MOTILAL OSWAL

24 September 2018
Update | Sector: Healthcare

Biocon

BSE SENSEX	S&P CNX
36,305	10,967

Bloomberg	BIOS IN
Equity Shares (m)	600
M.Cap.(INRb)/(USDb)	399.2 / 5.5
52-Week Range (INR)	696 / 320
1, 6, 12 Rel. Per (%)	15/1/74
12M Avg Val (INR M)	1564
Free float (%)	39.3

Financials & Valuations (INR b)

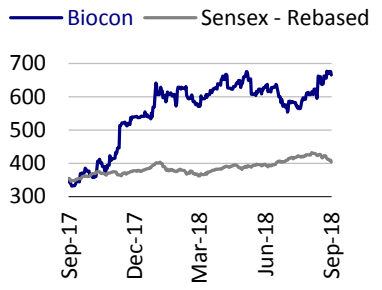
Y/E Mar	2018	2019E	2020E
Sales	41.3	53.9	74.6
EBITDA	8.3	13.2	21.0
Net Profit	3.7	6.3	12.5
Adj. EPS (INR)	6.2	10.6	20.9
EPS Gr. (%)	-39.2	71.1	96.5
BV/Sh. (INR)	86.3	93.9	108.6
RoE (%)	7.4	11.8	20.6
RoCE (%)	6.2	9.7	15.5
P/E (x)	107.1	62.6	31.9
P/BV (x)	7.7	7.1	6.1
EV/EBITDA (x)	48.0	30.1	18.8
Div. Yield (%)	0.2	0.4	0.8

Shareholding pattern (%)

As On	Jun-18	Mar-18	Jun-17
Promoter	60.7	60.7	60.7
DII	4.7	3.9	3.7
FII	17.9	18.5	16.9
Others	16.7	16.9	18.8

FII Includes depository receipts

Stock Performance (1-year)



CMP: INR665 TP: INR625(-6%) Neutral

Favorable regulatory outcome enhances biosimilars prospects

- **The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval for Biocon (BIOS)/Mylan's Neulasta biosimilar – Fulphila. Subsequent approval – post consideration by the regulatory agency – would enable BIOS/Mylan to launch Fulphila in the EU market.**
- **We note that a few more companies have also received a positive opinion from CHMP and filing of one more company is under review. This implies considerable competition for the product in the EU market.**
- **Separately, the week-long USFDA inspection at Biocon's Bengaluru drug substance facility was completed successfully on 21st September 2018 with zero 483s. This augurs well for the company's Fulphila sales in the US market.**
- **Given the favorable regulatory pathway emerging for biosimilars in the US/EU markets and the significant untapped market potential, we believe that biosimilars prospects remain very promising from a 4-5 year perspective. BIOS also stands to benefit from its improved traction in approved products and healthy pipeline of pending approvals.**
- **However, given the limited upside potential from current levels, we maintain our Neutral stance on the stock with a price target of INR625 (30x 12M forward earnings)**.

BIOS/Mylan clears major hurdle for Neulasta launch in EU: BIOS/Mylan has received a positive opinion from CHMP for its Neulasta biosimilar for the EU market. BIOS/Mylan also have in place the EU good manufacturing practices (GMP) certification for their drug product and drug substance facilities. Biocon/Mylan would be the fourth team to receive a positive opinion for Neulasta for the EU market. Accord (subsidiary of Intas Pharma) and Coherus received a positive opinion in July 2018, followed by Sandoz (Novartis division) and Cinfa Biotech in September 2018. Geodeon Richter's Neulasta biosimilar is under review. Typically, it takes 1.5-2 months post opinion to get approval from the EMA. Subsequently, BIOS/Mylan will have to submit relevant documents in each region of the EU and commercialization could take around 6-9 months. The global market size of Neulasta is ~USD4.5b (as of CY17; ex-US sales – USD600m). Considering the market size and the competitive scenario, we see limited scope for BIOS/Mylan from this opportunity on an annualized basis.

Don't see much regulatory headwinds for its drug product and drug substance facilities for US market: BIOS successfully completed the USFDA inspection (periodic GMP inspection) at its drug substance facility at Bengaluru with zero 483s (the facility was previously inspected in May 2017). Separately, the drug product facility was inspected in April-May 2018 and received the Establishment Inspection Report (EIR) in June 2018. Successful inspections at both its facilities imply minimal regulatory hurdles for sales of pegfilgrastim biosimilar in the US market.

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BIOS/MYL is well ahead in race for Neulasta biosimilar launch in US: Other than BIOS/MYL, leading companies vying for approval in the regulated markets are Apotex, Sandoz, Coherus, Pfizer and Dr. Reddy's Lab. Coherus' resubmission was accepted by USFDA on 14th May 2018. After receiving complete response letter (CRL) from USFDA, Sandoz has been working on issues highlighted by the regulator and planning for a resubmission in 2019. Federal Circuit has ruled in favor of Apotex for the biosimilar version of Neulasta in November 2017. However, Apotex has not yet received approval for its BLA (biologic license application) version. We believe that BIOS/MYL have considerable lead time available to benefit from the opportunity before any other company is granted approval.

Valuation and view: Once the positive opinion on Neulasta biosimilar for the EU market gets converted into approval, BIOS will have two biosimilars approved each for the US and EU markets. We remain positive on BIOS as it continues building a healthy pipeline of biosimilars for the regulated markets. Moreover, these biosimilars are relatively complex in nature and provide a strong entry barrier, enabling the company to deliver better growth in revenue and profitability. We value BIOS at 30x 12M forward earnings (unchanged) to arrive at price target of INR625. We maintain **Neutral** stance given the limited upside from current levels.

Exhibit 1: Regulatory inspection history over past one year

Location	Inspection end-date	Regulatory agency	Remarks
Bengaluru Drug substance facility	Sep-18	USFDA	Zero 483
Bengaluru Drug product facility	Mar-18	European Agency	Received EU GMP certification in July-2018
Bengaluru Drug product facility	April-May 2018	USFDA	Received EIR in June-2018
Malaysia manufacturing facility	Feb-18	USFDA	Issued form 483 with six observations
Bengaluru Drug product facility	May-June 2017	USFDA	Received EIR in Nov-17
Vishakhapatnam API facility	Sep-17	USFDA	Zero 483
Malaysia Insulin manufacturing facility	Apr-17	EMA	Received EU GMP certification in Sep-2017
Bengaluru Drug substance facility	Mar-17	European Agency	Received EU GMP certification in Jul-2017

Source: Company, MOSL

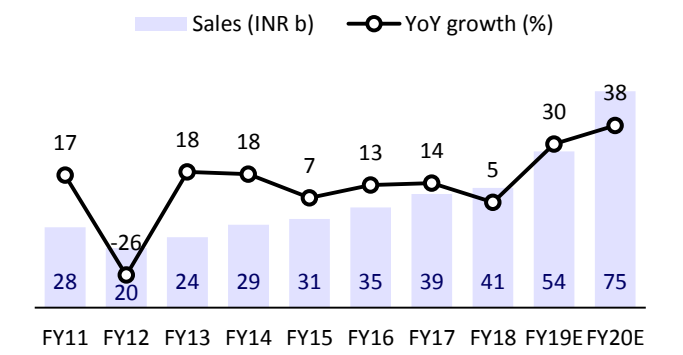
Exhibit 2: Key milestones for upcoming products for Biocon over next 12-18 months

Trastuzumab	❖ CHMP opinion on EMA submission
Insulin Glargine	❖ Litigation outcome and subsequent USFDA approval
Adalimumab	❖ Outcome of Phase 3 trials
Bevacizumab	❖ Outcome of Phase 3 trials
Insulin aspart	❖ Outcome of Phase 1 trials

Source: MOSL, Company

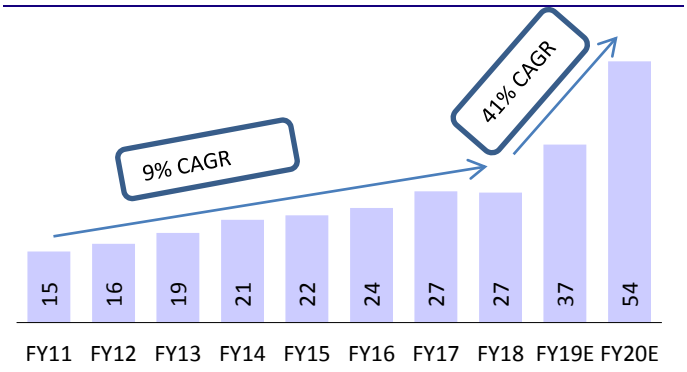
Story in charts

Exhibit 3: On track for strong revenue growth



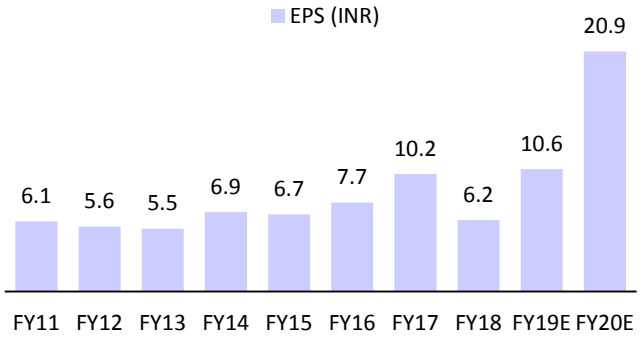
Source: Company, MOSL

Exhibit 4: Biopharma to be key growth driver



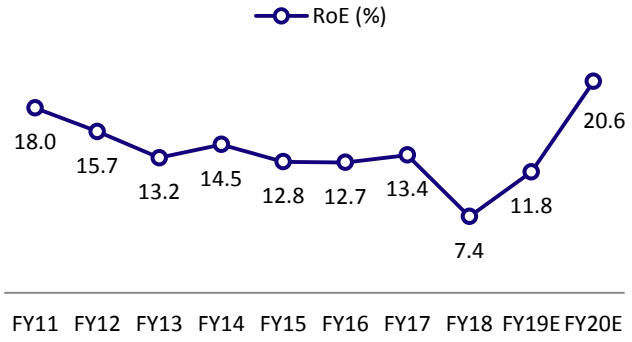
Source: Company, MOSL

Exhibit 5: EPS to almost triple over FY18-20



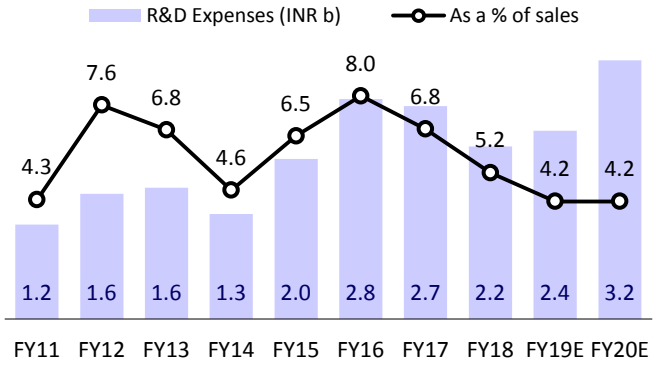
Source: Company, MOSL

Exhibit 6: Return ratios to pick up pace



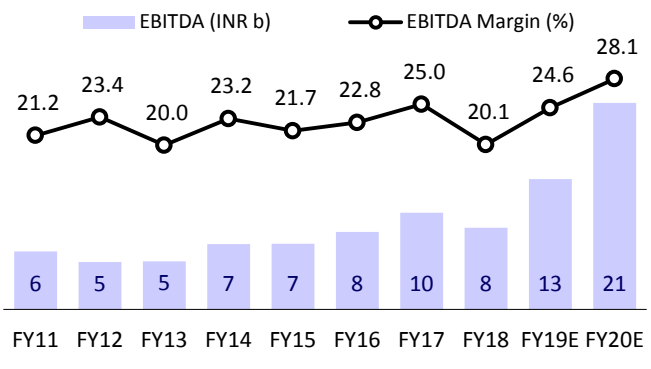
Source: Company, MOSL

Exhibit 7: R&D spend to continue rising on absolute basis



Source: Company, MOSL

Exhibit 8: Superior product mix to drive margins



Source: Company, MOSL

Valuation and view

Long-term industry view

US to remain focus geography

With intensifying competition in small molecules, the faster pace of approvals from the USFDA and reasonable experience in US generics, pharma companies have moved up the value chain toward larger molecules, which are either difficult to develop and/or difficult to manufacture. This would enable companies to face relatively low competition, and thus, better their sales/profitability. The phase of superior business from such molecules is subject to lead time for a company compared to peers.

Biosimilars – potential complex generics

Within the complex generics space, biosimilars remains an interesting business opportunity, with strong entry barriers on account of a relatively long gestation period for product/manufacturing capability and continuously evolving regulatory pathway. Even after crossing all these hurdles, if biosimilars are not interchangeable with innovator products, then it requires considerable marketing effort to generate prescription. Thus, competition is likely to remain contained over next 4-5 years.

BIOS in this backdrop

With significant efforts in developing products and building manufacturing capacity, BIOS is relatively ahead in race for biosimilars. This would provide considerable lead time to BIOS in such niche molecules, and thus, provide upside in terms of revenue and profitability. We value BIOS at 30x 12M forward earnings (unchanged) to arrive at a price target of INR625. We maintain our **Neutral** stance on limited upside from current levels.

Key catalysts to drive stock's performance over the medium term are:

- Biosimilars and generics approval in regulated market.
- Superior execution, which would enable gain considerable market share in approved products.

We believe that the following factors pose risks to our thesis:

- Delay in approval of key products.
- Slower off take of the biologics business.

Financials and Valuations

Income Statement (Consolidated) (INR m)

Y/E March	2012	2013	2014	2015	2016	2017	2018	2019E	2020E
Net Sales	**16,389**	**18,704**	**21,390**	**22,367**	**23,908**	**27,836**	**26,322**	**35,953**	**53,454**
Contract Research	4,101	5,572	7,137	8,225	10,599	11,380	14,975	17,934	21,162
Net Income	**20,490**	**24,276**	**28,527**	**30,592**	**34,507**	**39,216**	**41,297**	**53,887**	**74,617**
Change (%)	-26.0	18.5	17.5	7.2	12.8	13.6	5.3	30.5	38.5
Total Expenditure	15,691	19,423	21,902	23,940	26,654	29,421	33,006	40,656	53,665
EBITDA	**4,799**	**4,853**	**6,625**	**6,652**	**7,853**	**9,795**	**8,291**	**13,231**	**20,952**
Change (%)	-18.2	1.1	36.5	0.4	18.1	24.7	-15.4	59.6	58.4
Margin (%)	23.4	20.0	23.2	21.7	22.8	25.0	20.1	24.6	28.1
Depreciation	1,744	1,793	2,036	2,210	2,423	2,772	3,851	5,043	5,263
EBIT	**3,055**	**3,060**	**4,589**	**4,442**	**5,430**	**7,023**	**4,440**	**8,188**	**15,689**
Int. & Finance Charges	122	81	17	89	102	260	615	707	207
Other Income - Rec.	993	3,123	805	1,888	6,946	1,571	2,062	2,200	2,400
PBT	**3,926**	**6,101**	**5,377**	**6,241**	**12,274**	**8,334**	**5,887**	**9,681**	**17,882**
Tax	541	975	1,069	957	2,569	1,616	1,569	2,420	4,292
Tax Rate (%)	13.8	16.0	19.9	15.3	20.9	19.4	26.7	25.0	24.0
Minority Interest	0	38	170	310	744	760	594	888	1065
Adjusted PAT	**3,385**	**3,271**	**4,137**	**4,023**	**4,646**	**5,958**	**3,724**	**6,373**	**12,525**
PAT	**3,385**	**5,088**	**4,137**	**4,974**	**8,961**	**5,958**	**3,690**	**6,270**	**12,525**
Change (%)	-7.6	50.3	-18.7	20.2	80.2	-33.5	-39.2	71.1	96.5
Margin (%)	16.5	21.0	14.5	16.3	26.0	15.2	8.9	11.6	16.8

Consolidated Balance Sheet (INR m)

Y/E March	2012	2013	2014	2015	2016	2017	2018	2019E	2020E
Equity Share Capital	1,000	1,000	1,000	1,000	1,000	3,000	3,000	3,000	3,000
Other Reserves	21,715	25,937	29,258	31,697	39,329	45,368	48,808	53,317	62,179
Net Worth	**22,724**	**26,946**	**30,267**	**32,706**	**40,338**	**48,377**	**51,808**	**56,317**	**65,179**
Loans	2,571	2,488	8,497	10,306	24,673	22,054	19,201	20,201	21,201
Minority Interest	38	653	823	1,722	2,658	3,761	4,677	5,565	6,630
Deferred liabilities	5754	4689	6558	5934	3489	1964	2167	943	943
Capital Employed	**31,087**	**34,776**	**46,145**	**50,667**	**71,158**	**76,156**	**77,853**	**83,026**	**93,953**
Gross Block	20,590	24,961	27,218	29,750	33,113	53,269	57,532	63,032	68,532
Less: Accum. Deprn.	7,852	9,672	11,711	13,943	16,302	17,740	21,235	26,278	31,540
Net Fixed Assets	**12,738**	**15,289**	**15,507**	**15,807**	**16,811**	**35,529**	**36,297**	**36,754**	**36,992**
Capital WIP	2,863	2,054	10,831	14,939	20,597	5,327	7,789	7,789	7,789
Investments	5,563	5,866	7,649	2,303	9,015	12,538	6,752	6,411	6,622
Intangibles	1,235	1,290	1,442	2,320	2,470	3,787	5,937	6,531	7,184
Curr. Assets	**16,973**	**19,662**	**22,077**	**28,384**	**34,973**	**34,786**	**41,188**	**45,029**	**62,351**
Inventory	3,783	3,984	3,766	4,527	5,424	6,353	7,225	8,120	11,244
Account Receivables	4,917	5,097	5,998	7,705	7,145	8,832	10,639	11,811	16,354
Cash and Bank Balance	5,233	6,729	8,044	9,375	15,386	10,443	13,228	14,764	20,443
Loans & Advances	3,040	3,852	4,269	6,777	7,018	9,158	10,096	10,335	14,310
Curr. Liability & Prov.	**8,285**	**9,385**	**11,361**	**13,087**	**12,708**	**15,811**	**20,110**	**19,488**	**26,985**
Account Payables	6,170	6,920	9,595	11,355	12,334	15,343	19,645	16,240	22,487
Provisions	2,115	2,465	1,766	1,732	374	468	465	3,248	4,497
Net Current Assets	**8,688**	**10,277**	**10,716**	**15,297**	**22,265**	**18,975**	**21,078**	**25,541**	**35,366**
Appl. of Funds	**31,087**	**34,776**	**46,145**	**50,667**	**71,158**	**76,156**	**77,853**	**83,026**	**93,953**

E: MOSL Estimates

Financials and Valuations

Ratios							6.2	10.8	19.8
Y/E March	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019E**	**2020E**
Basic (INR)									
EPS	**5.6**	**5.5**	**6.9**	**6.7**	**7.7**	**10.2**	**6.2**	**10.6**	**20.9**
Cash EPS	8.5	11.5	10.3	12.0	19.0	14.6	12.6	18.9	29.6
BV/Share	37.9	44.9	50.4	54.5	67.2	80.6	86.3	93.9	108.6
DPS	1.7	2.5	1.7	1.7	1.7	2.6	1.6	2.7	5.2
Payout (%)	34.3	34.5	28.3	23.5	13.4	30.1	29.5	29.7	29.3
Valuation (x)									
P/E		122.0	96.4	99.2	85.9	65.2	107.1	62.6	31.9
Cash P/E		58.0	64.6	55.5	35.0	45.7	52.9	35.3	22.4
P/BV		14.8	13.2	12.2	9.9	8.2	7.7	7.1	6.1
EV/Sales		16.0	13.7	13.0	11.6	10.2	9.6	7.4	5.3
EV/EBITDA		80.1	59.1	59.8	50.8	40.6	48.0	30.1	18.8
Dividend Yield (%)		0.4	0.3	0.3	0.3	0.4	0.2	0.4	0.8
Return Ratios (%)									
RoE	15.7	13.2	14.5	12.8	12.7	13.4	7.4	11.8	20.6
RoCE	12.5	15.8	10.7	11.1	16.1	9.4	6.2	9.7	15.5
RoIC	16.9	13.7	18.5	17.2	17.1	15.3	6.7	11.8	21.1
Working Capital Ratios									
Fixed Asset Turnover (x)	1.7	1.7	1.9	2.0	2.1	1.5	1.1	1.5	2.0
Debtor (Days)	88	77	77	92	76	82	94	80	80
Inventory (Days)	67	60	48	54	57	59	64	55	55
Working Capital (Days)	62	53	34	71	73	79	69	73	73
Leverage Ratio (x)									
Current ratio	2.0	2.1	1.9	2.2	2.8	2.2	2.0	2.3	2.3
Debt/Equity	0.1	0.1	0.3	0.3	0.6	0.5	0.4	0.4	0.3

Consolidated Cash Flow Statement									(INR m)
Y/E March	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019E**	**2020E**
Oper. Profit/(Loss) before Tax	4,799	4,853	6,625	6,652	7,853	9,795	8,291	13,231	20,952
Interest/Dividends Recd.	993	3,123	805	937	2,630	1,571	2,062	2,200	2,400
Direct Taxes Paid	4,716	-2,040	800	-1,581	-5,014	-3,141	-1,366	-3,644	-4,292
(Inc)/Dec in WC	-3,836	-1,910	876	-3,251	-956	-1,653	682	-2,927	-4,146
CF from Operations	**6,673**	**4,025**	**9,106**	**2,758**	**4,513**	**6,572**	**9,669**	**8,859**	**14,914**
(Incr)/Dec in FA	-3,781	-3,535	-11,031	-6,618	-9,085	-6,220	-7,081	-5,500	-5,500
Free Cash Flow	**2,892**	**490**	**-1,925**	**-3,861**	**-4,572**	**352**	**2,588**	**3,359**	**9,414**
(Pur)/Sale of Investments	149	-358	-1,935	4,468	-6,862	-4,840	3,636	-252	-864
CF from investments	**-3,632**	**-3,893**	**-12,966**	**-2,151**	**-15,946**	**-11,060**	**-3,445**	**-5,752**	**-6,364**
Change in Net Worth	174	2,706	354	-414	4,190	3,871	796	0	0
(Inc)/Dec in Debt	-1,111	494	6,009	2,397	14,559	-2,276	-2,531	1,000	1,000
Interest Paid	-122	-81	-17	-89	-102	-260	-615	-707	-207
Dividend Paid	-1,162	-1,755	-1,170	-1,170	-1,204	-1,790	-1,089	-1,864	-3,664
CF from Fin. Activity	**-2,221**	**1,364**	**5,175**	**724**	**17,444**	**-455**	**-3,439**	**-1,571**	**-2,871**
Inc/Dec of Cash	**819**	**1,496**	**1,315**	**1,331**	**6,011**	**-4,943**	**2,785**	**1,536**	**5,679**
Add: Beginning Balance	4,414	5,233	6,729	8,044	9,375	15,386	10,443	13,228	14,764
Closing Balance	**5,233**	**6,729**	**8,044**	**9,375**	**15,386**	**10,443**	**13,228**	**14,764**	**20,443**

E: MOSL Estimates

Explanation of Investment Rating	
Investment Rating	**Expected return (over 12-month)**
BUY	>=15%
SELL	< - 10%
NEUTRAL	< - 10 % to 15%
UNDER REVIEW	Rating may undergo a change
NOT RATED	We have forward looking estimates for the stock but we refrain from assigning recommendation

*In case the recommendation given by the Research Analyst becomes inconsistent with the investment rating legend, the Research Analyst shall within 28 days of the inconsistency, take appropriate measures to make the recommendation consistent with the investment rating legend.

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