AXIS DIRECT

23 AUG 2017 | Company Update

BIOCON

PHARMACEUTICALS

BUY

Target Price: Rs 380

Regulatory bump in EU; potential delay ahead

EMA's Committee for Medicinal Products for Human use (CHMP) has asked Biocon to withdraw its Peg-filgrastim and Trastuzumab filings in EU post the recent inspections by European Regulatory authorities. While the drug substance facilities were approved, it highlighted the need for re-inspection of Biocon's drug product facilities. Biocon states it is on track to complete CAPA^ by end of this quarter (Sep'17) and would seek re-inspection and re-submission thereafter. We note that USFDA had 6 observations in Apr'17 on its drug product facility and 10 observations in its fill-finish line in Jun'17- could lead to regulatory delay.

We have currently built in monetization of Trastuzumab and Peg-filgrastim in EU by H2FY19 and H2FY20 respectively and in US by FY20 and H2FY20 respectively. We maintain estimates and **BUY** rating but cut multiple to factor in higher regulatory headwinds. Our revised TP is Rs 380 (32x FY19 EPS) vs. Rs 450 (38x FY19E EPS) earlier.

CMP	: Rs 327
Potential Upside	: 16%

MARKET DATA

No. of Shares	: 600 mn
Free Float	: 39%
Market Cap	: Rs 196 bn
52-week High / Low	: Rs 424 / Rs 268
Avg. Daily vol. (6mth)	: 3.2 mn shares
Bloomberg Code	: BIOS IB Equity
Promoters Holding	: 61%
FII / DII	: 17% / 3%

- **Filings withdrawn in EU: Trastuzumab (USD 2.1 bn market)** – Mylan-Biocon filing was accepted for review in Aug 2016, ahead of Samsung (accepted for review on Oct 2016), Celltrion (filed in Oct 2016) and Amgen (filed in Mar 2017). Biocon has now withdrawn the filing, given requirement for re-inspection. **Peg-filgrastim (USD 420 mn market) –** Mylan-Biocon filing was accepted for review in Jul 2016, but has now been withdrawn as part of the EMA* procedural requirements for reinspection. We note there is currently only 1 other application for biosimilar Peg-filgrastim currently under review by EMA (Coherus - file was accepted for EMA review on Nov 29, 2016, received CRL@ in the US). Although, we currently built in an EU launch for Trastuzumab for Mylan – Biocon in H2FY19 and Peg-filgrastim in H2FY20, the regulatory uncertainty may lead to potential delay in launch timelines.
- **USFDA regulatory overhang**: Biocon has filed for biosimilar Trastuzumab (USD 2.5 bn market – first Herceptin biosimilar filing accepted for USFDA review TAD# in Sep'17) and biosimilar Peg-filgrastim (USD 3.98 bn – TAD in Oct'17) in the US. However, Biocon's Bangalore facility was issued USFDA observations for its drug product facility post inspection in Apr'17 (8 observations) and sterile injectable fill-finish facility Jun'17 (10 observations).

(Continued on page 2...)

Financial summary (Consolidated)

Y/E March	FY16	FY17	FY18E	FY19E
Sales (Rs mn)	33,810	39,216	44,421	55,031
Adj PAT (Rs mn)	3,898	6,121	5,012	7,110
Con. EPS* (Rs)	-	-	8.9	13.2
EPS (Rs)	6.5	10.2	8.4	11.8
Change YOY (%)	(3.1)	57.0	(18.1)	41.9
P/E (x)	50.3	32.0	39.1	27.6
RoE (%)	10.7	13.8	9.8	12.8
RoCE (%)	10.5	12.1	10.4	13.3
EV/E (x)	26.7	21.2	19.3	14.0
DPS (Rs)	1.7	1.0	1.7	1.7

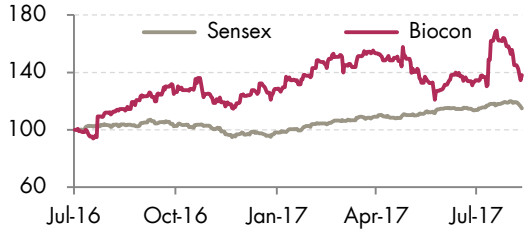
Source: *Consensus broker estimates, Company, Axis Capital

EMA: European Medicines agency; ^Correction and preventive action; @Complete Response Letter #Target Action Date

Valuation

Valuation	Old Mar'19	New Mar'19	Potential Mar'20
EPS	12	12	19
Target PE	38	32	25
R&D value	-	-	-
Target Price	450	380	487

Price performance



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While Biocon has responded with CAPA plan to the USFDA, and is undertaking corrective actions, we believe it may not receive USFDA final approval for (a) biosimilar Trastuzumab on its TAD in Sep'17 (although USFDA panel unanimously recommended approval for its proposed biosimilar filing for all indications), (b) biosimilar Peg-filgrastim on its TAD in Nov'17 until receipt of final USFDA clearance for the facility. We currently build in US launch for biosimilar Peg-filgrastim for Mylan – Biocon in H2FY20, biosimilar Trastuzumab in FY20.

Exhibit 1: Market dynamics for Biocon's key molecules

Product Name	Compound Patent expiry		Mkt size (USD mn)		No of players	
	US	EU	US	EU	US	EU
Glargine	Expired	Expired	3,563	887	3	3
Trastazumab	2019	Expired	2,534	2,076	3	4
Adalimumab	2022	2018	10,432	2,801	7	7
Pegfilgrastim	Expired	Expired	3,987	420	4	2

Source: Company, Axis Capital

Exhibit 2: PAT to grow multifold driven by its biosimilar pipeline in US & EU

(Rs mn)	FY17 (A)	FY18	FY19	FY20	FY21	FY22	FY23
Glargine			151	879	1,747	2,446	2,330
Trastuzumab			514	1,899	3,358	3,834	4,130
Adalimumab			-	-	1,264	1,760	2,297
Pegfilgrastim			-	1,467	1,997	2,733	3,055
Incremental PAT			**666**	**4,245**	**8,367**	**10,773**	**11,811**
Base business PAT#	**6,121**	**5,012**	**6,444**	**7,455**	**8,573**	**9,859**	**11,337**
Total PAT…(B)	**6,121**	**5,012**	**7,110**	**11,699**	**16,939**	**20,631**	**23,148**
Growth Multiplier…(B/A)				**1.9**	**2.8**	**3.4**	**3.8**

Source: Axis Capital

Growth Multiplier = Total PAT/FY17 PAT # build in 15% CAGR for base business PAT from FY21

Exhibit 3: While strong PAT growth visibility, cut target multiple on regulatory headwinds

Valuation	Mar'19 Old	Mar'19 New	Mar'20 Projected	Mar'21 Projected	Mar'22 Projected
PAT	7,110	7,110	11,699	16,939	20,631
EPS	11.8	11.8	19.5	28.2	34.4
Target PE	**38**	**32**	**25**	**22**	**20**
R&D value					
Target Price	450	380	487	621	688
Current market price		325			
Upside %		17%	50%	91%	112%
Potential annual return		17%	22%	24%	21%

Source: Axis Capital

build in 15% CAGR for base business PAT from FY21

**We note Celltrion trades at 30x CY18 EPS & Samsung Biologics trades at 254x CY18 EPS (as per BBG estimates)

Returns attractive for 3-5 year investment perspective

Exhibit 4: Biocon in a sweet spot – USD 61 bn biosimilar opportunity

Category	Molecule	Type	Status	Market Size* (US$ bn)
INSULINS	Rh Insulin	Recombinant Human Insulin	US development – Preclinical	3.2
	Glargine	Long Acting Basal Insulin	Global Phase 3, under review in EU. Approved in Japan	6.4
	Aspart	Rapid Acting Insulin Analog	Preclinical/Scale Up	4.5
	Lispro	Rapid Acting Insulin Analog	Preclinical/Scale Up	2.8
			Insulins Total Market Size (rounded off)	**17**
BIOSIMILARS	Adalimumab	Chronic Plaque Psoriasis	Global Phase 3	16.1
	Trastuzumab	mBreast Cancer	Global Phase 3, under review in US & EU	6.9
	Pegfilgrastim	Chemo-induced Neutropenia	Under review in US & EU	4.6
	Bevacizumab	Non-Squamous NSCLC, mColorectal Cancer	Global Phase 3 initiated, RoW Phase 3	6.9
	Filgrastim	Chemo-induced Neutropenia	Preclinical/Scale Up	1
	Etanercept	Auto-immune	Preclinical/Scale Up	8.9
			Biosimilars Total Market Size (rounded off)	**44**

Source: Company, Axis Capital

*Market Size of innovator products in the current portfolio: Innovator Sales CY 2016

Conversion into USD done using average exchange rate for CY 2016 as given on http://www.federalreserve.gov/releases/G5a/current/default.htm

Exhibit 5: Biosimilar pipeline: Competitive landscape

	Biosimilar Development Pipeline@			
Molecule	Pre-Clinical	Phase I	Phase III/Filed	Approved/ Marketed
pegfilgrastim	Pfizer	Dr. Reddy's	**Biocon - EMA/FDA;** Apotex -FDA/EMA; Coherus - FDA, EMA; Sandoz, Cinfa	
trastuzumab	Oncobiologics, Dr. Reddy's	Meiji Seika	**Biocon - EMA/FDA,** Celltrion - EMA, Samsung - EMA, Amgen, Pfizer, Hanhwa	
insulin glargine			**Biocon (EMA)**, Samsung - FDA	**Biocon – JP,** Eli Lilly – EU, US, JP, CAN, Samsung - EU
adalimumab	Epirus	Dr. Reddy's, Meiji Seika	**Biocon,** Samsung - EMA, Sandoz, Boehringer Ingelheim-FDA,EMA, Coherus, Momenta, Pfizer, Serono, Fuji Kirin, Oncobiologics	Amgen – US, EU
bevacizumab	Celltrion	Sandoz, Daiichi, Oncobiologics, Cipla	**Biocon (Global, RoW),** Amgen - FDA, EMA, Boehringer Ingelheim, Pfizer, Samsung, Fuji Kirin – Astra Zeneca, Dr Reddy	
filgrastim	**Biocon,** Pfizer		Apotex (US)	Sandoz – US, EU; Teva-JP,EU; Accord-EU, Apotex – EU, Hospira – EU, ANZ, Fuji – JP, CTA-EU, Ratiopharm EU
etanercept	**Biocon,** Celltrion	Hanwha-Merck Serono	Coherus, Lupin	Samsung – EU, Sandoz – FDA, EMA
insulin aspart	**Biocon**			
insulin lispro	**Biocon**		Sanofi-EMA	
rh-insulin	**Biocon – US**			

Source: Company, Axis Capital

Financial summary (Consolidated)

Profit & loss (Rs mn)

Y/E March	FY16	FY17	FY18E	FY19E
Net sales	33,810	39,216	44,421	55,031
Other operating income	-	-	-	-
Total operating income	**33,810**	**39,216**	**44,421**	**55,031**
Cost of goods sold	(12,904)	(14,466)	(16,325)	(19,811)
Gross profit	20,906	24,750	28,096	35,220
Gross margin (%)	*61.8*	*63.1*	*63.3*	*64.0*
Total operating expenses	(13,228)	(14,955)	(18,111)	(21,591)
EBITDA	**7,678**	**9,795**	**9,986**	**13,628**
EBITDA margin (%)	*22.7*	*25.0*	*22.5*	*24.8*
Depreciation	(2,487)	(2,772)	(3,858)	(4,413)
EBIT	**5,191**	**7,023**	**6,128**	**9,215**
Net interest	(293)	(260)	(715)	(712)
Other income	792	1,571	1,900	1,800
Profit before tax	**5,690**	**8,334**	**7,313**	**10,303**
Total taxation	(1,422)	(1,616)	(1,719)	(2,421)
Tax rate (%)	*25.0*	*19.4*	*23.5*	*23.5*
Profit after tax	4,268	6,718	5,594	7,882
Minorities	(587)	(760)	(832)	(1,072)
Profit/ Loss associate co(s)	217	163	250	300
Adjusted net profit	3,898	6,121	5,012	7,110
Adj. PAT margin (%)	*11.5*	*15.6*	*11.3*	*12.9*
Net non-recurring items	1,606	-	-	-
Reported net profit	5,504	6,121	5,012	7,110

Balance sheet (Rs mn)

Y/E March	FY16	FY17	FY18E	FY19E
Paid-up capital	1,000	1,000	1,000	1,000
Reserves & surplus	39,340	47,377	52,776	56,584
Net worth	40,340	48,377	53,776	57,584
Borrowing	24,670	22,054	21,957	21,869
Other non-current liabilities	-	-	-	-
Total liabilities	**67,670**	**74,192**	**80,326**	**85,119**
Gross fixed assets	34,036	54,361	65,287	71,287
Less: Depreciation	(16,553)	(18,110)	(21,968)	(26,381)
Net fixed assets	17,483	36,251	43,319	44,906
Add: Capital WIP	22,400	8,392	7,500	7,500
Total fixed assets	39,883	44,643	50,819	52,406
Total Investment	9,017	12,538	2,500	2,500
Inventory	5,420	6,353	7,404	9,172
Debtors	7,150	8,832	10,953	13,569
Cash & bank	15,380	10,443	24,806	26,491
Loans & advances	7,730	11,131	11,105	13,758
Current liabilities	16,910	19,748	27,261	32,777
Net current assets	18,770	17,011	27,007	30,213
Other non-current assets	-	-	-	-
Total assets	**67,670**	**74,192**	**80,326**	**85,119**

Source: Company, Axis Capital

Cash flow (Rs mn)

Y/E March	FY16	FY17	FY18E	FY19E
Profit before tax	5,690	8,334	7,313	10,303
Depreciation & Amortisation	2,487	2,772	3,858	4,413
Chg in working capital	*(1,762)*	*(2,270)*	*(499)*	*(5,005)*
Cash flow from operations	**3,706**	**6,400**	**7,768**	**6,202**
Capital expenditure	*(8,028)*	*(7,619)*	*(11,190)*	*(6,000)*
Cash flow from investing	**(11,417)**	**(4,985)**	**(11,190)**	**(6,000)**
Equity raised/ (repaid)	-	-	-	-
Debt raised/ (repaid)	*12,079*	*(1,232)*	*(97)*	*(87)*
Dividend paid	*(2,201)*	-	*(1,204)*	*(1,204)*
Cash flow from financing	**10,676**	**(1,775)**	**(1,301)**	**(1,291)**
Net chg in cash	2,965	(360)	(4,723)	(1,089)

Key ratios

Y/E March	FY16	FY17	FY18E	FY19E
OPERATIONAL				
FDEPS (Rs)	6.5	10.2	8.4	11.8
CEPS (Rs)	13.3	14.8	14.8	19.2
DPS (Rs)	1.7	1.0	1.7	1.7
Dividend payout ratio (%)	18.2	9.8	20.0	14.1
GROWTH				
Net sales (%)	9.4	16.0	13.3	23.9
EBITDA (%)	10.3	27.6	1.9	36.5
Adj net profit (%)	(3.1)	57.0	(18.1)	41.9
FDEPS (%)	(3.1)	57.0	(18.1)	41.9
PERFORMANCE				
RoE (%)	10.7	13.8	9.8	12.8
RoCE (%)	10.5	12.1	10.4	13.3
EFFICIENCY				
Asset turnover (x)	0.8	0.7	0.7	1.0
Sales/ total assets (x)	0.5	0.4	0.4	0.5
Working capital/ sales (x)	0.1	0.1	0.1	0.1
Receivable days	77.2	82.2	90.0	90.0
Inventory days	75.7	78.8	78.5	80.9
Payable days	85.2	91.8	106.5	106.5
FINANCIAL STABILITY				
Total debt/ equity (x)	0.6	0.5	0.4	0.4
Net debt/ equity (x)	0.2	0.2	(0.1)	(0.1)
Current ratio (x)	2.1	1.9	2.0	1.9
Interest cover (x)	17.7	27.0	8.6	12.9
VALUATION				
PE (x)	50.3	32.0	39.1	27.6
EV/ EBITDA (x)	26.7	21.2	19.3	14.0
EV/ Net sales (x)	6.1	5.3	4.3	3.5
PB (x)	4.9	4.1	3.6	3.4
Dividend yield (%)	0.5	0.3	0.5	0.5
Free cash flow yield (%)	(2.2)	(0.6)	(1.7)	0.1

Source: Company, Axis Capital

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