Ascelia Pharma

Potential FDA reread and upcoming EU talks

- Q3 in line, loss narrows vs. Q2
- FDA open to SPARKLE reread, endpoint still undefined
- Building blocks in place for the next phase

Q3 in line, loss narrows vs. Q2

Q3 EBIT was SEK -10m vs. SEK -12m in Q2'26. R&D costs fell to SEK -8m (vs. SEK -9m in Q2'26) and admin costs to SEK -3m (vs. SEK -3m in Q2). Operating cash flow before working capital moved from SEK -11m to SEK -10m in Q2'26. Liquid assets were SEK 28m at end of Q3, vs. SEK 38m at end of Q2. As before, Ascelia guides for a cash runway into Q2'27.

FDA open to SPARKLE reread, endpoint sill undefined

The Type A minutes confirm that the FDA maintains that approval of Orviglance requires new clinical evidence. However, importantly, it is open to consider a prospective reanalysis of the SPARKLE images with a different primary endpoint as a possible route to approval. It acknowledged the unmet medical need, the safety profile and T1 technical performance, and alignment was reached on the product quality observations. In reply to our question, management said the FDA has not suggested a specific endpoint, leaving it to the sponsor to propose one that is feasible and statistically robust. The CSO described the sticking point as the reread using the same type of evaluation as the first read. A Type C meeting is planned for early '27, before any image reading, with better agreement on the methodology as the expected outcome. In parallel, Ascelia is preparing a dialogue with European regulators on the approvability of Orviglance based on the existing data package, noting that they may take a different view of the data.

Furthermore, Oncoral received notably more attention than in the written report and in previous webcasts. Oncoral is positioned as a daily low-dose chemotherapy tablet, aimed at keeping drug levels steady and improving tolerability, rather than a simple oral version of the intravenous high-dose infusions given every few weeks today. Gastric cancer in combination with Lonsurf remains the lead path. The Phase 2 design is unchanged, and the start remains pending.

Building blocks in place for the next phase

The Type A meeting leaves Ascelia in a better regulatory position than the CRL alone implied. The FDA has acknowledged the unmet medical need, the safety profile and technical performance, and the product quality observations now have an agreed strategy, which somewhat lower the level of uncertainty. A reread of the SPARKLE data would build on the existing dataset and would require a much smaller financing need than a new study. The cost base has been lowered, and the partnering process is continuing alongside a planned dialogue with European agencies on the existing data package. Valuation remains suspended until there is more clarity.

Fast comment

Commissioned research

Not rated

Healthcare

ACE-SE/ACE SS

Share price (SEK)	5/11/2026	0.56
MCap (SEKm)		75
MCap (EURm)		7
No. of shares (m)		134.0
Free float (%)		94.5

Next event Q4 report 11 February 2027

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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)	-0.1	-0.3	-0.7	-1.4
EV/EBIT adj. (x)	-0.1	-0.3	-0.7	-1.4
P/E (x)	nm	nm	6.5	5.5
P/E adj. (x)	nm	nm	6.5	5.5
EV/sales (x)	--	--	-0.09	-0.28
FCF yield (%)	-116.8	-101.0	16.2	18.2
Le. adj. FCF yld. (%)	-118.4	-102.1	15.9	17.9
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

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