Ascelia Pharma re-evaluation outcome: SPARKLE meet primary endpoints

Ascelia Pharma **Research Note** 2024-05-02 13:58

Orviglance meets the primary endpoint in the SPARKLE study with a p-value of <0.001. Equally important in this situation is that ” The reliability of the data is solid and conclusive for all readers – this includes an acceptable level of variability”. We look forward to further details and clarifications on the call scheduled for 7 May (CET 14.00).

Johan Unnerus

The outcome is very positive. All three readers in the study achieved the primary endpoint with a very strong p-value (<0.001). Equally important is that the risk of a repeat issue with the reader variability is now cleared.

We look forward to further details regarding the roadmap to submission and the prospects of further disclosure of the secondary endpoints later in 2024.

Ascelia is expected to submit Orviglance by mid-2025, and we expect Ascelia to assess the alternative to secure a commercial partner for Orviglance. As a result, the extended analysis of SPARKLE will be interesting. Ascelia has referred to a cash position that will take Ascelia to Q2 2025.

The indication of orphan drugs and a solid primary endpoint outcome can contribute to attracting an industrial or commercial partner. A contract at this project stage (a positive primary endpoint ahead of submission) is typically related to higher royalty rates (or even profit sharing) and a modest level of upfront payment.

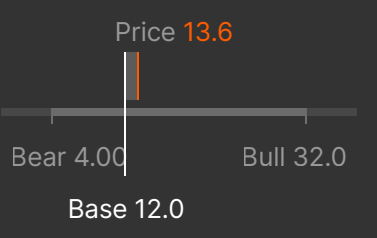
Our initial take ahead of a more extensive update after the presentation on the 7 May is that today’s result is to reduce the risk of SPARKLE passing the phase 3 stage.

Our Base Case in Ascelia, ahead of the re-reading consequence, was a Base Case of SEK 12 (Bull SEK 32 and Bvear SEK 4.0). Following the issue with intre reader variability, we used a LOS of 66.7%. The initial share price reaction suggests that the implied LOS is significantly above 66.7%, which is fair, especially as the primary endpoint success also reduces the risk of future extensive equity dilution.

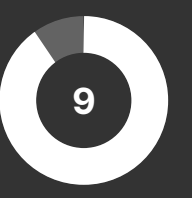
REDEYE

REDEYE QUALITY RATING

FAIR VALUE RANGE



TIMELINESS



KEY STATS

Market Cap	475.6 MSEK
Entprs. Value (EV)	459.9 MSEK
Net Debt (2024e)	-15.7 MSEK
30 Day Avg Vol	219 K
Shares Outstanding	34.9M
Price / Earnings	N/A
PEG	0.1x
Dividend Yield	N/A

Data from 2024-05-02 13:58

IMPORTANT INFORMATION

All information regarding limitation of liability and potential conflicts of interest can be found at the end of the report.

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