

February 12, 2024

## Biological E. Limited: Ratings reaffirmed

### Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Long-term term loans	\$84.7 million	\$36.75 million	[ICRA]AA- (Stable); reaffirmed
Long-term term loans	-	200.00	[ICRA]AA- (Stable); reaffirmed
Long-term – fund-based facilities	1,500.00	1,050.00	[ICRA]AA- (Stable); reaffirmed
Short-term – non-fund based facilities	190.00	130.00	[ICRA]A1+; reaffirmed
Long-term/ Short-term – fund-based/ non-fund based facilities	399.87	955.00	[ICRA]AA-(Stable)/[ICRA]A1+; reaffirmed
Long-term/ Short-term – unallocated facilities	-	153.02	[ICRA]AA-(Stable)/[ICRA]A1+; reaffirmed
<b>Total</b>	<b>\$84.7 million Rs. 2,089.87 crore</b>	<b>\$36.75 million Rs. 2,488.02 crore</b>	

\*Instrument details are provided in Annexure I

### Rationale

The reaffirmation of the ratings of Biological E. Limited (BEL) factors in its position as a key player in the global vaccines market with strong development capabilities and a strong history of supplying vaccines to UNICEF<sup>1</sup>, PAHO<sup>2</sup> and the Government of India (GOI). BEL is pre-qualified by WHO<sup>3</sup> for manufacturing vaccines like LPV, MR, and TCV<sup>4</sup> and is among the five global pre-qualified suppliers of LPV and one of the pre-qualified suppliers for the MR vaccine.

The ratings also draw comfort from BEL's healthy financial profile characterised by healthy operating profit margins (OPM), adequate liquidity position and growing non-Covid vaccines business, supported by a strong order book position, new product launches and ramp-up of some existing products. BEL witnessed a 49% growth in its consolidated revenues to Rs. 3,820.3 crore in FY2023, supported by ~Rs. 2,120 crore sales of its Covid-19 vaccines (Corbevax and Janssen & Janssen (or J&J) vaccine) and ~23% growth in its other existing business verticals. Despite no sales of Covid-19 vaccines in H1 FY2024, BEL registered revenues of ~Rs. 1,117.4 crore, as per provisional financials, from its existing business verticals. While overall revenues are expected to witness degrowth in FY2024 due to lack of Covid-19 vaccines sales, revenues from the existing business verticals are likely to witness healthy growth of 40-45%. ICRA notes that while LPV used to generate more than 70% of BEL's vaccine sales till FY2019, the concentration reduced to ~46% in FY2023, supported by new product launches like MR and TCV. Additionally, the introduction of new vaccines like nOPV2 and PCV-14<sup>5</sup> is expected to further reduce the concentration and support revenue growth.

BEL's OPM improved to 36.6% in FY2023 from 24.5% in FY2022 supported by the margin accretive Covid-19 vaccines business. However, OPM returned to pre-Covid levels of 25.2% in H1 FY2024 in the absence of sales of Covid-19 vaccines. On account of the lower-than-expected offtake of Covid-19 vaccines, BEL has terminated its agreement with J&J. ICRA notes the exceptional loss of Rs. 314.1 crore recognised by BEL in FY2023 on account of impairment of Corbevax inventory worth Rs. 934.1 crore and write-off of J&J inventory worth Rs. 359.3 crore. However, it also recognised exceptional gains of Rs. 979.3 crore on account of waiver of reservation fee and advance received from J&J, leading to net exceptional loss of Rs. 314.1 crore. BEL had Covid-

<sup>1</sup> United Nations Children's Fund

<sup>2</sup> Pan American Health Organisation

<sup>3</sup> World Health Organisation

<sup>4</sup> LPV: Liquid Pentavalent Vaccine; MR: Measles and Rubella; TCV: Typhoid Conjugate Vaccine

<sup>5</sup> nOPV2: novel Oral Poliomyelitis (polio) Vaccine type 2; PCV-14: Pneumococcal Conjugate Vaccine 14 valent

19 vaccines-related inventory of around Rs. 2,100 crore as on September 30, 2023, and further requirement of provisioning of inventory in case of lower offtake remains a possibility and shall be a key monitorable.

The ratings also consider BEL's elevated working capital intensity (net working capital/ operating income (NWC/OI) of 61% in FY2023) due to high inventory levels along with increased receivables as of March 31, 2023. BEL has pending receivables of ~Rs. 1,000 crore from GOI on account of supply of Corbevax during FY2022 and FY2023, whose receipt continues to remain a monitorable. However, BEL also has customer advances of ~Rs. 1,000 crore from GOI pertaining to its initial order of Corbevax, which has only been partially fulfilled on account of lower than expected offtake. The higher working capital intensity has resulted in higher reliance on debt and some moderation in debt protection metrics. Nonetheless these are expected to strengthen over the medium term supported by the expected healthy revenue growth from new product launches, improvement in profitability on account of benefits of economies of scale/product-mix and reduction in debt levels supported by healthy accrual generation. The ratings also factor in BEL's high revenue dependence on institutional segments (UNICEF, GOI) wherein, revenues are contingent upon tender wins and there is limited pricing flexibility.

The Stable outlook reflects ICRA's opinion that BEL will continue to benefit from its established business position in the global vaccines market, healthy order book and strong product pipeline. This is expected to support healthy scale up of operations and accruals generation over the near to medium term, supporting the company's credit profile.

## Key rating drivers and their description

### Credit strengths

**Established player in global vaccines segment with strong development capabilities** – BEL has a strong history of supplying vaccines to agencies like UNICEF, PAHO and GOI. It is also pre-qualified for supplying seven vaccines to WHO, which includes LPV, MR and TCV. This provides BEL with a significant competitive advantage in the global vaccine segment, creating entry barriers for new entrants. Further, BEL ranks among the three global LPV suppliers who are fully backward integrated into all antigens. This has enabled BEL to ensure the quality of antigens and facilitated cost competitiveness on the back of large-scale manufacturing for LPV.

**Healthy order book, strong product pipeline and ramp up of new products leading to reduction in product concentration risk** – BEL had a strong order book of Rs. 2,665 crore as on October 31, 2023, which included orders from UNICEF, PAHO and GOI. Further, commercialisation of PCV-14 and NoPV2 is expected to support revenue growth over the medium term. BEL's strong developmental capabilities leading to new product launches over the past few years have supported the diversification of its revenues. This has resulted in reduction in revenue contribution from LPV to ~46% in FY2023, from more than 70% in FY2019. Recent launches and future product pipeline are expected to further increase the diversification of BEL's revenue. BEL's pipeline includes PCV-24, Inactivated Poliomyelitis Vaccine (IPV) and liquid hexavalent vaccine, among others. Successful and timely launch of these vaccines shall remain a key for BEL's long-term growth. BEL also received ANDA<sup>6</sup> approval for launch of Enoxaparin sodium in the US, which is expected to drive revenue growth of its speciality generic injectables (SGI) segment. Further efforts towards new product launches across SGI and domestic branded formulations (DBF) are expected to support the growth of the pharma segment over the medium to long term.

**Financial profile characterised by healthy margins and adequate liquidity position** – BEL reported strong revenue growth and expansion in its operating margins in FY2023, supported by significant contribution from Covid-19 vaccine sales. However, despite strong growth in the vaccine business (excluding Covid-19 related), BEL's revenue and accrual generation is expected to moderate in FY2024 due to minimal Covid-19 vaccine sales. Nonetheless, BEL's financial profile is expected to remain comfortable, supported by scale up of operations with ramp-up of vaccines (excluding Covid-19) business, healthy margins and adequate liquidity position. Moreover, higher internal accrual generation shall also reduce the reliance on external debt, strengthening the company's debt protection metrics.

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<sup>6</sup> Abbreviated new drug application

## Credit challenges

**High inventory levels leading to increase in working capital intensity and higher reliance on debt** – Working capital intensity of the company continues to remain elevated on account of high inventory levels of ~Rs. 2,991 crore as on September 30, 2023, which also includes sizeable Corbevax related inventory. This has resulted in elevated debt levels for BEL on account of higher working capital requirement. While BEL is exploring various avenues to liquidate this inventory and has also recently received Emergency Use Listing (EUL) by WHO for Corbevax, sales of Corbevax and any further requirement of provision of this inventory shall continue to remain a key monitorable.

**High revenue dependence on institutional segment leading to limited pricing flexibility** – The institutional segment, which includes GOI and agencies like UNICEF and PAHO, continues to generate most of BEL's consolidated vaccine segment revenues. Since these businesses are largely tender driven, it exposes the company to risks of revenue fluctuations on account of tender losses, and restricts its pricing flexibility. However, the risk is partly mitigated by BEL's strong manufacturing capabilities and history of supplying vaccines to these agencies.

**Exposure to foreign exchange and regulatory risks** – As is the case with its peers, BEL also remains exposed to regulatory risks associated with the manufacturers of pharmaceutical products, including towards obtaining approvals like US FDA, WHO GMP and CDSCO<sup>7</sup>.

## Liquidity position: Adequate

The liquidity position of BEL is **adequate**, supported by steady internal accruals, cash and liquid investments of ~Rs. 65 crore, as on September 30, 2023, and unutilised bank lines of Rs. 784 crore, as on as on November 30, 2023. BEL has repayment obligations of ~Rs. 266.4 crore in FY2024 and ~Rs. 292.4 crore in FY2025. Further, it is also expected to incur a capex of up to Rs. 260 crore in FY2024 and Rs. 340 crore in FY2025. BEL has also availed a term loan of Rs. 200 crore during the year, which is expected to be utilised for reimbursing/funding its capex. Overall internal accrual generation and available undrawn lines are expected to be more than sufficient to fund the debt servicing obligations and planned capex over FY2024-FY2025.

## Rating sensitivities

**Positive factors** – The ratings can be upgraded if BEL demonstrates healthy growth in revenues and accrual generation aided by further diversification of its product mix, leading to considerable deleveraging and strengthening of its liquidity position.

**Negative factors** – The ratings may be downgraded, if the company's revenues and profitability weaken on a sustained basis, leading to pressure on cash flows, and an increase in debt levels. Further, increase in the company's working capital intensity of operations may also lead to pressure on the ratings. Specific metric which could also trigger a ratings downgrade would be interest coverage ratio lower than 7.0 times on a sustained basis.

## Analytical approach

Analytical Approach	Comments
Applicable rating methodologies	<a href="#">Corporate Credit Rating Methodology</a> <a href="#">Rating Methodology for Pharmaceutical Industry</a>
Parent/Group support	Not applicable
Consolidation/Standalone	ICRA has considered the consolidated financials of BEL.

<sup>7</sup> United States Food and Drug Administration, World Health Organisation – Good manufacturing practices and Central Drugs Standard Control Organisation

## About the company

Incorporated as Biological Products Private Limited in 1953, BEL is among the first private sector companies in India to manufacture biological products. The company was founded by Late Dr. DVK Raju, along with Dr. GAN Raju. BEL is a privately held company, with the promoters and their associate firms holding a 100% stake in the company.

The company derives revenues from two business segments—vaccines and pharmaceuticals (comprising formulations). Its vaccines drive most of its revenues from export markets, with supplies primarily to the institutional segment. Its pharma division, meanwhile, has mature yet strong brands in the domestic cough and cold, anti-coagulants, anti-venom, and gastro-intestinal segments, and has also forayed into regulated markets with a complex generic and injectables portfolio.

Over the 70 years of its operations, the company has gained several credentials, including being the first company in India to manufacture certain critical vaccines (such as anti-tuberculosis and Heparin), the largest manufacturer of the TT<sup>8</sup> vaccine with over 80% market share globally, a leader in snake anti-venom in India, and the leading LPV supplier in the world.

## Key financial indicators - audited

BEL – consolidated	FY2022	FY2023
Operating income	2,556.9	3,820.3
PAT	337.2	953.1
OPBDIT/OI	24.5%	36.6%
PAT/OI	13.2%	24.9%
Total outside liabilities/Tangible net worth (times)	2.6	1.5
Total debt/OPBDIT (times)	2.8	1.4
Interest coverage (times)	9.6	7.9

*PAT: Profit after Tax; OPBDIT: Operating Profit before Depreciation, Interest, Taxes and Amortisation; All calculations are as per ICRA's methodology*

## Status of non-cooperation with previous CRA: Not applicable

## Any other information: None

<sup>8</sup> Tetanus Toxoid

## Rating history for past three years

Instrument	Type	Current rating (FY2024)			Chronology of rating history for the past 3 years			
		Amount Rated	Amount outstanding as of Dec 31, 2023	Date & Rating in FY2024	Date & Rating in FY2023		Date & Rating in FY2022	Date & Rating in FY2021
				February 12, 2024	Nov 02, 2022	Aug 30, 2022	May 27, 2021	Aug 11, 2020
1 Term loans	Long-term	36.75 USD million Rs. 200.00 crore	USD 36.75 million	[ICRA]AA-(Stable)	[ICRA]AA-(Stable)	[ICRA]AA-(Stable)	[ICRA]A+(Stable)	[ICRA] A (Negative)
2 Fund-based Limits	Long-term	Rs. 1,050.00 crore	--	[ICRA]AA-(Stable)	[ICRA]AA-(Stable)	[ICRA]AA-(Stable)	[ICRA]A+(Stable)	[ICRA] A (Negative)
3 Non-fund Based Limits	Long-term	--	--	--	--	--	[ICRA]A+(Stable)	[ICRA] A (Negative)
4 Non-fund Based Limits	Short term	Rs. 130.00 crore	--	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+	[ICRA] A1	[ICRA] A1
5 Fund-based/ Non-fund Based Limits	Long Term/ Short term	Rs. 955.00 crore	--	[ICRA]AA-(Stable)/ [ICRA]A1+	[ICRA]AA-(Stable)/ [ICRA]A1+	[ICRA]AA-(Stable)/ [ICRA]A1+	[ICRA]A+(Stable)/ [ICRA] A1	[ICRA] A (Negative)/ [ICRA] A1
6 Unallocated	Long Term/ Short term	Rs. 153.02 crore	--	[ICRA]AA-(Stable)/ [ICRA]A1+	--	[ICRA]AA-(Stable)/ [ICRA]A1+	[ICRA]A+(Stable)/ [ICRA] A1	[ICRA] A (Negative)/ [ICRA] A1

## Complexity level of the rated instruments

Instrument	Complexity Indicator
Long-term – Term Loans	Simple
Long-term- Fund-based Facilities	Simple
Short-term- Non-fund Based Facilities	Very Simple
Long-term / Short-term – fund-based/ non-fund-based Facilities	Simple
Unallocated limits	Not applicable

The Complexity Indicator refers to the ease with which the returns associated with the rated instrument could be estimated. It does not indicate the risk related to the timely payments on the instrument, which is rather indicated by the instrument's credit rating. It also does not indicate the complexity associated with analysing an entity's financial, business, industry risks or complexity related to the structural, transactional, or legal aspects. Details on the complexity levels of the instruments are available on ICRA's website: [Click Here](#)

#### Annexure I: Instrument details

ISIN No	Instrument Name	Date of Issuance	Coupon Rate	Maturity Date	Amount Rated	Current Rating and Outlook
NA	Term Loan - 1	FY2018	SOFR+3.25%	FY2026	26.75 USD million	[ICRA]AA- (Stable)
NA	Term Loan - 2	FY2024	8.5%	FY2025	10.00 USD million	[ICRA]AA- (Stable)
NA	Term Loan - 3	FY2024	Repo rate +1.8%	FY2026	Rs. 200.00 crore	[ICRA]AA- (Stable)
NA	Long-term- Fund-based Facilities	NA	NA	NA	Rs. 1,050.00 crore	[ICRA]AA- (Stable)
NA	Short-term- Non-fund Based Facilities	NA	NA	NA	Rs. 130.00 crore	[ICRA]A1+
NA	Long-term / Short-term – fund-based/ non-fund-based Facilities	NA	NA	NA	Rs. 955.00 crore	[ICRA]AA- (Stable)/ [ICRA]A1+
NA	Unallocated limits	NA	NA	NA	Rs. 153.02 crore	[ICRA]AA- (Stable)/ [ICRA]A1+

Source: Company

[Please click here to view details of lender-wise facilities rated by ICRA](#)

#### Annexure II: List of entities considered for consolidated analysis

Company Name	Ownership	Consolidation Approach
<b>SUBSIDIARIES</b>		
BE Vaccine PTE Limited	100.0%	Full Consolidation
BE Pharmaceuticals AG	100.0%	Full Consolidation
Biotech Medical Private Limited	100.0%	Full Consolidation
BE Investments Private Limited	100.0%	Full Consolidation
Vaxenic India Private Limited	100.0%	Full Consolidation
BE Pharmaceuticals Private Limited	100.0%	Full Consolidation
<b>STEP-DOWN SUBSIDIARIES</b>		
BE Life Sciences AG	100.0%	Full Consolidation
BE Life Sciences Inc.	100.0%	Full Consolidation
Bio E Holdings Inc.	100.0%	Full Consolidation
BE Pharmaceuticals Inc.	100.0%	Full Consolidation
BE Pharma BV	100.0%	Full Consolidation
BE Immuno Sciences Inc.	100.0%	Full Consolidation

Source: Company's annual report FY2023

## ANALYST CONTACTS

**Shamsher Dewan**

+91 124 4545 5328

[shamsherd@icraindia.com](mailto:shamsherd@icraindia.com)

**Kinjal Shah**

+91 22 6114 3442

[kinjal.shah@icraindia.com](mailto:kinjal.shah@icraindia.com)

**Deepak Jotwani**

+91 4545 870124

[deepak.jotwani@icraindia.com](mailto:deepak.jotwani@icraindia.com)

**Gaurav Kushwaha**

+91 22 61143465

[gaurav.kushwaha@icraindia.com](mailto:gaurav.kushwaha@icraindia.com)

## RELATIONSHIP CONTACT

**L. Shivakumar**

+91 22 6114 3406

[shivakumar@icraindia.com](mailto:shivakumar@icraindia.com)

## MEDIA AND PUBLIC RELATIONS CONTACT

**Ms. Naznin Prodhani**

Tel: +91 124 4545 860

[communications@icraindia.com](mailto:communications@icraindia.com)

## Helpline for business queries

+91-9354738909 (open Monday to Friday, from 9:30 am to 6 pm)

[info@icraindia.com](mailto:info@icraindia.com)

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## ICRA Limited



### Registered Office

B-710, Statesman House, 148, Barakhamba Road, New Delhi-110001  
Tel: +91 11 23357940-45



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