BioVersys

Clinical update

Phase III enrolment commences for BV100

Healthcare

17 April 2026

BioVersys has announced the first patient visit in its pivotal Phase III RIV-TARGET study of BV100 in hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by carbapenem-resistant *Acinetobacter baumannii* (CRAB). This is in line with prior guidance, with the company on track to report top-line Phase III data by end-2027, followed by regulatory filing in 2028. We view this as a notable execution milestone, signalling BV100's progression into a registrational setting and reinforcing the company's near- to mid-term investment case. Looking ahead, we see the next key catalyst as the initiation of the Phase IIb open-label RIV-CARE study (supported by funding from the Wellcome Trust fund), which is expected to commence in Q226 and should provide supportive real-world and safety data. Our valuation remains unchanged at CHF71.3/share.

Year end	Revenue (CHFm)	PBT (CHFm)	EPS (CHF)	DPS (CHF)	P/E (x)	Yield (%)
12/24	1.2	(18.7)	(5.62)	0.00	N/A	N/A
12/25	3.3	(21.8)	(3.89)	0.00	N/A	N/A
12/26e	4.6	(40.6)	(7.24)	0.00	N/A	N/A
12/27e	6.8	(35.3)	(6.29)	0.00	N/A	N/A

Note: PBT and diluted EPS are on a company reported basis.

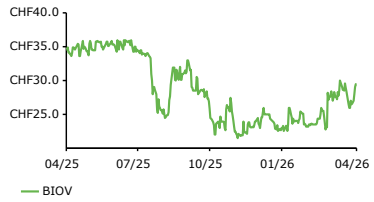
We see the commencement of patient enrolment as a strategically important step and expect focus to now intensify towards execution, including site activation, enrolment pace and interim safety monitoring. The Phase III RIV-TARGET will enrol c 300 patients across c 100 sites globally and compares BV100 (in combination with low-dose polymyxin B) against a colistin-based standard-of-care regimen. The primary endpoint is 28-day all-cause mortality, which we consider clinically meaningful and aligned with regulatory expectations in severe pneumonia settings. Enrolment is expected to complete by end-2027, with top-line data supporting potential regulatory filings in 2028. The design builds on earlier clinical evidence, where a Phase II study showed a marked reduction in mortality (28.5% at 28 days vs 60% for best available therapy), albeit in a small cohort (n=21).

Importantly, the Phase III trial is complemented by the RIV-CARE Phase IIb study (to commence in Q226), which should generate additional real-world and safety data, with an interim readout anticipated by end-2026. We view this as a supportive dataset, particularly in high-resistance settings, and relevant for shaping BV100's commercial positioning. We also note that BV100 has previously received Qualified Infectious Disease Product (QIDP) designation from the FDA, conferring benefits including Fast Track status, priority review and an additional five years of market exclusivity in the US. In our view, this should facilitate a relatively streamlined regulatory pathway for BV100, should clinical data continue to be positive.

CRAB has been classified as a priority-1 critical pathogen by the World Health Organization in the antimicrobial resistance (AMR) landscape, with limited treatment options and high mortality rates (up to 50% in severe infections). This highlights the significant unmet need and underpins the commercial opportunity for an effective therapy. BV100's differentiated mechanism (novel intravenous formulation of rifabutin enabling intracellular uptake in gram-negative bacteria) further strengthens its positioning versus legacy antibiotics.

Price	**CHF29.50**
Market cap	**CHF170m**
	CHF0.79/$
Net cash/(debt) at 31 December 2025	CHF60.8m
Shares in issue	5.8m
Free float	73.0%
Code	BIOV
Primary exchange	SWX
Secondary exchange	N/A

Share price performance



Business description

BioVersys is a multi-asset, clinical-stage biopharmaceutical company focused on the development of novel antibacterial products for serious life-threatening infections caused by multi-drug resistant bacteria.

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