

BSE SENSEX

33,781

S&P CNX

9,973

CMP: INR385**TP: INR355 (-8%)****Neutral**

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**Stock Info**

Bloomberg	BIOS IN
Equity Shares (m)	1,200
M.Cap.(INRb)/(USD b)	461.5 / 6.1
52-Week Range (INR)	400 / 211
1, 6, 12 Rel. Per (%)	4/48/64
12M Avg Val (INR M)	1563
Free float (%)	39.3

Financials & Valuations (INR b)

Y/E MARCH	2020	2021E	2022E
Sales	63.7	76.5	96.0
EBITDA	16.0	21.9	28.1
Adj. PAT	7.6	11.0	15.6
EBIT Margin (%)	16.5	20.1	22.3
Cons. Adj. EPS (INR)	6.3	9.2	13.0
EPS Gr. (%)	2.0	44.9	41.5
BV/Sh. (INR)	55.9	62.4	71.5

Ratios

Net D:E	0.3	0.2	0.2
RoE (%)	11.9	15.5	19.4
RoCE (%)	9.1	11.4	14.6
Payout (%)	29.3	29.3	29.3

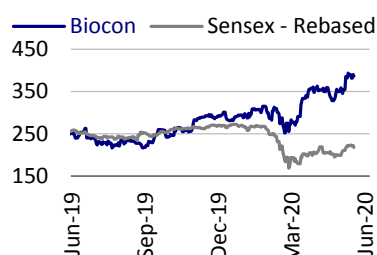
Valuations

P/E (x)	60.8	42.0	29.7
EV/EBITDA (x)	29.2	21.3	16.2
Div. Yield (%)	0.4	0.6	0.8
FCF Yield (%)	0.7	1.8	3.5
EV/Sales (x)	7.4	6.1	4.7

Shareholding pattern (%)

As On	Mar-20	Dec-19	Mar-19
Promoter	60.7	60.7	60.7
DII	7.3	5.6	4.4
FII	16.2	17.4	19.3
Others	15.8	16.4	15.6

FII Includes depository receipts

Stock Performance (1-year)**Major milestone hit with USFDA approval for Insulin Glargine****Expect USD130m over next 12 months from Glargine opportunity**

- Insulin Glargine (Semglee) is Biocon-Mylan's third biosimilar to be approved by the USFDA in a span of 24 months.
- Considering two competitors (Innovator- Sanofi; Biosimilar by Eli Lilly/Boehringer Ingelheim team; EL/BI) are already in the market and Biocon-Mylan are the third to get USFDA approval with other peers still under clinical phase, we expect Biocon (BIOS) to garner USD130m on an annualized basis from this opportunity, post commercialization in 2HFY21.
- We raise our EPS estimate by 3%/6% for FY21/FY22E to factor in better contribution from Insulin Glargine considering BIOS' early-mover advantage. Accordingly, we revise our price target to INR355 (from INR305 earlier) based on 25x 12 month forward earnings. While the earnings trajectory is expected to be strong over the next 2-3 years, we maintain Neutral as current valuation adequately factors in the same.

USFDA approval/favorable litigation outcome paves way for US launch of Semglee

- BIOS recently received the USFDA's approval for its Insulin Glargine (biosimilar version Semglee) for both versions (vial and pen). Insulin Glargine is used to control high blood sugar in (a) adults with Type-2 diabetes, and (b) adults and children with Type-1 diabetes. According to IQVIA, past 12- month MAT sales for Lantus (100 units/ml vial) stood at USD1.7b and for Lantus SoloSTAR (pen version) at USD4.3b.
- Further, BIOS-Mylan has recently won a favorable ruling from the US Patent and Trial Board (USPTAB) in the patent litigation against Sanofi for 4 device patents for Lantus SoloSTAR. The USPTAB found three of the four patents un-patentable. It also ruled in favor of BIOS-Mylan for 3 of the 5 claims on the fourth patent. Further, BIOS-Mylan has a covenant from Sanofi against getting sued on the remaining 2 claims. Moreover, in Mar'20, the US district Court of New Jersey ruled that Sanofi's 844 patent (product patent) was not infringed by Mylan's Insulin Glargine product. These rulings support commercialization of Semglee in the US.

Insulin Glargine – a limited competition opportunity

- EL/BI's Insulin Glargine 'Basaglar' is the only other biosimilar in the market, making it a 3-player market (including innovator) for Glargine post BIOS-Mylan launch. Although Merck/Samsung Bioepis have a tentative USFDA approval for Glargine in place, Merck had terminated its plans to commercialize the product in 2018.
- Sandoz/Gan & Lee is another player expected to have completed Phase 3 clinical trials, according to the clinicaltrial.gov data. It typically takes about 10 months for a 351 (k) BLA application to be approved by the USFDA after filing, provided there are no queries.

Tushar Manudhane - Research Analyst (Tushar.Manudhane@MotilalOswal.com); +91 22 6129 1536

Hitakshi Chandrani - Research Analyst (Hitakshi.Chandrani@motilalosal.com); +91 22 6129 1557/ **Bharat Hegde - Research Analyst**

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- Basaglar was launched in late CY16 in the US. It took Lilly/BI 8 quarters to steadily ramp up from USD60m in 2QCY17 to USD230m in 1QCY20. It had sales of USD876m in CY2019.
- Considering the limited competition and the ‘interchangeability’ approval not being in place yet, we expect gradual ramp-up for Insulin Gargline from the BIOS-Mylan team. Accordingly, we expect BIOS to garner USD130m over the next 12 months, which should subsequently build up gradually.

Valuation and view

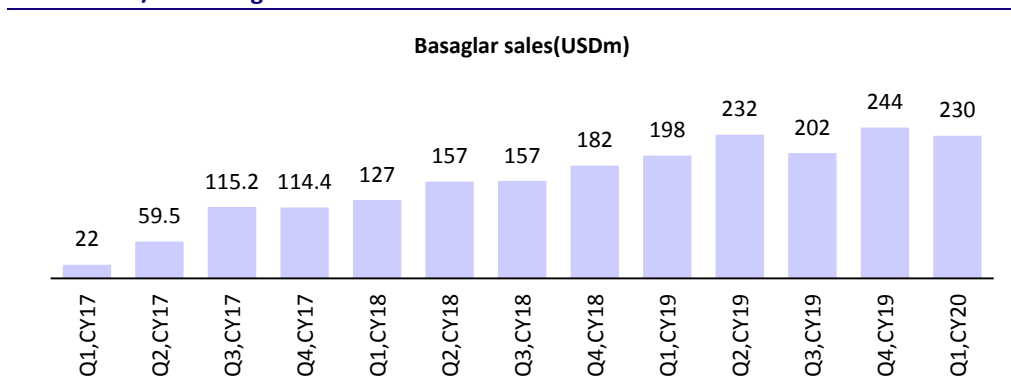
- We raise our EPS estimate by 3%/6% for FY21/FY22E to factor in the better contribution from Insulin Glargine, considering that BIOS-Mylan has an early-mover advantage.
- Over FY20-22E, we expect earnings CAGR of 23%, driven by revenue CAGR of 43% in Biologics and 11% in Small Molecules, along with a 420bp margin improvement. The biologics segment’s growth is expected to be led by potential launches/increased market share gain in existing products.
- We continue valuing BIOS at 25x 12 months forward earnings to arrive at price target of INR355 (prior: INR305). Considering the stretched valuation of 42x FY21E EPS of INR9.2 and 29.7x FY22E EPS of INR13, we maintain **Neutral** on the stock.

Exhibit 1: Eli Lilly’s Basaglar is the only other Insulin Glargine biosimilar currently being marketed in the US

Insulin Biosimilar development pipeline			Submissions		Approved/Marketed	
	Phase 1	Phase 3	EMA	FDA	EMA	FDA
Insulin Glargine	Lannett/HEC (completed trials)	Gan & Lee (expected to have completed trials on Feb 28, 2020)			Biocon, Eli Lilly, Merck (Terminated)	Eli Lilly, Merck (Tentative Approval, Terminated), Biocon (Approved)
Insulin Aspart			Sanofi			
Insulin Lispro					Sanofi	Sanofi
RH-Insulin	Biocon	Rechon				

Source: MOFSL, Company

Exhibit 2: EL/BI’s Basaglar recorded US sales of USD230m from Jan-Mar’20



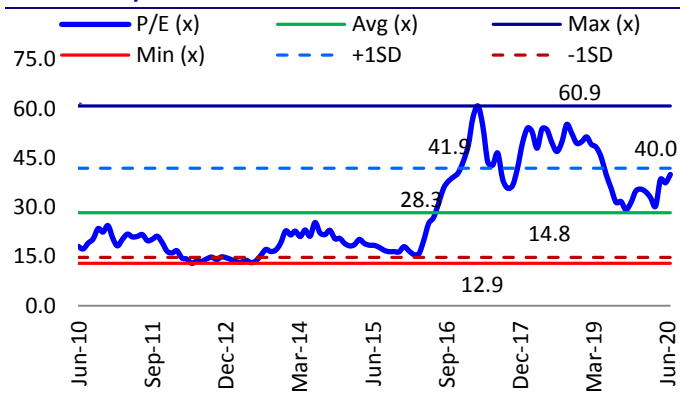
Source: MOFSL, Company

Exhibit 3: Glargine is Biocon's third approved product in the US

	US	EU
Early Development/ Preclinical	➤ Filgrastim	➤ Filgrastim
	➤ Pertuzumab	➤ Pertuzumab
	➤ Glargine 300 IU/ml	➤ Glargine 300 IU/ml
	➤ Lispro	➤ Lispro
Under Review	➤ Bevacizumab	➤ Bevacizumab
	➤ Aspart (Submission in Mid CY20)	➤ Aspart
Approved	➤ Glargine 100 IU/ml	➤ Pegfilgrastim
		➤ Etanercept
Marketed	➤ Trastuzumab	➤ Trastuzumab
	➤ Pegfilgrastim	➤ Glargine 100 IU/ml
		➤ Adalimumab

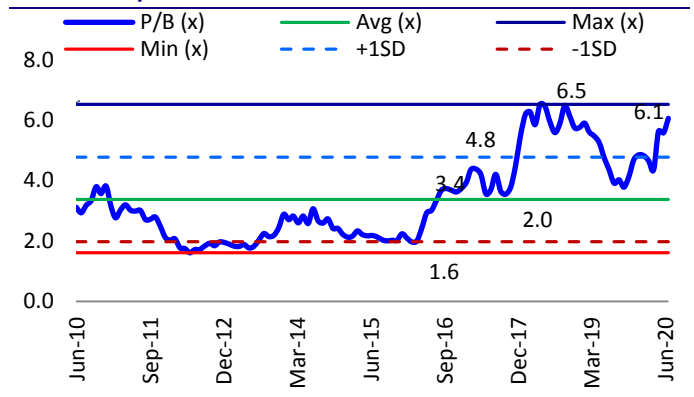
Source: MOFSL, Company

Exhibit 4: P/E chart



Source: MOFSL, Company, Bloomberg

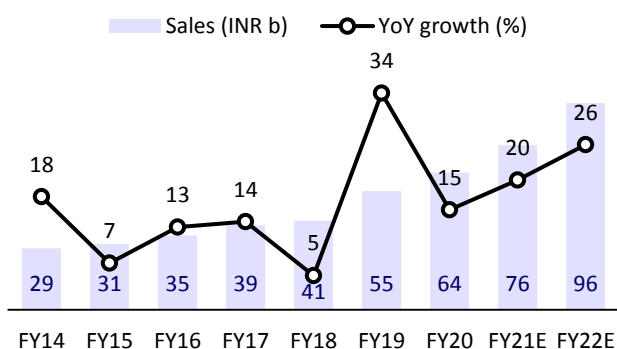
Exhibit 5: P/B chart



Source: MOFSL, Company, Bloomberg

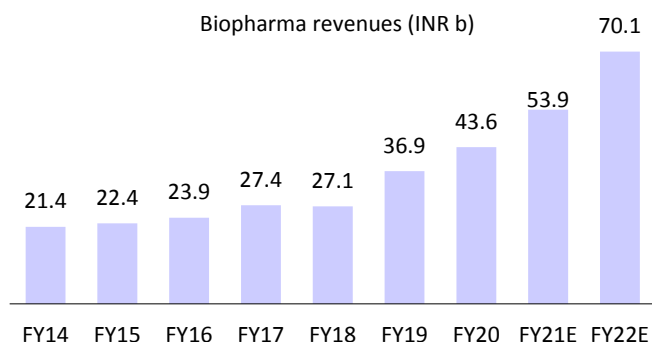
Story in charts

Exhibit 6: Expect revenues CAGR of ~23% over FY20-22



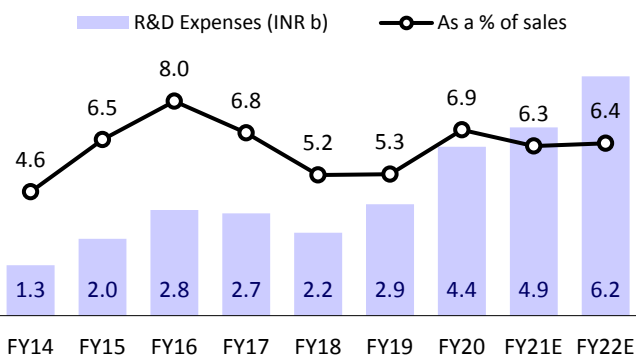
Source: MOFSL, Company

Exhibit 7: New launches to drive biopharma sales



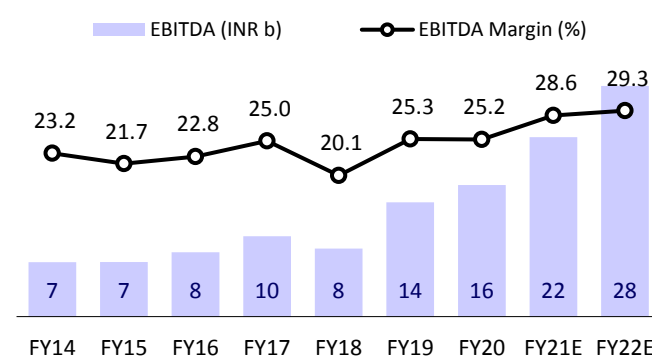
Source: MOFSL, Company

Exhibit 8: Absolute R&D spend increasing



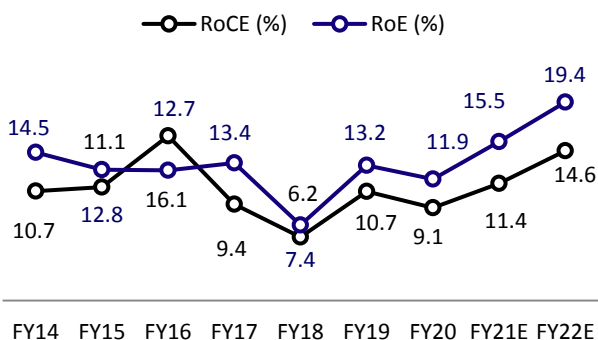
Source: MOFSL, Company

Exhibit 9: Superior product mix to drive margins



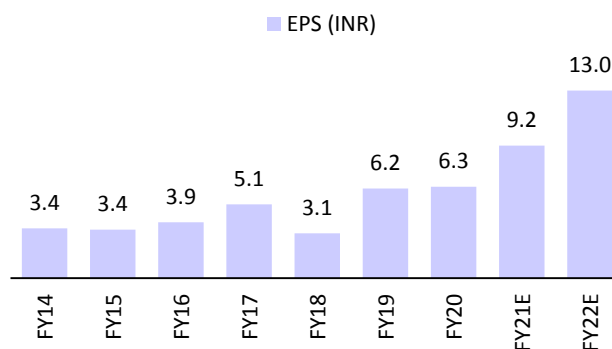
Source: MOFSL, Company

Exhibit 10: RoE on an upward trajectory



Source: MOFSL, Company

Exhibit 11: Expect EPS CAGR of 43% over FY20-22



Source: MOFSL, Company

Financials and Valuations

Income Statement (Consolidated)								(INR m)
Y/E March	2015	2016	2017	2018	2019	2020	2021E	2022E
Net Income	30,592	34,507	39,216	41,297	55,144	63,672	76,455	95,990
Change (%)	7.2	12.8	13.6	5.3	33.5	15.5	20.1	25.6
Total Expenditure	23,940	26,654	29,421	33,006	41,211	47,641	54,590	67,875
EBITDA	6,652	7,853	9,795	8,291	13,933	16,031	21,866	28,115
Change (%)	0.4	18.1	24.7	-15.4	68.0	15.1	36.4	28.6
Margin (%)	21.7	22.8	25.0	20.1	25.3	25.2	28.6	29.3
Depreciation	2,210	2,423	2,772	3,851	4,478	5,522	6,519	6,744
EBIT	4,442	5,430	7,023	4,440	9,455	10,509	15,347	21,371
Int. & Finance Charges	89	102	260	615	709	649	521	461
Other Income - Rec.	1,888	6,946	1,571	2,062	1,444	1,614	1,250	1,270
Extraordinary income					1,946	675		
PBT	6,241	12,274	8,334	5,887	12,136	12,149	16,076	22,180
Tax	957	2,569	1,616	1,569	2,123	3,151	3,858	5,279
Tax Rate (%)	15.3	20.9	19.4	26.7	17.5	25.9	24.0	23.8
Minority Interest	310	744	760	594	964	1345	1214	1336
Adjusted PAT	4,023	4,646	5,958	3,690	7,441	7,593	11,004	15,566
PAT	4,974	8,961	5,958	3,724	9,053	7,651	11,004	15,566
Change (%)	-2.8	15.5	28.3	-38.1	101.7	2.0	44.9	41.5
Margin (%)	16.3	26.0	15.2	8.9	16.4	12.0	14.4	16.2

Consolidated Balance Sheet								(INR m)
Y/E March	2015	2016	2017	2018	2019	2020	2021E	2022E
Equity Share Capital	1,000	1,000	3,000	3,000	3,000	6,000	6,000	6,000
Other Reserves	31,697	39,329	45,368	48,808	57,980	61,058	68,843	79,856
Net Worth	32,706	40,338	48,377	51,808	60,980	67,058	74,843	85,856
Loans	10,306	24,673	22,054	19,201	18,028	19,797	16,797	13,797
Minority Interest	1,722	2,658	3,761	4,677	6,089	6,773	7,987	9,323
Deferred liabilities	5934	3489	1964	2167	5816	13794	13748	13748
Capital Employed	50,667	71,158	76,156	77,853	90,913	107,422	113,376	122,725
Gross Block	29,750	33,113	53,269	57,532	68,240	85,167	88,667	91,167
Less: Accum. Deprn.	13,943	16,302	17,740	21,235	25,713	31,235	37,754	44,498
Net Fixed Assets	15,807	16,811	35,529	36,297	42,527	53,932	50,913	46,669
Capital WIP	14,939	20,597	5,327	7,789	12,869	15,765	18,265	20,765
Investments	2,303	9,015	12,538	6,752	10,118	9,661	3,376	5,693
Intangibles	2,320	2,470	3,787	5,937	8,303	11,974	13,171	14,489
Curr. Assets	28,384	34,973	34,786	41,188	44,860	49,426	64,306	81,394
Inventory	4,527	5,424	6,353	7,225	10,316	14,359	14,453	18,409
Account Receivables	7,705	7,145	8,832	10,639	12,918	12,237	18,224	23,011
Cash and Bank Balance	9,375	15,386	10,443	13,228	10,572	9,986	16,757	21,302
Loans & Advances	6,777	7,018	9,158	10,096	11,054	12,844	14,872	18,672
Curr. Liability & Prov.	13,087	12,708	15,811	20,110	27,764	33,336	36,657	46,285
Account Payables	11,355	12,334	15,343	19,645	26,959	32,306	32,048	40,500
Provisions	1,732	374	468	465	805	1,030	4,608	5,786
Net Current Assets	15,297	22,265	18,975	21,078	17,096	16,090	27,650	35,109
Appl. of Funds	50,667	71,158	76,156	77,853	90,913	107,422	113,376	122,725

Financials and Valuations

Ratios

Y/E March	2015	2016	2017	2018	2019	2020	2021E	2022E
Basic (INR)								
EPS	3.4	3.9	5.1	3.1	6.2	6.3	9.2	13.0
Cash EPS	6.0	9.5	7.3	6.3	11.3	11.0	14.6	18.6
BV/Share	27.2	33.6	40.3	43.2	50.8	55.9	62.4	71.5
DPS	0.8	0.8	1.0	1.0	0.5	1.6	2.3	3.2
Payout (%)	20.7	12.4	11.8	19.0	7.8	29.3	29.3	29.3
Valuation (x)								
P/E	114.8	99.5	75.5	124.1	62.1	60.8	42.0	29.7
Cash P/E	64.3	40.6	52.9	61.3	34.1	35.1	26.4	20.7
P/BV	14.1	11.5	9.6	8.9	7.6	6.9	6.2	5.4
EV/Sales	15.3	13.6	11.9	11.3	8.4	7.4	6.1	4.7
EV/EBITDA	70.1	59.6	47.7	56.4	33.4	29.2	21.3	16.2
Dividend Yield (%)	0.2	0.2	0.3	0.3	0.1	0.4	0.6	0.8
Return Ratios (%)								
RoE	12.8	12.7	13.4	7.4	13.2	11.9	15.5	19.4
RoCE	11.1	16.1	9.4	6.2	10.7	9.1	11.4	14.6
RoIC	17.2	17.1	15.3	6.7	14.5	12.0	15.9	21.7
Working Capital Ratios								
Fixed Asset Turnover (x)	2.0	2.1	1.5	1.1	1.4	1.3	1.5	2.0
Debtor (Days)	92	76	82	94	86	70	87	88
Inventory (Days)	54	57	59	64	68	82	69	70
Working Capital (Days)	71	73	79	69	43	35	52	53
Leverage Ratio (x)								
Current ratio	2.2	2.8	2.2	2.0	1.6	1.5	1.8	1.8
Net Debt/Equity	0.3	0.6	0.5	0.4	0.3	0.3	0.2	0.2

Consolidated Cash Flow Statement

(INR m)

Y/E March	2015	2016	2017	2018	2019	2020	2021E	2022E
Oper. Profit/(Loss) before Tax	6,652	7,853	9,795	8,291	13,933	16,031	21,866	28,115
Interest/Dividends Recd.	937	2,630	1,571	2,062	1,444	1,614	1,250	1,270
Direct Taxes Paid	-1,581	-5,014	-3,141	-1,366	1,526	4,827	-3,904	-5,279
(Inc)/Dec in WC	-3,251	-956	-1,653	682	1,326	420	-4,788	-2,914
CF from Operations	2,758	4,513	6,572	9,669	18,229	22,892	14,423	21,191
(Incr)/Dec in FA	-6,618	-9,085	-6,220	-7,081	-15,788	-19,823	-6,000	-5,000
Free Cash Flow	-3,861	-4,572	352	2,588	2,441	3,069	8,423	16,191
(Pur)/Sale of Investments	4,468	-6,862	-4,840	3,602	-5,475	-3,214	5,087	-3,634
CF from investments	-2,151	-15,946	-11,060	-3,479	-21,263	-23,037	-913	-8,634
Change in Net Worth	-554	4,094	2,783	443	2,433	703	0	1
(Inc)/Dec in Debt	2,397	14,559	-2,276	-2,531	-725	1,108	-3,000	-3,000
Interest Paid	-89	-102	-260	-615	-709	-649	-521	-461
Dividend Paid	-1,030	-1,107	-702	-702	-702	-2,239	-3,219	-4,553
CF from Fin. Activity	724	17,444	-455	-3,405	297	-1,077	-6,739	-8,013
Inc/Dec of Cash	1,331	6,011	-4,943	2,785	-2,737	-1,222	6,771	4,544
Add: Beginning Balance	8,044	9,375	15,386	10,443	13,228	10,572	9,986	16,757
Closing Balance	9,375	15,386	10,443	13,228	10,559	9,516	16,757	21,302

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

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