

# Hansa Biopharma: Soft Idefirix sales in Europe and a slipping US timetable for the US launch

Hansa Biopharma Research Note 2023-10-12 13:56 Updated 2023-10-12 15:07

Hansa has provided a clinical update and top-line results ahead of the Q3 results. After a relatively strong Q2, deliveries have been slow during Q3 with product sales of SEK 16m, which aligns with the modest Q1 earlier in 2023. Enrollments to the US Confides study have increased to 89 (76), and the number of sites has increased to 25 (20) due to a slow randomization process. Earlier, Hansa expected the randomization process to be complete in late 2023. Hansa is targeting a submission by 2025 (2024).



Johan Unnerus

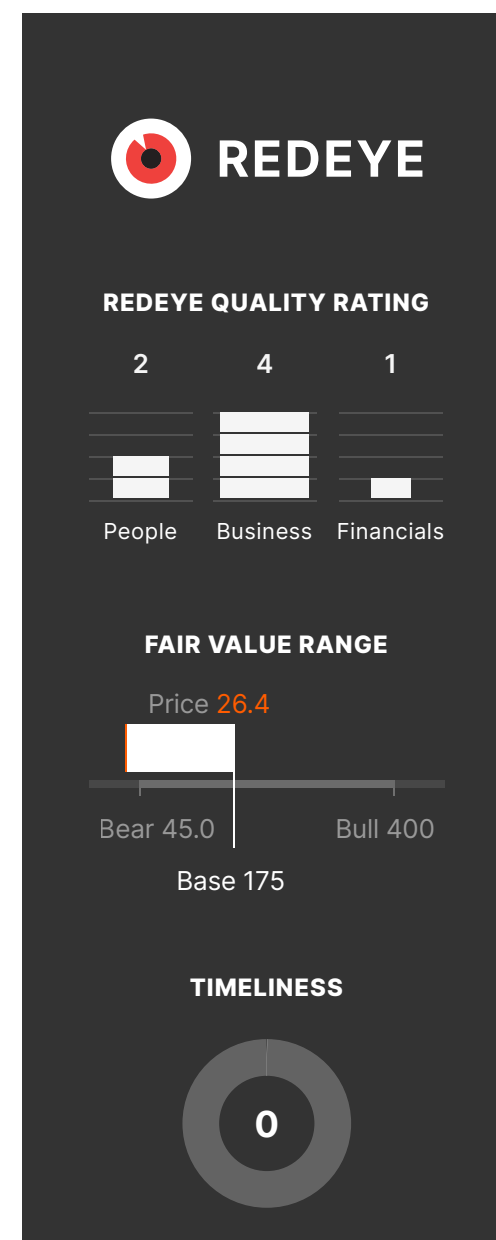
The US trial is essential (ConfideS). Hansa has amended the trial protocol to facilitate a broader set of donors for organ allocation and increase the number of participating centres to compensate for a slow randomization process. Hansa has;

- Already achieved its enrolment target (64 by mid-2023)
- Delayed its randomization target (from H2 2023 to mid-2024)
- Shifted its time to submission from 2024 to 2025, a delay of some six months, suggesting that the randomization process is slow

As a result, we point to an increased uncertainty regarding the time to randomization and Hansa's ability to submit by 2025. The combination of a lengthy sales process and a long US randomization process also contributes to the issue of the present market dynamics, including the risk that it will take a more extended period to adapt to and take full advantage of Hansa's Idefirix/Imlifidase. One reason for the soft European Q3 sales is that the Eurotransplant pilot program (initiated in late June) has failed to contribute to the patient flow during Q3. Hansa says that part of this support (up to 20 patients) is slipping into Q4.

We will pursue a negative sales revision. Earlier, we expected Hansa to add SEK 375m in growth capital by 2025, and we are likely to revise the required growth capital due to the slower sales uptake in Europe. Hansa has already indicated that it is unlikely to progress its AMR study into a formal phase 3. The slipping timetable for US support and a slow period of European sales confirms this outlook for AMR. The product is already approved, and we can expect external independent studies to be concluded in the AMR segment, especially if Hansa can demonstrate a positive Phase 2 outcome.

We look forward to the AMR Phase 2 results 2023, GBS top-line Phase 2 data, long-term (5-year) follow-up data for Idefirix, and completion of the Nice-R Phase 1 study. We also look forward to further clarification, including the randomization target during the Q3 presentation and the call on 26 October. The size of Hansa's initial market reaction is severe and partly understandable.



## KEY STATS

Market Cap	1.4 BSEK
Entprs. Value (EV)	749.9 MSEK
Net Debt (2023e)	-705.1 MSEK
30 Day Avg Vol	177 K
Shares Outstanding	55.0M
Price / Earnings	N/A
PEG	N/A
Dividend Yield	N/A

Data from 2023-10-12 15:08

## IMPORTANT INFORMATION

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

Redeye, Mäster Samuelsgatan 42, 10tr, Box 7141, 103 87 Stockholm. Tel. +46 8-545 013 30  
E-post: [info@redeye.se](mailto:info@redeye.se)