

Ascelia Pharma

CRL update

- CRL questions SPARKLE endpoint analysis; re-read rejected
- Ascelia disputes both points; expresses confidence
- Type A meeting next; outcomes range widely

The CRL's stated grounds

In the CRL (Complete Response Letter), the FDA states that SPARKLE failed its co-primary endpoints on the initial read, and rejects the subsequent re-evaluation on two grounds: i.) a risk that new readers were influenced by prior knowledge of the images/results; and ii) a scoring scope limited to T1-weighted images, which the FDA says cannot show added value over standard-of-care imaging (which includes non-T1 sequences).

Ascelia's response

The company disputes both points. It states the second readers had no prior knowledge of the images or earlier results, directly countering the FDA's bias concern. On imaging scope, the FDA's comment concerns what was *scored* in the re-read, while Ascelia's statement concerns what was *acquired* in the trial (confirming T1, T2 and DWI sequences were all collected), a distinction the company appears confident resolves the concern once clarified with the FDA. Ascelia also states its re-read approach was discussed with the FDA pre-submission, though the CRL itself does not address this either way. On product documentation, management seems confident and expects resolution in the near term. Overall, Ascelia maintains that SPARKLE was an adequate and well-controlled pivotal study providing a robust basis for evaluating Orvigance, while remaining confident the product documentation issues can be resolved in the near term.

What's next?

Ascelia maintains that it will submit a briefing package and request an expedited FDA Type A meeting, which, if granted, is typically held within 30 days of the request. Outcomes could range from a relatively quick resolution based on clarification alone, to a further re-read scoring the full set of acquired sequences rather than T1 only, or, in the worst case, a new pivotal trial with fresh patient data, a materially tougher and likely unfeasible scenario given the funding and timelines required. While the FDA has historically applied a stringent standard when reviewing CRL responses and may ultimately require a more extensive path forward, management's confidence suggests it expects one of the faster outcomes. Valuation remains suspended until there is more clarity.

Fast comment

Commissioned research

Not rated

Healthcare

ACE-SE/ACE SS

Share price (SEK)	10/7/2026	0.55
MCap (SEKm)		73
MCap (EURm)		7
No. of shares (m)		133.5
Free float (%)		96.2

Next event Q2 report 20 August 2026

Analyst:

georg.tigalonov-bjerke@abgsc.no, +47 22 01 60 84

SEKm	2024	2025	2026e	2027e
Sales	0	0	78	75
<i>Sales growth (%)</i>	--	--	--	-4.3
EBITDA	-68	-74	10	15
<i>EBITDA margin (%)</i>	--	--	13.4	19.7
EBIT adj.	-68	-74	10	15
<i>EBIT adj. margin (%)</i>	--	--	13.4	19.7
Pretax profit	-80	-77	11	14
EPS	-0.83	-0.60	0.09	0.10
<i>EPS growth (%)</i>	-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

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Norway
Ruseløkkveien 26, 8th floor
0251 Oslo
Norway
Tel: +47 22 01 60 00
Fax: +47 22 01 60 60

Denmark
Forbindelsesvej 12,
2100 Copenhagen
Denmark
Tel: +45 35 46 61 00
Fax: +45 35 46 61 10

Sweden
Regeringsgatan 25, 8th floor
111 53 Stockholm
Sweden
Tel: +46 8 566 286 00
Fax: +46 8 566 286 01

United Kingdom
10 Paternoster Row, 5th floor
London EC4M 7EJ
UK
Tel: +44 20 7905 5600
Fax: +44 20 7905 5601

USA
140 Broadway, Suite 4604
New York, NY 10005
USA
Tel. +1 212 605 3800
Fax. +1 212 605 3801

Singapore
10 Collyer Quay
Ocean Financial Center
#40-07, Singapore 049315
Tel +65 6808 6082

Germany
Schillerstrasse 2, 5. OG
60313 Frankfurt
Germany
Tel +49 69 96 86 96 0
Fax +49 69 96 86 96 99

Switzerland
ABG Sundal Collier AG
Representative Office
Schwanenplatz 4
6004 Lucerne
Switzerland
Tel +41 79 502 33 39