EDISON

SynAct Pharma

Secondary endpoints reshape the debate

Clinical trial update

Pharma and biotech

18 June 2026

We refresh our investment thesis for SynAct Pharma following top-line results from the Phase IIb ADVANCE trial. While the trial missed the primary DAS28-CRP endpoint, we are encouraged by other strong efficacy signals, particularly the 76.4% ACR20 response rate at the selected 40mg dose, comparable to biologics and JAK inhibitors. Significant improvements in C-reactive protein (CRP) and the Simplified Disease Activity Index (SDAI), together with a favourable safety and tolerability profile, support resomelagon's pro-resolution mechanism, a potentially important differentiator in the autoimmune space. The upcoming end-of-Phase II (EoP2) meetings with the FDA and EMA will be critical in determining the regulatory pathway and Phase III strategy. Pending regulatory feedback, we retain a 30% probability of success in rheumatoid arthritis (RA), while delaying our launch assumptions by one year and incorporating resomelagon's extended US market exclusivity through 2044. Our valuation remains largely unchanged at SEK2.25bn, or SEK40.0/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
12/25e	0.0	(119.0)	(2.17)	0.00	N/A	N/A
12/26e	0.0	(91.9)	(1.49)	0.00	N/A	N/A
12/27e	0.0	(50.8)	(0.76)	0.00	N/A	N/A

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

Positive efficacy signals despite mixed results

Although ADVANCE missed its primary endpoint, with a 0.21 placebo-adjusted DAS28-CRP improvement (against our expectation of around 0.8–1.0), we believe the result needs to be viewed in the context of an unusually high placebo response, absent in the prior BEGIN and EXPAND studies. More importantly, the trial generated encouraging efficacy signals across secondary endpoints, particularly ACR20, the FDA's preferred efficacy measure in RA registrational studies. There were also significant improvements in inflammatory markers, including CRP (13.5mg/L reduction vs 5.7mg/L for placebo) and SDAI (35.9 vs 28.5; p=0.03), supporting resomelagon's pro-resolution mechanism.

EoP2 meeting crucial to define future plans

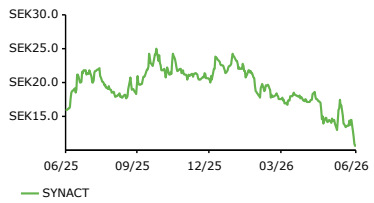
We believe the upcoming EoP2 discussions will be key in determining whether the findings are sufficient for a registrational programme and partnering discussions. In our view, the regulatory inclination towards ACR20 as well as signals on other secondary endpoints support further development. Favourable safety and extended US exclusivity through 2044 also strengthen the long-term investment case.

Valuation: SEK2.25bn or SEK40.0 per share

We maintain a 30% success probability in RA, pending feedback from the EoP2 meeting. We conservatively extend our launch expectations to 2032, from 2031 previously, while incorporating the extended US market exclusivity to 2044 (2041 previously). Our valuation remains largely unchanged at SEK2.25bn or SEK40.0 per share (SEK2.25bn or SEK40.1 per share previously).

Price	**SEK10.66**
Market cap	**SEK589m**
	SEK9.30/US$
Net cash/(debt) at 31 March 2026	SEK65.8m
Shares in issue	53.3m
Free float	53.3%
Code	SYNACT
Primary exchange	OMX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(21.8)	(37.0)	(33.5)
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

Phase II RESPIRE trial results	Q326
EoP2 meetings	Q326/Q426

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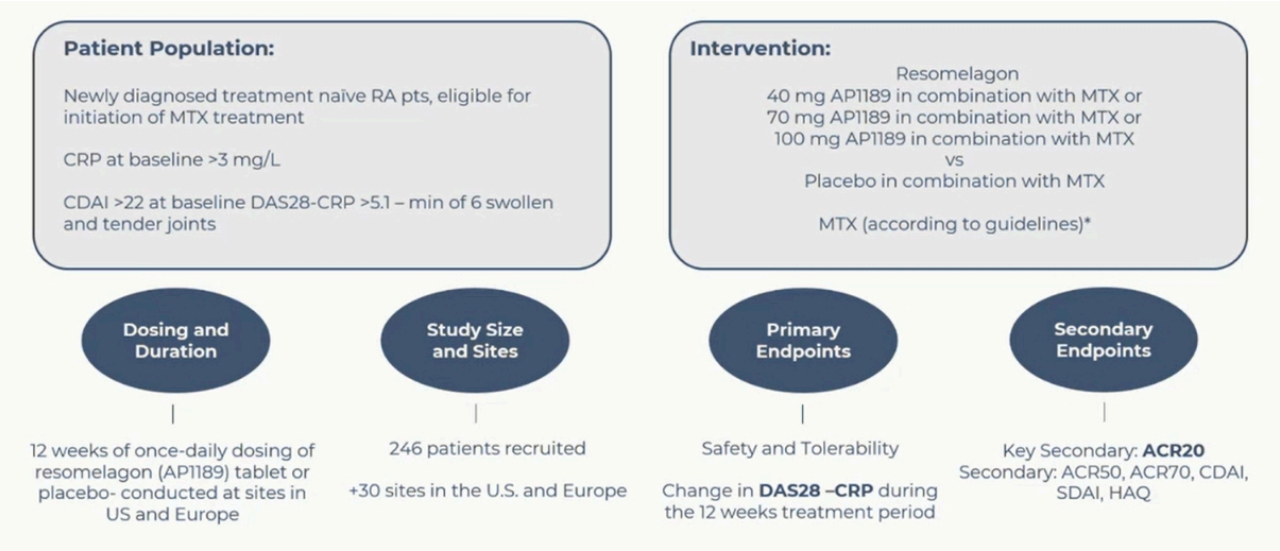
Phase IIb ADVANCE trial: Mixed outcome, supportive signals

ADVANCE identifies 40mg as the lead dose

SynAct recently reported top-line results from the Phase IIb ADVANCE trial, a 12-week, placebo-controlled study evaluating resomelagon in combination with methotrexate in 246 newly diagnosed, treatment-naïve RA patients with high disease activity. The primary endpoint was DAS28-CRP (which provides a measure of disease activity in RA using clinical and laboratory data, specifically looking at C-reactive protein) with American College of Rheumatology (ACR) response rates (ACR20, 50 and 70), clinical disease activity index (CDAI) scores and SDAI as the secondary endpoint measures. The trial tested three once-daily, oral doses of resomelagon (40mg, 70mg and 100mg). The primary objective of the trial was to assess efficacy, safety and tolerability as well as identify clinically relevant doses of resomelagon to be considered for Phase III. The trial design was optimised using observations from the previous Phase IIa BEGIN study and the Phase IIb EXPAND study. Exhibit 1 presents the ADVANCE trial design and endpoints.

Exhibit 1: Phase IIb ADVANCE trial – design and endpoints



Source: SynAct Pharma corporate presentation, June 2026

While the trial missed its primary DAS28-CRP endpoint, a key outcome was the identification of 40mg as the optimal dose for future development. The 40mg arm recruited 55 patients, versus 51 in the placebo arm. While slightly surprising (given that in the previous BEGIN and EXPAND studies, 100mg was judged as the optimal dose), this was not entirely unexpected given that management had previously hypothesised a non-linear dose-response relationship with resomelagon. This effectively means that higher doses do not necessarily translate into greater efficacy over time, which is consistent with the biology of melanocortin receptor agonists. We believe this provides greater clarity for Phase III planning and supports the biological rationale underpinning resomelagon's mechanism of action. Exhibit 2 and Exhibit 3 highlight the baseline data across cohorts and top-line results for the 40mg arm versus placebo across the major primary and secondary endpoints.

Exhibit 2: Baseline characteristics across cohorts

	Placebo + MTX N=51	Resomelagon 40 mg + MTX N=55	Resomelagon 70 mg + MTX N=55	Resomelagon 100 mg + MTX N=47
Age (years) Mean (SD)	57.63 (13.60)	61.51 (10.98)	56.87 (12.67)	56.38 (13.99)
Sex Female	35 / 51 (68.6%)	38 / 55 (69.1%)	39 / 55 (70.9%)	38 / 47 (80.9%)
Weight (kg) Mean (SD)	84.76 (19.46)	81.05 (15.26)	80.68 (13.52)	77.70 (15.80)
Time from diagnosis to baseline (days) Mean (SD)	59.98 (52.82)	62.82 (52.39)	69.25 (55.21)	62.28 (52.08)
ACR/EULAR group I / II / III	5/35/11	3/39/13	9/38/8	4/37/6
DAS28-CRP Mean (SD)	6.25 (0.69)	6.15 (0.72)	6.17 (0.80)	6.31 (0.76)
CDAI Mean (SD)	46.78 (11.54)	44.93 (10.22)	45.89 (11.77)	47.05 (11.55)
SDAI Mean (SD)	64.52 (21.57)	67..93 (38.61)	64.58 (24.45)	69.75 (31.26)
CRP, (mg/L) Mean (SD)	17.75 (19.40)	23.00 (35.52)	18.69 (21.60)	22.64 (27.33)

Source: SynAct Pharma corporate presentation, June 2026

Exhibit 3: ADVANCE trial results for the selected 40mg dose versus placebo

End of treatment Week 12- PP data set	Placebo + MTX (n=51)	40 mg Resomelagon + MTX (n=55)
ACR 20	60.8%	76.4% **p = 0.06**
ACR 50	35.3%	38.2% p > 0,05
ACR 70	11.8%	14.5% p > 0,05
Change in DAS28-CRP (mean± SE)	-1,79 (0,14) n = 51	-1,98 (0,14) p > 0,05
Change in CDAI (mean± SE)	-22,32 (1,55)	-23,47 (1,51) p > 0,05
Change in SDAI (mean± SE)	-28,50 (2,80) n = 51	-35,85 (2,71) **p = 0,030**
hsCRP (mg/dl mean)	From 17,7 to 12,0 p > 0,05	From 23,0 to 9,5 **p =0,0037**
NLR Post Hoc analysis	From 3,20 to 3,01 p > 0,05	From 3,46 to 2,91 **p =0,04**

Source: SynAct Pharma corporate presentation, June 2026

Strong placebo response masked treatment effect

In our previous note on SynAct Pharma, we highlighted that a placebo-adjusted improvement approaching 1.0 points on the DAS28-CRP scale would be considered meaningful, given precedence from the previous JAK inhibitor trials. As shown in Exhibit 3, the ADVANCE trial reported a placebo-adjusted improvement of 0.19 points (1.98 vs 1.79; p=0.168), missing the primary endpoint. However, we note that this miss was at least partially driven by the stronger than anticipated placebo response (c 50% higher than in previous studies, according to management). For context, the 1.98 point reduction reported for the selected 40mg dose in ADVANCE was broadly consistent with the results seen in the EXPAND study, where the comparable subgroup of newly diagnosed patients with high disease activity had delivered a DAS28-CRP reduction of 1.9 points. However, the key difference was the substantially higher placebo response (1.79 point reduction vs 1.2 point in EXPAND), which compressed the treatment-placebo delta. While the primary endpoint miss cannot be ignored, we believe that this observation lends some support to management's argument that the ADVANCE outcome may have been driven more by placebo arm dynamics, than lack of treatment benefit.

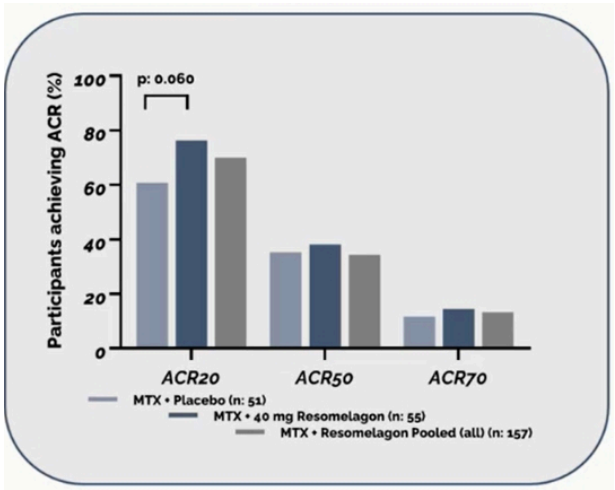
Secondary endpoints support continued development

In our view, the secondary endpoints data represent the most constructive aspect of the ADVANCE trial readout. Management noted that while all three tested doses demonstrated an ACR20 response greater than placebo, the 40mg dose delivered the highest benefit, with an ACR20 response of 76.4% (which corresponds to the percentage of patients achieving a 20% improvement in RA symptoms) versus 60.8% for placebo (Exhibit 4). Moreover, this benefit was amplified for the ACR/European Alliance of Associations for Rheumatology (EULAR) Class II–III subgroup (n=52), which reported an ACR20 of 76.9% versus 56.5% for placebo. Importantly, these findings are broadly consistent with signals previously observed in the inflammation-enriched populations from EXPAND (ACR20 of 82.1% (n=28) at 12 weeks versus 51.9% for placebo (n=27)), suggesting that the efficacy signal may be reproducible across studies.

Encouragingly, the ACR50 response seems to have improved in the ADVANCE trial in the treatment arm compared to EXPAND, with 38.9% of the patients in the treatment arm achieving ACR50 versus 25.0% in the EXPAND study. Management also noted that treatment responses continued to improve beyond week eight (Exhibit 5), indicating that ACR50 may improve incrementally with continued treatment. For reference, in a Phase III trial in RA, the treatment duration is typically 24–52 weeks. We therefore believe that a longer-term treatment window in a planned Phase III trial would be better aligned with resomelagon's biology and could potentially improve differentiation on deeper efficacy measures such as ACR50, ACR70 and remission rates.

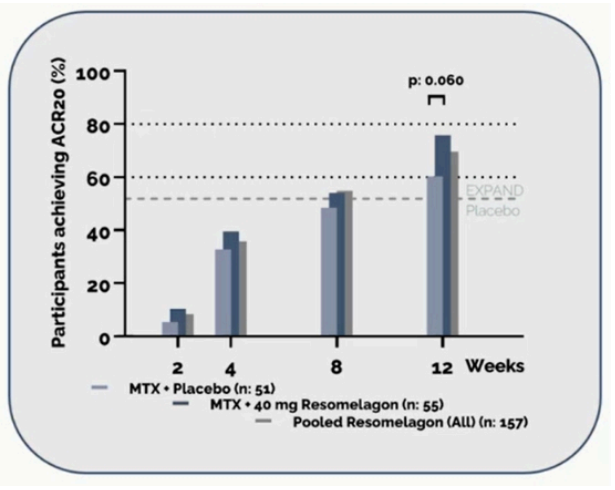
More broadly, we note that ACR20 response rates exceeding 75% compare favourably with those reported for several established biologics and JAK inhibitors, save for the unusually strong placebo response in ADVANCE. If resomelagon is able to replicate the ACR20 rates in subsequent, larger studies, without the placebo inflation, it could meaningfully strengthen the programme's potential.

Exhibit 4: ACR20 response at week 12



Source: SynAct Pharma corporate presentation, June 2026

Exhibit 5: ACR20 response over time

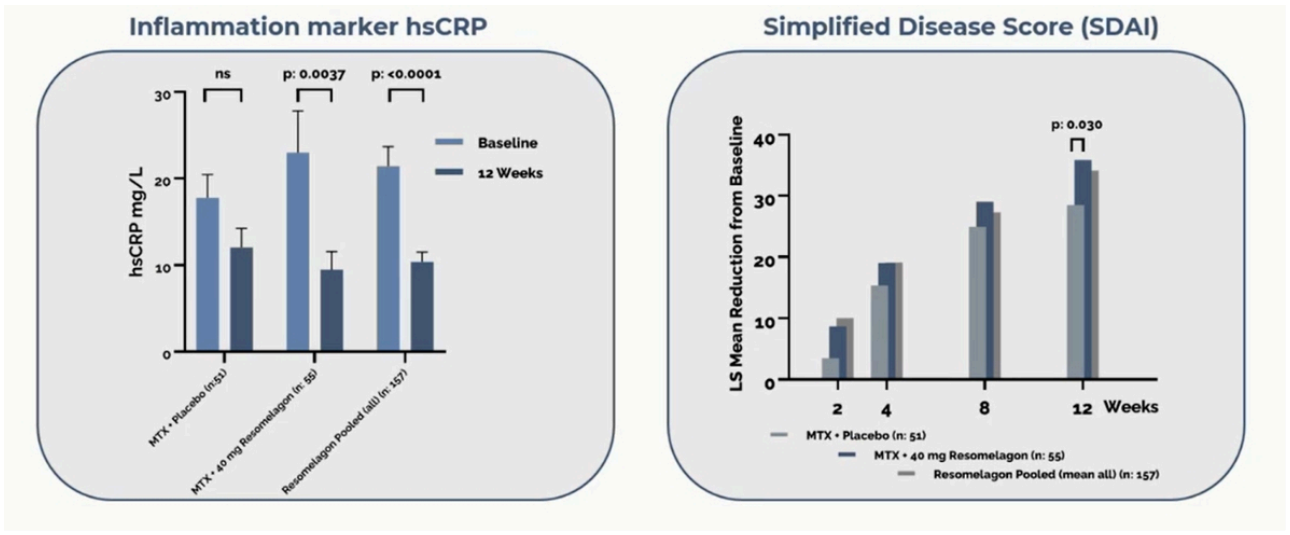


Source: SynAct Pharma corporate presentation, June 2026

Inflammatory biomarkers support mechanistic rationale

Beyond the ACR20 results, we believe the CRP and SDAI data provide important validation of resomelagon's proposed pro-resolution mechanism. The 40mg dose delivered a significant reduction in CRP, with mean levels declining from 23.0mg/L to 9.5mg/L, compared to a reduction from 17.7mg/L to 12.0mg/L in the placebo arm. Similarly, patients receiving resomelagon achieved a significantly greater improvement in SDAI than placebo (35.9 vs 28.5; p=0.03) (Exhibit 6). Importantly, both endpoints are closely linked to underlying inflammatory disease activity and are less susceptible to the subjective assessments that can influence composite clinical measures. Given that SDAI is recognised by regulators as an alternative measure of disease activity in dose-finding studies, the positive findings lend additional credibility to the overall efficacy profile. In our view, the consistency between CRP, SDAI and ACR20 suggests that the primary endpoint miss may not fully reflect the drug's therapeutic potential.

Exhibit 6: Significant improvement in inflammatory biomarkers



Source: SynAct Pharma corporate presentation, June 2026

A differentiated safety profile

While efficacy is likely to be the focus for investors following the ADVANCE readout, we believe that resomelagon's safety profile may be one of the drug's most important differentiators. Current RA treatment approaches are dominated by biologics and JAK inhibitors, which, despite their efficacy, are associated with recognised risks including serious infections, malignancies, major cardiovascular events and thromboembolic complications. Several approved JAK inhibitors, including Rinvoq and Olumiant, carry black box warnings in the US. Against this backdrop, ADVANCE

demonstrating a favourable safety and tolerability profile, with no evidence of immunosuppression, is a key positive. There were no serious adverse events in any of the three dose arms. Most adverse events were termed mild or moderate and while the 100mg cohort reported a proportionately larger number of adverse events, they were attributed to methotrexate treatment in most cases.

While longer-term studies will be required to confirm these findings, the combination of meaningful anti-inflammatory activity and preservation of immune function could support a differentiated positioning within the RA treatment landscape.

Regulatory feedback remains the key catalyst

Following the ADVANCE readout, management indicated that the next key milestone will be EoP2 meetings with the FDA and EMA, which we view as the most important near-term catalyst for SynAct. We expect upcoming discussions to centre around the strength of the secondary endpoint data and whether regulators view it as sufficient to support a registrational trial, despite the primary endpoint miss, otherwise additional confirmatory work could be required before Phase III. While primary endpoints are key considerations for regulators, we note that there are precedents, particularly in oncology and biomarker-driven indications, where supportive secondary endpoints and the broader weight of evidence have informed progression into late-stage development.

We believe the consistency of the ACR20, CRP and SDAI findings in ADVANCE, together with supportive signals from the earlier BEGIN and EXPAND studies, provide a solid basis for regulatory engagement. The outcome of these discussions will be critical in determining the Phase III design, endpoint selection and the need for any additional clinical work. A constructive regulatory outcome could materially reduce development risk, improve visibility on timelines and capital requirements, and strengthen SynAct's position in ongoing partnering discussions.

Accounting for the time required to prepare the data package for submission, we expect regulatory interactions to take place in H226, with feedback likely by late 2026 or early 2027. With top-line results from the Phase II RESPIRE study anticipated in Q326, we expect that data and insights from the trial may be used to further support regulatory discussions about resomelagon’s broader applicability.

Financials and valuation

Given that further clinical trial planning in RA will likely be driven by the results of the EoP2 meetings, we currently keep our probability of success for the RA programme unchanged at 30%. While we expect partnering discussions to continue through 2026, regulatory feedback will be a key determinant of both the timing and economics of any potential transaction. We had previously assumed a partnering deal in 2027, with a blended royalty rate of 20% of sales (in lieu of typical licensing deal terms, which include upfront and milestone payments). We keep these assumptions unchanged but conservatively extend our launch expectation by a year to 2032, from 2031 previously. We also adjust our model and forecasts for the recently announced extended IP protection for resomelagon in the US to July 2044, from 2041 previously.

Based on SynAct's end-Q126 net cash position of SEK65.8m, we estimate the company is funded into H127, providing sufficient runway beyond the anticipated RESPIRE top-line data and upcoming regulatory interactions.

Incorporating these changes, our valuation remains broadly unchanged at SEK2.25bn, or SEK40.0/share (Exhibit 7). While the share price reaction reflects uncertainty surrounding the primary endpoint miss, we believe upcoming regulatory feedback and RESPIRE data represent important catalysts that could provide greater clarity on the programme's development and commercial prospects and could serve as meaningful re-rating catalysts.

Exhibit 7: 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	5,771.1	30%	1,720.2	30.6
	Rheumatoid arthritis – flares	2033	1,000	2,360.7	15%	331.7	5.9
	Respiratory viral-infections	2029	360	1,407.2	20%	267.7	4.8
	Polymyalgia rheumatica	2032	180	405.8	10%	36.3	0.6
Direct costs to 2035 less tax				(172.3)		(172.3)	(3.1)
Net cash at end-March 2026				65.8		65.8	1.2
Valuation				**9,838.4**		**2,249.4**	**40.0**

Source: Edison Investment Research

Exhibit 8: 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)	(20.00)
G&A expenses	(44.83)	(40.49)	(31.54)	(32.17)	(32.81)
EBITDA	(149.18)	(89.36)	(115.89)	(91.55)	(52.55)
Operating Profit (before amort. and except.)	(149.94)	(89.98)	(116.54)	(92.07)	(52.81)
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)	(92.07)	(52.81)
Net Interest	0.22	(0.85)	(2.45)	0.16	2.05
Profit Before Tax (norm)	(149.72)	(90.82)	(118.99)	(91.91)	(50.76)
Profit Before Tax (reported)	(224.28)	(90.82)	(118.99)	(91.91)	(50.76)
Tax	8.47	8.42	8.17	8.17	8.17
Profit After Tax (norm)	(141.25)	(82.40)	(110.83)	(83.75)	(42.59)
Profit After Tax (reported)	(215.81)	(82.40)	(110.83)	(83.75)	(42.59)
Average Number of Shares Outstanding (m)	32.52	39.53	51.08	56.21	56.21
Basic EPS - normalised (SEK)	(4.34)	(2.08)	(2.17)	(1.49)	(0.76)
Basic EPS - reported (SEK)	(6.64)	(2.08)	(2.17)	(1.49)	(0.76)
BALANCE SHEET					
Fixed Assets	152.96	156.67	149.17	148.65	148.39
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	0.14	0.14
Current Assets	75.06	94.00	71.35	30.86	28.52
Stocks	0.00	0.00	0.00	0.00	0.00
Debtors and prepaid expenses	4.48	24.32	9.98	5.42	5.42
Cash	62.40	61.21	53.41	17.48	15.14
Other	8.19	8.47	7.97	7.97	7.97
Current Liabilities	24.94	28.46	21.52	21.52	61.52
Creditors and accrued expenses	19.48	27.44	20.63	20.63	20.63
Short-term borrowings	0.00	0.00	0.00	0.00	40.00
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	131.85	89.26
CASH FLOW					
Operating Cash Flow	(100.18)	(89.20)	(97.33)	(81.24)	(42.33)
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	0.00	0.00
Acquisitions/disposals	0.37	0.00	0.00	0.00	0.00
Financing	53.98	87.41	90.46	45.31	0.00
Dividends	0.00	0.00	0.00	0.00	0.00
Net Cash Flow	(45.82)	(1.79)	(6.87)	(35.93)	(42.33)
Opening net debt/(cash)	(108.25)	(62.40)	(61.21)	(53.41)	(17.48)
Other	(0.03)	0.61	(0.93)	0.00	0.00
Closing net debt/(cash)	(62.40)	(61.21)	(53.41)	(17.48)	24.86

Source: SynAct Pharma accounts, Edison Investment Research

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