Biocon

Strongly positioned for high growth phase

January 21, 2022

Pharmaceuticals | Result Update

BUY (no change)

CMP: Rs 377

Target Price: Rs 460 (Rs 400) ▲

Potential Upside: 22%

- EBITDA (+22% YoY) was 6% above our est. on strong growth in Biosimilars (led by bGlargine) and lower R&D. Adj. for MTM loss#, EBITDA grew 44% YoY.
- Expect strong growth momentum in (1) Biosimilars with Glargine; pipeline (Aspart, Beva, Adalimumab, Rhi), (2) Vaccine (H2'23), (3) Syngene, (4) Generics.
- We factor in vaccine estimates (but cut multiple on stake dilution). Rolled-over TP of Rs 460 on 33% EBITDA CAGR over FY21-24 (9% for FY19-21). **BUY** stays.

Market Data

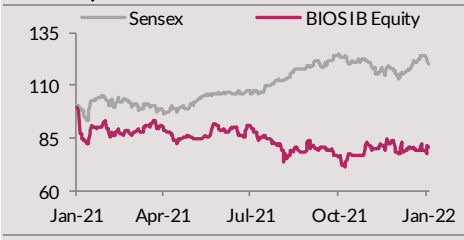
No. of shares	: 1,201 mn
Free Float	: 39%
Market Cap	: USD 6,075 mn
52-week High / Low	: Rs 456 / Rs 315
Avg. Daily vol. (6mnth)	: 2.9 mn shares
Bloomberg Code	: BIOS IB Equity
Promoters Holding	: 61%
FII / DII	: 16% / 8%

Key growth driver %	FY22E	FY23E	FY24E
Biosimilars	21%	26%	30%
Gross margin	67.7%	67.9%	67.9%
EBITDA margin	23.8%	25.4%	25.8%

Result Update (Rs bn)

Y/E March	Q3'22	YoY	QoQ
Net Sales	21,742	17%	18%
Gross margin	67.2%	-254 bps	-208 bps
EBITDA	4,882	22%	10%
EBITDA margin	22.5%	87 bps	-177 bps
Adj. PAT	1,711	4%	-1%
Biosimilars	9,814	28%	32%

Relative performance



Source: Bloomberg, Axis Capital

Revenue growth led by strong performance in Biosimilars

Revenue grew 17% YoY to Rs 24.7 bn on 28% YoY growth in Biosimilars (+32% QoQ) on interchangeable insulin glargine supplies in US coupled with growth in EMs and better traction in developed markets across key products. Research Services (Syngene) business was up 10% YoY. Generics business recovered by 8% YoY (+15% YoY) on launch of Everolimus in US and pick-up in demand in its API business.

EBITDA beat on sales growth and lower R&D

Gross margin at 67.2% declined 54 bps YoY (-208 bps QoQ) due to higher input costs. Higher staff cost, lower R&D and higher other costs (due to Rs 770 mn MTM loss related to investment in Adagio) led to EBITDA of Rs 4.8 bn (+22% YoY) and margin of 22.5% (+85 bps YoY). Adjusted for MTM loss, EBITDA was at Rs 5.6 bn (+41% YoY) and margin was at ~26% (+440 bps YoY). Reported PAT was up 11% YoY at Rs 1.87 bn. Adjusted for forex gain (Rs 190 mn), PAT was at Rs 1.7 bn (+4% YoY).

Key highlights from management call

Expects strong growth momentum in Biosimilar business led by (a) Insulin Glargine with interchangeable launch in US and traction from contracted formularies (Prime Therapeutics, Express Scripts, and Walgreens), (b) better traction in Fulphila and Ogivri, and (c) incremental sales/ EBITDA from Vaccine business (from H2FY23). Aspart approval/ launch delayed due to CRL and uncertainty on Beva timeline were negatives. Generics to see growth/ profitability improvement with limited competition launches. R&D was lower due to delay in clinical trials, but expected to increase from Q4FY22 as next wave Biosimilar R&D picks up.

Outlook and valuations

Improving opportunity is unlocking value for Biosimilar players globally – Celltrion^ (14% EPS CAGR CY20-22E, trades at 34x CY22E) and Samsung Biologics^ (44% EPS CAGR CY20-22E, trades at 103x CY22E). We introduce vaccine estimates and raise FY23/24E EPS by 9%/21%; cut multiple to 33x Dec'23 (from 36x) on stake dilution with rolled-over TP of Rs 460 vs Rs 400 (36x Sep'23E). Maintain **BUY.**

Financial summary (Consolidated)

Y/E March	FY20	FY21	FY22E	FY23E	FY24E
Sales (Rs mn)	63,005	71,058	81,364	1,13,323	1,49,226
EBITDA (Rs mn)	16,031	16,526	19,352	28,775	86,468
Adj. PAT (Rs mn)	6,628	5,979	7,203	12,880	18,015
Con. EPS* (Rs)	-	-	6.0	10.7	13.7
EPS (Rs)	5.5	5.0	6.0	10.7	15.0
Change YoY (%)	(8)	(10)	20	79	40
RoE (%)	10.4	8.3	9.0	14.9	18.9
RoCE (%)	13.2	9.8	9.1	14.4	47.8
P/E (x)	68.2	75.6	62.8	35.1	25.1
EV/E (x)	28.7	28.7	24.2	16.5	5.6

Source: *Consensus broker estimates, Company, Axis Capital

#Mark-To-Market loss related to investment in Adagio was at Rs 770 mn

^ Celltrion and Samsung Biologics estimates, as per Bloomberg

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Key concall highlights

Particulars	Comments
Outlook	• Expects growth to improve in 2022 for Biosimilars business led by (a) strong traction from interchangeable Insulin Glargine supplies in US (launched in Sep'21) given listing as preferred formularies (Express script, Walgreens, and Prime Therapeutics), (b) better traction in Fulphila and Ogivri, (c) capacity expansion at Malaysia plant, and (d) other launches (Beva, Aspart). • Expects to sustain/ improve core EBITDA margin (ex-R&D) for Biosimilar business; R&D to increase with progress in pipeline to clinical stage. • Expects incremental sales/ EBITDA potential with vaccine supplies from H2FY23 as part of Serum Institute deal. • Generics to see growth/ profitability improvement with limited competition launches (Everolimus, etc); however, expects price pressure to continue. • Multiple initiative like PLI schemes, progress in novel molecules, capacity expansion across business and new launches to provide mid-to-long term growth visibility.
Biosimilars	• Semglee/ interchangeable bGlargine launched in US by partner Viatris. It has already received preferred status in the national formularies of two leading US Pharmacy Benefit Managers (PBMs), Prime Therapeutics and Express Scripts, and will also be offered through Walgreens Prescription Savings Club. • Biocon/ Viatris has adopted a dual brand strategy by launching interchangeable biosimilar Glargine in both branded (Semglee) and unbranded versions to address all customer segments. Currently, on co-pay statistics, the commercial/ formularies capture ~30% market, Medicare around 35% and Medicaid around 15-17%. • The company continued to maintain a steady market share (8-10%) for bTrastuzumab (Ogivri) in the US and bPegfilgrastim (Fulphila) in the US and key EU countries. • Branded Formulations – India reported double-digit growth for Q3. • Regulatory – on Aspart CRL, 2 aspects were highlighted by the FDA: (1) More data needed for diluent used to dilute the drug for lighter patients, (2) Complete data requested for the CAPA filed for recent inspection. Company continues to hope to get approval by H2FY23 (vs Q4FY22 earlier).
Generics	• Q3FY22 saw Covid-related challenges starting to wane leading to normalized operations. However, the business continues to face headwinds due to pricing pressure in various markets, increase in solvent and other raw material prices and higher logistic costs. • Following the USFDA Remote Interactive Evaluation for oral solid manufacturing facility in Bengaluru in Sep'21, Biocon received 1 USFDA approval in US (Mycophenolic Acid). It also received 2 approvals in Europe (Everolimus tablets, Fingolimod capsule). • Greenfield Immunosuppressants API manufacturing facility in Visakhapatnam continues to remain on track – to be commissioned by the end of FY22, with qualification and validation in FY23. Also looking to add fermentation capabilities in the long-term.
Novel	• Equillium (US-based partner) has announced plans to initiate a Phase-3 pivotal study for use of Itolizumab in first line treatment of Acute Graft Versus Host Disease (aGVHD) following regulatory feedback from the USFDA; on track to initiate the study in Q4CY21. • In Q2FY22, Bicara Therapeutics (Boston-based associate) continued to make progress in the dose finding part of the Phase 1 trial for its lead program, BCA101, as single agent and in combination with a PD1 inhibitor. On the basis of the current progress, Bicara anticipates declaring the recommended dose for expansion by the end of CY21.
Strategic partnership with Serum	• Strategic alliance with Serum Institute Life involving a merger of Covishield Technologies Private Ltd (CTPL) into Biocon Biologics (for 15% stake for 100 mn vaccine dose supplies per annum for 15 years – starting Oct'22) is on track. Strong vaccine opportunity seen with plans to launch Covid vaccines followed by next-gen vaccines. Initially, the contracted 100 mn doses (from CTPL deal) could generate upto USD 400 mn in revenue with core EBITDA margin at Biocon Biologics company level (mid to high 30s).
Balance sheet and Cash flow highlights	• Net Working Capital days remained sequentially flat at 102 days (vs 102 days in Sep'21; 79 days on Mar'21) with steady inventory days at 113 (vs 114 in Sep'21; 94 days on Mar'21) and increase in payable days to 75 vs 69 days on Sep'21 (76 days in Mar'21) offset by increase in receivable days to 64 (vs 58 in Sep'21; 61 days on Mar'21). • Gross debt at Rs 48.8 bn (vs. Rs 43.13 bn as on Mar'21) and net debt stood at Rs 18.15 bn (vs Rs 10.89 bn in Mar'21).
Other highlights	• Malaysia facility enjoys 15-year tax incentives for phase-1. The company is in talks to get similar tax incentives for the phase-2, which is under expansion. Malaysia plant expected to be profitable from Q4FY22. • On strong global demand for insulin, Biocon has initiated investments for the expansion of its insulin manufacturing facility in Malaysia. This capex will be part of the USD 100-150 mn overall Biologics capex plan. • Looking to exit Adagio investment (~USD 5 mn) in the near term once price stabilizes.

Exhibit 1: Revenue growth led by strong performance in Biosimilars and recovery in generics business

(Rs mn)	% of Q3'22 sales	Q3'21	Q2'22	Q3'22	YoY chg	QoQ chg	9M'21	9M'22	YoY chg
Generics	28%	5,607	5,300	6,074	8%	15%	17,859	16,237	-9%
Biosimilars	45%	7,689	7,425	9,814	28%	32%	21,366	24,820	16%
Novel Biologics	1%	-	121	156	NA	NA	0	387	NA
Research Services	30%	5,845	6,102	6,414	10%	5%	15,257	18,461	21%
Licensing fees#	1%	110	130	170	55%	31%	319	400	25%
Less (inter segment revenue)	-3%	-631	-544	-716			-1,536	-2,153	
Total Revenue		**18,510**	**18,404**	**21,742**	**17%**	**18%**	**52,946**	**57,752**	**9%**
Total (ex-one off & Research Services)		**12,665**	**12,302**	**15,328**	21%	25%	**37,689**	**39,291**	**4%**

Source: Company, Axis Capital; # Licensing fees distributed among different business segments

Exhibit 2: EBITDA growth led by higher sales and lower R&D

	Reported					Axis Est.		Reported		
	Q3'21	Q2'22	Q3'22	YoY chg	QoQ chg	Q3'22E	vs. Est. (%)	9M'21	9M'22	YoY chg
Net Sales	**18,510**	**18,404**	**21,742**	**17%**	**18%**	**20,661**	**5%**	**52,946**	**57,752**	**9%**
Material costs	5,599	5,651	7,129	27%	26%	6,508	10%	16,329	18,901	16%
Gross Profit	**12,911**	**12,753**	**14,613**	**13%**	**15%**	**14,153**	**3%**	**36,617**	**38,851**	**6%**
Employee expenses	4,633	4,788	4,950	7%	3%	5,062	-2%	12,889	14,098	9%
R&D expenses	1,710	1,460	1,380	-19%	-5%	1,715	(0)	4,264	4,040	-5%
Net other expenses	2,573	2,047	3,401	32%	66%	2,789	22%	7,147	7,480	5%
Total Expenses	**14,515**	**13,946**	**16,860**	**16%**	**21%**	**16,074**	**5%**	**40,629**	**44,519**	**10%**
EBITDA	**3,995**	**4,458**	**4,882**	**22%**	**10%**	**4,587**	**6%**	**12,317**	**13,233**	**7%**
Adj EBITDA (ex-Licensing inc., forex and R&D)	**5,628**	**5,829**	**6,140**	**9%**	**5%**	**6,302**	**-3%**	**16,475**	**16,792**	**2%**
Other income	279	1,049	483	73%	-54%	(50)	(11)	617	2,004	225%
Depreciation	1,863	2,015	2,057	10%	2%	2,085	(0)	5,308	6,020	13%
Interest	48	225	147	206%	-35%	185	(0)	238	571	140%
PBT	**2,363**	**3,267**	**3,161**	**34%**	**-3%**	**2,267**	**39%**	**7,388**	**8,646**	**17%**
Tax	489	463	493	1%	6%	453	9%	1,521	1,529	1%
Share of JV profit	(8)	(506)	(472)	5800%	-7%	(50)	8	(94)	(1,539)	1537%
Adjusted PAT	**1,638**	**1,720**	**1,711**	**4%**	**-1%**	**1,384**	**24%**	**5,263**	**4,725**	**-10%**
Extra ordinary income/ (exp.)	48	(337)	160			-		(115)	(627)	
Reported PAT	**1,686**	**1,383**	**1,871**	**11%**	**35%**	**1,384**	**35%**	**5,148**	**4,098**	**-20%**
Adj EPS	**1.4**	**1.4**	**1.4**	**4%**	**-1%**	**1.2**	**24%**	**4.4**	**3.9**	**-10%**
Costs as a % of sales										
Gross margin (%)	**69.8%**	**69.3%**	**67.2%**	**-254 bps**	**-208 bps**	**68.5%**	**-129 bps**	**69.2%**	**67.3%**	**-189 bps**
EBITDA margin (%)	**21.6%**	**24.2%**	**22.5%**	**87 bps**	**-177 bps**	**22.2%**	**25 bps**	**23.3%**	**22.9%**	**-35 bps**
Adj EBITDA margin (%)	**30.4%**	**31.7%**	**28.2%**	**-217 bps**	**-343 bps**	**30.5%**	**-226 bps**	**31.1%**	**29.1%**	**-204 bps**
Material cost	30.2%	30.7%	32.8%	254 bps	208 bps	31.5%	129 bps	30.8%	32.7%	189 bps
Employee cost	25.0%	26.0%	22.8%	-226 bps	-325 bps	24.5%	-173 bps	24.3%	24.4%	7 bps
Other expenditure	13.9%	11.1%	15.6%	174 bps	452 bps	13.5%	214 bps	13.5%	13.0%	-55 bps
R&D expenses	9.2%	7.9%	6.3%	-289 bps	-159 bps	8.3%	-195 bps	8.1%	7.0%	-106 bps
Income tax rate (%)	20.7%	14.2%	15.6%	-510 bps	142 bps	20.0%	-440 bps	20.6%	17.7%	-290 bps

Source: Company, Axis Capital; Note: Q2FY22 PAT adjusted for exceptional loss of Rs 701 mn includes (1) loss of Rs 274 mn related to modification of the optionally convertible debenture of Goldman Sachs and related tax impact of Rs 49 mn, (2) export incentive reversals of Rs 427 mn and tax impact of Rs 75 mn, (3) minority interest impact of Rs 68 mn, and (4) forex gain of Rs 200 mn

- Higher other costs (+32% YoY) was due to Rs 770 mn MTM loss related to investment in Adagio. Adjusted for MTM loss, EBITDA was at Rs 5.6 bn (+41% YoY) and EBITDA margin was at ~26% (+440 bps YoY).

Exhibit 3: Biosimilar business performance

	Q3'21	Q2'22	Q3'22	YoY chg	QoQ chg	9M'21	9M'22	YoY chg
Biosimilar sales	7690	7430	9,810	28%	32%	21,370	24,820	16%
Core EBITDA*	**2850**	**3040**	**3,630**	**27%**	**19%**	**7,990**	**9,380**	**17%**
EBITDA margin	**37.1%**	**40.9%**	**37.0%**	**-6 bps**	**-391 bps**	**37.4%**	**37.8%**	**40 bps**
PBT	1110	1190	2,010	81%	69%	2,970	4,210	42%
PBT margin	14.4%	16.0%	20.5%	605 bps	447 bps	13.9%	17.0%	306 bps
Net R&D	NA	760	640	NA	NA	NA	1,990	NA
% of sales	NA	10.2%	6.5%	NA	NA	NA	8.0%	NA

Source: Company, Axis Capital, * Core EBITDA defined as EBITDA including other income, before R&D, forex, licensing and mark-to-market loss on Adagio investment (in Q3'22) and any forex impact

Exhibit 4: Generics business performance

(Rs mn)	Q3'21	Q2'22	Q3'22	YoY chg	QoQ chg	9M'21	9M'22	YoY chg
Generics sales	5670	5300	6,070	7%	15%	17,920	16,230	-9%
PBT	530	500	670	26%	34%	2,190	1,460	-33%
PBT margin %	9.3%	9.4%	11.0%	169 bps	160 bps	12.2%	9.0%	-323 bps

Source: Company, Axis Capital

Exhibit 5: EBIT margin declined for Biosimilars due to one-time MTM loss; improved for Generics business

Segmental EBIT margin (%)	Q3'21	Q2'22	Q3'22	YoY chg	QoQ chg	9M'21	9M'22	YoY chg
Generics	9.6	9.4	11.0	132 bps	157 bps	12.3	9.0	-334 bps
Biosimilars	14.4	23.5	12.6	-177 bps	-1086 bps	13.9	16.1	218 bps
Novel Biologics	NA	NA	NA	NA	NA	NA	NA	NA
Research Services	19.9	18.5	20.0	9 bps	152 bps	18.2	18.2	4 bps
Total	**12.0**	**14.6**	**12.0**	**0 bps**	**-257 bps**	**12.7**	**11.9**	**-82 bps**

Source: Company, Axis Capital

Exhibit 6: Gross and net R&D spend was lower YoY; expects to increase from Q4FY22

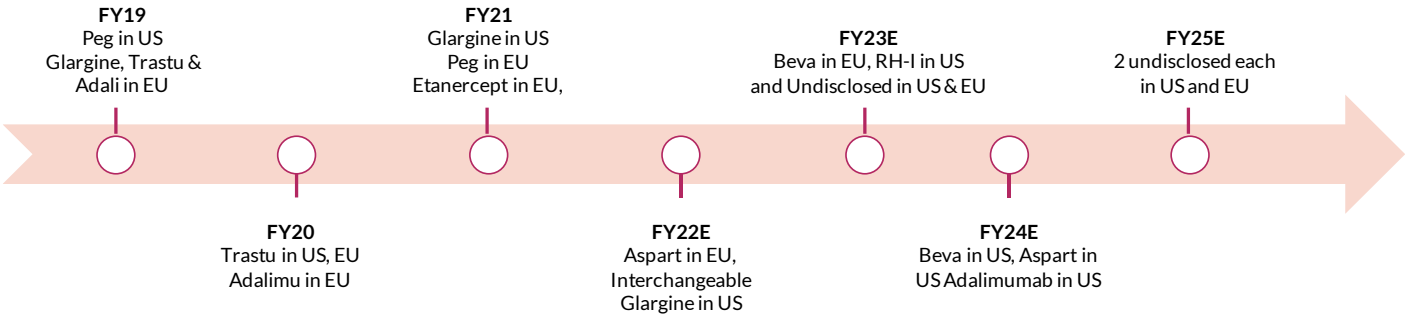
(Rs mn)	Q3'21	Q2'22	Q3'22	YoY chg	QoQ chg	9M'21	9M'22	YoY chg
Gross R&D expense	1,830	1,650	1,780	-3%	8%	4,904	4,790	19%
% of biopharma sales	14.4%	13.4%	11.6%	-284 bps	-284 bps	13.0%	12.2%	55 bps
Revenue (expensed in P&L)	1,710	1,460	1,380	-19%	-5%	4,264	4,040	26%
% of biopharma sales	13.5%	11.9%	9.0%	-450 bps	-450 bps	11.3%	10.3%	105 bps
Capital	120	190	400	233%	111%	640	750	-16%
% of biopharma sales	0.9%	1.5%	2.6%	166 bps	166 bps	1.7%	1.9%	-50 bps

Source: Company, Axis Capital

Biosimilars and novel molecule pipeline update

Mylan partnered program	
Insulin Glargine	• Expects share ramp-up after next formulary cycle in CY22 • Received interchangeability designations from USFDA in Jul'21 and launched in Sep'21 • Listed on Prime Therapeutics, Express Scripts, and Walgreens Prescription Savings Club
Trastuzumab	• Expects gradual pick-up in market share given chronic nature of the drug • Witnessed positive trend as market share was steady at 11% in overall market by end of Q3'22
Pegfilgrastim	• Market share stagnant at ~16%; ramp-up expected on increased production capacity and targeting another 1/3rd of the market (340B segment) coupled with new contracting cycle • Expects to improve traction with visible trend of shift from KITs to syringes
Bevacizumab	• Approval from European Commission in Apr'21; commercialized in several EU markets, including Germany, Croatia, Czech Republic, Slovakia • In Feb'20, Biocon/Mylan submitted BLA with USFDA in US (USD 3 bn); filing under review; goal date deferred • Awaiting USFDA response on remote inspection of manufacturing facility; approval/ launch timeline uncertain
Insulin Aspart	• Received European Commission approval for Europe market (USD 666 mn) in Feb'21; launch timeline not disclosed • In Sep'21, received final approval in Canada • BLA under review by USFDA for US market (USD 1.5 bn). USFDA issued form 483 with 6 observations in pre-approval inspection of Malaysia plant; responded with CAPA plan and expects to get approval soon (Q4FT22), launch will depend on approval date as well as entry into contracting cycle • In Jan'22, received CRL from USFDA highlighted (1) more data needed for diluent used to dilute the drug for lighter patients and (2) complete data requested for the CAPA filed for recent inspection. Expects to get approval by H2'23
Adalimumab	• USFDA approval in Jul'20; launch will be in Jun'23 (patent settlement)
Etanercept	• Received marketing authorization from EU in Jun'20; launched in Aug'20; US filing expected in near term
Biocon's own programs	
Itolizumab	• Equillium to initiate a Pivotal Study in early 2022 for use in First-Line treatment of Acute Graft-Versus-Host Disease (aGVHD) • Repurposed for prevention & treatment of COVID-19 complications in India in 2020; granted 'Restricted Emergency Use' approval in Sep '20 for treatment of Cytokine Release Syndrome in 'Moderate to Severe' Acute Respiratory Distress Syndrome patients

Exhibit 7: Biocon Biologics timelines – Biosimilars launch visibility every year



Source: Company, as per Axis Capital assumptions

Exhibit 8: Growth visibility remains on key assets

(Rs mn)	FY19	FY20	FY21	FY22E	FY23E	FY24E
Glargine	61	115	90	372	1,701	2,162
Trastuzumab	94	454	1,738	2,347	2,244	2,459
Adalimumab	-	-	332	354	443	2,322
Pegfilgrastim	994	3,181	2,814	3,041	3,573	3,298
Etanercept	-	-	159	254	382	286
Bevacizumab	-	-	-	278	557	1,189
Insulin Aspart	-	-	-	66	304	843
Rh-Insulin	-	-	-	-	238	583
Incremental PAT	**1,149**	**3,750**	**5,134**	**6,712**	**9,442**	**13,142**
Base business PAT	**6,089**	**2,878**	**845**	**491**	**550**	**616**
Total PAT	**7,238**	**6,628**	**5,979**	**7,203**	**9,992**	**13,758**
YoY Growth (%)	**107**	**-8**	**-10**	**20**	**39**	**38**

Source: Company, Axis Capital

Exhibit 9: Revenue break-up

(Rs mn)	% of FY21 sales	FY21	FY22E	FY23E	FY24E	CAGR (FY21-24E)
Generics	32%	23,359	22,425	24,891	27,629	6
Biosimilars	38%	28,002	35,357	46,105	59,213	28
Vaccines	0%	-	-	12,962	25,924	NA
Novel Molecules	0%	-	550	605	666	NA
Research Svcs	30%	21,843	25,983	31,333	38,956	21
Total	**100%**	**73,204**	**84,315**	**1,15,896**	**1,52,388**	**28**
EBITDA		**16,526**	**19,352**	**28,775**	**38,566**	**33**
EBITDA margin		**23.3%**	**23.8%**	**25.4%**	**25.8%**	

Source: Company, Axis Capital

Exhibit 10: Biocon Biologics (BBL) - Unlocking biosimilars value via monetization

Investors	% stake acquired	Investment (USD mn)	Valuation (USD mn)	Comments
True North	2.44%	75	3,000	One of the first PE investor acquired stake in Jan'20
Tata Capital	0.85%	30	3,500	Acquired stake in Jul'20
Goldman Sachs	-	150	3,940	Issued optionally convertible debentures (OCDs) in Nov'20
ADQ	1.80%	75	4,170	Acquired stake in Jan'21
Serum	15%	-	4,900	In Sep'21, Serum acquires ~15% stake for which it will get committed access to a 100 mn doses of vaccines per annum for 15 years starting from Oct'22

Source: Company, Axis Capital; Post PE investment Biocon stake in BBL was at ~89.89% and post Serum entry stake reduces to ~74.9%

Exhibit 11: Competitive landscape for Pegfilgrastim

Company	US Filing Status	EU Filing Status
Mylan/Biocon	**Approved and launched in Jun'18**	**Received approval in Nov'18**
Coherus	Received approval in Nov'18, launched Udenyca in Jan'19	Received approval in Sep'18
Sandoz	Approval and launch of Ziextenzo in Nov'19 at WAC price of USD 3,925 (~37% discount to Neulasta) vs. 33% discount by Biocon/Mylan & Coherus	Received approval in Nov'18
Apotex/ Intas (Accord)	Filing accepted in Dec'14, Apotex won the patent infringement lawsuit in Sep'16 filed on it by Amgen; No further updates	Received approval in Sep'18
Pfizer / Hospira	Received approval in Jun'20; Launched in Jan'21	Received approval in Nov'20
Lupin	BLA filing accepted by USFDA in Jun'21; expects approval in 12-18 months	Under clinical stage
Dr Reddy's/ Fresenius Kabi	BLA filed in May'20; expects approval in CY21	Under clinical stage
Aurobindo (CuraTeQ)		Filed in Aug'21
Mundipharma (Cinfa)		Launched in Feb'19; approval in Nov'18
USV (Juta Pharma)		Received approval in Jun'19

Source: Companies, USFDA, EMA, Axis Capital

Exhibit 12: Pegfilgrastim market share trend vs. peers

Pegfilgrastim brand name	Player	Nov'20	Dec'20	Mar'21	Jun'21	Sep'21	Oct'21	Nov'21
Fulphila	Biocon/Mylan	16%	16%	16%	17%	17%	15%	15%
Udenyca	Coherus	46%	46%	43%	37%	35%	34%	33%
Neulasta	Amgen	33%	31%	26%	26%	25%	25%	25%
Ziextenzo	Sandoz	6%	7%	14%	18%	20%	22%	22%
Nyvepria	Pfizer	-	-	0%	2%	4%	5%	5%

Source: Bloomberg

Exhibit 13: Competitive landscape for Trastuzumab

Company	US Filing Status	EU Filing Status
Mylan/Biocon	**Approved in Dec'17, launched (420 mg & 150 mg) in Dec'19**	**Launched in Q4'19; approved in Dec'18**
Amgen/Allergan	Approved in Jun'19; launched at-risk (420 mg) in Jul'19 at WAC discount of 15% at USD 3,697 per vial	Launched in Jun'18; approved in May'18
Pfizer	Approved in Mar'19; launched in Feb'20	Approved in Jul'18
Celltrion/Teva	Approved in Dec'18; launched in Mar'20	Launched in May'18 by Mundipharma, approved in Feb'18
Biogen/Samsung Biologics	Approved in Jan'19; launched in Apr'20	Launched in Mar'18 by Merck, approved in Nov'17
Hanwha/ Prestige		Filed in EU
Shanghai Henlius/ Accord		Approved in Jul'20 and launched in Sep'20
Tanvex Biopharma	Filed in Oct'21; Expects potential FDA by Q4'22	
Sandoz/EirGenix	Filed in Dec'21; expects potential FDA in CY22	Filed in Dec'21
Others	2+ players in global Phase 1/3 clinical trials	3+ players in global Phase 1/3 clinical trials

Source: Companies, Axis Capital, USFDA, EMA

Exhibit 14: Trastuzumab market share trend vs. peers

Trastuzumab brand name	Player	Nov'20	Dec'20	Mar'21	Jun'21	Sep'21	Oct'21	Nov'21
Ogivri	Biocon/Mylan	7%	7%	8%	9%	9%	9%	10%
Kanjinti	Amgen	25%	27%	30%	31%	32%	32%	31%
Herceptin	Roche	64%	62%	55%	50%	45%	44%	44%
Trazimera	Pfizer	3%	4%	6%	9%	12%	13%	13%
Ontruzant	Merck/ Samung	0.3%	0.3%	1%	1%	2%	2%	2%

Source: Bloomberg

Exhibit 15: Competitive landscape for Insulin Glargine

Company	US Filing Status	EU Filing Status
Mylan/Biocon	**Received second CRL in Aug'19 (first in Jun'18); filed in Sep'17; In Mar'20, got favourable ruling in Lantus device litigation and IP litigation (in May'20); Final approval in Jun'20; launched in Sep'20 in US market and received interchangeable designation in Jul'21** and launch was in Sep'21	**Received approval in Mar'18; launched in Nov'18**
Eli Lilly/Boehringer Ingelheim	Received approval. Product launched in Dec'16; Received approval as Biosimilar in Dec'21	Received approval in Sep'14. Product launched in Aug'15
Sandoz/ Gan & Lee	Phase 3 trials	Phase 3 trials
Lannett	Initiated clinical trials in Jun'19; submitted a new drug application for a clinical trial and expects to commence roughly March 2022. Targeted BLA submission in CY23, setting up for CY24 launch	
Samsung/Merck	Decided to withdraw from the market after failing to make sufficient headway; Tentative approval in July'17	Received approval in Jan'17

Source: Companies, Axis Capital, USFDA, EMA

Exhibit 16: Insulin Glargine market share trend vs. peers

Insulin Glargine brand name	Player	Nov'20	Dec'20	Mar'21	Jun'21	Sep'21	Oct'21	Nov'21
Semglee	Biocon/Mylan	0.2%	0.2%	1%	2%	2%	2%	2%
Lantus	Sanofi	19%	19%	19%	18%	18%	18%	17%
Lantus Solostar	Sanofi	55%	55%	56%	56%	57%	56%	57%
Basaglar	Eli Lilly	25%	25%	24%	24%	23%	24%	24%

Source: Bloomberg

Exhibit 17: Adalimumab: Market size: US – USD 13.7 bn, EU – USD 3.1 bn, RoW – USD 3.1 bn

Adalimumab: Increased competition in both US and EU		
Mylan/Biocon/ Fujifilm	**Approved in Jul'20; Settled for launch in 2023**	**Launched in Oct'18, Brand name - Hulio**
Amgen	Approved in Sept'16. Settled for launch on Jan 31, 2023	Launched in Oct'18
Biogen/Samsung Biologics	Approved in Jul'19; Settled for launch in Jun'23	Launched in Oct'18
Boehringer Ingelheim	Approved in Aug'17; undertaking interchangeability studies. Settled for launch in Jul'23	Approved in Nov'17; however, withdrew from all ex-US markets
Sandoz	Approved in Oct'18; settled for launch in Sep'23	Launched in Oct'18
Pfizer	Approved in Nov'19; settled for launch in Nov'23	Approved in Feb'20; no launch due to unfavorable market
Fresenius Kabi	-	Launched in May'19; approved in Apr'19
Celltrion	-	Approved in Feb'21
Samsung Bio	Approved in Jul'19; settled for launch in Nov'23	Approved in Aug'17
Momenta	Positive Phase III data announced in Nov'16	Positive Phase III data announced in Nov'16
Coherus Biosciences	Approved in Dec'21; settled for launch in Aug'23	Reported positive topline results from the first of three ongoing pharmacokinetic bioequivalence in Aug 2017

Source: Companies, USFDA, EMA, Axis Capital

Exhibit 18: Insulin Aspart: Market size: US – USD 1.5 bn, EU – USD 666 mn, RoW – USD 814 mn

Mylan/Biocon	**Under review; recently had USFDA inspection and received CRL in Jan'22**	**Approved in Feb'21**
Sanofi	**Currently in Phase 3 trials**	**Approved in Jun'20**

Source: Companies, USFDA, EMA, Axis Capital

Exhibit 19: Bevacizumab: Market size: US - USD 3 bn, EU - USD 1.9 bn, RoW - USD 2.2 bn

Company	US Filing Status	EU Filing Status
Mylan/Biocon	**Under approval process; pending plant inspection**	**Approved in Apr'21; expects to launch in FY22**
Amgen/Allergan	US approval in Sep'17; launched in Jul'19; as of Aug'21 market share was at ~49% (Bloomberg)	EU approval in Jan'18; not yet launched in EU
Pfizer	Approved in Jun'19 and launched in Dec'19; as of Aug'21 market share was at ~49% (Bloomberg)	EU approval in Feb'19
Samsung Bio	Under clinical trials	Approved in Aug'20
Centus Biotherapeutics		Approved in Sep'20
Mabxience Research (Amneal)	Under clinical trials	Approved in Mar'21; launched in Apr'21
STADA Arzneimittel		Approved and launch in Mar'21
Others	Multiple other players under clinical trial stage	

Source: Companies, USFDA, EMA, Axis Capital

Exhibit 20: Etanercept: Market size: US – USD 4.8 bn, EU – ~USD 1 bn, RoW – ~USD 1.3 bn

Company	US filing status	EU filing status
Mylan/Biocon/Lupin		**Approval in May'20 and launched in Aug'20**
Sandoz	Approval in Aug'16; not yet launched due to court injunction; Arguments pertaining to patent invalidation were heard in Nov'18; the Court's verdict is awaited	Approval and launched in Jun'17
Samsung Bioepis	Approval in Apr'19	Approval and launched in Jan'16
Coherus	Currently in Phase 3 trials	Currently in Phase 3 trials
Hanwha	Currently in Phase 3 trials	Currently in Phase 3 trials

Source: Companies, USFDA, EMA, Axis Capital

Exhibit 21: Biosimilars assets trading at discount (given recent correction)

Segments	P/E (x)	Dec'23E EPS (Current)	Value per share (Rs)	Equity value (Rs mn)
Generics	8	2.4	19	22,978
Biosimilar	29	11.2	325	3,90,776
Novel Molecules	-	-	-	-
Research Services	35	5.1	177	2,12,649
Unallocable	13	(4.7)	(62)	(73,889)
SoTP TP (Rs)	**33**	**13.9**	**460**	**5,52,514**
Axis TP	**33**	**13.9**	**460**	**5,52,117**
CMP (Rs)	377			
No. of shares (mn)	1,201			
Market Cap (Rs mn)	4,52,626			

	Equity value (Rs mn)	Eq. value (USD mn)
Biologics: Mkt Cap - Equity value of biz (ex-biologics)*	2,35,485	3,107
Standalone value of Biologics	3,90,776	5,155

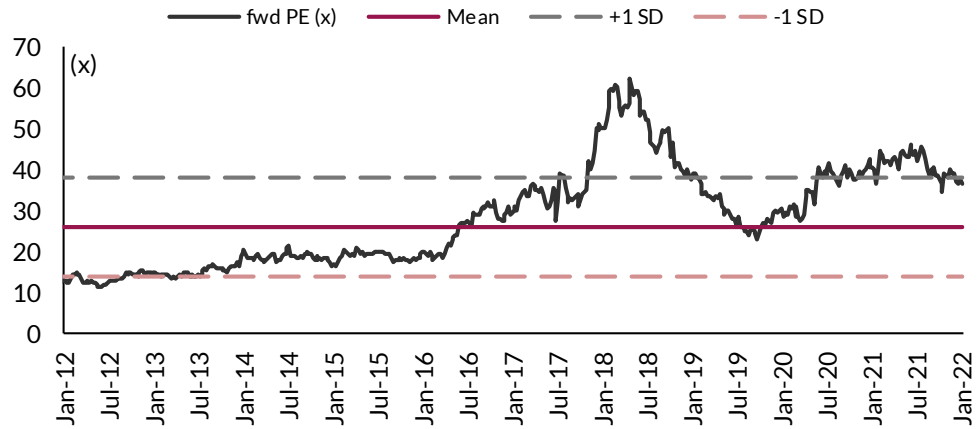
Source: Company, Axis Capital; Date as of 22 Jan 2022, *assuming 20% Hold Co discount in Research Services (Syngene)

Exhibit 22: Change in estimates

	FY22E			FY23E			FY24E		
Rs mn	**Previous**	**Revised**	**% change**	**Previous**	**Revised**	**% change**	**Previous**	**Revised**	**% change**
Sales	80,140	81,364	2	98,724	1,13,323	15	1,19,766	1,49,226	25
EBITDA	19,399	19,352	(0)	25,287	28,775	14	31,872	38,566	21
EBITDA margin %	24.2	23.8	-174bps	25.6	25.4	-86bps	26.6	25.8	-289bps
PAT	7,566	7,203	(5)	11,822	12,880	9	14,829	18,015	21
EPS (Rs)	6.3	6.0	(5)	9.8	10.7	9	12.4	15.0	21

Source: Axis Capital

Exhibit 23: 1-year forward P/E band



Source: Bloomberg

Financial Summary (Consolidated)

Profit & Loss (Rs mn)

Y/E March	FY20	FY21	FY22E	FY23E	FY24E
Net sales	63,005	71,058	81,364	1,13,323	1,49,226
Total operating income	63,005	71,058	81,364	1,13,323	1,49,226
Cost of goods sold	(19,895)	(22,085)	(26,280)	(36,377)	-
Gross profit	43,110	48,973	55,083	76,946	1,49,226
Gross margin (%)	68.4	68.9	67.7	67.9	100.0
Total operating expenses	(27,079)	(32,447)	(35,731)	(48,171)	(62,759)
EBITDA	16,031	16,526	19,352	28,775	86,468
EBITDA margin (%)	25.4	23.3	23.8	25.4	57.9
Depreciation	(5,522)	(7,151)	(8,122)	(8,645)	(10,122)
EBIT	10,509	9,375	11,230	20,130	76,346
Net interest	(649)	(577)	(754)	(728)	(671)
Other income	1,614	2,545	2,400	2,230	2,250
Profit before tax	11,474	11,343	12,876	21,632	77,925
Total taxation	(3,151)	(2,215)	(2,313)	(4,759)	(6,605)
Tax rate (%)	27.5	19.5	18.0	22.0	8.5
Profit after tax	8,323	9,128	10,563	16,873	71,320
Minorities	(1,227)	(1,057)	(2,410)	(3,205)	(4,572)
Profit/ Loss associate co(s)	(289)	(792)	(1,700)	(500)	(350)
Adjusted net profit	6,628	5,979	7,203	12,880	18,015
Adj. PAT margin (%)	10.5	8.4	8.9	11.4	12.1
Net non-recurring items	854	1,426	(701)	-	-
Reported net profit	7,482	7,405	6,502	12,880	18,015

Balance Sheet (Rs mn)

Y/E March	FY20	FY21	FY22E	FY23E	FY24E
Paid-up capital	6,000	6,000	6,003	6,003	6,003
Reserves & surplus	61,058	70,269	77,674	83,456	95,616
Net worth	67,058	76,269	83,677	89,459	1,01,619
Borrowing	19,797	44,811	43,915	41,719	39,633
Other non-current liabilities	5,363	15,356	15,389	15,460	15,546
Total liabilities	98,991	1,45,243	1,52,993	1,58,253	1,70,698
Gross fixed assets	90,087	1,00,448	1,20,448	1,36,448	1,51,448
Less: Depreciation	(31,659)	(38,342)	(46,464)	(55,109)	(65,230)
Net fixed assets	58,428	62,106	73,984	81,339	86,218
Add: Capital WIP	21,960	28,002	8,500	8,000	7,000
Total fixed assets	80,388	90,108	82,484	89,339	93,218
Total Investment	9,661	19,519	19,519	19,519	19,519
Inventory	14,359	18,666	23,053	28,331	37,307
Debtors	12,237	12,176	14,489	21,733	30,663
Cash & bank	9,986	20,154	25,600	17,217	13,101
Loans & advances	17,807	24,600	27,121	37,774	49,742
Current liabilities	45,447	39,980	39,274	55,661	72,851
Net current assets	8,942	35,616	50,990	49,394	57,961
Total assets	98,991	1,45,243	1,52,993	1,58,253	1,70,698

Source: Company, Axis Capital

Cash flow (Rs mn)

Y/E March	FY20	FY21	FY22E	FY23E	FY24E
Profit before tax	11,474	11,343	12,876	21,632	30,023
Depreciation & Amortisation	5,522	7,151	8,122	8,645	10,122
Chg in working capital	(1,651)	(4,238)	(9,891)	(15,802)	(23,128)
Cash flow from operations	**12,831**	**11,597**	**7,148**	**8,214**	**8,833**
Capital expenditure	(18,294)	(17,367)	(20,000)	(16,000)	(15,000)
Cash flow from investing	**(15,589)**	**(36,247)**	**(20,000)**	**(16,000)**	**(15,000)**
Equity raised/ (repaid)	-	-	-	-	-
Debt raised/ (repaid)	186	5,872	(896)	(2,196)	(2,086)
Dividend paid	(701)	-	(720)	(720)	(720)
Cash flow from financing	**3,876**	**25,640**	**(1,616)**	**(2,916)**	**(2,806)**
Net chg in cash	1,118	990	(14,469)	(10,702)	(8,973)

Key ratios

Y/E March	FY20	FY21	FY22E	FY23E	FY24E
OPERATIONAL					
FDEPS (Rs)	5.5	5.0	6.0	10.7	15.0
CEPS (Rs)	10.8	12.1	12.2	17.9	23.4
DPS (Rs)	0.5	-	0.6	0.6	0.6
Dividend payout ratio (%)	8.4	-	11.1	5.6	4.0
GROWTH					
Net sales (%)	14.3	12.8	14.5	39.3	31.7
EBITDA (%)	15.0	3.1	17.1	48.7	200.5
Adj net profit (%)	(8.4)	(9.8)	20.5	78.8	39.9
FDEPS (%)	(8.4)	(9.8)	20.4	78.8	39.9
PERFORMANCE					
RoE (%)	10.4	8.3	9.0	14.9	18.9
RoCE (%)	13.2	9.8	9.1	14.4	47.8
EFFICIENCY					
Asset turnover (x)	0.8	0.7	0.7	0.9	1.0
Sales/ total assets (x)	0.5	0.4	0.4	0.6	0.7
Working capital/ sales (x)	0.0	0.1	0.3	0.3	0.3
Receivable days	71	63	65	70	75
Inventory days	112	125	136	122	217
Payable days	103	101	85	94	166
FINANCIAL STABILITY					
Total debt/ equity (x)	0.3	0.6	0.5	0.4	0.4
Net debt/ equity (x)	0.0	0.2	0.1	0.1	0.1
Current ratio (x)	1.2	1.9	2.3	1.9	1.8
Interest cover (x)	16.2	16.2	14.9	27.7	113.8
VALUATION					
PE (x)	68.2	75.6	62.8	35.1	25.1
EV/ EBITDA (x)	28.7	28.7	24.2	16.5	5.6
EV/ Net sales (x)	7.3	6.7	5.8	4.2	3.2
PB (x)	6.7	5.9	5.4	5.1	4.4
Dividend yield (%)	0.1	-	0.2	0.2	0.2
Free cash flow yield (%)	(1.2)	(1.3)	(2.8)	(1.7)	(1.4)

Source: Company, Axis Capital

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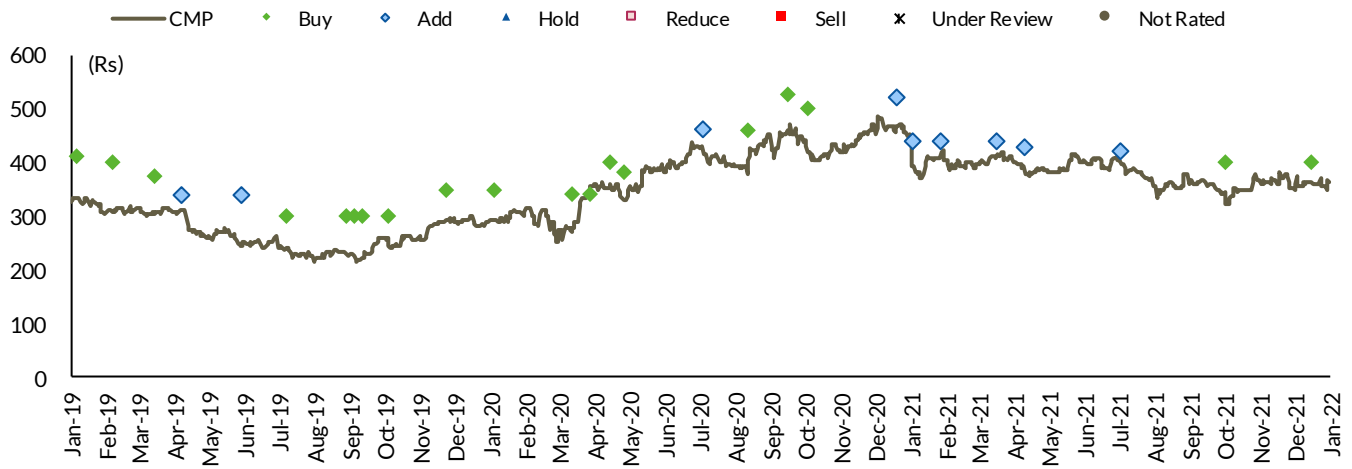
DEFINITION OF RATINGS	
Ratings	**Expected absolute returns over 12 months**
BUY	More than 15%
ADD	Between 5% to 15%
REDUCE	Between 5% to -10 %
SELL	More than -10%

Biocon (BION.BO, BIOS IN) Price and Recommendation History



Date	Target Price	Reco	Date	Target Price	Reco	Date	Target Price	Reco
25-Jan-19	410	Buy	01-Apr-20	340	Buy	29-Apr-21	430	Add
25-Feb-19	400	Buy	17-Apr-20	340	Buy	23-Jul-21	420	Add
03-Apr-19	375	Buy	04-May-20	400	Buy	22-Oct-21	400	Buy
26-Apr-19	340	Add	16-May-20	380	Buy	04-Jan-22	400	Buy
17-Jun-19	340	Add	24-Jul-20	460	Add			
26-Jul-19	300	Buy	01-Sep-20	460	Buy			
17-Sep-19	300	Buy	06-Oct-20	525	Buy			
23-Sep-19	300	Buy	23-Oct-20	500	Buy			
01-Oct-19	300	Buy	08-Jan-21	520	Add			
23-Oct-19	300	Buy	22-Jan-21	440	Add			
12-Dec-19	350	Buy	16-Feb-21	440	Add			
24-Jan-20	350	Buy	06-Apr-21	440	Add			

Source: Axis Capital