ABG SUNDAL COLLIER

Ascelia Pharma

Fast comment

Commissioned research

Not rated

Healthcare

ACE-SE/ACE SS

Share price (SEK)	19/8/2026	0.55
MCap (SEKm)		73
MCap (EURm)		7
No. of shares (m)		133.5
Free float (%)		96.2

Next event Q3 report 5 November 2026

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Still alive: Fighting to reverse the FDA setback

- Type A meeting with the FDA scheduled for September 9
- Implementing cost-saving measures
- Conf call at 10am CET

Recent and upcoming relevant events

Following the July 2, 2026 Complete Response Letter for Orviglance, which cited concerns over the SPARKLE re-read (potential reader bias and a T1-only scoring scope) alongside small product documentation questions, Ascelia disputed both clinical grounds while acknowledging the product quality points, and moved to request an expedited Type A meeting. The FDA has now accepted that request and scheduled the meeting for September 9, 2026. Ahead of it, Ascelia has submitted a briefing package addressing each CRL topic, confirming it has aligned with and implemented the FDA's product quality recommendations, and defending the scientific rationale for the SPARKLE re-read, including reader training and the use of T1-weighted imaging as the basis for assessing lesion visualisation. Management reiterates confidence in the overall data package, with an update expected once official meeting minutes are received following the September 9 meeting (issued within 30 days, i.e. by mid-September).

Implementing cost-saving measures

Operating cash flow was SEK -14m (SEK -16m in Q1'26), as opex decreased 30% q-o-q. Following a directed share issue of gross SEK 20m in the quarter, cash and cash equivalents came in at SEK 34m (SEK 38m in Q1'26). After quarter's end, Ascelia has implemented cost-saving measures including the departure of the CFO to provide flexibility for supporting activities related to the CRL, which is stated to extend the cash runway into Q2'27.

Conference call at 10am

Ascelia will host a conference call at 10am CET today.

Disclosures and analyst certifications are located on pages 3-4 of this report.

SEKm	2024	2025	2026e	2027e
Sales	0	0	78	75
Sales growth (%)	--	--	--	*-4.3*
EBITDA	-68	-74	10	15
EBITDA margin (%)	--	--	*13.4*	*19.7*
EBIT adj.	-68	-74	10	15
EBIT adj. margin (%)	--	--	*13.4*	*19.7*
Pretax profit	-80	-77	11	14
EPS	-0.83	-0.60	0.09	0.10
EPS growth (%)	*-74.3*	*-28.4*	*nm*	*17.4*
EPS adj.	-0.83	-0.60	0.09	0.10
DPS	0.00	0.00	0.00	
EV/EBITDA (x)	-0.0	-0.3	-0.8	-1.5
EV/EBIT adj. (x)	-0.0	-0.3	-0.8	-1.5
P/E (x)	nm	nm	6.3	5.4
P/E adj. (x)	nm	nm	6.3	5.4
EV/sales (x)	--	--	-0.11	-0.30
FCF yield (%)	-118.9	-102.9	16.5	18.5
Le. adj. FCF yld. (%)	-120.6	-104.0	16.2	18.2
Dividend yield (%)	0.0	0.0	0.0	0.0
Net IB debt/EBITDA (x)	0.7	0.7	-7.9	-6.5
Le. adj. ND/EBITDA (x)	0.7	0.7	-8.0	-6.6

Source: ABG Sundal Collier, Company Data

Analyst Certification

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