BioVersys

A step-change year for development activity

FY25 results

Healthcare

26 March 2026

BioVersys's FY25 results underscore a transition into a catalyst-rich, late-stage development phase. Following FDA clearance, first patient dosing in the registrational Phase III trial for lead asset BV100 is set to commence in April 2026. The Phase IIb real-world evidence study will run in parallel, supported by the Wellcome Trust-funded ADVANCE-ID network, with both studies reading out in H227. Pipeline momentum extends to alpibectir (partnered with GSK), where a GSK-led Phase IIb/c pulmonary TB study initiated in March 2026, while a Phase IIb TB meningitis trial (BioVersys-led) is planned for Q226. Dual readouts by end-2027 are expected to shape the Phase III strategy. Earlier-stage assets BV500 (Shionogi collaboration) and BV200 continue to progress, adding pipeline depth. Reflecting BV100's advancement into Phase III, we increase its probability of success (PoS) to 60% (from 50%), driving a valuation uplift to CHF71.3/share (from CHF61.9).

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.

BV100 set for Phase III

BV100 is approaching a key inflection point as it advances towards Phase III (RIV-TARGET) in VABP and HABP, supported by encouraging Phase II data. Following FDA clearance in March 2026, first patient dosing is expected in April. In parallel, the Phase IIb RIV-CARE study will generate real-world evidence in drug-resistant populations, strengthening BV100's clinical and commercial positioning. The next 18–24 months will be catalyst-rich, with interim data (H226), DSMB reviews (H226/H127) and top-line readouts (H227) expected to shape the approval pathway.

Mid-stage momentum builds for alpibectir

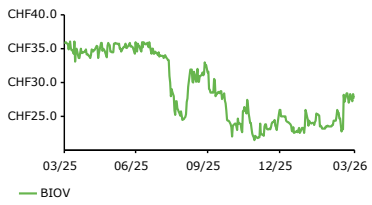
2026 should also see momentum building for second asset alpibectir across both partnered and internal programmes. Partner GSK has initiated a Phase IIb/c trial in pulmonary tuberculosis (TB, first patient dosed in March 2026), while BioVersys is preparing to commence a Phase IIb study in TB meningitis in Q226, targeting a high unmet need population. The dual-track strategy expands the asset's clinical and commercial potential, with readouts from both studies, expected by end-2027, key to defining the Phase III pathway and overall positioning.

Valuation: CHF416.2m or CHF71.3 per share

With the Phase III regulatory clearance and commencement for BV100, we raise the PoS for the programme to 60% (previously 50%), while keeping all other long-term assumptions unchanged. Reflecting this and the latest net cash (CHF60.8m at end-FY25), our valuation for BioVersys upgrades to CHF416.2m or CHF71.3/share (from CHF361.6m or CHF61.9/share). Based on management guidance (operating loss of CHF40–45m in FY26), 2027 debt maturities and our burn estimates, we see BioVersys funded into 2028, past key inflection points.

Price	**CHF27.80**
Market cap	**CHF165m**
	CHF0.79/$
Net cash 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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Pipeline offers a range of potential upcoming catalysts

BioVersys is focused on the development of novel antibacterial treatments for serious, life-threatening, multi-drug resistant infections (Exhibit 1). As a reminder, the company's candidates originated from its proprietary discovery platforms, the ansamycin discovery and transcriptional regulator inhibitory compound (TRIC) platforms, adding scope to its value offering by providing a sustainable engine for generating novel candidates with differentiated mechanisms to overcome resistance. Encouragingly, clinical-stage candidates BV100 and alpibectir both have Qualified Infectious Disease Product designations, giving five additional years of market exclusivity and eligibility for priority review. Alpibectir also has Orphan Drug designation, offering tax credits for qualifying trials, user fee exemptions and up to seven years of exclusivity.

We provide an overview of the current ongoing activities for each of BioVersys's drug candidates below. For a more detailed discussion of the company's background and clinical data to date, we direct readers to our recently published initiation of coverage note.

Exhibit 1: BioVersys drug development pipeline

Program	Indication	R&D/Preclinical	Phase 1	Phase 2	Phase 3	Expected Key Catalyst	Commercial Rights
BV100 *FDA QIDP*	Hospital infections *Acinetobacter baumannii* (VABP/HABP & BSI) advanceid.	*Phase 3 trial (RIV-TARGET)*				FPFV: April 2026	
		Phase 2b trial (RIV-CARE)				FPFV: H1 2026	
Alpibectir *FDA QIDP Orphan Drug FDA/EMA*	Tuberculosis: • Multi-drug resistant • TB-Meningitis	*Pulmonary TB*				Phase 2b/c start: March 2026 Phase 2 start: H1/2026	GSK
		TB meningitis					
BV200 *Anti-virulence TRIC platform*	Atopic dermatitis *Staphylococcus aureus* Innosuisse					IND Filing: H1 2027	
BV500 *Ansamycin platform*	CF and COPD: Non-tuberculous mycobacteria infection CF AMR Syndicate RESPIRI NTM					License Option: 2027	SHIONOGI license option
BV Discovery	Targets undisclosed						

Source: BioVersys Annual Report 2025

BV100

Lead asset BV100 is a product of BioVersys's ansamycin discovery programme, and is an intravenous rifabutin formulation being developed for carbapenem-resistant *Acinetobacter baumannii* (CRAB) infections, one of the highest priority antibiotic-resistant pathogens. BV100 is currently involved in the registrational Phase III RIV-TARGET programme focused on ventilator-associated bacterial pneumonia (VABP, for which encouraging data have previously been generated in Phase IIb), alongside hospital-acquired bacterial pneumonia (HABP). The FDA provided regulatory clearance for RIV-TARGET in March 2026 (Exhibit 2).

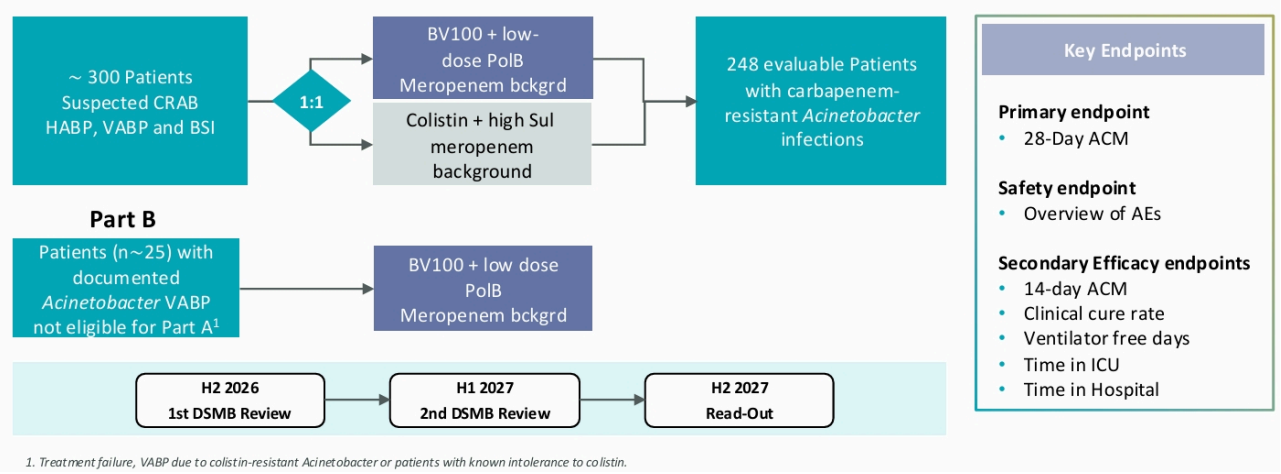
RIV-TARGET is designed as a randomised, active-controlled, two-part parallel-group Phase III trial (expected n=300). Participants will be randomised 1:1 to receive either BV100 plus low-dose polymyxin B (primary last-resort therapy for CRAB infections) or a standard-of-care regimen of colistin plus high-dose ampicillin-sulbactam, with meropenem permitted as background therapy in cases of polymicrobial infection. The primary endpoint is 28-day all-cause mortality. The design broadly mirrors the prior Phase II study in VABP, where BV100 demonstrated a meaningful survival signal versus best available therapy (25%, vs 60% mortality). The trial includes an open-label, non-randomised cohort (Part B) evaluating BV100 plus low-dose polymyxin B in treatment-refractory patients, including those with CRAB infections resistant to polymyxins or where prior polymyxin-based therapy has failed. Approximately 25 participants are anticipated to be enrolled in this cohort. Management has communicated that the trial is on track to dose the first patient in RIV-TARGET in April 2026, representing a key upcoming milestone.

Alongside Phase III, BioVersys is also advancing the open-label Phase IIb RIV-CARE study, which will be conducted

with the ADVANCE ID network and supported by Wellcome funding. This study is expected to begin in Q226 and is intended to generate additional real-world evidence for BV100 in settings with very high drug resistance. We see this as strategically important, as it should help sharpen the future commercial positioning of BV100 and support discussions with potential partners and regulators. Separately, BioVersys initiated a China Phase I bridging study in November 2025, which should allow Chinese sites to join the global Phase III programme from H226.

Looking ahead, the key milestones for 2026 will be the commencement of patient dosing in both RIV-TARGET and RIV-CARE, completion of the China Phase I study and an interim update from RIV-CARE by end-2026. Beyond this, company guidance points to top-line data from both RIV-TARGET and RIV-CARE by end-2027. Importantly, management has stated that the Phase III package has been shaped through regulatory interactions with the FDA, EMA and Chinese authorities, with the intention of supporting approval discussions across all three jurisdictions. Should these operations remain on track, and the efficacy signals seen in Phase II translate into Phase III, BV100 has the potential to become BioVersys's first commercial product and the central value driver for the company over the medium term.

Exhibit 2: Design of the registrational Phase III RIV-TARGET trial



Source: BioVersys corporate presentation Q1 2026

Alpibectir

Alpibectir originated from the TRIC platform, and is, to our knowledge, the most advanced small molecule drug candidate targeting bacterial transcriptional regulators for TB treatment. It is currently being developed in partnership with GSK, where development costs and any future net revenues are shared on a 50/50 basis. A dual strategy is being taken with alpibectir, whereby the candidate is being developed for two indications in parallel: drug-resistant pulmonary TB (led by GSK) and TB meningitis (led by BioVersys).

For GSK, the current priority for alpibectir is the ongoing Phase IIb/c trial, for which the first patient was dosed in March 2026, evaluating AlpE (alpibectir in combination with the TB treatment potentiator ethionamide) in pulmonary TB. More specifically, the study has been designed to test AlpE in combination with three first-line TB drugs (rifampicin, pyrazinamide and ethambutol) in drug-susceptible TB patients for two months, followed by standard therapy alone (rifampicin and isoniazid) for an additional 18 weeks. Key outcome measures are based on efficacy, safety and pharmacokinetics. Top-line results are expected by end-2027. The trial is being conducted within the UNITE4TB consortium, a public–private partnership, and is taking place across six African countries. The programme builds on an earlier Phase IIa open-label, 14-day study (ENABLE trial) assessing AlpE alongside first-line TB therapy. Top-line data for ENABLE are anticipated in Q226.

For BioVersys, the focus for alpibectir is on TB meningitis, where the company is preparing for a Phase IIb trial. This is expected to be a multicentre, open-label, randomised, active-controlled study assessing the pharmacokinetics, safety and exploratory efficacy of AlpE in newly diagnosed TB meningitis patients. Patient recruitment is on track to commence in Q226, representing a key upcoming milestone for the programme. We expect trial conclusion during 2027.

We understand that BioVersys and GSK are aligned on the subsequent Phase III strategy focusing on a single pivotal trial in TB meningitis, rather than pulmonary TB. The significant unmet medical need and orphan indication status should enable use of the Limited Population Pathway for Antibacterial and Antifungal Drugs, allowing approval based on relatively small study patient populations. Importantly, this focused approach may even yield a full label encompassing both TB meningitis and pulmonary TB, based on Phase II efficacy data in the former indication and Phase III data in the

latter, should the data be positive. This strategy would accelerate time to approval, while reducing development costs and clinical execution complexity.

Preclinical candidates

- **BV500**, developed through BioVersys's ansamycin discovery platform, is partnered with Shionogi as part of a CHF484m biobuck deal (announced in July 2025). It is being developed as a potential treatment for broad-spectrum non-tuberculous mycobacteria infections, which include indications such as cystic fibrosis and chronic obstructive pulmonary disease. BioVersys and Shionogi are jointly advancing this programme, with Shionogi bringing expertise in infectious diseases, as well as an established presence in the Japanese market, all while providing BioVersys with non-dilutive funding. Preclinical research will continue throughout 2026, with the next milestone being candidate selection (most likely in 2027).
- **BV200**, developed through the company's TRIC platform, is a combination of anti-virulence agents designed to address *Staphylococcus aureus* infections, for indications such as atopic dermatitis. The programme is in the preclinical stages; an Investigational New Drug filing is targeted for H127. This candidate has Innosuisse grant funding under the Swiss Accelerator programme, providing non-dilutive support for the programme.

Financials

R&D picking up pace in H225

BioVersys reported its FY25 results, representing the first full year of financials following its IPO in February 2025, which raised gross proceeds of CHF76.7m. As a clinical-stage company, BioVersys does not yet generate product revenues; however, it reported CHF0.8m in revenue during the year, which was related to its research collaboration agreement with Shionogi, signed in July 2025 for its preclinical asset BV500, targeting non-tuberculous mycobacteria infections. As a reminder, the agreement includes upfront and near-term payments of up to CHF5.5m (CHF1.5m upfront and up to CHF4m in technology access fees), in addition to potential regulatory and commercial milestone payments of up to CHF479m, contingent on Shionogi exercising its licence option (which we anticipate could occur by 2027, subject to successful development progress). Based on the structure of the agreement, we estimate that the remaining CHF4.7m of the near-term payments will be received and recognised as revenue across FY26 and FY27.

In addition to collaboration revenues, BioVersys reported CHF2.5m in R&D tax credits, grant income and subsidies (FY24: CHF1.2m), reflecting increased development activity. Given that these credits largely reflect reimbursements of eligible R&D expenditures from government programmes, we expect them to fluctuate in line with the company's development activity. Overall, operating income for FY25 increased to CHF3.3m, compared to CHF1.2m in FY24.

Operating expenses for FY25 totalled CHF23.2m (FY24: CHF19.9m), with the increase primarily driven by higher R&D investment. R&D expenses rose 27.5% y-o-y to CHF16.5m (FY24: CHF12.9m), accounting for approximately 71% of total operating costs. As expected, R&D spend was weighted towards the second half of the year (CHF10.3m in H225 vs CHF6.2m in H125), reflecting the ramp-up of preparatory activities for the BV100 registrational Phase III trial. G&A expenses remained broadly stable at CHF6.7m, compared to CHF7.0m in FY24, indicating a relatively controlled corporate overhead base despite increased development activity. Overall, BioVersys reported an operating loss of CHF20.0m in FY25, representing a 6.6% increase from CHF18.7m in FY24. Notably, this was below management's prior guidance of CHF29m. In our view, this variance is likely attributable to the timing of certain R&D expenditures shifting into FY26, rather than any structural change in the underlying cost base.

Estimates revision

FY26 is expected to represent a significant step-up in development activity, driven by the initiation of the BV100 Phase III registrational study (RIV-TARGET), the Phase IIb real world study (RIV-CARE) and the Phase II study for alpibectir in TB meningitis (TBM). Management has guided for an operating loss of CHF40–45m for FY26 and a period end cash balance of c CHF43m, implying a substantial increase in R&D spend as the BV100 programme progresses through its pivotal stage. Reflecting this guidance, we revise our FY26 R&D estimates upwards to CHF37.0m, from CHF21.7m previously, to account for a greater concentration of Phase III-related costs being recognised during the year. We expect the bulk of the BV100 trial-related expenditure to be incurred in FY26, with FY27 increasingly focused on later-stage activities, including data package preparation and regulatory submission.

On the revenue side, we forecast BioVersys to receive CHF2.4m in near-term payments from Shionogi in FY26, alongside CHF2.3m in R&D tax credits and grant income (versus CHF1.6m in our prior estimates), reflecting the higher anticipated level of development activity. Based on the FY25 run-rate and observed cost discipline, we revise our FY26 G&A estimate downwards to CHF8.0m (from CHF9.6m previously). Taken together, we project an operating loss of CHF40.4m for FY26, positioning our estimate at the lower end of management's guided range.

For FY27 we forecast operating income of CHF6.8m (including CHF2.4m from Shionogi) and an operating loss of CHF34.7m, reflecting continued, albeit gradually moderating, development expenditure as key programmes advance towards later-stage milestones.

Funded into 2028

BioVersys ended FY25 with a gross cash balance of CHF82.5m, supported by IPO proceeds and the drawdown of the final CHF7.5m tranche of its European Investment Bank (EIB) loan facility in December 2025. Net cash at year-end stood at CHF60.8m. Based on our updated cash burn projections and factoring in upcoming debt maturities (including the first CHF5m EIB tranche due in August 2027, unless refinanced), we estimate that the company has sufficient funding to support its planned clinical and operational activities into 2028. However, we note that a modest bridging financing requirement (c CHF10–20m) could arise in early 2028, ahead of the anticipated commercial launch of BV100 and the subsequent ramp-up in revenues.

Valuation

We continue to value BioVersys using a risk-adjusted net present value (rNPV) methodology, incorporating its two key clinical-stage programmes, BV100 and alpibectir. Our core assumptions for both programmes remain broadly unchanged following the FY25 results, with one key update relating to BV100.

For BV100, we increase our PoS to 60% (from 50% previously), reflecting the regulatory clearance and initiation of the Phase III registrational trial (with first patient dosing expected in April 2026). We continue to assume a trial cost of around CHF40m, with another c CHF10m attributed to data package preparation, regulatory filing and pre-launch preparations following the Phase III trial. As outlined in our initiation report, we expect the Phase IIb real-world study (RIV-CARE), planned for initiation in Q226, to be largely funded by the Wellcome Trust funds (SGD220m/CHF14m), which we estimate will cover approximately 75% of the study costs.

We maintain our peak sales assumption for BV100 at $700m in CRAB infections, with a projected market launch in 2028. Following the increase in PoS, our rNPV valuation for BV100 rises to CHF327.9m (CHF56.2/share), up from CHF270.8m (CHF46.4/share) previously, and represents c 80% of our total equity valuation.

For alpibectir, we leave our assumptions unchanged. The self-sponsored TBM study remains on track for initiation in Q226, and we continue to model an initial launch in 2031, with peak sales of $400m. We apply a PoS of 30% for TBM and 15% for pulmonary TB, resulting in an rNPV of CHF27.6m (CHF4.7/share).

Incorporating the updated PoS for BV100, model roll-forward and the latest net cash position of CHF60.8m, our valuation for BioVersys increases to CHF416.2m (CHF71.3/share), compared to CHF361.6m (CHF61.9/share) previously. Exhibit 3 presents a breakdown of our rNPV valuation for BioVersys.

Exhibit 3: BioVersys risk-adjusted net present value

Product	Indication	Expected launch	Peak sales ($m)	NPV (CHFm)	Probability	rNPV (CHFm)	rNPV/share (CHF)
BV100	Carbapenem-resistant *Acinetobacter baumannii*	2028	700	549.7	60%	327.9	56.2
Alpibectir	TB meningitis	2031	100	35.7	30%	10.2	1.7
	Drug-resistant pulmonary TB	2032	300	118.2	15%	17.4	3.0
Net cash at end-December 2025				60.8		60.8	10.4
Valuation				**764.4**		**416.2**	**71.3**

Source: Edison Investment Research

Exhibit 4: Financial summary

Year end 31 December, CHF000s	2023 IFRS	2024 IFRS	2025 IFRS	2026e IFRS	2027e IFRS
PROFIT & LOSS					
Revenue and other income	**1,139**	**1,213**	**3,268**	**4,629**	**6,794**
Sales	0	0	800	2,350	2,350
R&D tax credit	858	734	1,342	1,650	3,699
Government and other grants	0	0	0	0	0
Cost of Sales	0	0	0	0	0
Gross Profit	**1,139**	**1,213**	**3,268**	**4,629**	**6,794**
R&D expenses	(14,825)	(12,947)	(16,502)	(36,995)	(33,052)
G&A expenses	(4,011)	(6,988)	(6,729)	(8,003)	(8,393)
D&A	(273)	(282)	(297)	(223)	(214)
EBITDA	**(17,424)**	**(18,440)**	**(19,666)**	**(40,147)**	**(34,437)**
Operating Profit (before amort. and except.)	**(17,697)**	**(18,722)**	**(19,963)**	**(40,369)**	**(34,651)**
Intangible Amortisation	0	0	0	0	0
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit/(loss)	**(17,697)**	**(18,722)**	**(19,963)**	**(40,369)**	**(34,651)**
Net Interest	(604)	3	(1,851)	(259)	(689)
Profit Before Tax (norm)	**(18,301)**	**(18,719)**	**(21,814)**	**(40,628)**	**(35,339)**
Profit Before Tax (FRS 3)	**(18,301)**	**(18,719)**	**(21,814)**	**(40,628)**	**(35,339)**
Tax	0	0	(16)	0	0
Profit After Tax (norm)	**(18,301)**	**(18,719)**	**(21,830)**	**(40,628)**	**(35,339)**
Profit After Tax (FRS 3)	**(18,301)**	**(18,719)**	**(21,830)**	**(40,628)**	**(35,339)**
Average Number of Shares Outstanding ('000)	2,986	3,332	5,615	5,615	5,615
EPS - normalised (CHF)	(6.13)	(5.62)	(3.89)	(7.24)	(6.29)
EPS - (IFRS) (CHF)	(6.13)	(5.62)	(3.89)	(7.24)	(6.29)
BALANCE SHEET					
Fixed Assets	**581**	**558**	**765**	**542**	**329**
Intangible Assets	0	0	0	0	0
Tangible Assets	581	558	765	542	329
Investments	0	0	0	0	0
Current Assets	**33,586**	**34,398**	**89,871**	**51,292**	**13,457**
Cash and cash equivalents	24,376	26,619	82,505	43,190	4,544
Prepaid expenses and other receivables	2,360	1,779	7,366	8,103	8,913
Current financial assets	4,000	6,000	0	0	0
Other	2,850	0	0	0	0
Current Liabilities	**9,367**	**9,673**	**8,896**	**14,934**	**11,216**
Trade payables	1,289	706	2,470	2,964	3,557
Accrued expenses	2,203	3,446	2,872	3,446	4,136
Short-term borrowings	1,784	4,305	1,208	6,178	1,178
Other current liabilities	4,091	1,216	2,346	2,346	2,346
Long-Term Liabilities	**16,224**	**14,601**	**21,929**	**17,717**	**18,726**
Long-term borrowings	15,678	13,761	21,440	17,228	18,237
Employee benefit liabilities	546	840	489	489	489
Net Assets	**8,576**	**10,682**	**59,811**	**19,183**	**(16,156)**
CASH FLOW					
Operating Cash Flow	**(11,655)**	**(15,574)**	**(21,946)**	**(39,098)**	**(33,645)**
Net interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(49)	(38)	(216)	0	0
Acquisitions/disposals	3,342	(2,000)	6,000	0	0
Equity Financing	(2)	14,331	69,905	0	0
Debt proceeds/repayment	7,132	(251)	2,670	(217)	(5,000)
Dividends	0	0	0	0	0
Others	0	5,113	0	0	0
Net Cash Flow	(1,232)	1,581	56,413	(39,315)	(38,645)
Opening cash	**26,561**	**24,376**	**26,619**	**82,505**	**43,190**
Other	(953)	662	(527)	0	0
Closing cash	**24,376**	**26,619**	**82,505**	**43,190**	**4,544**
Net cash/(debt)	**11,296**	**9,654**	**60,776**	**20,702**	**(13,951)**

Source: Company documents, Edison Investment Research

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