EDISON

SynAct Pharma

Broader resomelagon opportunity taking shape

Q226 results

Pharma and biotech

24 August 2026

SynAct's Q226 results marked a strategically important period in defining resomelagon's clinical and commercial opportunity. Following June's Phase IIb ADVANCE data, we expect RA to remain the principal value driver, with ACR20, CRP and SDAI signals sufficiently encouraging to support a potential Phase III path despite the missed DAS28-CRP primary endpoint. Importantly, the opportunity in acute settings is becoming more tangible. While RESOVIR-2 and RESPIRE are testing resomelagon's host-directed, pro-resolution mechanism across viral infections, we view the post-period Hipolabor agreement as early external validation of commercial interest in dengue and a credible route to market in Brazil, while preserving global rights. The SEK100m Fenja financing facility de-risks near-term development plans with headroom into Q327. Reflecting modest seasonality-related timeline shifts, our valuation adjusts to SEK39.4/share.

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/24	0.0	(90.8)	(2.08)	0.00	N/A	N/A
12/25	0.0	(119.0)	(2.17)	0.00	N/A	N/A
12/26e	0.0	(101.4)	(1.68)	0.00	N/A	N/A
12/27e	0.0	(63.3)	(0.98)	0.00	N/A	N/A

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

ADVANCE signals support Phase III push

We believe the June 2026 ADVANCE readout was more constructive than the primary-endpoint miss might suggest. A 76.4% ACR20 response at 40mg (p=0.06) was comparable to JAK inhibitors, alongside significant CRP and SDAI improvements. While the 0.19-point placebo-adjusted DAS28-CRP benefit fell short of our c 1.0-point benchmark, consistency across clinical and biomarker endpoints supports further development. We view the upcoming EoP2 discussions with the FDA and EMA as crucial in establishing if the dataset supports direct Phase III progression and how trial design can better manage placebo variability.

Viral opportunity gathering momentum

Seasonality has reset the viral programmes' prior Q326 readout timeline, but we view this as a timing issue rather than a change in the central valuation thesis. A weaker Brazilian dengue season has prompted SynAct to split RESOVIR-2, with renewed recruitment planned for H127, while an early European flu has pushed RESPIRE recruitment into Q127. Importantly, the post-period Hipolabor agreement provides early external validation of the dengue commercial opportunity and a route to market in Brazil. The revised plans appear sensible, although proof of concept now moves into 2027, modestly affecting our commercial timeline expectations.

Valuation: Adjusts slightly to SEK39.4 per share

Following Q226, we leave our RA assumptions unchanged but defer our assumed launch for respiratory viral infections to 2030 from 2029. Dengue remains excluded from our valuation, providing upside as clinical and commercial visibility improves. Reflecting revised viral timelines and the latest net cash position, our valuation adjusts to SEK2.22bn or SEK39.4/share, from SEK2.25bn or SEK40.0/share.

Price	**SEK19.84**
Market cap	**SEK1,115m**
	SEK9.30/US$
Net cash/(debt) at 30 June 2026	SEK14.2m
Shares in issue	56.2m
Free float	56.5%
Code	SYNACT
Primary exchange	OMX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	2.7	36.5	10.6
52-week high/low		SEK25.3	SEK7.1

Business description

SynAct Pharma is a clinical-stage biotechnology company focused on the development of treatments to resolve, rather than inhibit, ongoing inflammatory processes in acute and chronic diseases.

Next events

End-of Phase II meeting regulatory package submission	H226
Q326 results	November 2026

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Phase IIb ADVANCE data: Moving the needle

Secondary signals keep Phase III path open

The quarter's defining event was the top-line readout from the Phase IIb ADVANCE study, evaluating resomelagon alongside methotrexate in first-line, newly diagnosed rheumatoid arthritis (RA) patients with high disease activity and evidence of systemic inflammation. In our view, ADVANCE remains SynAct's most consequential clinical milestone to date, with RA continuing to underpin the bulk of our valuation.

As discussed previously, ADVANCE missed its primary disease activity score in 28 joints using the C-reactive protein (DAS28-CRP) endpoint, although management believes the unexpectedly strong placebo response, c 50% higher than in prior studies, contributed materially to the outcome. The placebo-adjusted benefit was 0.19 points (1.98 vs 1.79; p=0.168), well below what we had considered a compelling level of differentiation (0.8–1.0-point improvement). That said, the 1.98-point improvement in the 40mg arm was meaningful in isolation and closely matched the 1.9-point reduction observed in the relevant subgroup of the earlier EXPAND study. This consistency across studies is notable, even if the lack of placebo separation tempers the strength of the conclusion.

Importantly, the efficacy signal was not confined to DAS28-CRP. We place particular weight on the American College of Rheumatology (ACR) response measures, given their broad acceptance and frequent use as primary efficacy endpoints in registrational RA studies. At 40mg, ADVANCE delivered an ACR20 response of 76.4% versus 60.8% for placebo, increasing to 76.9% versus 56.5% in the ACR/European Alliance of Associations for Rheumatology (EULAR) Class II–III subgroup. While cross-trial comparisons should be treated cautiously, the absolute response rate compares favourably with those reported for established biologic and Janus kinase (JAK) therapies. In our view, this supports further development, potentially with tighter patient selection to enrich for those most likely to benefit.

The biomarker data provide an additional layer of support. C-reactive protein (CRP) declined from 23.0mg/L to 9.5mg/L at 40mg, versus 17.7mg/L to 12.0mg/L for placebo, while the Simplified Disease Activity Index (SDAI) improved by 35.9 points versus 28.5 points, reaching statistical significance (p=0.03). The alignment of a clinical response measure, an objective inflammatory biomarker and an accepted disease-activity index strengthen the argument that resomelagon is pharmacologically active, even if placebo variability limited the study's ability to demonstrate clear separation on DAS28-CRP. For further details on the ADVANCE data, please refer to our previous update note.

Regulatory alignment key to Phase III

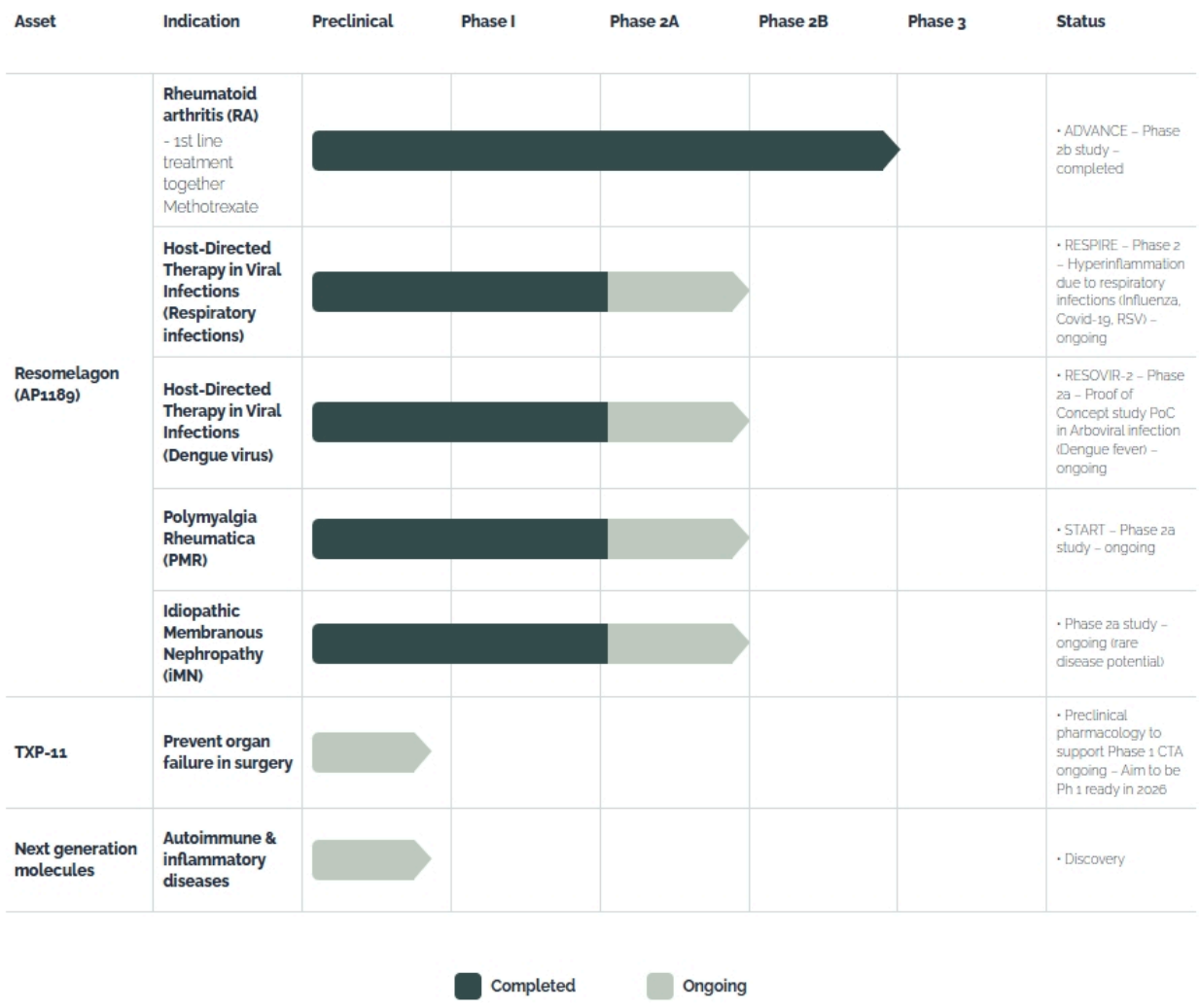
Given these observations, we expect the Phase III planning and design to underscore resomelagon's success potential in RA. In the Q226 report, management highlighted that the Phase III design could seek to demonstrate the full ACR20 response and subsequent ACR50 responses beyond 12 weeks, alongside larger treatment groups and refined patient selection, including repeated pre-treatment inflammatory biomarker assessments to confirm stable disease. We see merit in this approach. We had previously noted that response appeared to strengthen after week eight, suggesting that a 24-week or longer pivotal design may better capture the kinetics of an inflammation-resolution therapy, while improved patient selection could help reduce the placebo variability that complicated interpretation of ADVANCE.

We therefore view the upcoming End-of-Phase II (EoP2) regulatory interactions with the FDA and EMA as the next major value-inflection point. The company is in the process of preparing a comprehensive data package for the meetings, with submission likely in H226. The central issue will be whether regulators consider the totality of the ADVANCE evidence sufficient to support direct progression into a registrational programme despite the primary endpoint miss and what design modifications would be required. We maintain that a direct and clearly defined Phase III path would materially reduce regulatory uncertainty and, in our view, also strengthen SynAct's position in partnering negotiations, given the interest already received by the company at Bio International. Conversely, a requirement for another confirmatory Phase II study would extend timelines and increase funding needs. Pending these discussions, we continue to assume direct Phase III progression and retain our 30% probability of success for first-line RA.

Acute setting opportunity gaining traction

We see the acute setting as an important second pillar for resomelagon alongside the core RA opportunity. While RA offers the larger, chronic-use commercial setting and remains the principal driver in our valuation, the ongoing Phase II RESOVIR-2 and RESPIRE studies (Exhibit 1) will be instrumental in establishing whether resomelagon's host-directed, pro-resolution mechanism can translate into the acute viral inflammation setting, where excessive immune activation contributes to disease severity. Success would therefore represent more than incremental indication expansion. It could broaden the mechanistic validation of resomelagon, diversify clinical development risk and create commercial optionality across a distinct treatment setting.

Exhibit 1: SynAct development pipeline



Source: SynAct Pharma

Brazil deal de-risks the commercial pathway

We view the Hipolabor term sheet as an early signal of commercial interest in resomelagon's potential in dengue and other acute viral infections. The proposed structure aligns incentives through a 50:50 split of development costs and profits, while preserving SynAct's rights outside Brazil and across other indications. Hipolabor is an established Brazilian pharmaceutical company and the country's largest manufacturer of injectable generics, with more than 100 registered products, nationwide hospital and outpatient reach and domestic manufacturing infrastructure. We believe these capabilities should materially reduce SynAct's local execution burden and support regulatory and commercial preparations if RESOVIR-2 (discussed in more detail below) delivers supportive data.

The commercial opportunity is substantial, albeit inherently volatile. The World Health Organization estimates 100m

to 400m dengue infections annually, with no specific treatment currently available for dengue or severe dengue. Brazil recorded more than 10m cases during the exceptional 2024 outbreak, while incidence can vary materially year to year. Indeed, 2026 has been an unusually weak season, with c 1.2m reported cases according to management, highlighting both the opportunity and the challenges of developing therapies for an outbreak-driven disease.

We note that the agreement remains non-binding at present, with completion of definitive terms expected in the coming months, representing an important near-term catalyst. The economics are potentially attractive: SynAct would retain a 50% share of Brazilian profits alongside additional sales milestones linked to the initial $200m of cumulative net sales. This could offer richer economics than a conventional royalty licence, although SynAct also retains meaningful development funding and execution exposure. We therefore await a definitive agreement and further clinical progress before incorporating the dengue opportunity into our forecasts and valuation.

RESPIRE: Q326 timeline slips, wider recruitment supports H227 readout

RESPIRE is a 96-patient, randomised Phase II study evaluating resomelagon 100mg once daily for 14 days in hospitalised adults with respiratory insufficiency caused by influenza, respiratory syncytial virus (RSV) or COVID-19. Its day-28 primary endpoint is a severe composite including death, invasive ventilation and organ support. The study remains strategically important for SynAct as it tests whether resomelagon's host-directed, pro-resolution mechanism can translate across respiratory viruses rather than targeting a single pathogen.

While the study was expected to readout in Q326, recruitment has been slower than anticipated, challenged by an unusually early influenza season in Europe, which reduced the pool of eligible patients after sites became active in Q126. SynAct has responded by onboarding new sites in New Zealand (Auckland, Christchurch and Wellington) to capture the Southern Hemisphere respiratory season and expects recruitment to restart in Europe when infection rates rise again from late Q426 and Q127.

We do not view the slower-than-initially-expected RESPIRE recruitment as particularly unusual for an acute respiratory study, where enrolment is inherently exposed to the timing and severity of seasonal viral circulation, an issue that has affected several previous RSV and influenza trials. For context, AstraZeneca/Sanofi's Phase III MELODY study of nirsevimab was paused in 2020 amid reduced RSV circulation before resuming in 2021; nirsevimab was subsequently approved as Beyfortus in 2023. While the programmes are not clinically comparable, the precedent illustrates how viral epidemiology can materially affect recruitment independent of the underlying therapeutic hypothesis.

With recruitment now spanning both hemispheres, we estimate top-line data in H227, and, accordingly, defer our assumed launch to 2030 from 2029. All other programme assumptions remain unchanged.

RESOVIR-2: Protocol reset preserves optionality

RESOVIR-2 is an investigator-sponsored Phase II study, targeting c 120 symptomatic dengue patients, randomised 1:1 to resomelagon or placebo on top of supportive care. The primary study objective is the time to disease resolution using a composite endpoint, with warning signs and severe dengue among the secondary measures. As with RESPIRE, recruitment has been constrained by an unusually mild dengue season in Brazil. Encouragingly, management reports that sufficient patients have been treated to confirm, on a blinded basis, the feasibility of the primary endpoint and validate key sample-size and powering assumptions.

SynAct now plans to amend the protocol so that patients recruited to date form an initial study part, which will be unblinded and analysed, followed by a second recruitment phase during the H127 dengue season. We view this as a logical response to the recruitment challenge, preserving the value of data already generated rather than forcing an underpowered readout or restarting the study. Importantly, analysis of the first cohort could help refine the subsequent stage, including endpoint assumptions and powering, potentially improving the robustness of the eventual dataset.

We currently assign no value to the dengue opportunity, providing potential upside as RESOVIR-2 advances towards registration and commercialisation.

Financials

Lower losses, higher cash burn in Q226

Q226 financial results were relatively uneventful compared with the strategic developments. As a clinical-stage company, SynAct reported no revenues during the quarter and recorded an operating loss of SEK24.6m, down 19.1% y-o-y and 19.6% q-o-q. This was primarily driven by lower R&D expenses, which fell to SEK15.5m from SEK23.7m in Q225, reflecting the completion of the ADVANCE study. On the other hand, G&A expenses increased by 37.0% y-o-y and 18.8% q-o-q, offsetting some of the benefit from the lower R&D. The quarterly net loss narrowed to SEK22.0m from SEK27.5m.

Cash conversion was less favourable. Despite lower losses in the quarter, operating cash outflow increased materially to SEK34.5m (SEK18.8m in Q225), with the differences largely reflecting working-capital movements. SynAct also recorded an outflow of SEK13.9m from investing activities. Overall, cash burn in the quarter rose sharply to SEK48.4m, with SynAct exiting Q226 with SEK14.2m of cash and cash equivalents.

Fenja financing extends strategic runway

The liquidity position has been subsequently bolstered by the SEK100m convertible financing facility raised in July from Fenja Capital, of which SynAct has drawn down SEK50m. The remaining amount is available for drawdown in Q426 at the company's discretion (subject to a 10% market capitalisation cap; SEK1bn). The facility matures in December 2027. With additional capital in hand, we estimate that SynAct is funded into Q327 (in line with management guidance), providing greater flexibility to complete Phase III readiness work and progress partnering discussions.

The convertibles have a SEK24.60 conversion price, with up to 2.03m shares issuable from the first SEK50m draw. Full utilisation could lead to c 6.7% dilution from the convertibles, while 2.04m associated warrants at SEK27.55 represent a further c 3.5% potential dilution. Drawn amounts bear interest at the three-month Stockholm Interbank Offered Rate, subject to a 2% floor, plus 8%, and the facility includes a 3.5% arrangement fee. A six-month lock-up on shares issued through conversion or warrant exercise should limit near-term selling pressure. While the facility comes with relatively high servicing costs, we believe the flexible drawdown structure provides SynAct with useful strategic headroom while limiting upfront dilution ahead of potential partnering for resomelagon, one of the most significant re-rating events for the company.

Estimate revisions

Following the Q226 results, we make modest revisions to our FY26 and FY27 forecasts. With ADVANCE now complete, we expect R&D spend to moderate in H226 and therefore retain our FY26 R&D estimate of SEK59.9m. We modestly increase G&A to SEK34.7m from SEK32.2m, reflecting the H126 run-rate, resulting in a revised FY26 operating loss of SEK94.6m versus SEK92.1m previously. We also incorporate higher financing costs associated with the Fenja facility, increasing our FY26 net loss estimate to SEK93.3m from SEK83.8m.

For FY27, we raise our R&D expectations to SEK25.0m from SEK20.0m to reflect the extended RESPIRE timeline, with topline data now expected in H227 rather than Q326. Consequently, we now forecast FY27 operating and net losses of SEK60.4m and SEK55.1m, respectively, versus SEK52.8m and SEK42.6m previously.

Valuation: Increased strategic optionality, but further proof required

In our last update note following the ADVANCE readout, we had retained our underlying assumptions for resomelagon in newly diagnosed RA (including a 30% probability of success, a 2032 launch and $2.3bn in peak sales). We maintain our stance pending FDA and EMA feedback from the EoP2 meeting. Equally, we do not yet assign a separate value to the Brazilian dengue opportunity while the Hipolabor arrangement remains a term sheet and before RESOVIR-2 has generated interpretable efficacy data. The key change to our valuation comes from the respiratory viral infections opportunity for which we have delayed the estimated launch by a year to 2030, following the recent recruitment update from the company.

Incorporating the above as well as the latest net cash position, our valuation for SynAct adjusts modestly to SEK2.22bn or SEK39.4/share, from SEK2.25bn or SEK40.0/share previously. Exhibit 2 presents a breakdown of our valuation for SynAct.

Exhibit 2: SynAct risk-adjusted net present value

Product	Indication	Expected launch	Peak sales ($m)	NPV (SEKm)	Probability	rNPV (SEKm)	rNPV/share (SEK)
Resomelagon	Rheumatoid arthritis – newly diagnosed patients	2032	2,300	5,893.5	30%	1,756.7	31.2
	Rheumatoid arthritis – flares	2033	1,000	2,410.7	15%	338.7	6.0
	Respiratory viral-infections	2030	360	1,348.4	20%	254.1	4.5
	Polymyalgia rheumatica	2032	180	414.4	10%	37.0	0.7
Direct costs to 2035 less tax				(185.8)		(185.8)	(3.3)
Net cash at end-June 2026				14.2		14.2	0.3
Valuation				**9,895.5**		**2,215.0**	**39.4**

Source: Edison Investment Research

Although not yet fully captured in our valuation, we believe recent developments have improved the quality of SynAct's strategic optionality. ADVANCE generated encouraging clinical and biomarker evidence supporting continued development and a plausible Phase III path, although the primary endpoint miss remains the key regulatory risk. The Hipolabor term sheet demonstrates tangible commercial interest in the acute inflammation setting, and the Fenja facility gives management increased headroom and more time to negotiate. The next major catalysts are therefore regulatory alignment on a Phase III RA pathway, conversion of the Hipolabor term sheet into a definitive agreement and timely execution of the revised viral programmes. A direct Phase III path would materially improve the investment case; conversely, a requirement for further Phase II work would extend timelines, increase funding needs and likely delay partnering.

Exhibit 3: Financial summary

SEKm	2023	2024	2025	2026e	2027e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	0.00	0.00	0.00	0.00	0.00
Licensing income	0.00	0.00	0.00	0.00	0.00
Royalties	0.00	0.00	0.00	0.00	0.00
Others	0.00	0.00	0.00	0.00	0.00
Cost of Sales	0.00	0.00	0.00	0.00	0.00
Gross Profit	0.00	0.00	0.00	0.00	0.00
R&D expenses	(105.06)	(49.31)	(85.61)	(59.91)	(25.00)
G&A expenses	(44.83)	(40.49)	(31.54)	(34.69)	(35.38)
EBITDA	(149.18)	(89.36)	(115.89)	(94.08)	(60.12)
Operating Profit (before amort. and except.)	(149.94)	(89.98)	(116.54)	(94.60)	(60.38)
Intangible Amortisation/impairment	(74.56)	0.00	0.00	0.00	0.00
Exceptionals	0.00	0.00	0.00	0.00	0.00
Other	0.00	0.00	0.00	0.00	0.00
Operating Profit	(224.50)	(89.98)	(116.54)	(94.60)	(60.38)
Net Interest	0.22	(0.85)	(2.45)	(6.84)	(2.92)
Profit Before Tax (norm)	(149.72)	(90.82)	(118.99)	(101.44)	(63.31)
Profit Before Tax (reported)	(224.28)	(90.82)	(118.99)	(101.44)	(63.31)
Tax	8.47	8.42	8.17	8.17	8.17
Profit After Tax (norm)	(141.25)	(82.40)	(110.83)	(93.27)	(55.14)
Profit After Tax (reported)	(215.81)	(82.40)	(110.83)	(93.27)	(55.14)
Average Number of Shares Outstanding (m)	32.52	39.53	51.08	55.54	56.21
Basic EPS - normalised (SEK)	(4.34)	(2.08)	(2.17)	(1.68)	(0.98)
Basic EPS - reported (SEK)	(6.64)	(2.08)	(2.17)	(1.68)	(0.98)
BALANCE SHEET					
Fixed Assets	152.96	156.67	149.17	162.55	162.29
Intangible Assets	152.16	154.59	147.82	147.82	147.82
Tangible Assets	0.66	1.94	1.21	0.70	0.44
Investments	0.14	0.14	0.14	14.03	14.03
Current Assets	75.06	94.00	71.35	44.04	39.16
Stocks	0.00	0.00	0.00	0.00	0.00
Debtors and prepaid expenses	4.48	24.32	9.98	10.89	5.42
Cash	62.40	61.21	53.41	25.19	25.78
Other	8.19	8.47	7.97	7.97	7.97
Current Liabilities	24.94	28.46	21.52	61.21	111.21
Creditors and accrued expenses	19.48	27.44	20.63	10.31	10.31
Short-term borrowings	0.00	0.00	0.00	50.00	100.00
Lease liabilities and others	5.45	1.02	0.90	0.90	0.90
Long-Term Liabilities	26.90	27.89	28.70	26.13	26.13
Long-term borrowings	0.00	0.00	0.00	0.00	0.00
Other long-term liabilities	26.90	27.89	28.70	26.13	26.13
Net Assets	176.19	194.32	170.29	119.25	64.10
CASH FLOW					
Operating Cash Flow	(100.18)	(89.20)	(97.33)	(106.55)	(49.41)
Net interest	0.00	0.00	0.00	0.00	0.00
Tax	0.00	0.00	0.00	0.00	0.00
Capex	0.00	0.00	0.00	(13.89)	0.00
Acquisitions/disposals	0.37	0.00	0.00	0.00	0.00
Financing	53.98	87.41	90.46	42.23	0.00
Dividends	0.00	0.00	0.00	0.00	0.00
Net Cash Flow	(45.82)	(1.79)	(6.87)	(78.22)	(49.41)
Opening net debt/(cash)	(108.25)	(62.40)	(61.21)	(53.41)	24.81
Other	(0.03)	0.61	(0.93)	0.00	0.00
Closing net debt/(cash)	(62.40)	(61.21)	(53.41)	24.81	74.22

Source: Company documents, Edison Investment Research

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