Rs208.85
Sun Pharmaceutical Industries (SUN.NS)	U (05/29/2017)	Rs609.95

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