EDISON

# BioVersys

Regulatory update

## Fast Track de-risks BV100's regulatory pathway

Healthcare

7 September 2026

**BioVersys has received US FDA Fast Track designation for BV100 in hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by carbapenem-resistant *Acinetobacter baumannii* (CRAB), providing incremental regulatory de-risking of its lead Phase III asset. The designation enables more frequent FDA interaction and eligibility for rolling review, potentially improving regulatory visibility and streamlining the filing process. BV100 is being evaluated in two complementary studies: the registrational, randomised Phase III RIV-TARGET and the open-label, South-East Asia-focused Phase IIb RIV-CARE. While RIV-TARGET is expected to readout in H227, we see the key nearer-term catalyst as the interim RIV-CARE data, expected by end-2026. RIV-CARE compares BV100 with locally selected best available therapy (potentially including Xacduro, the current US guideline-preferred sulbactam-based treatment) and should provide useful evidence on efficacy and differentiation in high-resistance settings.**

| 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 |

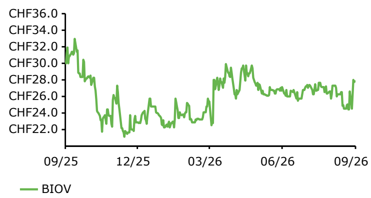
Note: PBT and diluted EPS are on a company reported basis.

CRAB remains one of the most challenging hospital pathogens to treat, predominantly affecting critically ill and immunocompromised patients and carrying mortality rates of up to 50%. BioVersys estimates there are more than 1m severe CRAB infections globally, with resistance particularly high in Asia. While the prior Phase II study produced a c 50% relative reduction in 28-day mortality versus best available therapy (BAT), the definitive test remains RIV-TARGET, which is enrolling c 300 patients across c 100 sites and compares BV100 plus low-dose polymyxin B against colistin plus high-dose ampicillin-sulbactam. The primary endpoint is 28-day all-cause mortality. We expect top-line data in H227, which we believe will represent the most important clinical and valuation inflection point for BioVersys. We currently assign BV100 a 60% probability of success in HABP/VABP and model global peak sales of c $700m, which is materially higher than the average peak sales for anti-infectives. We note that BV100 also holds the Qualified Infectious Drug Product designation from the FDA (which provides an additional five years of market exclusivity). The recent Fast Track designation therefore de-risks the regulatory pathway further, in our opinion.

In the nearer term, we see interim data from the c 100-patient RIV-CARE study, expected around end-2026, as the key potential re-rating catalyst. Unlike RIV-TARGET, which employs a fixed comparator, RIV-CARE benchmarks BV100-based regimens (including low-dose polymyxin B plus either ceftazidime/avibactam or cefiderocol) against locally selected BAT, which in principle could include newer agents such as Xacduro. We therefore see RIV-CARE as potentially informative from a commercial perspective, particularly as treatment guidelines evolve. Positive efficacy signals against a dynamic BAT arm would strengthen the case that BV100 can remain relevant alongside newer therapies. We maintain our estimates and valuation ahead of the company's H126 results on 9 September.

| | |
|---|---|
| **Price** | **CHF28.00** |
| **Market cap** | **CHF164m** |
| | CHF0.79/$ |
| Net cash at 31 December 2025 | CHF60.8m |
| Shares in issue | 5.9m |
| 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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