

BioVersys

Poised to unlock value in critical AMR

Initiation of coverage

Healthcare

10 February 2026

BioVersys is focused on developing novel drugs to address antimicrobial resistance (AMR). Lead asset BV100 is targeting carbapenem-resistant *Acinetobacter baumannii* (CRAB) infections, a significant unmet need (with a mortality rate of >50%). It has demonstrated compelling results in Phase II, and a registrational Phase III programme is due to commence in early 2026. Second asset alpibectir is being developed in a 50/50 partnership with GSK, aiming to address drug-resistant tuberculosis (TB); Phase II studies in distinct TB indications are due to conclude in 2027. The pipeline is powered by two proprietary discovery platforms, which have also generated preclinical candidates BV500 (partnered with Shionogi) and BV200. Current cash reserves provide a runway to H128, past key milestones, including the BV100 Phase III readout. We initiate coverage with a valuation of CHF361.1m or CHF61.9/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
12/25e	1.1	(29.3)	(5.44)	0.00	N/A	N/A
12/26e	1.6	(29.0)	(5.39)	0.00	N/A	N/A
12/27e	1.7	(30.5)	(5.66)	0.00	N/A	N/A

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

BV100: Key value driver entering Phase III

BV100 is an intravenous formulation of rifabutin developed to evade resistance mechanisms in severe gram-negative infections. BV100's initial focus is CRAB, a WHO priority-1 pathogen associated with high mortality and rising resistance to last-line antibiotics. In a Phase IIb trial in ventilator-associated bacterial pneumonia (VABP), it showed a 76% relative risk reduction in 14-day mortality. The Phase III trial is due to launch in early 2026, targeting VABP, hospital-acquired bacterial pneumonia and bloodstream infections. This will run in parallel to a Phase IIb real-world evidence (RWE) study, which should support the clinical utility of BV100 in broader populations. Interim readouts are expected from H226, representing near-term catalysts, before conclusion and potential FDA submission in 2027.

Alpibectir: Addressing critical TB needs

Alpibectir is an ethionamide (Eto) potentiator, targeting TB meningitis and drug-resistant pulmonary TB, where mortality remains high and treatment options limited by resistance, toxicity and long treatment durations. While this is a challenging indication to target, we believe the programme provides BioVersys with diversified exposure to a large global infectious disease market, supported by non-dilutive funding and a partnership with GSK, mitigating development risk while preserving meaningful long-term value potential. Data from Phase II programmes (expected in 2027) will be a key catalyst.

Valuation: CHF361.1m or CHF61.9 per share

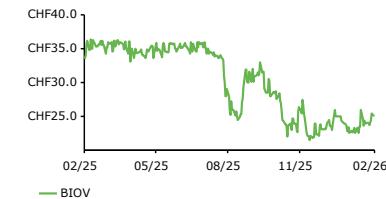
We value BioVersys at CHF361.1m or CHF61.9 per share, using a risk-adjusted net present value (rNPV) approach for its two clinical assets, BV100 and alpibectir, with the former driving the bulk of our valuation (75%).

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Price	CHF24.40
Market cap	CHF139m
	CHF0.79/\$
Estimated net cash at 31 December 2025	CHF63.4m
Shares in issue	5.8m
Free float	73.0%
Code	BIOV
Primary exchange	SWX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(5.2)	(1.3)	
52-week high/low	CHF37.0	CHF21.2	

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.

Next events

BV100 Phase III launch	Early 2026
Alpibectir Phase II launch(es)	H126
BV100 Phase IIb (RWE) interim report	H226

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BioVersys is a research client of Edison Investment Research Limited

Investment summary

Company description: Addressing AMR where current options fall short

BioVersys is a Switzerland-based clinical-stage biopharmaceutical company, developing novel antibacterial drugs to address serious, life-threatening, multi-drug-resistant infections. It successfully completed its IPO on the SIX Swiss Exchange in February 2025, raising CHF76.7m. The company's pipeline includes multiple assets, led by BV100, targeting CRAB infections. Following encouraging results in Phase II, BV100 is preparing to enter Phase III in early 2026 for VABP, hospital-acquired bacterial pneumonia (HABP) and bloodstream infections (BSIs); top-line results are expected in H227. Second asset alpibectir is being developed through a 50/50 partnership with GSK. It is involved in two Phase II programmes, focused on multi-drug-resistant pulmonary TB and TB meningitis, with trial conclusions also expected in 2027. Provided the data are supportive, management is pursuing a strategy involving a single pivotal Phase III trial in TB meningitis, aiming for this to be sufficient for a label in pulmonary TB as well; the feasibility of this approach will be determined by end-of-Phase II meetings with regulators. Preclinical candidates include BV500, partnered with Shionogi as part of a CHF484m biobuck deal, and BV200. These are expected to enter the clinic in H226 and 2027, respectively. All development candidates are derived from BioVersys's proprietary platforms (the ansamycin discovery and transcriptional regulator inhibitory compound (TRIC) platforms), adding scope to the company's value offering.

Financials: Relatively robust cash position post-IPO

BioVersys remains reliant on external funding as a pre-revenue, clinical-stage company; however, the February 2025 IPO materially strengthened the balance sheet, with CHF76.7m gross proceeds, lifting cash reserves to CHF92.1m at end-June 2025, with around CHF78m still on the books at end-FY25. With advanced stage clinical activities commencing in 2026 (including the Phase III pivotal trial for lead asset BV100), we expect R&D activities to intensify and remain elevated through FY26 and FY27. The balance sheet pressure would be partially mitigated by non-diluted R&D funding, including CHF14m from Wellcome Trust Funds for the Phase IIb study for BV100 (which we estimate will fund c 75% of the trial costs). Together with further non-dilutive support (Shionogi, GSK collaboration), we believe BioVersys's liquidity extends into H128, providing visibility through key clinical milestones and limiting near-term financing risk. Potential R&D support from BARDA for the BV100 Phase III programme should further de-risk its clinical plans.

Valuation: CHF361.1m or CHF61.9 per share

We value BioVersys at CHF361.1m (CHF61.9/share) using an rNPV methodology, based exclusively on its clinical-stage portfolio (BV100 and alpibectir), with preclinical assets excluded. Our equity value includes end-FY25 estimated net cash of CHF63.4m. We forecast cash flows through patent expiry, applying stage-adjusted probabilities of success (PoS) and a 12.5% discount rate. BV100 is the core value driver, contributing c 75% of the group's rNPV. With BV100 targeting CRAB-related HABP, VABP and BSIs, we model a 2028 launch with peak penetration of 25% (the US/EU) and 15% (China) and peak global sales of c US\$700m as our base case. We assign the programme a 50% PoS. Second asset alpibectir provides diversified TB exposure across TB meningitis and multi-drug-resistant TB (MDR-TB), with potential pivotal stage studies planned to commence in 2027. We assume tiered pricing, staggered launches (2031–32) and conservative success probabilities (30% for TB meningitis and 15% for MDR-TB) for this programme.

Sensitivities: Value creation rests on clinical execution in Phase III

BioVersys is subject to typical biotech risks, including trial setbacks, regulatory uncertainties and funding requirements. Key company-specific sensitivities are clinical and execution risks around BV100's registrational programme. Initial Phase II data have been encouraging, but confirming efficacy in Phase III will be crucial. For alpibectir, development is tied to GSK, meaning BioVersys lacks full control of the programme. The plan for a single pivotal trial is subject to successful Phase II data and interactions with regulators. Furthermore, should these candidates make it to market, their commercial uptake is contingent on the nature of the reimbursement environment and the competitive landscape, both of which are evolving. Given the time horizons associated with drug development, BioVersys is reliant on external financing, heightening its funding risks. It currently has a cash runway into H128, past multiple upcoming milestones. Non-dilutive sources of funding, such as inflows from Shionogi (partner for BV500), alleviate some of these sensitivities, but delays, challenges to obtaining capital or increased expenses may restrict operational headroom. Should further capital be raised through equity issuances, this may be dilutive for current shareholders.

Pipeline targets highly resistant and life-threatening indications

BioVersys's clinical development pipeline is powered by two proprietary platforms, generating drug candidates that aim to address the growing threat of AMR (Exhibit 1). By focusing on life-threatening infections characterised by having a high resistance to standard of care (SoC) treatments, BioVersys is strategically positioned to address urgent unmet medical needs in this disease area. The pipeline includes a diverse portfolio of differentiated drug candidates with first- and best-in-class potential, led by BV100 and alpibectir, both of which target pathogens designated as critical priorities by the World Health Organization (WHO) and the US Centers for Disease Control and Prevention.

Lead asset BV100 is a novel intravenous formulation of rifabutin, targeting CRAB, a priority-1 critical pathogen causing severe hospital-acquired infections with mortality rates as high as 50%. Following compelling Phase II results, BV100 is advancing into a global Phase III registrational programme in VABP, HABP and BSIs; this is due to commence patient dosing in early 2026. The programme is supported by a complementary Phase IIb study to gather RWE in populations resistant to the latest approved drugs, taking combination therapies. The majority of this study is funded by the Wellcome Trust, and it is expected to launch in early 2026.

Second asset alpibectir, being developed in partnership with GSK, is an ethionamide (Eto) potentiator for TB, including pulmonary TB and MDR-TB meningitis. Alpibectir has delivered proof-of-concept (PoC) data in Phase IIa in pulmonary TB (led by GSK), and is progressing to additional Phase II trials in both pulmonary TB and TB meningitis, with the latter (led by BioVersys) offering a potential route to expedited approval based on significant unmet medical need through the limited population antibacterial drug (LPAD) pathway. We note that BV100 and alpibectir both have Qualified Infectious Disease Product (QIDP) designations, giving five additional years of market exclusivity and eligibility for priority review. Alpibectir also has Orphan Drug Designation (ODD), offering tax credits for qualifying trials, user fee exemptions and up to seven years of exclusivity. These regulatory designations provide important development and commercial advantages. It also qualifies for a priority review voucher under FDA programmes supporting neglected diseases posing threats of public health emergencies, representing additional value to be unlocked.

The earlier-stage pipeline includes BV500, targeting non-tuberculous mycobacteria infections (for indications such as cystic fibrosis (CF) and chronic obstructive pulmonary disease (COPD)), and BV200, a combination of anti-virulence agents targeting *Staphylococcus aureus* infections (for indications such as atopic dermatitis). The development path for BV500 is subject to a research collaboration and exclusive licence option with Shionogi, with BioVersys eligible for CHF5m in upfront and near-term milestones, alongside development, regulatory and sales milestones worth up to CHF479m, plus royalties on future sales. These assets are derived from BioVersys's two proprietary technology platforms (the ansamycin discovery and TRIC platforms), which provide a sustainable engine for generating novel candidates with differentiated mechanisms to overcome resistance.

Exhibit 1: BioVersys's drug development pipeline

Program	Indication	R&D/Preclinical	Phase 1	Phase 2	Phase 3	Expected Key Catalyst	Commercial Rights	Potential
BV100 FDA QIDP	Hospital infections <i>Acinetobacter baumannii</i> (VABP/HABP & BSIs) advancedid.		<i>Phase 3 trial</i>			PPFV: H2 2025		Total Addressable Market ~\$4.8bn \$800m in Expected peak sales
Alpibectir FDA QIDP Orphan Drug FDA/EMA	Tuberculosis: • Multi-drug resistant • TB-Meningitis		<i>Pulmonary TB</i>			Pulmonary TB Phase 2a/b: H1 2025 TBM Phase 2b: Q1 2026		\$400m in Expected peak sales – 50% to BioVersys
BV200 Anti-virulence TRIC platform	Atopic dermatitis <i>Staphylococcus aureus</i> 		<i>TB meningitis</i>			IND Filing: H1 2027		
BV500 Ansamycin platform	CF and COPD: Non-tuberculous mycobacteria infection CF AMR Syndicate					License Option: 2027		up to CHF 479m in milestones, + tiered royalties on global sales
BV Discovery	Targets undisclosed							

Source: Company information. Note: Data as of September 06, 2024; VABP: Ventilator Associated Bacterial Pneumonia; HABP: Hospital Acquired Bacterial Pneumonia; BS: Blood Stream Infections; Eto: Ethionamide; FDA QIDP: FDA Qualified Infectious Disease Product Designation; 5 years additional market exclusivity (until 2045 for BV100) and the possibility of fast-track approval; MoA: Mechanism of Action; IND: Investigational New Drug; CF: Cystic Fibrosis; COPD: Chronic Obstructive Pulmonary Disease.

Source: BioVersys corporate presentation (Q126)

BV100: Lead asset designed to address severe hospital infections

The unmet need in CRAB infections

Acinetobacter baumannii is one of the most problematic pathogens, causing severe infections, predominantly in intensive care unit (ICU) settings. It is responsible for an estimated c 215k life-threatening infections annually across major markets (the US, Europe and Japan), and over 2.5m per year in China and emerging markets. Patients at highest risk include those requiring ventilation support, those with prolonged ICU stays, immunocompromised patients and those with recent surgical procedures or with indwelling medical devices. The pathogen thrives in hospital environments, as it is able to persist on the surfaces of medical equipment, facilitating transmission in critical care settings where vulnerable patients face the risk of potentially severe outcomes.

The emergence of carbapenem resistance has transformed *Acinetobacter baumannii* from a manageable pathogen in the [1980s](#) into a critical threat. Carbapenems (broad-spectrum antibiotic agents, part of the widely used beta-lactam class of antibiotics) have historically been used to treat such infections, but overall resistance now exceeds 50% globally. There appears to be substantial variation in resistance rates across geographies, with a 40–50% rate in the US, 60–70% in China and over 70% in Southern and Eastern Europe. This widespread resistance has effectively eliminated what was once a reliable treatment option, forcing clinicians to turn to increasingly toxic and/or less efficacious alternatives.

The current treatment landscape for CRAB infections is constrained. Polymyxins represent a primary last-resort therapy, despite historical concerns around toxicity (often associated with kidney and neurological side effects). Newer antibiotic agents, such as cefiderocol (Fetroja, [approved](#) in 2019) and sulbactam-durlobactam (Xacduro, [approved](#) in 2023), have expanded the treatment options, however resistance mechanisms continue to evolve, and many patients fail on these therapies. Combination regimens using multiple antibiotics are frequently employed, but evidence supporting specific combinations remains limited, and the approach may increase the risk of toxicity without proven benefit in efficacy.

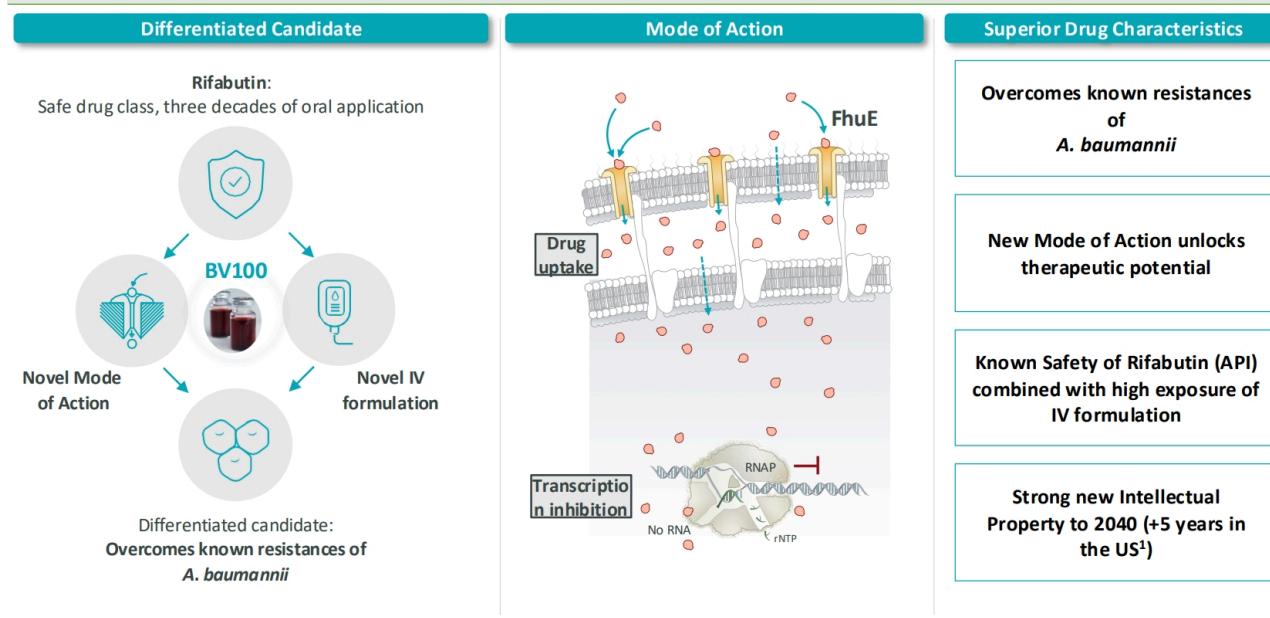
CRAB infections have a significant impact on clinical outcomes, with pneumonia and BSIs caused by CRAB carrying mortality rates of [c 50%](#), and patients averaging 19-day stays in ICU settings at an estimated cost of \$200k per patient in the US. The combination of high mortality, prolonged hospitalisation, substantial healthcare costs and increasing resistance to even last-resort therapies creates an urgent need for novel treatments with differentiated mechanisms. Further, the WHO's [designation](#) of CRAB as a priority 1-critical pathogen reflects this unmet medical need, highlighting the necessity for improved options.

BV100 mechanism and rationale

BioVersys's potential solution to address the unmet need in CRAB infections leverages the novel mechanism of action of rifabutin, a well-characterised active pharmaceutical ingredient with over three decades of application as an oral medication. Rifabutin works by inhibiting the bacterial RNA polymerase B, preventing bacterial replication. While the safety of rifabutin is well established, oral administration has previously failed to achieve sufficient exposure for activity against *Acinetobacter baumannii*. BioVersys's innovation lies in developing the first intravenous formulation of rifabutin, enabling the consistent bloodstream levels required for robust efficacy against this pathogen.

Stemming from BioVersys's ansamycin discovery platform, BV100 is differentiated from conventional antibiotic agents due to its novel uptake mechanism (Exhibit 2). Unlike many antibiotics that often rely on passive diffusion, rifabutin is specifically recognised by FhuE (an outer membrane receptor of *Acinetobacter baumannii*), such that upon rifabutin binding, FhuE promotes its active transport into the bacterial cell. This can be thought of as a 'Trojan horse' strategy that achieves high intracellular drug concentrations and has the potential to evade the resistance mechanisms that have rendered other antibiotics ineffective. This receptor-mediated uptake represents, to our knowledge, a first-in-class mechanism for activity against *Acinetobacter baumannii*.

Preclinical research has been extensive, with *in vitro* studies showing potency against carbapenem-resistant and multi-drug-resistant *Acinetobacter baumannii* isolates, with animal models further validating its potential.

Exhibit 2: BV100 mechanism of action

Source: Company information. Note: MoA: Mode of Action; FhuE: Membrane protein acting as a receptor; MDR: Multidrug resistant; SoC: Standard of Care. 1. Due to QIDP designation by FDA received in May 2019.
Source: BioVersys corporate presentation (Q126)

Phase I studies establish favourable profile across key parameters

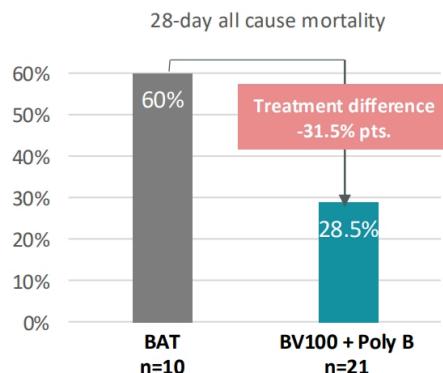
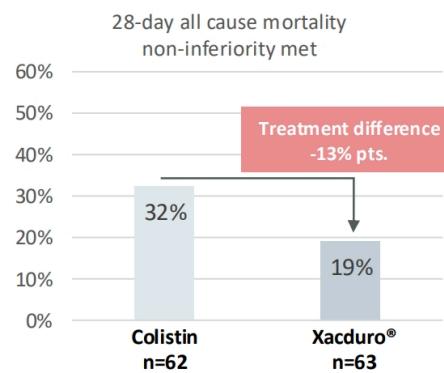
BV100 has completed a comprehensive Phase I programme comprising [multiple](#) studies that enrolled a total of 236 participants, evaluating safety, tolerability, pharmacokinetics and potential drug-drug interactions (DDIs). The programme included single- and multiple-ascending dose studies, two separate DDI assessments, renal and hepatic impairment investigations, alongside a bronchoalveolar study to measure lung penetration. Encouragingly, across this clinical research, BV100 was consistently well tolerated, with the only observed adverse events considered typical of the study populations, and no safety concerns attributable to the drug candidate.

Several outcomes from the Phase I programme provide advantages, with the target population of BV100 being critically ill ICU patients. For example, the renal and hepatic impairment studies showed that no dose adjustments were required for patients with compromised kidney or liver function. This is an important consideration, since organ dysfunction is common in septic ICU patients, and dose modifications have the potential to complicate how they are managed. Further, the DDI studies revealed only very low potential for clinically significant interactions, despite the complex treatment regimens typical of ICU settings. In addition, the bronchoalveolar study provided compelling data to suggest that BV100 achieves very good lung penetration, directly supporting its application in pneumonia-associated conditions. Finally, the pharmacokinetic profile of the candidate supports twice-daily dosing, which is considered practical for administration in ICUs, aligning with standard antibiotic dosing regimens.

Phase II VABP trial delivers compelling efficacy signals

BioVersys's Phase II trial ([NCT05685615](#)) in VABP ran from H123 through to [H224](#), based in Europe. It enrolled 31 patients in Part A (21 receiving BV100 at one of two dose levels plus a low-dose polymyxin, and 10 in the control arm receiving the best available therapy (BAT)) and eight patients in Part B (all of whom had treatment-refractory conditions or polymyxin-resistant infections, receiving BV100 plus BAT). The primary endpoint assessed pharmacokinetics, while key secondary endpoints included 14-day and 28-day all-cause mortality (ACM), test of cure/clinical cure rates, ventilator-free days and time spent in the ICU.

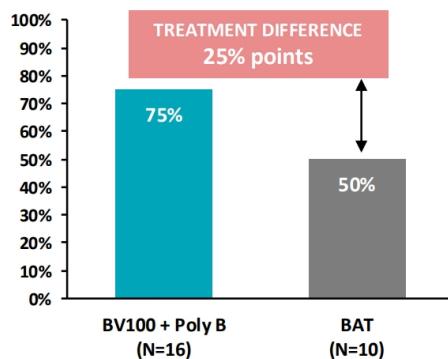
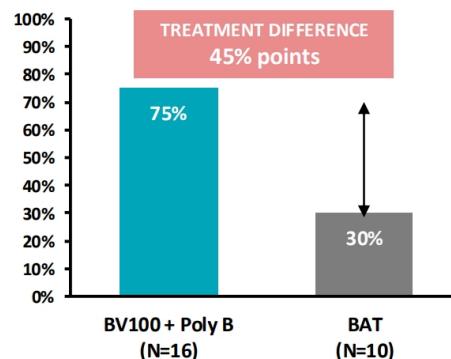
In our view, the [efficacy results](#) (from Part A only, as Part B did not have a control arm) were encouraging, with BV100 demonstrating a clear survival benefit (Exhibit 3). The 14-day ACM in the combined BV100 arms was 9.5%, compared to 40.0% in the control arm, representing a 30.5% absolute benefit, and a 76.3% relative risk reduction. At 28 days, mortality remained notably lower at 28.5%, compared to 60.0% in the control arm, representing a 31.5% absolute benefit and 52.5% relative risk reduction.

Exhibit 3: BV100 demonstrated clear survival benefit in Phase II
BV 100 – Phase 2 VABP data

Xacduro® – Phase 3 data for point of reference only


- ✓ Part B (Pol B resistant patients): 6 patients in total, 4 microbiologically cured and 4 survived
- ✓ Part A: Identified 8 patients with XacDuro or Cefiderocol resistance: 5 on BV100, all survived; 3 in BAT arm, all 3 died.

Source: BioVersys corporate presentation (Q126)

Additional efficacy measures were encouraging, with favourable microbiological responses (eradication or presumed eradication of infection) achieved in 75% of BV100-treated patients, compared to 50% in the control arm, and clinical cure rates (defined as test of cure being 7 ± 2 days after end of treatment) at 75% with BV100, compared to 30% with the control (Exhibit 4). We believe that these efficacy signals are particularly positive given the disease severity of the patient population.

Exhibit 4: BV100 showed improved responses in Phase II
BV100 Part A versus BAT: Carbapenem-resistant micro-ITT¹
Microbiological favorable response² at ToC

Clinical Cure³ at ToC


¹Carbapenem-resistant *Acinetobacter* m-ITT population (Primary efficacy analysis population). ²Microbiological favorable response = eradication or presumed eradication; ³Clinical cure defined as at ToC (7 ± 2 days after End of Treatment). ⁴ Reference FDA briefing document 04.17.23.

BAT = Best Available Therapy; ToC = Test of Cure; ITT = Intend to Treat; EOT = End of Treatment.

Source: BioVersys corporate presentation (Q126)

While the Part B outcomes came from a small population, the data provided PoC that BV100 has the potential to achieve clinical benefit in patients who have failed prior therapy, and patients suffering from totally drug-resistant infections. Of the six evaluable patients at test of cure, four were considered clinically cured. Seven patients were evaluable for survival at the end of the study, with four having survived (out of the eight), despite having infections with no remaining treatment options at the outset of the study. None of the patient deaths were directly related to CRAB infection, or BV100 treatment.

Contextualising these results against alternative treatment options highlights the potential for BV100 to offer differentiation. Xacduro demonstrated a 13% absolute increase in mortality benefit, compared to colistin (also known as polymyxin E) in its Phase III trial, while showing improvements of 21.6% and 26.0% in microbiological response and clinical cure, respectively. BV100's Phase II signals exceed these benchmarks, suggesting potential best-in-class positioning, although we caution against direct read-across, and note that this is a single Phase II study involving a smaller study population, based only in Europe. Importantly, the safety profile also remained favourable throughout the Phase II trial, with no treatment-related serious adverse events or deaths attributed to BV100. Adverse events were

consistent with those expected in critically ill ICU patients, and the tolerability profile supports the combination approach with a low-dose polymyxin.

Key focus: Phase III programme with complementing Phase IIb study

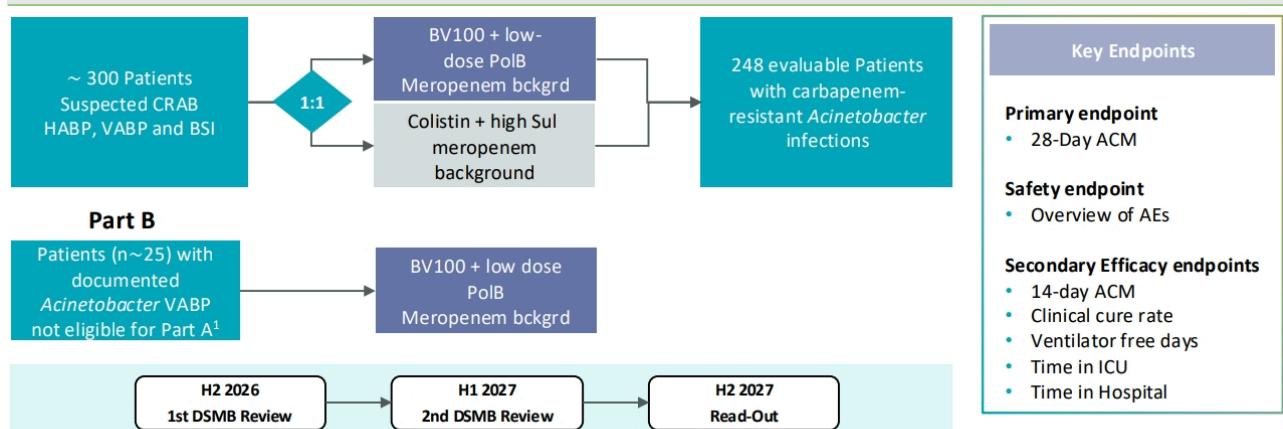
Having completed the first country regulatory submission in [December 2025](#), BioVersys is preparing to launch a global Phase III non-inferiority trial in early 2026 to support regulatory submissions in the US, Europe and China. The Phase III study will recruit c 300 patients with suspected CRAB infections in HABP, VABP or BSIs (note that Xacduro was also tested in VABP in Phase II, before being tested in HABP, VABP and BSIs in Phase III), targeting c 250 evaluable patients to be enrolled (after accounting for a modest dropout rate based on Phase II experience). Participants will be randomised 1:1 to receive either BV100 plus low-dose polymyxin B with meropenem background therapy, or a colistin-based control regimen with high-dose sulbactam and meropenem background therapy. The trial design is sponsor-blinded, rather than fully double-blinded, reflecting practical considerations of ICU settings where treatment administration requires flexibility. The primary endpoint is ACM at 28 days, representing an objective outcome measure favoured by the FDA, eliminating any subjectivity in efficacy measures. Secondary endpoints include 14-day mortality, clinical cure rates, ventilator-free days, time spent in the ICU and in hospital, alongside comprehensive safety assessments (Exhibit 5).

The company is aligned with regulators through successful end-of-Phase II meetings with the FDA and analogous discussions with the EMA and China's NMPA. Importantly, the trial has been designed to satisfy all three regulatory authorities simultaneously, providing a potentially streamlined path to global approval. We highlight that BV100 benefits from QIDP designation, granted in 2019 for HABP, VABP and BSI, which provides priority review and five additional years of US market exclusivity (provided it is successful with regulatory approval), extending protection to 2045, beyond the 2040 main patent expiry. The trial is due to commence in early 2026, representing a significant near-term milestone.

In parallel, BioVersys is planning a complementary Phase IIb open-label study to generate RWE demonstrating the clinical utility of BV100 in populations that are taking various combination therapies with high drug resistance levels. This RWE study has been designed to recruit c 115 patients, targeting c 90 evaluable patients among them. We understand that this will mainly be based across South-East Asian countries with elevated pan-drug-resistant rates. Participants will be randomised 2:1 to receive one of two BV100-based combinations, or BAT. Critically, the study is specifically targeting patients infected with *Acinetobacter baumannii* strains that are resistant to the newest approved antibiotics, including Xacduro and Fetroja (populations where treatment options have been exhausted). The trial will also explore activity in ventriculitis and meningitis, potentially supporting future label expansions, although we await more details on this front.

The launch of this Phase IIb study is also expected in early 2026, and is being supported by the [Wellcome-funded](#) ADVANCE-ID network, though BioVersys will be operating the study. Interim data are expected in late H226. While traditionally such differentiation studies are conducted post-approval (Phase IV), BioVersys has advanced this research to generate health economics data to support reimbursement negotiations, and to provide evidence for antimicrobial stewardship committees that determine formulary inclusion. It is our opinion that the interim readout from this Phase IIb study could be a significant catalyst that may facilitate partnership discussions, as it will provide initial signals from this global registration programme.

Exhibit 5: Design of the global registration programme for BV100



1. Treatment failure, VABP due to colistin-resistant *Acinetobacter* or patients with known intolerance to colistin.

Source: BioVersys corporate presentation (Q126)

Market opportunity, commercial strategy and potential indication expansion

The potential market for BV100 is substantial, growing in line with rising carbapenem-resistance rates. The total addressable market was valued at c \$3.8bn in 2022 ([according](#) to Grand View Research) and estimated to reach \$5.2bn by 2030, corresponding to a compound annual growth rate of 4.8%. Should BioVersys's clinical data continue to be supportive, we believe there could be a sizeable opportunity in this space. The company's commercial strategy envisions targeted key account management (selecting specific groups to work with where the need/opportunity is greatest). It is evaluating self-commercialisation in the US and European markets, though this will depend on reimbursement reform progress. The UK already has an annual access fee model for new antibiotics (decoupled from volume), and similar reforms are anticipated in Europe from 2026. If broader reimbursement reforms are implemented, BioVersys may self-commercialise in the US, a strategy becoming increasingly viable when revenues are decoupled from volume. Should such reforms not come to fruition, we expect management to seek regional partners.

For China, BioVersys is seeking a commercial partner with established hospital relationships and regulatory expertise. As part of its strategy for China, the company has established a wholly-owned Chinese subsidiary to support local development, and has a Chinese Phase I bridging trial ongoing for BV100 (a regulatory requirement for including China in the Phase III programme). This study, [initiated](#) in November 2025 and expected to conclude in 2026, will assess the safety and pharmacokinetics of BV100 in a Chinese population, allowing for simultaneous regulatory submissions to China's NMPA, alongside the FDA and EMA. Ultimately, the integrated development approach positions BV100 for synchronised approvals across major geographies.

The competitive landscape for CRAB infection treatments includes both approved products and clinical-stage drug candidates; however, as discussed above, BV100 has shown preliminary signs of differentiation compared to Xacduro (which we note does not currently have approval in Europe or Japan), though we caution against direct read-across between clinical trials. Clinical-stage potential competitors include Roche's zosurabipalpin (moving to Phase III without Phase II data disclosure), various polymyxin analogues and β -lactam/ β -lactamase inhibitor combinations, though none have demonstrated comparable efficacy signals to date, to our knowledge. Overall, we believe that the novel mechanism of action of BV100 offers differentiation from existing resistance mechanisms affecting other classes (Exhibit 6).

Beyond the initial target indications, we note that BV100 offers expansion potential to additional CRAB infections. The Phase IIb RWE study is exploring activity in broader indications, potentially representing incremental opportunities that may be pursued in post-approval studies or expanded development efforts. Should BioVersys pursue such opportunities, it could add upside optionality as the programmes advance, especially since the asset remains wholly owned, providing maximum flexibility as it advances through late-stage clinical development.

Exhibit 6: Differentiated benefits of BV100 versus the competitive landscape

Company	Product	Development stage	Risk of pre-existing resistance	Mode of action	Approved underlying API with good safety	Synergy with SoC
BioVersys	BV100	Phase III-ready	Low-risk	New	Yes	Good
Generic	Polymyxin / Colistin (SoC)	Marketed	High-risk	Established	Approved, but some toxicity concerns	(Marketed)
Innoviva / Entasis Therapeutics	Xacduro	Marketed	Medium-risk	Established	Yes	(Marketed)
Roche	Zosurabipalpin	Moving to Phase III with no Phase II data	Tbd	New	No	Poor
Arta Bio	MEM-ANT3310	Phase I completed	Medium-risk	Established	No	Tbd
Polymyxin analogues						
Omnix Medical	OMN6	Phase Ib/IIa ongoing	Medium-risk	New	No	Tbd
MicuRx Pharmaceuticals	MRX-8	Phase I completed	Medium-risk	Established	No	Poor
Brii Biosciences	Soralimixin	Phase I completed	Medium-risk	Established	No	Poor
<i>Sper Therapeutics (discontinued)</i>	SPR 206	Discontinued	Medium-risk	Established	No	Poor

Source: Company resources; Edison Investment Research

Alpibectir to tackle TB, in partnership with GSK

TB represents a persistent global threat

TB remains a leading [cause](#) of death from infectious diseases, with an [estimated](#) c 10.7m cases and c 1.2m deaths each year worldwide. The burden is disproportionately concentrated in low- and middle-income countries, with India, China, the Russian Federation and the Philippines accounting for over half of cases. However, drug-resistant TB represents

a growing challenge across all geographies, including high-income nations, where outbreaks create persistent public health concerns. The emergence of resistance has transformed TB from a curable disease into an increasingly challenging medical issue, with MDR-TB carrying high mortality rates (as high as 50% in conditions like TB meningitis).

SoC treatment for drug-susceptible TB typically includes a combination of multiple antibiotics requiring daily administration for a number of months, with poor adherence undermining cure rates. Drug resistance can exacerbate these challenges, with resistance to drugs such as isoniazid and Eto (typical anti-TB agents) now exceeding 30% in certain regions, such as China. These drugs are also associated with undesirable side effects, with Eto having dose-limiting gastrointestinal and hepatic toxicity and tolerability issues restricting its use. Treatment failure rates in TB are considered unacceptably high, leaving many patients with significantly limited treatment options.

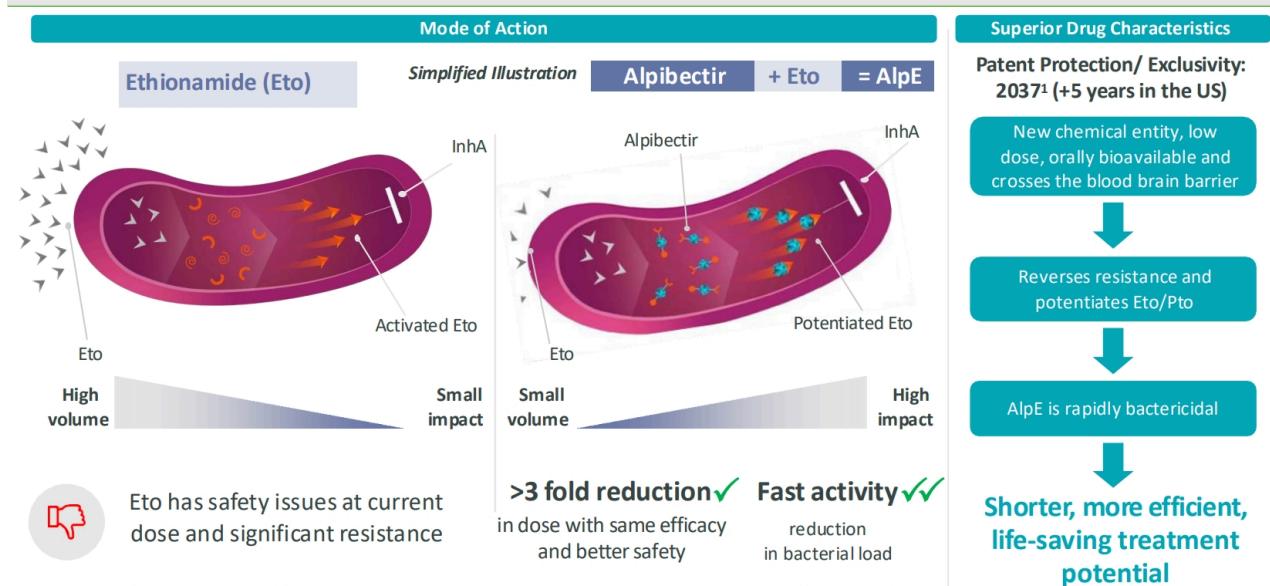
Alpibectir mechanism offers a first-in-class approach

Alpibectir represents the most advanced small molecule in the clinic targeting bacterial transcriptional regulators for TB treatment, to our knowledge, having been developed through BioVersys's TRIC platform. The candidate offers a first-in-class mechanism of action focused on potentiating Eto (Exhibit 7). The innovation lies in the ability of alpibectir to activate an alternative pathway for Eto activation within mycobacteria. Eto is a pro-drug, meaning that conventionally it requires conversion to its active form within the body by an enzyme (EthA) before it inhibits its target (InhA). Importantly, resistance can stem from mutations in EthA, preventing its ability to activate Eto. Alpibectir circumvents this resistance mechanism by activating an alternative pathway (MymA/VirS), converting Eto to its active form, restoring antibacterial activity against Eto-resistant strains, potentiating the efficacy of Eto. This potentiation enables a threefold reduction in Eto dosing while maintaining or improving its potency, directly addressing tolerability issues that have restricted its use. The alpibectir-Eto combination (termed AlpE) demonstrates rapid bactericidal effects, with some research showing similar activity to an isoniazid control.

Critically for TB meningitis, both alpibectir and Eto penetrate the blood-brain barrier. This characteristic, alongside the rapid bactericidal activity and ability to overcome resistance, positions AlpE as uniquely suited for TB meningitis, where existing treatments often fail due to inadequate exposure in the brain or resistance. We understand that this will be BioVersys's initial primary target indication for alpibectir.

In a Phase I study involving 80 healthy participants, alpibectir was found to be safe and well tolerated, with favourable pharmacokinetics. Following this, alpibectir was investigated (by partner GSK) in a Phase IIa trial in combination with Eto, which delivered promising results in 2024 (discussed in further detail below).

Exhibit 7: Alpibectir mechanism of action



Source: BioVersys corporate presentation (Q126)

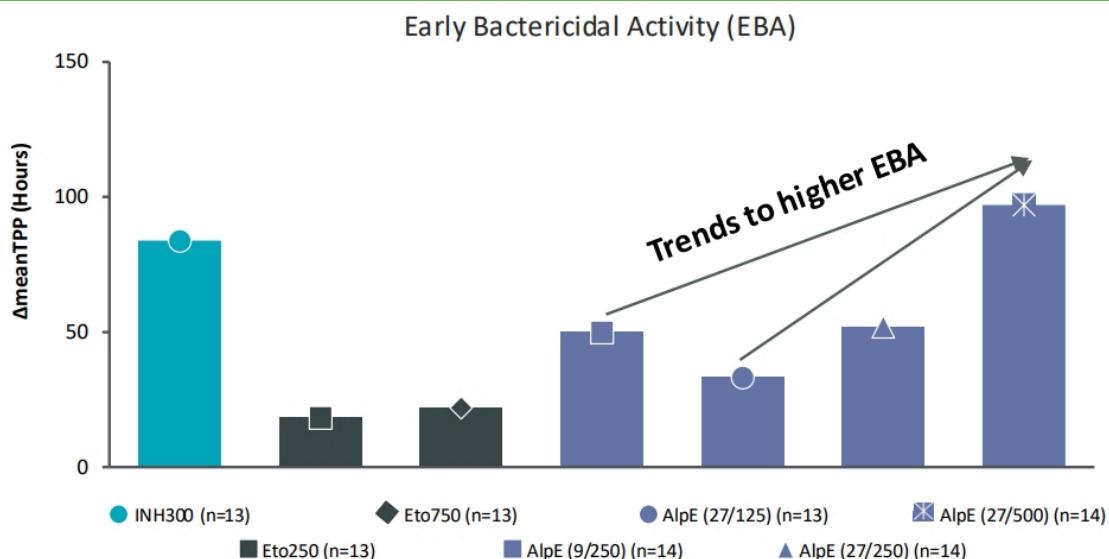
Phase II in pulmonary TB, led by GSK

Alpibectir has been developed in collaboration with GSK since its early stages, with GSK's involvement providing external validation of the candidate's potential, in our view. GSK's decision to invest equity in BioVersys's 2024 Series C financing round further underscores GSK's confidence in the programme (GSK holds a c 4.35% stake in the company).

Under the partnership structure, development costs and future net revenues are shared 50/50. Overall, management estimates that c 70% of total programme costs are covered through non-dilutive sources of capital, from institutions (either directly or through related organisations) such as the Wellcome Trust, the European Union and the Bill & Melinda Gates Foundation, with the remaining costs split between GSK and BioVersys. We note that while this structure provides BioVersys with access to GSK's extensive TB capabilities and resources, it also means GSK controls key development decisions. Therefore, BioVersys may have limited influence over the development pace, though we understand that the parties collaborate closely on trial planning, and overall we view this as a cost-effective approach for BioVersys to advance the candidate.

The Phase IIa trial ([NCT05473195](#)) was an early bactericidal activity (EBA) study assessing AlpE in newly diagnosed pulmonary TB patients, with the primary endpoint measuring seven-day antimycobacterial activity. The trial tested various dose combinations of alpibecir with Eto, alongside control arms receiving isoniazid or Eto alone. The results demonstrated a clear PoC, whereby optimal doses of AlpE achieved rapid bactericidal activity comparable to isoniazid (Exhibit 8). The safety profile was favourable, with the combination generally well tolerated, and the reduced Eto exposure potentially limiting the gastrointestinal and hepatic toxicity associated with higher doses. These results validate the novel mechanism of action, providing a robust foundation for advancing the candidate into larger efficacy studies.

Exhibit 8: Phase IIa proof-of-concept data in pulmonary TB



Source: BioVersys corporate presentation (Q126)

GSK initiated an additional Phase II study ([NCT06748937](#)) in pulmonary TB during Q125, [conducted](#) through the UNITE4TB consortium. This study represents the first evaluation of AlpE in combination with standard first-line TB drugs, with the initial portion focused on dose optimisation over a relatively short treatment duration. In cohort 2, AlpE will replace isoniazid in the regimen as part of the planned future use of the combination, to establish the safety of this five-drug combination. Top-line data from the initial portion are expected within Q126. Further to this, an additional Phase IIb/c trial ([NCT05807399](#)), sponsored by GSK, is being run that will evaluate AlpE (in combination with SoC pulmonary TB drugs) in one of the arms; data from this trial are expected in 2027.

Phase II in TB meningitis, led by BioVersys

In parallel with the pulmonary TB programme, BioVersys is preparing a Phase IIb trial in TB meningitis, due to commence in Q126 (Exhibit 9). This will be a multicentre, open-label, randomised, active-controlled study assessing pharmacokinetics, safety and exploratory efficacy of AlpE in newly diagnosed TB meningitis patients. Despite the significant burden of this condition, there are currently no anti-TB agents specifically approved for TB meningitis, with treatment relying on off-label therapies, many of which only achieve suboptimal brain penetration. In our view, the combination of high mortality and the absence of specifically approved treatment options creates an attractive opportunity for BioVersys, and a favourable regulatory path for expedited development. The Phase IIb study will be run by an academic consortium comprising the University of Lille (France) and clinical sites across sub-Saharan African countries where TB meningitis is particularly prevalent. This Phase IIb trial is anticipated to commence within Q126, and will primarily generate pharmacokinetics data to confirm alpibecir and Eto concentrations in the brain, while providing preliminary insights into efficacy, alongside safety. The study is intended to complement GSK's pulmonary TB programme, which collectively will provide the foundation for a potential registrational strategy focused on TB meningitis.

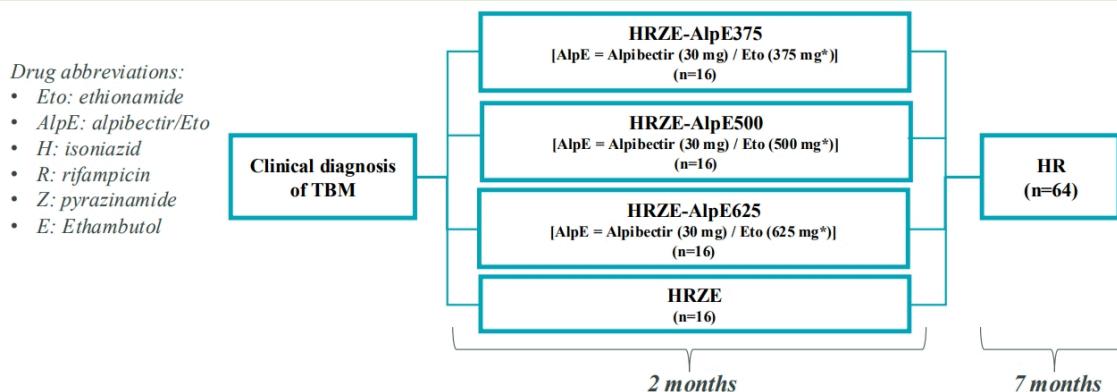
as the main target indication.

We understand that BioVersys and GSK are aligned on the optimal Phase III strategy involving a single pivotal trial in TB meningitis, rather than pulmonary TB. The rationale is that the significant unmet medical need and orphan indication status enables use of the [LPAD pathway](#), which permits approval based on relatively small study patient populations compared to more typical registrational trials (as may be required if pulmonary TB were the main target indication). Importantly, this focused approach has the potential to yield a full label encompassing both TB meningitis and pulmonary TB indications, based on Phase II efficacy data in the former indication and Phase III data in the latter, provided the data are supportive. This strategy would accelerate time to approval, while reducing development costs and clinical execution complexity.

We note that the MDR-TB meningitis indication qualifies for a priority review voucher under FDA programmes supporting neglected diseases posing threats of public health emergencies. BioVersys estimates this to have a value of c \$100m, representing additional value to be unlocked that would be split 50/50 between BioVersys and GSK. Overall, we believe that the combination of ODDs from both the FDA ([2023](#)) and EMA ([2025](#)), alongside QIDP status (providing priority review and extending US exclusivity to 2042) and priority review voucher eligibility, creates an attractive collection of incentives supporting expedited development and enhanced commercial protection.

The most significant inflection point for alpibectir will be the conclusion of the Phase II trials (expected in 2027), after which end-of-Phase II meetings will determine the viability of a single registrational programme.

Exhibit 9: Design of the Phase IIb trial for alpibectir in TB meningitis



Source: BioVersys corporate presentation (Q126)

Potentially sizeable commercial opportunity for alpibectir

The addressable market for alpibectir spans isoniazid-resistant TB in pulmonary TB, MDR-TB and TB meningitis, with management estimating the total market potential at c \$1.1bn based on 2028 projected incidence. This encompasses over 50k cases in major markets, and more than 10.4m cases in China and emerging markets, with resistance rates ranging between 2% and 17% (varying by geography and specific indication). Importantly, TB meningitis, though representing just 2–4% of TB cases, is likely to command premium pricing given the orphan indication status and high mortality without effective treatment. We discuss our assumptions for peak sales, penetration and pricing in more detail below.

Earlier-stage pipeline further validates platform offerings

BV500 in NTM, partnered with Shionogi

Preclinical candidate BV500 aims to address non-tuberculous mycobacteria (NTM) infections in patients with CF and COPD, representing high-need indications with c 250k patients worldwide, concentrated predominantly in the US and Japan. Current treatment requires prolonged multi-drug regimens lasting 12–18 months, and is often associated with undesirable side effects resulting in poor tolerability and often treatment discontinuation. Derived from BioVersys's ansamycin platform, BV500 comprises novel ansamycin antibiotics engineered with improved properties (such as: oral bioavailability; broad activity across NTM subspecies; mitigation of potential DDIs) and mechanisms to overcome resistance. Preclinical validation has been supportive, with lead molecules demonstrating superior potency versus

reference drugs across multiple NTM models.

In July 2025, BioVersys entered into a research collaboration and exclusive licence option [agreement](#) with Shionogi, offering CHF5m in upfront and near-term payments, with potential milestones up to CHF479m, plus royalties on future sales. The parties are jointly developing clinical candidates, with Shionogi bringing expertise in NTM infections and an established presence in the Japanese market. It is our opinion that this partnership validates the potential of BV500, while providing non-dilutive funding. It also offloads c CHF5m in development costs through to end-2027, enabling BioVersys to maintain its focus on its lead clinical candidates. The programme benefits from grant funding through the CF AMR Syndicate (second milestone [achieved](#), according to the announcement in early 2025) and participation in the EU IMI2-funded RespiriNTM consortium. Clinical candidate selection is ongoing with Investigational New Drug (IND) filing targeted for H226, positioning BV500 to enter the clinic potentially within the same period under Shionogi's operational leadership.

BV200 offers an opportunity in atopic dermatitis

BV200 represents a potentially first-in-class anti-virulence approach targeting *Staphylococcus aureus* in mild-to-moderate atopic dermatitis, a chronic inflammatory skin condition affecting millions globally. Derived from the company's TRIC platform, BV200 inhibits an accessory gene regulator (called AgrA), blocking the production of bacterial toxins that trigger the condition. The strategic rationale for this programme extends beyond addressing AMR, in that it also has the potential to reduce progression to severe atopic dermatitis, which requires more expensive biologic immunomodulators, addressing a patient population that is currently underserved by current treatment options.

BioVersys has identified a lead candidate and established a stable topical formulation with predicted shelf life exceeding two years. The programme is advancing through the preclinical stages of development to produce drug substance for IND-enabling toxicology studies, with IND filing targeted for H127. This candidate has Innosuisse grant funding under the Swiss Accelerator programme, providing non-dilutive support for this candidate.

Platform technologies serve as a foundation

BioVersys's pipeline is underpinned by two platforms serving as research engines for generating novel antibiotics. The TRIC platform aims to identify drug candidates that target novel bacterial pathways, overcome resistance and reduce virulence. This approach has yielded alpibectir and BV200, demonstrating versatility across diverse bacterial pathogens and disease contexts. The ansamycin platform leverages medicinal chemistry capabilities, and aims to develop next-generation antibiotics with optimised pharmacological properties and address drug-resistant infections. It has generated BV100 and BV500. In our view, the ability of these platforms to produce multiple clinical and preclinical candidates across various bacterial targets validates their broad applicability, while providing diversity for BioVersys's pipeline. Beyond current pipeline assets, both platforms offer the potential for additional partnerships targeting specific bacterial pathogens or indications where transcriptional regulation or ansamycin mechanisms could provide therapeutic benefit. We believe that platform out-licensing represents a potential value creation opportunity, though we acknowledge that, for now, management's focus remains on advancing the current lead assets.

Outlook: Multiple catalysts on the horizon

BioVersys expects multiple milestones and potential catalysts across 2026 and 2027 (Exhibit 10). For BV100, one of the most important investment drivers, in our view, will be the first data safety monitoring board (DSMB) review for the Phase III programme, most likely in H226. Management has also specifically identified the Phase IIb RWE study interim report as a significant milestone, with the potential to support both regulatory discussions and partnering prospects. For alpibectir, while the ongoing pulmonary TB studies are important, we believe that real value creation will stem from the TB meningitis programme, for which the Phase IIb trial is anticipated to conclude in early 2027, informing plans for a potentially pivotal Phase III programme within the same year.

Exhibit 10: Multiple milestones and potential catalysts expected across 2026 and 2027

	H126	H226	2027
BV100	<ul style="list-style-type: none"> • Phase III launch • Phase IIb RWE launch • Phase I China complete • Phase III China onboard 	<ul style="list-style-type: none"> • DSMB-1 Phase III • PoC in label expansion • Interim report Phase IIb 	<ul style="list-style-type: none"> • DSMB-2 Phase III • Phase III conclusion • FDA submission • Phase IIb conclusion
Alpibectir (50/50 partnership with GSK)	<ul style="list-style-type: none"> • Phase II data pulmonary TB • Phase IIb launch TB meningitis 	• Phase IIb/c pulmonary TB ongoing	<ul style="list-style-type: none"> • Phase IIb conclusion TB meningitis • Phase IIb/c conclusion pulmonary TB • Phase III start (late-2027 or 2028)
BV500	• Pre-IND meeting	<ul style="list-style-type: none"> • IND/CTA • Phase I 	
BV200		• Pre-IND meeting	<ul style="list-style-type: none"> • IND/CTA • Phase I
Potential upside events	• Additional partnerships		<ul style="list-style-type: none"> • Potential commercial partnerships

Source: Company resources; Edison Investment Research

Management team

CEO and co-founder: Dr Marc Gitzinger. Marc is the CEO and co-founder of BioVersys. He has over 10 years of experience in the biotech industry, having launched a university spin-off in the field of AMR and grown it into a multi-asset clinical-stage company. Some of these assets aim to address unmet medical needs in infectious conditions such as TB and hospital-acquired *Acinetobacter* infections. Marc has raised over \$70m in equity financing and secured more than \$30m in non-dilutive funding. He has also established several partnerships with big pharma and other development organisations. He is a multi-award-winning biotech CEO, having received, among others, the Swiss Technology Award 2011, Venture Kick 2009 and Venture Leaders 2008 and 2017 awards for his work in founding and advancing BioVersys. He is president of the board of the BEAM Alliance, a European association representing over 70 European and international small and medium enterprises active in antimicrobial research and development, and board member of the AMR Industry Alliance. He is also the co-author on several high-ranked scientific publications and patents in the field of AMR.

CFO: Hernan Levett. Hernan has over 28 years of experience in finance, with 21 years specifically concentrated in the pharmaceutical industry. He has experience in investor relations, financial planning, strategic oversight and organisational development. Before his role at BioVersys, Hernan was CFO at Spexis, a pharmaceutical company listed on the SIX Swiss Exchange, where he played a pivotal role in both formulating financing strategies and negotiating a \$182m licensing agreement with Fosun Pharma. He also had a noteworthy tenure at Nasdaq-listed Auris Medical Holding in the role of CFO, where he oversaw multiple financing transactions and initiated strategic adjustments to preserve the company's Nasdaq standing. Before his roles at Spexis and Auris, Hernan gained experience in diverse finance positions at organisations such as Acino Pharma, InterMune and Novartis. Hernan is a certified public accountant from the Universidad de Buenos Aires.

See below the Edison executive interview we recently conducted with BioVersys's CEO and CFO.

BioVersys – Edison executive interview

Source: Edison Investment Research

Sensitivities

BioVersys is exposed to clinical and regulatory risks, as well as financing and operational risks that are typical of all biotechs. These include the unpredictable nature of clinical trials, regulatory discussions, competitor successes and partnering setbacks, in addition to risks associated with funding and the commercialisation of its drug candidates. As a clinical-stage company with no approved products or commercial revenues, BioVersys's value proposition is solely dependent on the successful development and commercialisation of pipeline assets, creating inherent execution risks.

Specifically for BioVersys, clinical and regulatory risks represent the most immediate sensitivities. While BV100 has delivered encouraging Phase II efficacy signals, the Phase III programme must replicate these results in a larger, more diverse patient population. The design entails a sponsor-blinded approach, which may be at risk of introducing some bias; however, the objective primary endpoint measure mitigates this concern. In terms of regulatory risks for BV100, unexpected safety outcomes, or a lack of efficacy during Phase III, would substantially affect the opportunity for the candidate. For alpibectir, development risks are somewhat exacerbated by the operational control of GSK, whereby BioVersys cannot directly accelerate timelines or adjust the strategy for the asset, creating dependency on partner priorities. While the Phase III strategy in TB meningitis is attractive, it remains subject to regulatory clearance and acceptance of the LPAD pathway, alongside agreement that the pulmonary TB data support a broad label.

We note that the commercial potential of the candidates is subject to sensitivities associated with market access and competitive positioning. Despite compelling clinical differentiation, the commercial success of BV100 will depend on reimbursement reform implementation, and failure of such initiatives to achieve wide usage may constrain pricing and uptake. The competitive landscape also continues to evolve, with multiple CRAB-targeting candidates in development, which may erode market share if they are approved with comparable or superior safety and/or efficacy profiles. For alpibectir, positioning as a first-line add-on therapy will likely require WHO guideline inclusion and acceptance by national TB programmes, particularly in high-burden countries where cost considerations may have an impact on usage.

Access to financing is another important sensitivity to consider, which is true for most clinical-stage biotechs. For BioVersys, financing is mainly required to advance BV100 through Phase III, but also to support the broader pipeline. While the company currently has a relatively secure cash runway into H128, it may be required to raise additional capital to continue its clinical development activities. The Shionogi collaboration for BV500 alongside other sources of non-dilutive funding such as BARDA mitigate some near-term capital needs, but any delays or increased development costs could compress the runway. Management has communicated that it is actively seeking partnerships for BV100 in China,

though we note that there remains an ongoing uncertainty around the timing and scope of such a deal. If further raises are realised through equity issuances, there may be dilution risks for shareholders.

Valuation

We value BioVersys at CHF361.1m (CHF61.9/share) using an rNPV methodology. Our enterprise value is derived exclusively from the company's clinical-stage portfolio, comprising:

- BV100 in HABP, VABP and BSIs related to CRAB, and
- alpibectin in TB meningitis and isoniazid-resistant/MDR pulmonary TB.

Preclinical assets (BV200 and BV500) are currently excluded and will be incorporated as they advance into the clinic. Our equity value includes an estimated end-FY25 net cash position of CHF63.4m, comprising CHF78.0m gross cash, offset by CHF14.6m bank debt (primarily European Investment Bank facilities, with maturities in H227 and H229, with a further CHF7.5m available for drawdown) and CHF0.2m of lease liabilities.

All assets are modelled through patent expiry/market exclusivity, with a steady decline assumed thereafter. We apply stage-adjusted PoS, flexed for indication-specific risk, and discount cash flows at 12.5%, Edison's standard rate for clinical-stage assets.

BV100: Core value driver (c 75% of group rNPV)

BV100 is the principal contributor to our valuation, reflecting its advanced stage and the unmet need in CRAB infections, a WHO priority-1 pathogen associated with 30–60% mortality and carbapenem resistance exceeding 50% in many regions.

Key valuation assumptions

Geographic focus: we model the US, EU and China as the core markets, reflecting both disease incidence and commercial potential. Japan is excluded given low carbapenem resistance rates (<5%). In China, resistance rates are among the highest globally (>70%).

Target population: our addressable population is ICU patients, representing the highest unmet need. We assume:

- VABP, HABP and BSIs represent c 20% of ICU admissions;
- of the above, around 10% are due to *Acinetobacter baumannii*; and
- of these, 50–70% of these are carbapenem resistant.

This implies an annual BV100 eligible population of c 70,000 in the US, c 85,000 in the EU and c 400,000 in China.

Pricing and treatment duration: we assume a 10-day average treatment course, in line with guideline ranges (7–14 days) and the longer durations typically required for MDR infections. We assume a treatment cost of \$2,000 per patient per day in the US, with a realisable price of \$1,500 assuming a 25% payor discount. This is benchmarked against the c \$1,900 per day treatment cost for Xacduro. For the EU and China, we assume more conservative per-patient per-day realisable prices of \$900 and \$300, respectively.

Clinical timelines and costs:

- Phase III pivotal trial (n=250) starting in Q126: estimated cost of c \$50m, including c \$120k per patient plus \$5–7m overheads (2026–28).
- Phase IIb open-label study (n=90) in South-East Asia: total cost of c \$12m, with c 75% funded by the Wellcome Trust.

We assume combined data from both studies support registration in the US, EU and China.

Commercial ramp:

- Launch is assumed in 2028, following Phase III completion in 2027.

- Patent exclusivity to 2040 (the EU/China) and 2045 (the US), reflecting incremental US QIDP exclusivity.
- Peak penetration: 25% in the US/EU and 15% in China, with peak sales in 2037.

This results in implied global peak sales of c \$700m for BV100. We apply a 50% PoS, slightly below typical anti-infective benchmarks, reflecting the biological and clinical complexity of CRAB. We will reassess our assumption as the Phase III programme progresses. We assume self-commercialisation in major markets, although regional partnerships (notably in China) remain a likely option.

Reflecting these assumptions, BV100 contributes CHF270.8m (CHF46.4/share), representing c 75% of the total group value for BioVersys.

Alpibectir: Secondary value driver

BioVersys's other clinical-stage asset, alpibectir, represents a secondary value component for the company, reflecting both the clinical and commercial complexities in TB. Its dual strategy of targeting TB meningitis (BioVersys-led) and MDR pulmonary TB (partnered with GSK) aims to provide diversified exposure to TB.

Key valuation assumptions

Target geographies: with TB incidence disproportionately skewed towards emerging geographies, we segment key geographies into high-income markets (the US, EU, Japan) and low-to-mid-income markets (LMICs, including China, India, others), where incidence is highest.

Target population:

- TB meningitis: c 250,000 patients (based on an incidence rate of 2–4% of all TB cases), predominantly located in emerging markets (c 10% of patients in China).
- MDR/isoniazid-resistant TB: c 1.6 million patients, assuming 10% incidence in high-income markets and 25% in LMICs. Similar to TB meningitis, emerging markets make up the majority of the target patient population.

Drug pricing and treatment duration: we assume tiered pricing across geographies:

- the US/EU: \$30k per course.
- Upper-middle income (eg China): \$3k.
- Lower-middle income: \$900.

Pricing is benchmarked to bedaquiline, a key component of the current SoC BPaLM regimen for MDR cases. We assume a treatment duration of six months across all patient subsets.

Development plan: while the Phase II trial in pulmonary TB is ongoing (undertaken by GSK), the investigator-initiated Phase II trial in TB meningitis is expected to commence in Q126. We assume both Phase II trials to complete in 2027, with the pivotal Phase III study (n=350) to be initiated in 2028. For now, we assume a single Phase III study will suffice for regulatory approval across both indications, but we will reassess this assumption with further clarity on the clinical plans and pathway. We also model that 50% of the R&D-related expenses for the Phase III are funded through non-dilutive research grants and public financing.

Commercial ramp:

- TB meningitis: given the high unmet need and mortality rates (c 50%), we assume penetration rates of 30–60% across geographies, including 45% in China. Overall, we estimate peak sales potential of \$100m in TB meningitis, assigning a 30% PoS, with market launch in 2031.
- MDR-TB: lower peak penetration rates of 10–25% (including 20% in China), reflecting the more competitive treatment landscape with the established BPaLM regime. We estimate peak sales potential of \$300m in this subset, albeit with a lower 15% PoS, given the elevated development and commercial risk. We assume market launch in 2032.

Overall alpibectir contributes CHF27.0m (CHF4.6/share) to our valuation.

Exhibit 11 presents a breakdown of our rNPV valuation for BioVersys.

Exhibit 11: BioVersys risk-adjusted NPV valuation

Product	Indication	Expected launch	Peak sales (\$m)	NPV (CHFm)	Probability	rNPV (CHFm)	rNPV/share (CHF)
BV100	Carbapenem-resistant <i>Acinetobacter baumannii</i>	2028	700	544.5	50%	270.8	46.4
Alpibectir	TB meningitis	2031	100	34.9	30%	10.0	1.7
	Drug-resistant pulmonary TB	2032	300	115.5	15%	17.0	2.9
Estimated net cash at end-December 2025				63.4		63.4	10.9
Valuation				758.4		361.1	61.9

Source: Edison Investment Research

Scenario analysis

As noted above, BioVersys's valuation is highly leveraged to BV100. Given the binary clinical and commercial nature of the late-stage anti-infectives programme, we also introduce bear and bull case scenarios to capture both downside risk and upside optionality around our base case assumptions.

Our base case, as outlined above, assumes peak penetration of 25% in the US and EU and 15% in China, a US realisable price of \$1,500 per patient per day, a 2028 launch and peak global sales of \$700m. This yields an rNPV of CHF270.8m or CHF46.4/share for BV100 and a valuation of CHF361.1m or CHF61.9/share for BioVersys.

Bear case

In our bear case scenario, we stress test our assumptions, building in slower uptake, pricing pressure and a delayed launch. We assume peak penetration of 15% in the US and EU and 8% in China, a US realisable price of \$1,200 per patient per day and a market launch in 2029. This results in a peak sales estimate of \$320m and an rNPV of CHF124.4m or CHF21.3/share for BV100 and CHF214.7m or CHF36.8/share for BioVersys.

Bull case

In our bull case scenario, we assume enhanced commercial adoption with increased penetration driven by rising CRAB resistance, limited competition, favourable reimbursement and accelerated approval. We assume peak penetration of 35% in the US and EU and 25% in China, a US realisable price of \$1,800 per patient per day, a 2027 market launch and peak sales of \$964m. Under these assumptions, BV100 generates an rNPV of CHF482.0m (CHF82.6/share), while BioVersys is valued at CHF572.3m (CHF98.0/share).

Blended valuation

Note that even in our bear case scenario, the implied valuation of CHF36.8/share suggests material upside versus the current share price (CHF25.1 as of 09 February 2026). Assigning probability weights of 50% to the base case and 25% each to the bear and bull cases (reflecting post-approval commercial risk) results in a blended valuation of CHF64.7/share for BioVersys. Exhibit 12 summarises the full set of scenario assumptions.

Exhibit 12: Scenario analysis

Variable	Bear	Base	Bull
Peak penetration (US/EU)	15%	25%	35%
Peak penetration (China)	8%	15%	25%
Peak global sales (US\$m)	320	700	964
Launch	2029	2028	2027
Realised US price/day (US\$)	1,200	1,500	1,800
BioVersys rNPV valuation (CHFm)	214.7	361.1	572.3
BioVersys per share valuation (CHF)	36.8	61.9	98.0
Assigned weights	25.0%	50.0%	25.0%
Blended rNPV valuation (CHFm)			377.3
Blended per share valuation (CHF)			64.7

Source: Edison Investment Research

Sensitivity analysis

All three scenarios above assume that the PoS (50%) and discount rate (12.5%) remain unchanged. Given the high sensitivity of our valuation to these inputs, we also present a two-variable sensitivity analysis across a range of PoS and discount rates (Exhibit 13). This highlights the impact of shifts in clinical risk perception and cost of capital on the base-case valuation.

Exhibit 13: Sensitivity table (BioVersys valuation, CHF/share)

	BV100 probability of success									
	30.0%	35.0%	40.0%	45.0%	50.0%	55.0%	60.0%	65.0%	70.0%	
Discount rates	10.5%	50.5	56.3	62.1	67.8	73.6	79.4	85.1	90.9	96.7
	11.0%	48.5	54.0	59.4	64.9	70.4	75.9	81.3	86.8	92.3
	11.5%	46.6	51.8	57.0	62.2	67.4	72.6	77.8	83.0	88.2
	12.0%	44.8	49.7	54.7	59.6	64.5	69.5	74.4	79.3	84.3
	12.5%	43.1	47.8	52.5	57.2	61.9	66.5	71.2	75.9	80.6
	13.0%	41.5	46.0	50.4	54.9	59.3	63.8	68.3	72.7	77.2
	13.5%	40.0	44.2	48.5	52.7	57.0	61.2	65.4	69.7	73.9
	14.0%	38.6	42.6	46.7	50.7	54.7	58.8	62.8	66.8	70.9
	14.5%	37.2	41.1	44.9	48.8	52.6	56.4	60.3	64.1	68.0

Source: Edison Investment Research

Financials

As a pre-revenue, clinical-stage biopharmaceutical company, BIOV remains reliant on external funding to support its development activities. The successful IPO in February 2025 materially strengthened the balance sheet, generating gross proceeds of CHF76.7m and lifting cash reserves to CHF92.1m at end-June 2025 (from CHF26.6m at end-December 2024).

For H125, the company reported operating income of CHF0.6m (H124: CHF0.5m), primarily reflecting grant income and R&D tax credits. Operating expenses totalled CHF9.9m (H124: CHF10.9m), comprising CHF6.2m in R&D and CHF3.7m in G&A costs. This translated into an operating loss of CHF9.4m (H124: loss of CHF10.4m) and a net loss of CHF11.0m (H124: CHF10.4m). Net cash outflow from operations was CHF9.6m, equating to an average monthly cash burn of approximately CHF1.6m.

The strengthened balance sheet is reflected in shareholders' equity of CHF69.9m at end-June 2025, up materially from CHF10.7m at end-2024, with the equity ratio improving to 74% (from 31%). Headcount stood at 29 full-time equivalents, with around three-quarters of employees dedicated to R&D activities, underscoring the company's development-stage focus.

Outlook and funding visibility

Following the H125 results, management upgraded its full-year 2025 guidance, now expecting an operating loss of CHF29m (from CHF32m previously) and year-end cash of approximately CHF78m. We believe that the step-up in H225 costs is primarily attributable to Phase III preparation for BV100, including contract research organisation selection and the IND and clinical trial application submissions to the required regulatory authorities. With the initiation of the pivotal BV100 trial, we expect R&D intensity to remain elevated through FY26 and FY27. We project operating losses of CHF29.6m and CHF30.5m in FY26 and FY27, respectively.

Importantly, the Phase IIb RWE study for BV100 is expected to be c 75% funded by the Wellcome Trust under the ADVANCE-ID/NSU network (c S\$22m/CHF14m in total funding), materially reducing BioVersys's cash burn. On this basis, we believe existing liquidity is sufficient to fund operations into H128, providing visibility through key milestones, including BV100 Phase III initiation, Phase III completion (expected H227) and regulatory filings. In addition, we see potential upside from non-dilutive US government support, including possible BARDA funding for the BV100 Phase III programme. Given the critical nature of MDR infections, agencies such as BARDA and CARB-X have been providing R&D support to promising clinical programmes. We note that in July 2025 BARDA issued a request for proposals (RFP) seeking an intravenous antibiotic for HABP/VABP and BSIs caused by drug-resistant pathogens, with eligibility extending to assets with an FDA-aligned Phase III development plan. While the timing of such funding for BV100 remains unclear, if awarded this could meaningfully extend BioVersys's cash runway and reduce the financing risk around Phase III execution and subsequent regulatory filings.

The strengthened financial position from recent deals (the Shionogi licensing agreement: CHF5m upfront plus another c CHF5m cost savings; funding from the Wellcome Trust) also provides operational flexibility. In addition, we understand that the alpibectir programme with GSK is supported by non-dilutive public funding (we assume this to be c 50% for the Phase II TB meningitis study), with the remaining costs shared 50/50 between GSK and BioVersys. Overall, we believe BioVersys is well-capitalised to execute its clinical strategy across multiple value inflection points over the next 24 months, with limited near-term financing risk.

Exhibit 14: Financial Summary

	2023 IFRS	2024 IFRS	2025e IFRS	2026e IFRS	2027e IFRS
Year end 31 December, CHF'000s					
PROFIT & LOSS					
Revenue and other income	1,139	1,213	1,141	1,636	1,706
Sales	0	0	0	0	0
R&D tax credit	858	734	777	1,261	1,300
Government and other grants	0	0	0	0	0
Cost of Sales	0	0	0	0	0
Gross Profit	1,139	1,213	1,141	1,636	1,706
R&D expenses	(14,825)	(12,947)	(21,023)	(21,665)	(22,212)
G&A expenses	(4,011)	(6,988)	(9,174)	(9,588)	(10,041)
D&A	(273)	(282)	(198)	(134)	(99)
EBITDA	(17,424)	(18,440)	(28,859)	(29,482)	(30,449)
Operating Profit (before amort. and except.)	(17,697)	(18,722)	(29,056)	(29,617)	(30,547)
Intangible Amortisation	0	0	0	0	0
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(17,697)	(18,722)	(29,056)	(29,617)	(30,547)
Net Interest	(604)	3	(200)	603	70
Profit Before Tax (norm)	(18,301)	(18,719)	(29,256)	(29,014)	(30,477)
Profit Before Tax (FRS 3)	(18,301)	(18,719)	(29,256)	(29,014)	(30,477)
Tax	0	0	0	0	0
Profit After Tax (norm)	(18,301)	(18,719)	(29,256)	(29,014)	(30,477)
Profit After Tax (FRS 3)	(18,301)	(18,719)	(29,256)	(29,014)	(30,477)
Average Number of Shares Outstanding ('000)	2,986	3,332	5,381	5,381	5,381
EPS - normalised (CHF)	(6.13)	(5.62)	(5.44)	(5.39)	(5.66)
EPS - (IFRS) (CHF)	(6.13)	(5.62)	(5.44)	(5.39)	(5.66)
BALANCE SHEET					
Fixed Assets	581	558	405	316	262
Intangible Assets	0	0	0	0	0
Tangible Assets	581	558	405	316	262
Investments	0	0	0	0	0
Current Assets	33,586	34,398	80,239	55,908	21,261
Cash and cash equivalents	24,376	26,619	78,029	53,477	18,587
Prepaid expenses and other receivables	2,360	1,779	2,210	2,431	2,674
Current financial assets	4,000	6,000	0	0	0
Other	2,850	0	0	0	0
Current Liabilities	9,367	9,673	6,194	12,925	7,803
Trade payables	1,289	706	776	931	1,117
Accrued expenses	2,203	3,446	2,880	3,456	4,147
Short-term borrowings	1,784	4,305	1,322	7,322	1,322
Other current liabilities	4,091	1,216	1,216	1,216	1,216
Long-Term Liabilities	16,224	14,601	15,244	10,105	11,005
Long-term borrowings	15,678	13,761	14,404	9,265	10,165
Employee benefit liabilities	546	840	840	840	840
Net Assets	8,576	10,682	59,207	33,193	2,716
CASH FLOW					
Operating Cash Flow	(11,655)	(15,574)	(23,282)	(27,507)	(28,845)
Net interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(49)	(38)	(45)	(45)	(45)
Acquisitions/disposals	3,342	(2,000)	8,000	3,000	0
Equity Financing	(2)	14,331	69,912	0	0
Debt proceeds/repayment	7,132	(251)	(3,175)	0	(6,000)
Dividends	0	0	0	0	0
Others	0	5,113	0	0	0
Net Cash Flow	(1,232)	1,581	51,410	(24,552)	(34,890)
Opening cash	26,561	24,376	26,619	78,029	53,477
Other	(953)	662	0	0	0
Closing cash	24,376	26,619	78,029	53,477	18,587
Net cash/(debt)	11,296	9,654	63,405	37,990	8,201

Source: Company documents, Edison Investment Research

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Revenue by geography

N/A

Management team
Chief executive officer and co-founder: Dr Marc Gitzinger

Marc is the CEO and co-founder of BioVersys. He has over 10 years of experience in the biotech industry, having launched a university spin-off in the field of AMR and grown it into a multi-asset clinical-stage company. Some of these assets aim to address unmet medical needs in infectious conditions such as TB and hospital-acquired *Acinetobacter* infections. Marc has raised over \$70m in equity financing and secured more than \$30m in non-dilutive funding. He has also established several partnerships with big pharma and other development organisations. He is a multi-award-winning biotech CEO, having received among others the Swiss Technology Award 2011, Venture Kick 2009 and Venture Leaders 2008 and 2017 awards for his work in founding and advancing BioVersys. He is president of the board of the BEAM Alliance, a European association representing over 70 European and international small and medium enterprises active in antimicrobial research and development, and board member of the AMR Industry Alliance. He is also the co-author on several high-ranked scientific publications and patents in the field of AMR.

Chief development officer: Dr Glenn Dale

Glenn is chief development officer of BioVersys and an expert in the field of infectious diseases. He is also the author of numerous publications and inventor on many patents. Since February 2019, Glenn has led clinical development activities at BioVersys, applying his 25 years of R&D experience and knowledge in the modern development of antibiotics. Glenn obtained his PhD in biochemistry in 1993 from the University of Basel. Following postdoctoral studies in Basel he has held the following positions: group leader at Roche, head of biology, site head at Morphochem and scientific coordinator responsible for preclinical research at Arpida. In 2009, he joined Polyphor where he led antibiotic research and early development, successfully transitioning Murepavadin (POL7080) from preclinical activities to Phase III studies. Glenn also has experience in presenting to, and discussing with, European and US regulatory authorities (eg scientific advice meetings (MHRA, EMA), type C meetings (FDA) and end-of-Phase II meetings (FDA)).

Chief financial officer: Hernan Levett

Hernan is CFO of BioVersys with over 28 years of experience in finance, with 21 years specifically concentrated in the pharmaceutical industry. He has experience in investor relations, financial planning, strategic oversight and organisational development. Before his role at BioVersys, Hernan was CFO at Spexis, a pharmaceutical company listed on the SIX Swiss Exchange, where he played a pivotal role in both formulating financing strategies and negotiating a \$182m licensing agreement with Fosun Pharma. He also had a noteworthy tenure at Nasdaq-listed Auris Medical Holding in the role of CFO, where he oversaw multiple financing transactions and initiated strategic adjustments to preserve the company's Nasdaq standing. Before his roles at Spexis and Auris, Hernan gained experience in diverse finance positions at organisations such as Acino Pharma, InterMune and Novartis. He is a certified public accountant from the Universidad de Buenos Aires.

Chief scientific officer: Dr Daniel Ritz

Daniel is the chief scientific officer of BioVersys, having joined the company in 2025, with expertise in small-molecule drug discovery and infection biology. He recently served as senior director responsible for lead discovery and biology technologies at Idorsia, where he was in charge of initiating new discovery programmes, lead candidate identification and leading microbiology for vaccine programmes targeting gram-negative and *C. diff* infections. Before that, he had built the cell metabolism and anti-infectives group, where he led discovery and development efforts for small molecule cell metabolism modulating inhibitors for infectious disease, immunology and oncology applications. Previously, he led the discovery of anti-infectives at Actelion, working on the discovery and development of cadazolid for the treatment of *C. diff* infections. During his tenure, he advanced multiple projects from inception through to lead candidate optimisation and preclinical development. Daniel received his undergraduate degree in biochemistry and his PhD in microbiology from the ETH in Zurich, Switzerland, and completed a postdoctoral training as research fellow in the lab of Jon Beckwith at Harvard Medical School in Boston, US. He has co-authored over 30 papers and holds several patents.

Principal shareholders

	%
AMR Action Fund	15.98
UBS Global Asset Management	5.69
GSK	4.35
Candriam	3.91
Barris AG	3.42
Marc Jaquet	3.14

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