BioVersys

Clinical progress, commercial optionality

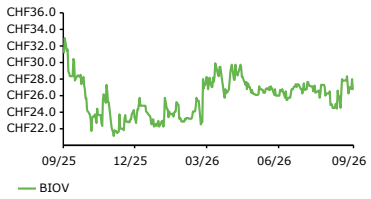
H126 results

Healthcare

17 September 2026

Price	**CHF27.00**
Market cap	**CHF158m**
	CHF0.79/$
Net cash/(debt) at 30 June 2026	CHF47.1m
Shares in issue	5.9m
Free float	73.0%
Code	BIOV
Primary exchange	SWX
Secondary exchange	N/A

Share price performance



Business description

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

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BioVersys's H126 results mark a key transition in the investment case towards pivotal clinical execution. The Phase III RIV-TARGET commenced recruitment in April, with end-2027 enrolment guidance maintained. While several clinical milestones have shifted modestly, including top-line data now expected in early 2028, we do not view this as materially concerning, with the slippage attributed more to logistics than regulatory or study design issues. RIV-CARE is approaching FPFV, and we see H127 interim data (previously end-2026) as crucial in establishing BV100's differentiation in high-resistant settings. Alpibectir is also progressing, with the GSK-led pulmonary TB study underway and the BioVersys-led TB meningitis study targeting FPFV in Q426 (Q226 previously). Notably, FY26 operating loss guidance has improved to CHF32–34m, with only c CHF3m attributable to R&D phasing; cash guidance has increased to CHF53m. Reflecting H126 adjustments, our valuation rises modestly to CHF71.8/share.

Year end	Revenue (CHFm)	PBT (CHFm)	EPS (CHF)	DPS (CHF)	P/E (x)	Yield (%)
12/24	1.2	(18.7)	(5.62)	0.00	N/A	N/A
12/25	3.3	(21.8)	(3.89)	0.00	N/A	N/A
12/26e	4.8	(33.4)	(5.71)	0.00	N/A	N/A
12/27e	6.1	(40.4)	(6.90)	0.00	N/A	N/A

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

BV100: De-risking through execution

BV100 remains the principal value driver, with the RIV-TARGET initiation the key H126 highlight. Focus now shifts to execution and enrolment delivery, ahead of top-line readouts in early 2028. The recent Fast Track designation supports faster, more efficient FDA review, potentially expediting approval. Moreover, RIV-CARE remains strategically important, as H127 interim data could provide earlier evidence of differentiation in highly resistant patients and strengthen positioning versus newer therapies. Interestingly, the proposed EU reimbursement reforms and subscription-style models seem to be reshaping the European commercial economics for novel antimicrobials, broadening BV100's long-term value opportunity.

Alpibectir: A credible secondary value driver

Momentum is building behind second asset alpibectir, although the BioVersys-led Phase II TB meningitis study has seen a modest start-up delay, with first patient first visit (FPFV) now expected in Q426. We do not view the timing shift as material given continued regulatory progress. GSK's Phase IIb/c STEP2C pulmonary TB study is also advancing after FPFV in March 2026. With both programmes progressing, alpibectir remains an important second value driver beyond BV100. Pending greater visibility, we retain end-2027 top-line readout assumption for both studies.

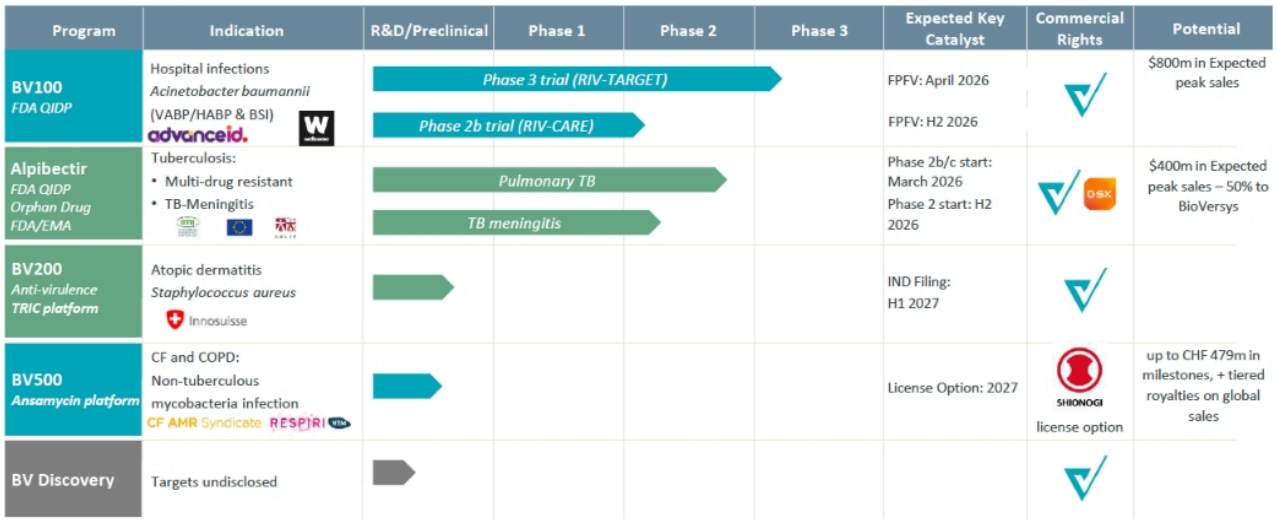
Valuation: Slight uplift to CHF71.8/share

Reflecting the H126 results, we rephrase some R&D expenditure into FY27 and update for the latest net cash position. We do not view the timeline shifts as material and leave our long-term assumptions unchanged. Our valuation increases marginally to CHF419.0m or CHF71.8/share, from CHF416.2m or CHF71.3/share.

H126 defined by meaningful clinical and regulatory progress

BioVersys is differentiated as one of the relatively few listed pure-play anti-infectives companies, focused on developing novel therapies for serious, life-threatening infections caused by drug-resistant pathogens. Its pipeline is led by Phase III-stage BV100 in carbapenem-resistant *Acinetobacter baumannii* (CRAB) infections, alongside alpibectir in tuberculosis (TB) and earlier-stage antimicrobial programmes, including BV500 and BV200, underpinned by its proprietary ansamycin discovery and transcriptional regulator inhibitory compound (TRIC) platforms (Exhibit 1). This provides investors with differentiated exposure to the growing antimicrobial resistance (AMR) theme through a focused, clinically advanced portfolio.

Exhibit 1: BioVersys development pipeline



Source: BioVersys corporate presentation, September 2026

BV100: One step closer to the market in H126

The central highlight of the H126 results remains the ongoing pivotal Phase III RIV-TARGET study of BV100 in ventilator-associated bacterial pneumonia (VABP) and hospital-acquired bacterial pneumonia (HABP) caused by CRAB, which has been classified as a critical-priority pathogen by the World Health Organization. RIV-TARGET is designed as a randomised, active-controlled, two-part parallel-group Phase III trial, enrolling c 300 patients across 100 sites in c 15 countries globally. It compares BV100 plus low-dose polymyxin B with colistin plus high-dose ampicillin-sulbactam, with 28-day all-cause mortality as the primary endpoint. The study is primarily a non-inferiority trial with an additional test for superiority and is intended to support initial regulatory submissions to the FDA, EMA and China's NMPA. The trial also 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. Around 25 participants are anticipated to be enrolled in this cohort.

Early recruitment signals encouraging

Following FPFV in April 2026, management has indicated that over 50% of the participating countries have been activated, with the focus now on site ramp-up and enrolment momentum. The first data safety monitoring board (DSMB) review is expected before end-2026, providing an important early safety checkpoint. Notably, the broader global development infrastructure is also falling into place. Completion of the Chinese Phase I bridging study in April enables Chinese sites to join RIV-TARGET, with FPFV in China expected in March 2027 (previously end-2026). While the top-line readout timeline has shifted modestly to early 2028, management continues to guide to last patient enrolment by end-2027 and first regulatory submissions around mid-2028. We do not view this slight delay in timelines as materially concerning, given that management has attributed this to logistical issues associated with moving study drug, assessment kits and other materials through customs and into trial sites, rather than regulatory delays or changes to the study design. BioVersys also noted that recruitment at currently active sites is running ahead of internal expectations, with the possibility of enrolment completing ahead of schedule not ruled out (should the current pace be sustained),

although the complexity of ICU studies and the capacity of individual hospitals remain limiting factors.

We remind readers that the clinical rationale for Phase III testing is supported by encouraging efficacy signals from the prior Phase II study, which demonstrated a 28-day all-cause mortality of 28.5% with BV100 versus 60% with best available therapy, alongside bacterial clearance of 75% versus 50% and clinical cure of 75% versus 30%. While we caution that this was a small trial (n=30) and Phase III replication will be critical to establish efficacy, the magnitude and consistency across endpoints remain encouraging. In our view, the principal near-term deliverable is now execution, with recruitment pace and eventual replication of the encouraging Phase II mortality signal the key determinants of further de-risking.

The regulatory backdrop has also strengthened. In September 2026, the FDA granted BV100 Fast Track designation, complementing its existing Qualified Infectious Disease Product (QIDP) designation, awarded in 2019. Fast Track status can facilitate more frequent interaction with the FDA and potential for rolling review, while QIDP designation provides eligibility for priority review and an additional five years of US regulatory exclusivity if approved. In our view, these designations should help streamline regulatory engagement and could support a more efficient review process while enhancing the commercial durability of BV100 (upwards of 10 years of market exclusivity) if successfully approved.

RIV-CARE remains strategically important

While RIV-TARGET remains the primary pivotal-stage study for BV100, we also view the open Phase IIb RIV-CARE study as strategically important given that it is designed to generate additional real-world evidence for BV100 in settings with very high drug resistance and against contemporary best available therapy, including newer treatments such as Xacduro, which is increasingly being recommended as the primary treatment for CRAB infections in the US. The study will recruit around 115 patients across 25–30 sites in four to five countries in South-East Asia (countries with high treatment resistance rates, upwards of 70%), with Wellcome funding offsetting a substantial proportion (c 75%) of the programme cost. 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.

An interim readout from the study is now planned for H127 versus end-2026 previously. The study endpoints are broadly similar to those used in the earlier Phase II trial, including all-cause mortality, microbiological cure and safety. We expect this will allow investors to assess whether the earlier efficacy profile translates into a more resistant, real-world patient population. Management indicated that around 30% of total recruitment would be sufficient to generate interim data.

Europe moves higher up the commercial agenda

Another key takeaway from the H126 results and subsequent management call was the improving commercial outlook for BV100 in Europe. While the US remains the primary target market, management acknowledged that the European opportunity for BV100 is becoming increasingly relevant as the reimbursement environment begins to address one of the key structural challenges of antimicrobial development, stewardship, which mandates novel antibiotics to be used selectively (to prevent treatment resistance), making traditional volume-price economics less attractive. This backdrop is starting to evolve, however. The UK has already introduced a subscription model whereby qualifying antimicrobials receive fixed annual payments based on their value to the healthcare system rather than usage volumes, improving revenue visibility while preserving stewardship principles. Management believes similar initiatives could make Europe materially more attractive than assumed in its earlier commercial planning.

Potentially more significant is the EU's proposed Transferable Exclusivity Voucher (TEV) framework for qualifying priority antimicrobials under the recently implemented policy reforms. The mechanism would provide 12 months of additional data protection, which could either be applied to another eligible medicine or sold to another pharmaceutical company, creating a potentially monetisable source of value largely independent of antibiotic sales volumes. Management estimates potential voucher economics at €150–300m, with c €200m cited as a reasonable reference point, and believes BV100 could be well positioned to qualify given its focus on a priority resistant pathogen. However, with final eligibility criteria still to be clarified, we currently do not incorporate TEV proceeds into our base-case valuation, but note the upside potential with further clarity. We continue to estimate peak sales of $700m for BV100 (more conservative than management's estimate of c $800m) but will revisit this assumption with increased visibility.

CRAB: Evolving competitive landscape, but resistance remains a limiting factor

CRAB remains one of the most difficult hospital-acquired infections to treat, with pneumonia and bloodstream infections associated with mortality rates of up to c 50%. Resistance to carbapenems is widespread (upwards of 50%, including over 70% in China and Southern and Eastern Europe) and clinicians have historically relied on last-resort therapies such as polymyxins, despite meaningful toxicity. While newer agents, including cefiderocol (Fetroja) and sulbactam-

durlobactam (Xacduro), have expanded the treatment landscape, resistance and treatment failure remain important concerns.

Xacduro has nevertheless raised the efficacy benchmark. In its registrational Phase III ATTACK study, 28-day all-cause mortality was 19.0% with Xacduro versus 32.3% with colistin, an absolute benefit of c 13pp. By comparison, BV100's Phase II study reported 28-day mortality of 28.5% versus 60.0% with best available therapy, representing a materially larger 31.5pp absolute reduction and a 52.5% relative risk reduction. While we caution against direct cross-trial comparisons, the signal remains encouraging. From an investment perspective, RIV-TARGET is therefore critical to establishing whether BV100 can reproduce this mortality benefit in a larger pivotal setting, while RIV-CARE should help define its differentiation in patients with highly resistant infections and following newer therapies.

Alpibectir: Mid-stage validation in progress

Clinical momentum with alpibectir continues, providing BioVersys with a differentiated second clinical asset beyond BV100. To our knowledge, alpibectir is the most advanced small-molecule candidate targeting bacterial transcriptional regulators for TB. The programme is partnered with GSK on a 50:50 cost- and net-revenue-sharing basis and follows a dual development strategy across pulmonary TB, led by GSK, and TB meningitis, led by BioVersys.

In pulmonary TB, GSK's Phase IIb/c STEP2C study remains the principal development focus, with FPFV achieved in March 2026. The study is evaluating AlpE, alpibectir combined with ethionamide, alongside first-line TB therapy. 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, among the key outcome measures. Top-line results are expected by end-2027. The programme builds on the earlier Phase IIa ENABLE study, assessing AlpE alongside first-line TB therapy. An important near-term catalyst is the November Union Conference, where GSK will present more detailed efficacy data from the ENABLE study, providing additional insight into the rationale for progression into STEP2C.

The BioVersys-led Phase II TB meningitis study has experienced a modest delay, with the first site to be onboarded in September 2026 and FPFV now expected in Q426 versus Q226 previously. We do not currently view this as indicative of an underlying development issue, particularly given ongoing regulatory progress. The multicentre, randomised, active-controlled study will assess pharmacokinetics, safety and exploratory efficacy in newly diagnosed TB meningitis patients. Pending greater visibility on recruitment, we continue to model readouts from both programmes by end-2027, which should provide an important basis for determining the subsequent registrational strategy. We retain our c $400m peak sales assumption for alpibectir, underpinning its role as an important secondary growth driver beyond BV100.

Financials

For H126, operating income increased to CHF2.0m from CHF0.6m in H125, comprising CHF0.8m of revenue under the Shionogi research collaboration for BV500 and CHF1.2m of other operating income, including R&D tax credits, grants and cost reimbursements. We note that under the agreement, BioVersys is eligible for CHF5.0m in upfront and near-term research payments, while the partnership is expected to remove c CHF5.8m of BioVersys development expenditure through end-2027. Following clinical candidate selection, Shionogi may exercise its licence option, triggering potential development, regulatory and sales milestones of up to CHF479m, alongside tiered royalties on global sales. To date, a total of CHF1.6m has been recognised as income by BioVersys.

As expected, the transition of BV100 into pivotal development drove a marked increase in R&D expenditure to CHF13.6m from CHF6.2m in H125, representing c 82% of operating expenses. Conversely, G&A declined to CHF3.0m from CHF3.7m, reflecting lower consultancy and advisory costs following the 2025 IPO. Consequently, the operating loss increased to CHF14.6m from CHF9.4m, while the net loss was CHF15.6m versus CHF11.0m. Operating cash outflow was c CHF13.0m, equivalent to an average monthly cash burn of approximately CHF2.2m.

More notable, in our view, was the material improvement to FY26 guidance. Management now expects an operating loss of CHF32–34m, versus CHF40–45m previously, while year-end cash guidance has increased to CHF53m from c CHF43m. Importantly, we note that the improvement is not predominantly the result of R&D phasing into FY27 due to the slight shift in clinical timelines. Of the CHF8–10m operating loss improvement, management indicated that only c CHF3.1m relates to phasing of RIV-TARGET expenditure, primarily associated with logistics and country/site start-up. The remainder reflects c CHF3.3m of lower pass-through costs following negotiations with vendors and the CRO, c CHF1.0m of G&A and other project efficiencies, and c CHF0.5m of higher revenue and other income.

Estimates revisions reflect updated clinical timelines

Reflecting the H126 results and improved near-term cost visibility, we have made modest revisions to our forecasts. We now estimate FY26 R&D expenditure of CHF31.1m, versus CHF37.0m previously, reflecting lower expected spend during the year. We increase our FY27 R&D forecast to CHF39.0m from CHF33.1m, partly reflecting the rephasing of development expenditure into 2027, while also taking a more conservative view on continued late-stage clinical investment. We make smaller adjustments to operating income and G&A to reflect the H126 run-rate. Overall, we now forecast an operating loss of CHF32.3m in FY26, versus CHF40.4m previously, and CHF39.2m in FY27, versus CHF34.7m previously.

Funded into 2028, past key readouts

BioVersys ended H126 with CHF69.3m of cash, compared with CHF82.5m at end-FY25. Based on our revised cash-burn assumptions, including repayment of the first CHF5m European Investment Bank (EIB) tranche in August 2027, we estimate that existing liquidity should fund operations into early 2028, broadly consistent with management's guidance of funding into 2028 and potentially covering the expected RIV-TARGET top-line readout. However, we continue to see scope for a modest bridging financing requirement of c CHF10–20m to support regulatory filing activities, currently expected around mid-2028, and provide sufficient headroom ahead of a potential BV100 launch and subsequent revenue ramp.

Valuation

We value BioVersys using a risk-adjusted net present value (rNPV) methodology, incorporating its two key clinical-stage programmes, BV100 and alpibectir. Our core long-term assumptions remain broadly unchanged following the H126 results. As noted above, while certain development timelines have shifted modestly, we do not believe the changes warrant a material revision to our long-term assumptions at this stage.

For BV100, we retain our $700m peak sales assumption in CRAB infections and continue to model a potential launch in 2028, based on top-line Phase III data in early 2028 followed by regulatory filings by mid-2028. Our base case currently assumes self-commercialisation, particularly in the US and Europe, consistent with the significant value BioVersys could retain from a wholly owned commercial strategy. However, management remains open to regional commercial partnerships, particularly into China, where discussions with potential partners are ongoing. A regional licensing agreement could therefore provide additional non-dilutive upside through potential upfront and milestone payments, while reducing BioVersys's commercial investment requirements. We will revisit both our launch and commercial assumptions as visibility on RIV-TARGET enrolment and partnering strategy improves. We note that BV100 remains the principal driver of our valuation, accounting for over 80% of total equity value.

For alpibectir, our assumptions also remain unchanged. While FPFV for the BioVersys-led Phase II TB meningitis study is now expected in Q426 versus Q226 previously, we do not consider the modest delay material to the programme's longer-term outlook. We continue to model an initial launch in 2031 and peak sales of c $400m, applying probabilities of success of 30% for TB meningitis and 15% for pulmonary TB.

Incorporating our revised near-term forecasts, model roll-forward and latest net cash position, our BioVersys valuation increases marginally to CHF419.0m, or CHF71.8/share, from CHF416.2m, or CHF71.3/share, previously (Exhibit 2). Importantly, our valuation does not currently include potential proceeds from an FDA priority review voucher for alpibectir or a potential EU Transferable Exclusivity Voucher for BV100. We estimate that, if successfully secured and monetised, these incentives could represent c €300–400m of additional upside optionality, although eligibility, timing and ultimate monetisation value remain uncertain, and we therefore exclude them from our base case for now.

Exhibit 2: 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	575.5	60%	342.7	58.7
Alpibectir	TB meningitis	2031	100	37.7	30%	10.8	1.8
	Drug-resistant pulmonary TB	2032	300	125.0	15%	18.4	3.1
Net cash at end-June 2026				47.1		47.1	8.1
Valuation				**785.4**		**419.0**	**71.8**

Source: Edison Investment Research

Exhibit 3: 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**	**4,803**	**6,092**
Sales	0	0	800	2,350	2,350
R&D tax credit	858	734	1,342	1,980	3,107
Government and other grants	0	0	0	173	0
Cost of Sales	0	0	0	0	0
Gross Profit	**1,139**	**1,213**	**3,268**	**4,803**	**6,092**
R&D expenses	(14,825)	(12,947)	(16,502)	(31,070)	(38,973)
G&A expenses	(4,011)	(6,988)	(6,729)	(6,030)	(6,310)
D&A	(273)	(282)	(297)	(265)	(243)
EBITDA	**(17,424)**	**(18,440)**	**(19,666)**	**(32,031)**	**(38,947)**
Operating Profit (before amort. and except.)	**(17,697)**	**(18,722)**	**(19,963)**	**(32,297)**	**(39,191)**
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)**	**(32,297)**	**(39,191)**
Net Interest	(604)	3	(1,851)	(1,108)	(1,183)
Profit Before Tax (norm)	**(18,301)**	**(18,719)**	**(21,814)**	**(33,404)**	**(40,374)**
Profit Before Tax (FRS 3)	**(18,301)**	**(18,719)**	**(21,814)**	**(33,404)**	**(40,374)**
Tax	0	0	(16)	(14)	0
Profit After Tax (norm)	**(18,301)**	**(18,719)**	**(21,830)**	**(33,418)**	**(40,374)**
Profit After Tax (FRS 3)	**(18,301)**	**(18,719)**	**(21,830)**	**(33,418)**	**(40,374)**
Average Number of Shares Outstanding ('000)	2,986	3,332	5,615	5,851	5,851
EPS - normalised (CHF)	(6.13)	(5.62)	(3.89)	(5.71)	(6.90)
EPS - (IFRS) (CHF)	(6.13)	(5.62)	(3.89)	(5.71)	(6.90)
BALANCE SHEET					
Fixed Assets	**581**	**558**	**765**	**916**	**673**
Intangible Assets	0	0	0	138	138
Tangible Assets	581	558	765	778	535
Investments	0	0	0	0	0
Current Assets	**33,586**	**34,398**	**89,871**	**59,288**	**16,552**
Cash and cash equivalents	24,376	26,619	82,505	53,395	10,070
Prepaid expenses and other receivables	2,360	1,779	7,366	5,893	6,482
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**	**17,813**	**18,926**
Long-term borrowings	15,678	13,761	21,440	17,324	18,437
Employee benefit liabilities	546	840	489	489	489
Net Assets	**8,576**	**10,682**	**59,811**	**27,457**	**(12,918)**
CASH FLOW					
Operating Cash Flow	**(11,655)**	**(15,574)**	**(21,946)**	**(28,519)**	**(38,325)**
Net interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(49)	(38)	(216)	(374)	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	(29,110)	(43,325)
Opening cash	**26,561**	**24,376**	**26,619**	**82,505**	**53,395**
Other	(953)	662	(527)	0	0
Closing cash	**24,376**	**26,619**	**82,505**	**53,395**	**10,070**
Net cash/(debt)	**11,296**	**9,654**	**60,776**	**30,812**	**(8,626)**

Source: Company documents, Edison Investment Research

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