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Biocon Ltd

Weak quarter; Growth levers intact

Pharmaceuticals Sharekhan code: BIOCON Result Update

Summary

- We retain Buy on the stock of Biocon with an unchanged price target (PT) of Rs. 470.
- Q1FY22 was a weak quarter and results missed estimates. Performance was impacted due to 2nd wave of Covid in India.
- Growth outlook across all the business is strong with Biologics segment expected to be the key growth driver. In the near term interchangeability status for Semglee and approval for bAspart, if received could be the key triggers
- After a weak performance in Q1FY22, management has shared a promising growth outlook which augurs well from a growth perspective.

Q1FY2022 was a weak quarter for Biocon Limited (Biocon) and the results missed ours as well as the street's estimates. Lower than estimated performance of the generic segment, due to the impact of the second wave of COVID, which led to disruptions of operations at both Bangalore and Hyderabad plants. This coupled with pricing pressures in the US formulations segment adversely impacted the performance. The topline growth was muted at 4% YoY to Rs 1761 cr backed by a 10% and 41% y-o-y growth in the biosimiars and research services segment, while the generic segment revenues declined by 21.7% y-o-y. The operating margins at 22.1% declined by 229 bps y-o-y due to a 210 bps contraction in gross margins. Consequently, the adjusted PAT for the quarter at Rs 84 cr declined 43% y-o-y and missed estimates. Biocon sees a strong growth outlook across its business – biologics, generics and research services. Strengthening of the insulin and oncology franchise backed by new product approvals expected, geographic expansion and higher market penetrations would drive the growth for the biosimilars business. Also the company is working towards identifying the next set of biosimilars which could propel the growth for the company in the coming years. The generic business is also well placed to grow backed by expected commissioning of new facilities at Vizag, new product pipeline and focus on non-US markets. After a blip in the performance for Q1Fy22, the generic segment operations are expected to normalize in the coming quarters. Backed by new client wins and expected traction, the research services performance is expected to grow. Overall after a weak quarter, the management has shared a promising growth outlook for the rest of year and this augurs well from a growth perspective.

Key positives

- The biologics segment's revenue staged a growth of 10% y-o-y in challenging times.
- Entered 7 new markets with the biosimilars and received marketing authorization for bBevacizumab form TAG – Australia and MHRA (UK)
- * USFDA confirms pre-approval inspection of Malaysian plant for BLA for bAspart in Q3CY2021.

Key negatives

Generic segment revenues declined by 22% y-o-y impacted by the second wave of COVID in India

Our Call

Valuation: Retain Buy with an unchanged PT of Rs 470: Biocon has laid a strong platform for growth of the biosimilars in insulin and oncology franchise across its key markets. Expected approval for interchangeability status of Semglee and launch of Insulin Aspart would strengthen the insulin franchise further while the launch of bBevacizumab in US would fortify the presence in the Oncology space. This coupled with the efforts to increase penetration in existing markets and tap new markets would drive growth of Biosimilars. Further the performance of the generic segment is expected to normalize in the coming quarters after a weak show in Q1FY22 hit by 2nd wave of pandemic in India. Focus to grow the formulations business outside US, expected new product approvals, and new capacity commissioning at Vizag are the key drivers for generic business. Given the weak performance in Q1FY22 we have cut our estimates by 9%/5% for FY22E and FY23E respectively. At CMP, the stock is trading at P/E multiples of 41.8x/25.9x its FY2022E/FY2023E earnings. Further, a possible listing of its wholly owned subsidiary – Biocon Biologics – provides a significant value-unlocking opportunity to shareholders of Biocon. Given the strong growth outlook we retain Buy on the stock with an unchanged price target (PT) of Rs. 470.

Key Risks

A delay in product approvals or the negative outcome of facility inspection by the USFDA can affect future earnings prospects.

Valuation					Rs cr
Particulars	FY19	FY20	FY21	FY22E	FY23E
Net sales	5514.4	6300.5	7106.0	8946.4	11586.5
Operating Profit	1393.7	1603.1	1652.8	2304.2	3287.5
OPM (%)	25.3%	25.4%	23.3%	25.8%	28.4%
Adj. PAT	729.1	709.6	573.1	1142.5	1846.5
EPS (Rs)	6.1	5.9	4.8	9.5	15.4
PER (x)	65.5	67.3	83.3	41.8	25.9
EV/Ebidta (x)	34.8	31.0	30.5	21.3	14.6
P/BV (x)	7.8	7.1	6.3	5.5	4.6
ROCE (%)	9.9	9.3	6.3	9.6	13.7
RONW (%)	11.4	10.6	7.5	13.1	17.6

Source: Company; Sharekhan estimates



What has changed in 3R MATRIX			
	Old		New
RS		\leftrightarrow	
RQ		\leftrightarrow	
RV		\leftrightarrow	

Reco/View	Change
Reco: Buy	\leftrightarrow
CMP: Rs. 398	
Price Target: Rs. 470	\leftrightarrow
↑ Upgrade ↔ Maintain	↓ Downgrade

Company details

Market cap:	Rs. 47,802 cr
52-week high/low:	Rs. 488 /363
NSE volume: (No of shares)	43.4 lakh
BSE code:	532523
NSE code:	BIOCON
Free float: (No of shares)	47.2 cr

Shareholdina (%)

Promoters	60.7
FII	17.2
DII	7.1
Others	15.0

Price chart



Price performance

(%)	1m	3m	6m	12m
Absolute	0.2	0.2	1.1	-7.5
Relative to Sensex	-1.1	-10.5	-7.3	-46.4

Sharekhan Research, Bloomberg



Weak quarter; results miss estimates: Biocon reported a weak performance for the quarter with the results missing estimates. Disruptions due to the second wave of COVID impacted the generic segment performance, which led to the weak performance in Q1FY22. The topline growth was muted at 4% YoY to Rs 1761 cr backed by a 11% and 41% y-o-y growth in the biosimilars and research services segment, while the generic segment revenues declined by 21.7% y-o-y. The revenues were below estimates. The operating margins at 22.1% declined by 229 bps y-o-y due to 210 bps contraction in gross margins. The operating profit declined by 5.8% y-o-y to 389 cr and was below estimates. In Q1FY22, Biocon's share of loss for the quarter from associate – Biacara was higher at Rs 56 cr v/s Rs 4 cr in Q1FY21 and the depreciation was also up by 17% y-o-y for the quarter. Consequently, the adjusted PAT stood at Rs 84 Cr, declined by 43% y-o-yand missed estimates.

Growth outlook for the biosimilar business stays strong: The biosimilar segment's sales stood at Rs. 758 crore for the quarter, which is a growth of 10% y-o-y and 14% sequentially. During Q1FY22, the company expanded its footprint by entering 7 new geographies, while it also received approval from TGA Australia for bBevacizumab. Also the strong growth of COVID-led portfolio in India – Remndesivir and Italizumab added to the topline growth of the biosimilars business. bTrastuzumab reported a strong uptake in the other emerging markets such as Brazil and retained leadership position with a 39% market share, which is commendable. The other biosimilars - bTrastuzumab, bPeqfilgrastim and bGlargine saw a healthy growth in the US markets with steady increase in the market share. Going ahead in the near future USFDA's response to the interchangeability status for Insulin Glargine (Semglee) and inspection of the Malaysian plant (Scheduled in Q3CY21) are the key triggers for growth. Approval of Malaysian plant would enable the launch of the Insulin Aspart in the US markets, thus strengthening the insulin in the US markets. Further the fillings of the Aspart have been done considering the interchangeability aspect as well. Post the expected the approval for Semglee, Aspart would also stand a higher chance to gain interchangeability status. This points at huge growth potential. In addition to this, Biocon is also awaiting the USFDA inspection for its Bangalore Biologic plant, post which it it could launch Bevacizumab in the US markets, thus strengthening the oncology franchise further. Cumulatively, a comprehensive product portfolio in the biosimilars segment, a healthy new product pipeline, and geographic expansion would be key growth drivers, albeit in the long term.

Covid's second wave impacts Generic segment; business likely to normalize in coming quarters: Biocon's generics business constitutes the API as well as the formulations segments with APIs constituting around 80% of the segment's performance. The balance 20% is from the formulations segments. The segment's performance was severely impacted in Q1FY22 due to the disruptions on account of second wave of Covid. Consequently, the revenues from the segment declined by 22% y-o-y. In addition to this, Biocon's US formulations business is witnessing severe pricing pressures, but the company looks to mitigate the same through market share gains and new product launches. Going ahead, the management expects the generics business to normalize as it has completed the vaccinations drive for its employees and consequently the impact on the operations at the Hyderabad and Bangalore generic plants could be comparatively lower in case of a third wave of COVID. Otherwise, the management expects the business momentum to normalize in the coming quarters. Therefore, focus to grow the formulations business outside US, expected new product approvals, and new capacity commissioning at Vizag would be the key growth drivers for the generics segment.

Q1FY2022 Conference Call Highlights

Regulatory approvals for Biosimilars: Oncology drug bBevacizumab received marketing Authorization from the TGA, Australia. In addition to this, the company is planning to launch bBevacizumab in the European countries of Germany, Austria and Poland during Q2Fy22. Also the USFDA has confirmed the inspection for the Malaysian plant during Q3CY2021 for the company's BLA for insulin Aspart. Once approved could further strengthen Biocon's insulin franchise

Generics: During the quarter, the company launched two new formulations products in the US - Labetalol Hydrochloride tablets and Esomeprazole Magnesium Delayed-Release capsules. Labetalol Hydrochloride is used to treat high blood pressure and helps in prevention of cardiovascular complications while Esomeprazole Magnesium, a proton pump inhibitor, is indicated for treatment of gastroesophageal reflux diseases. Labetalol Hydrochloride's estimated market size in the US of $^{\sim}$ \$63 mn while that of Esomeprazole Magnesium is \$230 mn in the US. In addition to this Tacrolimus capsules launched in Q3FY2020 are gainint traction gradually.

Vizag Greenfield plant: After COVID-19 related delays, the work at the Greenfield immunosuppressant plant at Visakhapatnam has begun and the company expects the commissioning to happen in FY2022.

Biacara Therapeutocs Inc.: During the quarter the company reported a loss from the associate company – Biacara to the tune of Rs 56 cr and expects the losses to sustain for a few quarters tosustain given that the company is in a startup stage. Biocon expects significant read outs from Biacara in FY2022 and is also looking at venture funding to support the clinical development



Results Rs cr

Particulars	Q1FY22	Q1FY21	YoY (%)	Q4FY21	QoQ (%)
Total Income	1761.0	1694.0	4.0	1843.0	-4.4
Operating profit	389.0	413.0	-5.8	437.0	-11.0
Other income	47.0	18.0	161.1	45.0	4.4
EBIDTA	436.0	431.0	1.2	482.0	-9.5
Interest	20.0	13.0	53.8	34.0	-41.2
Depreciation	195.0	167.0	16.8	184.0	6.0
PBT	221.0	251.0	-12.0	264.0	-16.3
Adj. PAT	84.0	148.0	-43.2	81.0	3.7
Reported PAT	84.0	148.0	-43.2	254.0	-66.9
Margins			BPS		BPS
OPM (%)	22.1	24.4	-229 bps	23.7	-162 bps

Source: Company; Sharekhan Research



Outlook and Valuation

■ Sector view - Improving growth prospects

Indian pharmaceutical companies are better placed to harness opportunities and report healthy growth going ahead. They are among the most competitive globally and hold a sizeable market share in most developed as well as other markets. Moreover, other factors such as easing of pricing pressures (especially in the US generics market), rise in product approvals, plant resolutions by the USFDA, strong growth prospects in domestic markets, and emerging opportunities in the API space would be key growth drivers. This would be complemented by strong capabilities developed by Indian companies (leading to a shift towards complex molecules and biosimilars) and commissioning of expanded capacities by select players over the medium term. Collectively, this indicates a strong growth potential going ahead for Indian pharmaceutical companies.

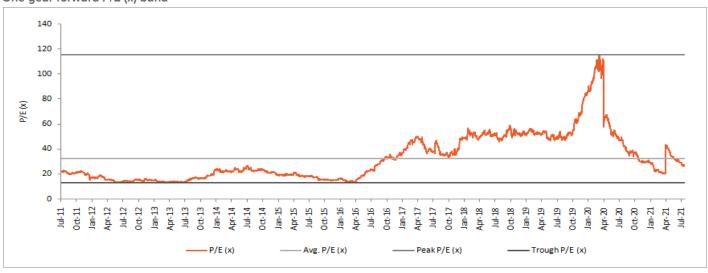
■ Company outlook - Strong outlook for Biologics business

Biocon is a leading company manufacturing biosimilars in India and one of the few global companies to receive approvals for its products across the regulated markets of – US, EU, Japan, and other developed markets. The company is expected to benefit substantially from the opportunities in the lucrative biosimilars space. A robust opportunity lies ahead in the biosimilars segment for Biocon, as some key global brands would lose patent exclusivity in the medium to long term. Price erosion in biosimilars is much lower than that in the other segments as of now and this works to the company's advantage. Scientific expertise in developing and manufacturing complex biosimilars together with commercialisation strength of partner companies would further strengthen Biocon's presence in globally in the biosimilars. Moreover, with the possible listing of Biocon Biologics, there exists a significant value unlocking opportunity going ahead. Though given the headwinds, the growth momentum in the near term could slow down, but growth levers over the long term stay intact.

■ Valuation - Retain Buy with an unchanged PT of Rs 470

Biocon has laid a strong platform for growth of the biosimilars in insulin and oncology franchise across its key markets. Expected approval for interchangeability status of Semglee and launch of Insulin Aspart would strengthen the insulin franchise further while the launch of b Bevacizumab in US would fortify the presence in the Oncology space. This coupled with the efforts to increase penetration in existing markets and tap new markets would drive growth of Biosimilars. Further the Generic segment performance is expected to normalize in the coming quarters after a weak show in Q1FY22 hit by the second wave of COVID. Focus to grow the formulations business outside US, expected new product approvals, and new capacity commissioning at Vizag are the key drivers for generic business. Given the weak performance in Q1FY22 we have cut our estimates by 9%/5% for FY22E and FY23E respectively. At its CMP, the stock is trading at P/E multiples of 41.8x/25.9x its FY2022E/FY2023E earnings. Further, a possible listing of its wholly owned subsidiary – Biocon Biologics – provides a significant value-unlocking opportunity to shareholders of Biocon. Given the strong growth outlook, we retain Buy on the stock with an unchanged price target (PT) of Rs. 470.

One-year forward P/E (x) band



Source: Sharekhan Research

Peer valuation

	CMP O/S		СМР		MCAP		P/E (x)		EV.	/EBITDA	(x)		RoE (%)	
Particulars	(Rs / Share)	Shares (Cr)	(Rs Cr)	FY21	FY21E	FY22E	FY21	FY21E	FY22E	FY21	FY21E	FY22E		
Aurobindo Pharma	964	58.6	56,467	22.8	14.7	12.2	10.3	8.3	6.4	12.8	16.2	16.6		
Sun Pharma	694	239.9	166,510	24.5	24.8	22.3	19.5	17.0	14.9	14.6	12.8	12.6		
Biocon	398	120.0	47,802	83.3	41.8	25.9	30.5	21.3	14.6	7.5	13.1	17.6		

Source: Company, Sharekhan Research



About company

Established in 1978, Bengaluru-based Biocon is India's premier biotechnology company. Biocon is now a fully integrated biopharma player with API manufacturing facilities, strong capabilities in biologics, innovative drug development, and a branded generics business in India. With over 25 years of expertise in fermentation technology, the company has built a strong presence in lucrative high-growth segments such as statins, immuno-suppressants, and anti-diabetes drugs. Biocon is among the few companies globally to have received approvals for its biosimilars from developed countries such as the US, EU, Australia, and Japan.

Investment theme

Biocon has one of the largest global biosimilars portfolios, spanning from recombinant human Insulin (rh-Insulin), insulin analogs, monoclonal antibodies, and other biologics for diabetes, oncology and immunology. Thus, Biocon has the early-mover advantage as global markets have begun to accept biosimilars and the role they are expected to play in increasing access to high-quality and yet affordable drugs and improve quality of life for patients around the world. The company is expected to benefit substantially from the opportunities in the lucrative biosimilars space, as some key global brands would lose patent exclusivity in the medium to long term. Scientific expertise in developing and manufacturing complex biosimilars together with commercialisation strength of partner companies would further strengthen Biocon's presence in globally in the biosimilars. Moreover, with the possible listing of Biocon Biologics, there exists a significant value unlocking opportunity going ahead.

Key Risks

Any delay in product approvals, change in regulatory landscape or negative outcome of the facility inspection by the USFDA can affect future earnings prospects.

Additional Data

Key management personnel

Ms. Kiran Mazumdar Shaw	Executive Chairperson Biocon Limited
Mr. Siddharth Mittal	CEO & Managing Director — Biocon Limited
Mr. Indraneel Sen	Chief Financial Officer

Source: Company

Top 10 shareholders

Sr. No.	Holder Name	Holding (%)
1	Glentec International	19.77
2	Life Insurance Corp of India	1.67
3	ICICI Prudential Asset Management	1.43
4	Jupiter Investment Management Group	1.32
5	NATIONAL WESTMINSTER	1.1
6	Aditya Birla Sun Life Asset Management	1.07
7	Standard Life Aberdeen PLC	1.06
8	Mirae Asset Large Cap fund	1.02
9	Societe Generale SA	1.01
10	Norges Bank	0.86

Source: Bloombera

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Understanding the Sharekhan 3R Matrix

Right Sector	
Positive	Strong industry fundamentals (favorable demand-supply scenario, consistent industry growth), increasing investments, higher entry barrier, and favorable government policies
Neutral	Stagnancy in the industry growth due to macro factors and lower incremental investments by Government/private companies
Negative	Unable to recover from low in the stable economic environment, adverse government policies affecting the business fundamentals and global challenges (currency headwinds and unfavorable policies implemented by global industrial institutions) and any significant increase in commodity prices affecting profitability.
Right Quality	
Positive	Sector leader, Strong management bandwidth, Strong financial track-record, Healthy Balance sheet/cash flows, differentiated product/service portfolio and Good corporate governance.
Neutral	Macro slowdown affecting near term growth profile, Untoward events such as natural calamities resulting in near term uncertainty, Company specific events such as factory shutdown, lack of positive triggers/events in near term, raw material price movement turning unfavourable
Negative	Weakening growth trend led by led by external/internal factors, reshuffling of key management personal, questionable corporate governance, high commodity prices/weak realisation environment resulting in margin pressure and detoriating balance sheet
Right Valuation	
Positive	Strong earnings growth expectation and improving return ratios but valuations are trading at discount to industry leaders/historical average multiples, Expansion in valuation multiple due to expected outperformance amongst its peers and Industry up-cycle with conducive business environment.
Neutral	Trading at par to historical valuations and having limited scope of expansion in valuation multiples.
Negative	Trading at premium valuations but earnings outlook are weak; Emergence of roadblocks such as corporate governance issue, adverse government policies and bleak global macro environment etc warranting for lower than historical valuation multiple.

Source: Sharekhan Research



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