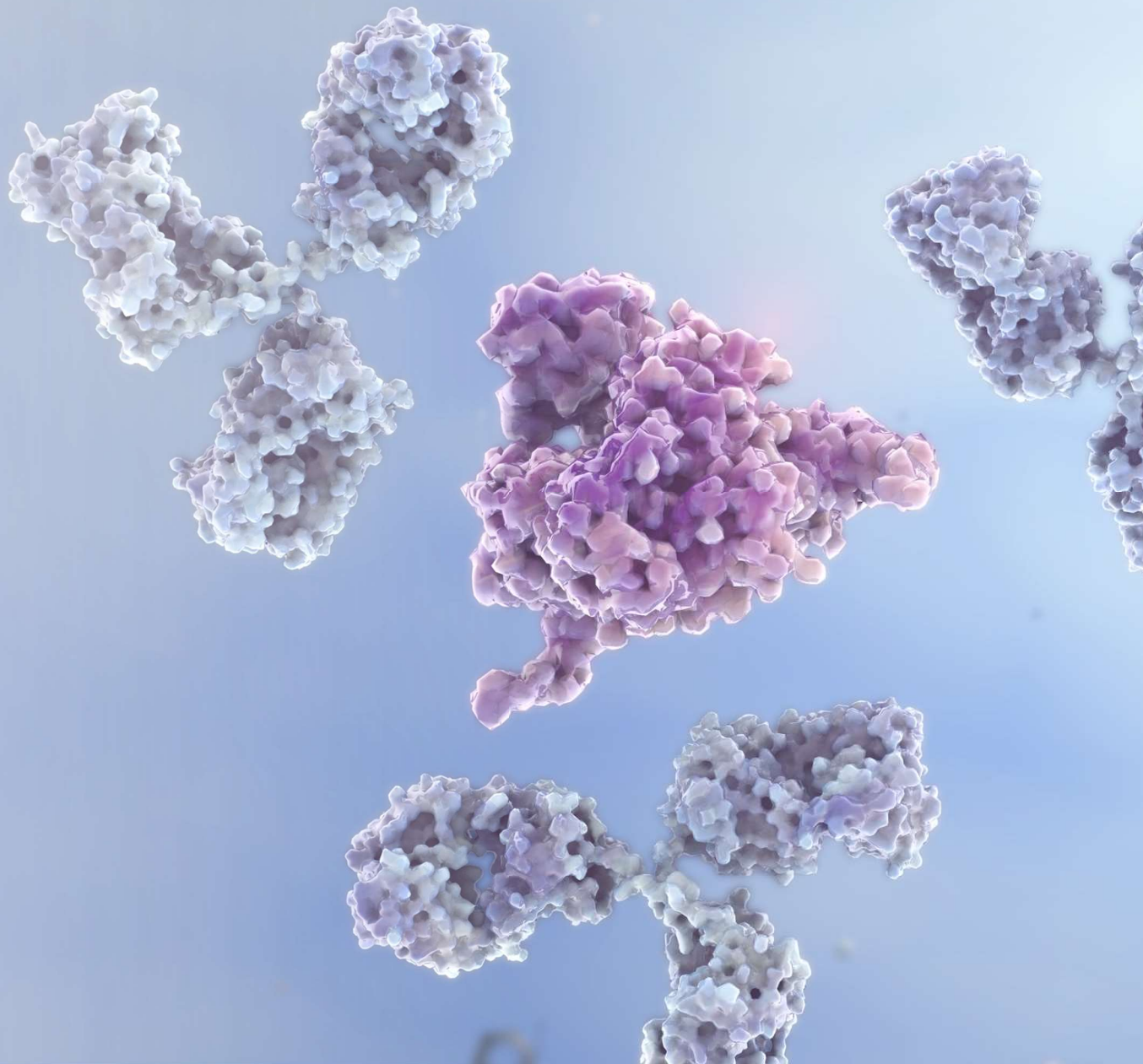
Interim Report

January - December 2025

HANSA BIOPHARMA



Strong Q4 with 76.0 MSEK in revenue, up 135% from Q4 2024
Submission of a Biologic License Application (BLA) to FDA for Imlifidase in Desensitization for Kidney Transplantation

Business Update

- **Q4 revenue** totalled 76.0 MSEK representing a 135% growth over the same period last year with product revenues representing 61.1 MSEK, a growth of 139% compared to Q4 in 2024 (25,6 MSEK). **Full year revenue** totaled 222.3 MSEK, compared to 171.3 MSEK for the same period in 2024. Full year IDEFIRIX product sales totaled 204.7 MSEK and represented an increase of 64.6 MSEK or 46% compared to the same period a year ago (140.1 MSEK). Sales achieved across all key European markets in Q4, including Germany.
- Progress has been made regarding temporary funding for IDEFIRIX in Catalunya, Spain. Formal notification and logistics still needed to be addressed, however initial requests from transplant centers indicate clear improvement.
- Hansa successfully completed a directed share issue raising approximately 671.5 MSEK (approximately $71.3M) before transaction costs with participation from both new and existing shareholders, adding Polar Capital as a significant shareholder.
- In Q4 a reorganization was implemented to strengthen the European and International Commercial and Medical Affairs operations. Max Sakajja was appointed as Vice President, General Manager Europe and International and will lead both the Commercial and Medical Affairs organizations across the regions. Max will report to Maria Törnsén, Chief Operating Officer and US President.

Financial Summary

Amounts in MSEK, unless otherwise stated	Q4 2025	Q4 2024	12M 2025	12M 2024
Revenue	76.0	32.3	222.3	171.3
- Including: Product sales	61.1	25.6	204.7	140.1
SG&A expenses	(101.6)	(89.0)	(356.6)	(344.3)
R&D expenses	(74.4)	(101.4)	(304.7)	(375.7)
Loss from operations	(124.9)	(174.2)	(520.7)	(637.9)
Loss for the period	(165.0)	(276.9)	(529.3)	(807.2)
Net cash used in operations	(177.5)	(147.8)	(549.2)	(674.9)
Cash and short-term investments	701.1	405.3	701.1	405.3
EPS before and after dilution (SEK)	(1.62)	(4.08)	(6.52)	(12.85)
Number of outstanding shares	101,763,222	67,814,241	101,763,222	67,814,241
Weighted average number of shares before and after dilution	101,763,222	67,814,241	81,200,543	62,834,848
Number of employees at period end	125	135	125	135

Clinical Pipeline Update

- **Biologics License Application (BLA) submitted** to the U.S. Food and Drug Administration (FDA) in December as planned for the use of imlifidase in the desensitization of highly sensitized patients awaiting kidney transplantation. Awaiting FDA decision on Priority Review, which if granted, would result in a PDUFA date in August.
- **Phase 3 trial** in anti-glomerular basement membrane (anti-GBM) disease did not meet its primary endpoint of renal function at 6 months, evaluated by estimated glomerular filtration rate (eGFR). Although imlifidase performed as expected, the control arm consisting of an optimized standard of care protocol, generated results which were substantially better than what historically has been observed with traditional standard of care.
- **Initial clinical data** from the first patient in the GNT-018-IDES trial were presented at the European Society of Gene and Cell Therapy. Data showed that imlifidase rapidly and effectively can remove AAV antibodies and function as a pre-treatment to enable gene therapy in patients with Crigler–Najjar syndrome and pre-formed antibodies towards the gene therapy AAV vector.
- **HNSA-5487 to be taken forward** in the rare neurological indication Guillain-Barré syndrome (GBS). Interaction with FDA planned for 1H 2026 to agree on the clinical development program.

Upcoming Key Catalysts & Subsequent Events - 1H 2026

Desensitization Kidney Transplant

- **Notification from the FDA regarding acceptance** of the BLA and communication of PDUFA date* is expected in February (60 days after the submission).
- Readout of topline data from PAES – European confirmatory trial, expected mid-year.

Desensitization Gene Therapy

- **Phase 2:** Global trial in Crigler-Najjar syndrome with Genethon (GNT-018-IDES) Recruitment phase conclusion targeted for mid-year.

Autoimmune Disease

- **FDA interactions** regarding clinical development program for HNSA-5487 in Guillain-Barré Syndrome (GBS).

Subsequent Events

- As planned, Hansa satisfied its January 2026 **NovaQuest milestone payment**. The next NovaQuest milestone payment is not due until June 2027, approximately 17 months from now.

* PDUFA date - date for FDA's decision regarding a new drug application. Hansa's PDUFA date is expected to be August or December 2026 depending on whether or not priority review is granted.

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabiopharma.com.

Strong sales, Submission of BLA to FDA and Successful Capital Raise

Renée Aguiar-Lucander
CEO, Hansa Biopharma

As we closed out 2025, the 4th quarter provided another important proof point of Hansa Biopharma's journey to transform treatment options for patients with rare immunologic diseases. We successfully filed our BLA with the FDA within 3 months of receiving top line data from our Phase 3 study, showcasing the strong expertise and experience which exists in the company. Since I joined at the end of April initiatives implemented have generated a business which is more focused, resilient and has the skill base required to execute on the priorities of 2026. We have delivered meaningful progress—commercially, strategically, and scientifically—while reinforcing the financial and organizational foundation for sustainable growth. This progress reflects the inherent strength of our innovative enzyme technology platform, the positive impact of organisational and cultural change and implementation of core strategic imperatives. We are now in a position to fully pursue our unwavering commitment to improving outcomes for patients.

Commercial Growth and Market Expansion. Full year revenues amounted to 222.3 MSEK (~$24.7m) reflecting growth over last year of 30%, with product sales of IDEFIRIX representing 204.7 MSEK ($22.7m), which represents a 46% increase compared to the same period last year. Fourth-quarter product sales totalled 61.1 MSEK, up from 25.6 MSEK (+139%) in Q4 2024. This growth reflects continued adoption across all major European markets and underscores the clinical value of IDEFIRIX and the momentum we are building for highly sensitized patients awaiting kidney transplantation.

We continued to make progress in market access across Europe in 2025, with positive reimbursement decisions and updated guidelines. In December we advanced toward temporary funding in Catalunya, Spain. In France, the ANSM approved a government backed reimbursement framework for highly sensitized lung transplant patients through the national health insurance system. This milestone expands the clinical reach of IDEFIRIX beyond kidney transplantation and highlights the unmet medical need and potential in other solid organ transplants.

Regulatory Milestone in the U.S. A key achievement this quarter was the submission of our Biologics License Application (BLA) to the U.S. FDA for imlifidase in the desensitization of highly sensitized patients awaiting kidney transplantation. We have requested Priority Review, which, if granted, could enable access already in Q4 2026 for patients who currently face years on dialysis and limited transplant options. This milestone represents a pivotal moment for Hansa and for thousands of patients living with end-stage renal disease. Subject to approval, we plan to commercialize imlifidase in the US and have begun building the infrastructure and resources required for a successful launch.

In Q4 we also hosted a virtual event with leading transplant surgeons Dr. Robert Montgomery, MD, PhD (NYU Langone Transplant Institute) and Dr. Matthew Cooper, MD (Medical College of Wisconsin). They shared insights into the significant unmet medical need, lack of treatment alternatives and the transformative potential of imlifidase for highly sensitized patients in the US.

Pipeline Progress and Innovation. We are also excited by the promise of imlifidase in gene therapy. Initial clinical data from the first patient in the Genethon GNT-018-IDES trial, presented at ESGCT, demonstrated that imlifidase can effectively remove AAV antibodies, enabling gene therapy in patients with pre-existing immunity. This further indicates the enabling of treatment possibilities for genetic disorders, and we look forward to generating additional clinical data in 2026.

While our Phase 3 trial in anti-GBM disease did not meet its primary endpoint, the data revealed meaningful clinical benefit with approximately 60% of patients treated with imlifidase followed by optimised standard of care (SoC) as defined in the study protocol were dialysis independent at 6 months. This represents a substantial improvement compared to what is generally observed in clinical practise with SoC, where typically only 20-25% of patients are dialysis independent at 6 months. However, the treatment response was similar in patients in the control arm treated with an optimised version of SoC alone.

Looking ahead, we have decided to advance our next-generation enzyme, HNSA-5487, in the rare neurological condition known as Guillain-Barré Syndrome (GBS). Interactions with the FDA regarding the clinical development program are planned for the first half of 2026, and we are very excited about the potential of this program, based on the highly supportive data generated in a Phase 2 trial with imlifidase.

Strengthening Our Foundation To support these ambitions, we completed a directed share issue raising approximately 671.5 MSEK (~$71.3m) before transaction costs, with strong participation from both new and existing shareholders.

We also announced a reorganization to enhance our European and International Commercial and Medical Affairs operations, appointing Max Sakajja as Vice President, General Manager Europe and International. These changes reflect our commitment to operational excellence and will enable improved transparency, forecasting, and execution—critical enablers for sustainable growth in 2026 and beyond.

Looking Ahead We enter 2026 with great confidence, high aspirations and clear focus on execution. Our team has exceptional experience across regulatory affairs, US product launches, market access and medical affairs. We are rapidly advancing our next generation compound as well as earlier programs into highly attractive indications and we look forward to sharing that continued progress during 2026. Our near-term priority however is clear: Obtain FDA approval and ensure a successful U.S. launch of imlifidase. In parallel, we are targeting enhanced performance across Europe in 2H following the readout of the PAES confirmatory trial and effects from initiatives rolled out during Q1.

With a strong foundation, an experienced team, the strong clinical benefit of imlifidase shown in ConfIdeS and a clear strategic roadmap, we are confident in our ability to create long-term value for all our stakeholders.

Thank you for your continued trust and support!

Imlifidase Commercial and Pipeline Update

Commercial Update

EU: Kidney transplantation in highly sensitized patients

IDEFIRIX continues to progress across European and international markets. Full year product sales were 46% higher compared to the same period in 2024. Q4 2025 product sales were 139% higher than Q4 2024. Sales were achieved across all key European markets, including Germany.

In France, ANSM[1] approved a compassionate use framework for IDEFIRIX in highly sensitized lung transplant patients, following a request from French lung transplant experts. As a result, IDEFIRIX is now reimbursed by the national health insurance system for use in lung transplantation.[2]

In Catalunya, Spain, progress has been made toward securing temporary funding for IDEFIRIX. While formal notifications to pharmacists and finalization of logistics are still pending. Initial requests from transplant centers indicate meaningful forward momentum.

In Q4 we reorganized the European and International operations and appointed Max Sakajja as Vice President, General Manager Europe and International. Mr. Sakajja will lead both the Commercial and Medical Affairs organizations across the regions and will report to Maria Törnsén, Chief Operating Officer and US President.

In December, Teona Johnson was appointed as Senior VP US Commercial with start date January 1, 2026. Teona will lead the US Commercial launch (subject to FDA approval). Ms Johnson brings significant US launch experience to Hansa and recent experience in transplant and nephrology.

Pipeline Update

BLA submitted to FDA

BLA submitted for the use of imlifidase in the desensitization of highly sensitized adult patients undergoing deceased donor kidney transplantation. The application is based on the successful outcome of the pivotal US Phase 3 ConfIdeS trial in highly sensitized patients. FDA has granted Hansa Biopharma Fast Track and Orphan Drug Designation and Hansa has requested Priority Review.

ConfIdeS pivotal U.S. Phase 3 Trial - 20-HMedIdeS-17

Full Phase 3 ConfIdeS results will be submitted for presentation at a major medical congress in 2026, with Hansa targeting the American Transplant Congress in Boston this June 2026.

Long-term follow-up Trial of Kidney Transplant Patients - 17-HMedIdeS-14

Publication in Transplant International: Five years follow up of imlifidase desensitized kidney transplant recipients, by Stanley Jordan, Jan Tollemar, Anna Runström, Kristoffer Sjöholm, Ashley Vo, Bengt von Zur Mühlen, Torbjörn Lundgren, Christophe Legendre, Niraj Desai, Robert Montgomery, Bonnie Lonze, Tomas Lorant. Demonstrates durable, long-term outcomes comparable to standard transplantations.

SRP-9001-104 Phase 1b Trial in Duchenne Muscular Dystrophy (DMD)

Hansa and Sarepta are actively reviewing data and discussing next steps.

Genethon Phase 2 Trial in Crigler Najjar - GNT-018-IDES

Initial data from the first patient treated in the GNT-018-IDES trial, presented at the European Society of Gene and Cell Therapy, demonstrated that imlifidase can remove pre-existing AAV antibodies and enable gene therapy in patients with Crigler–Najjar syndrome who have re-formed antibodies towards the gene therapy AAV vector.

In this first treated patient, imlifidase given before GNT0003 safely cleaved and inactivated AAV antibodies, allowing administration of the gene therapy, with no severe side effects reported. GNT0003 significantly lowered the patient's bilirubin levels, enabling discontinuation of phototherapy—previously required for 12 hours per day—at 16 weeks post-treatment in accordance with the study protocol. Longer-term data are still needed to confirm the benefits of the gene therapy treatment. This marks the first successful gene therapy in a Crigler–Najjar patient with antibodies to AAV8. If confirmed in the next stages of the trial, this approach could provide a new therapeutic option for patients currently excluded from gene therapy due to AAV antibodies.

Phase 3 anti-glomerular basement membrane (anti-GBM) Disease Trial - GOOD-IDES-02

Global pivotal Phase 3 trial in anti-GBM disease did not meet its primary endpoint. The endpoint was renal function at 6 months, evaluated by estimated glomerular filtration rate (eGFR). Approximately 60% of patients treated with imlifidase, followed by an optimised SoC protocol defined in the trial, did not require dialysis at 6 months, which represented a substantial improvement and clinical benefit compared to what has been observed in historical control cohorts. Outcomes generally observed in these patients reflect only 20-25% who do not require dialysis at 6 months. However, the treatment response was similar in patients in the control arm treated with the optimised SoC alone.

Phase 2 Guillain-Barré Syndrome (GBS) Study - 15-HMedIdeS-11

Publication of Phase 2 data with imlifidase expected in 2026.

Next step: Decision to go forward with our next generation enzyme HNSA-5487 in GBS. Interactions with FDA planned to 1H 2026 for clinical development program.

[1] ANSM, The French National Agency for Medicines and Health Products Safety

[2] https://ansm.sante.fr/tableau-acces-derogatoire/idefirix

Focused Pipeline in Desensitization and Autoimmune Diseases

	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Partner	Upcoming Milestone
idefirix (imlifidase)	Desensitization Kidney Transplantation						Mid 2026: EU PAES data read out
	Desensitization Kidney Transplantation						Q1 2026: Determination of BLA acceptance by FDA and PDUFA* date
	Desensitization Gene Therapy (Crigler-Najjar syndrome)					GENETHON	1H 2026: complete enrolment
	Desensitization Gene Therapy (DMD)					SAREPTA	Discussions ongoing regarding next steps
	Autoimmune AAV Investigator Initiated Trial (IIS)[1]						Recruitment phase concluded
HNSA-5487	Autoimmune GBS						1H 2026: Interactions with the FDA planned regarding the clinical development program

DMD: Duchenne muscular dystrophy
AAV: ANCA-associated vasculitis
GBS: Guillain-Barré syndrome

*Prescription Drug User Fee Act

[1] Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

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Financial Review 2025: Fourth Quarter & Year to Date

Revenue

Revenue for the fourth quarter 2025 totaled 76.0 MSEK (Q4 2024: 32.3 MSEK) consisting of IDEFIRIX product sales of 61.1 MSEK (Q4 2024: 25.6 MSEK) and contract revenue of 14.8 MSEK (Q4 2024: 6,7 MSEK). Fourth quarter 2025 contract revenue was primarily driven by the recognition of the AskBio agreement. The corresponding contract revenue for the same period in 2024 reflected revenues from the Sarepta agreement which were fully recognized in 2024.

Full year 2025 revenue totaled 222.3 MSEK (2024: 171.3 MSEK) including IDEFIRIX product sales of 204.7 MSEK (2024: 140.1 MSEK) and contract revenue of 17.5 MSEK (2024: 31.2 MSEK). Full year product revenue increased by 64.6 MSEK or 46.1%.

Sales General & Administrative (SG&A) expenses

SG&A expenses for the fourth quarter 2025 totaled 101.6 MSEK (Q4 2024: 89.0 MSEK) and 356.5 MSEK for the full year 2025 (full year 2024: 344.3 MSEK). The year-over-year fourth quarter as well as year to date expense increase was 12.2 MSEK and reflects increased costs associated with the expected U.S. market launch in mid-2026.

For the full year 2025, non-cash expenses for the Company's long-term incentive programs (LTIP) were included in SG&A and totaled 22.5 MSEK compared to 21.7 MSEK for the same period in 2024.

Research & Development (R&D) expenses

R&D expenses for the fourth quarter 2025 totaled 74.4 MSEK (Q4 2024: 101.4 MSEK) and 304.7 MSEK for the full year 2025 (full year 2024: 375.7 MSEK). Year-over-year fourth quarter R&D expenses were 27.0 MSEK favorable compared to the prior year. For the full year 2025, R&D expenses were 71.0 MSEK favorable compared to the same period a year ago. This favorable variance was driven by savings associated with the restructuring activities implemented in 2024, offset by continued investments in the U.S. Phase 3 ConfIdeS study, EMA post-approval commitments and CMC development expense for HNSA-5487.

Non-cash expenses related to the Company's LTIP program were included in R&D expense and totaled 12.0 MSEK for the full year 2025 compared to 10.0 MSEK during the same period in 2024.

Other operating income/expenses, net and finance income/expenses, net

Other operating income/expenses, net, primarily included gains or losses from foreign exchange rate fluctuations in operations. For the full year 2025, the Company recorded an income of 1.9 MSEK, and an expense of 5.7 MSEK for 2024. The change is primarily due to a strengthening in the exchange rate of the Swedish Krona primarily against the US dollar and Euro, affecting deferred revenue as well as accounts payable and receivable positions on the balance sheet.

Financial income/expenses, net, for the fourth quarter of 2025, totaled an expense of 39.7 MSEK (Q4 2024 expense of 99.9 MSEK). For the full year 2025, the expense totaled 6.3 MSEK compared to an expense of 166.3 MSEK for the full year 2024. The financial expenses, primarily driven by foreign exchange as the Swedish Krona exchange rate compared to the US dollar strengthened. This impacted the interest associated with the NovaQuest loan. The full year 2025 financial expenses included non-cash interest expense associated with the NovaQuest loan of 128.1 MSEK (full year 2024: 134.1 MSEK), a non-cash loss of 59,4 MSEK (full year 2024: 0.0) from the loan restructuring modification, favorable foreign exchange fluctuations associated with the NovaQuest loan to 178.7 MSEK (full year 2024 unfavorable: 85.7 MSEK), and other items including a non-cash retroactive adjustment related to interest and capitalized development costs for the first three quarterly results (see Notes 3 and 5).

Financial results

The loss from operations for the fourth quarter 2025 totaled 124.9 MSEK (Q4 2024: 174.2 MSEK) and a loss of 520.7 MSEK for the full year 2025 (full year 2024: 637.9 MSEK). The decrease in Hansa's operating loss for the full year 2025 compared to the same period previous year was driven by lower overall expenses as well as increased sales.

The fourth quarter loss for the period totaled 165.0 MSEK (Q4 2024: 276.9 MSEK) and for the full year 2025 the loss for the period totaled 529.3 MSEK (full year 2024: 807.2 MSEK).

Cash flow, cash and investments

Net cash used in operating activities for the fourth quarter 2025 totaled 177.5 MSEK (Q4 2024: 147.8 MSEK) and 549.2 MSEK for the full year 2025 (full year 2024: 674.9 MSEK). The change compared to the prior year was driven by lower operating expenses and a positive change in working capital balance sheet accounts. The two share issuances completed in 2025 increased cash balances by 847.2 MSEK net of transaction costs.

Cash and cash equivalents totaled 701.1 MSEK at December 31, 2025, compared to 405.3 MSEK at December 31, 2024.

Parent Company

The parent company's revenue for the fourth quarter of 2025 totaled 76.0 MSEK (Q4 2024: 32.3 MSEK) and for the full year 2025 to 222.3 MSEK (full year 2024: 171.3 MSEK). The fourth quarter 2025 parent company loss for the period totaled 192.1 MSEK (Q4 2024: 306.6 MSEK) and for the full year 2025 the loss for the period was 644.5 MSEK (full year 2024: 926.4 MSEK).

The parent company shareholders' equity at December 31, 2025, totaled 1,067.0 MSEK compared to 674.4 MSEK at December 31, 2024.

The Group consists of the parent company, Hansa Biopharma AB, and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc., Hansa Biopharma Italy S.r.l. and Hansa Biopharma Australia PTY LTD. On December 31, 2025, Hansa Biopharma Inc. had thirteen employees, Hansa Biopharma Ltd nine employees and Hansa Biopharma S.r.l. three employees.

Financial Review 2025: Fourth Quarter & Year to Date (continued)

Long-term incentive programs

At Hansa Biopharma's previous Annual General Meetings, shareholders resolved to adopt various share-based LTIP programs. As of December 31, 2025, the Company incurred non-cash equity-based compensation expense under the following LTIP programs: 2020, 2021, 2022, 2023, 2024 and 2025.

The respective non-cash costs related to the ongoing LTIP programs are summarized in the table below. In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants. For further information on the different LTIP programs, please refer to Hansa Biopharma's 2024 Annual Report which can be found at www.hansabiopharma.com.

Ongoing programs	LTIP 2020	LTIP 2021	LTIP 2022	LTIP 2023	LTIP 2024	LTIP 2025
Maximum number of issuable shares*	594,776	19,500	6,500	549,434	1,090,774	7,440,231
Number of allocated outstanding share rights and options	457,520	15,000	5,000	427,575	848,851	4,476,250
Number of allocated outstanding warrants	-	-	-	-	-	1,688,250
Estimated total cost including social contributions for outstanding share rights and options, KSEK	25,863	15,473	7,966	13,619	29,584	62,645
Total cost per program, including social contributions as of December 31, 2025 YTD, KSEK	-	(14)	2,943	3,585	9,234	18,789
Total costs, including social contributions, as of December 31, 2025 YTD, KSEK						**34,537**

Risks and uncertainties

Hansa's business is subject to a variety of external and internal factors that may significantly affect the Company's financial performance and position - many of which are partially or entirely beyond the Company's control. When evaluating the Company's prospects, it is important to consider these risks, alongside the potential for earnings growth in order to form a balanced and realistic assessment of the Company's expected development.

Since the fourth quarter 2022, Hansa has capitalized development costs related to IDEFIRIX following the conditional approval granted by the EMA (see Note 4). In 2023, based on conditional approval, the parent company also revalued the underlying intangible asset related to IDEFIRIX. Both the decision to begin development costs and the revaluation of the intangible assets in the parent company were based on the assessment that Hansa is likely to obtain final EMA approval for the commercialization of IDEFIRIX. As part of the conditional approval, the EMA required Hansa to conduct two clinical trials to support final approval:

a) A five-year follow-up study of 46 patients previously treated with IDEFIRIX in a Phase II trial was performed. This follow-up clinical study was finalized and submitted to EMA in December 2023. In 2024, EMA finalized its review and the study was approved.

b) A post-authorization efficacy and safety (PAES) study, involving 50 kidney transplant patients treated with IDEFIRIX with a reference group of 50 transplant patients receiving standard-of-care treatment without IDEFIRIX was completed in Q1 2025. Following the completion of the study, patients will be monitored for one year to assess the long-term effect of the drug. The objective of the follow up study is to determine whether outcomes in highly sensitized patients treated with IDEFIRIX are comparable to those receiving standard treatment. Hansa currently has no indication that the study would be unsuccessful.

Given that the follow-up study has been approved and there are no indications that the PAES study will be unsuccessful, Hansa considers the risk of not meeting EMA's conditions for final approval to be low.

Risk factors include, among others, uncertainties regarding clinical trials and regulatory approvals, collaborations and partnerships, intellectual property rights, reliance on key products, market dynamics and competition, manufacturing and supply chain challenges, pricing and reimbursement, as well as dependence on key persons and financial risks.

The Board of Directors and management remain focused on cash flow and are actively working to secure long-term, sustainable financing for both ongoing and planned development projects. The Company expects its current cash position to support operations into 2027. The Company continues to explore opportunities to fund operations, including debt restructuring and a range of business development opportunities, such as regional and global development and commercial partnerships, the outcome of which remain uncertain at this time. A detailed overview of the key risks and uncertainties facing Hansa can be found in the English version of the Company's 2024 Annual Report (pages 32-35).

On a regular basis, Hansa's Board of Directors and senior management review the development of these risks and uncertainties. No material changes from the presentation in the 2024 Annual Report have been identified as of the date of this quarterly report.

Financial Review 2025: Fourth Quarter & Year to Date (continued)

Other information

Contacts

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Hansa Biopharma
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Legal Disclaimer

This financial report includes statements that are forward-looking, and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are developments within research programs. This is a translated version of the Swedish original.

Dividend

The board proposes that no dividend will be paid for the financial year 2025.

Financial Calendar 2026

March 26, 2026	Annual and Sustainability Report for 2025
April 23, 2026	Interim Report for January – March 2026

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares December 31, 2025	101,763,222
Market Cap December 31, 2025	~3.50 BSEK (USD ~$380M)
Ticker	HNSA
ISIN	SE0002148817

Top 10 Shareholders as of December 31, 2025

Shareholder Name	Number of Shares	Ownership %
Redmile Group LLC	17,509,214	17.21%
Polar Capital LLP	11,062,102	10.87%
NovaQuest Capital Management LLC	6,398,981	6.29%
Theodor Jeansson Jr.	3,700,000	3.64%
Avanza Pension	3,671,202	3.61%
Fourth Swedish National Pension Fund (AP4)	2,569,000	2.52%
Handelsbanken Fonder	2,290,638	2.25%
Thomas Olausson	2,117,000	2.08%
Fidelity Investments (FMR)	2,041,400	2.01%
Hansa Biopharma AB	2,029,269	1,99%
All other	48,374,416	47.53%
Total Shares Outstanding	101,763,222	100.00%

Source: Modular Finance compiled and processed data from various sources, including Euroclear, Morningstar, FactSet and the Swedish Financial Supervisory Authority (Finansinspektionen).

Hansa Biopharma had approximately 20,000 shareholders as of December 31, 2025.

The Board of Directors and the Chief Executive Officer affirm that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and give a fair view of the group's financial position and results. The interim report has been prepared in accordance with generally accepted accounting principles for the group and the parent company and gives a fair overview of the development of the group's and the parent company's operations, financial positions, and results.

Lund, Sweden, February 10, 2025

Peter Nicklin
Chairman of the Board

Hilary Malone
Board member

Eva Nilsagård
Board member

Mats Blom
Board member

Elisabeth Björk
Board member

Michael Bologna
Board member

Jonas Wikström
Board member

Natalie Berner
Board member

Renée Aguiar-Lucander
President & CEO

This report has not been reviewed by the company's auditors.

Unaudited Condensed Financial Statements

Unaudited condensed consolidated statement of financial position

KSEK	Note	December 31 2025	2024
ASSETS			
Non-current assets			
Intangible assets	4, 5	230,561	197,333
Property and equipment		2,945	4,682
Trade receivables & unbilled revenues	2	126,249	118,186
Right-of-use assets		10,401	13,198
Total non-current assets		**370,156**	**333,339**
Current assets			
Inventories		6,132	2,610
Trade receivables	2	53,872	26,779
Current receivables, non-interest bearing		35,524	32,574
Cash and cash equivalents		701,083	405,280
Total current assets		**796,611**	**467,243**
TOTAL ASSETS		**1,166,767**	**800,642**
EQUITY AND LIABILITIES			
Shareholders' equity		**(84,134)**	**(589,833)**
Non-current liabilities			
Long-term loan	3	785,676	1,064,645
Deferred tax liabilities		259	168
Provisions		8,838	4,259
Lease liabilities		2,995	6,678
Deferred revenue		1,606	-
Refund liabilities		40,868	59,038
Total non-current liabilities		**840,242**	**1,134,788**
Current liabilities			
Short-term loan		136,869	-
Tax liabilities		1,827	2,705
Lease liabilities		8,276	7,684
Current liabilities, non-interest bearing		66,285	55,491
Deferred revenue		-	16,334
Refund liabilities		76,264	64,484
Accrued expenses		121,138	108,989
Total current liabilities		**410,659**	**255,687**
TOTAL EQUITY AND LIABILITIES		**1,166,767**	**800,642**

Unaudited condensed consolidated statement of profit or loss and other comprehensive income (loss)

KSEK	Note	Q4 2025	Q4 2024	12 Months 2025	12 Months 2024
Revenue	2	75,990	32,337	222,265	171,316
Cost of revenue		(24,655)	(13,488)	(83,559)	(83,554)
Sales, general and administration expenses		(101,620)	(88,994)	(356,547)	(344,270)
Research and development expenses	4	(74,429)	(101,449)	(304,735)	(375,716)
Other operating income/(expenses), net		(200)	(2,580)	1,866	(5,654)
Loss from operations		**(124,914)**	**(174,174)**	**(520,710)**	**(637,878)**
Financial income		24,865	3,844	170,803	20,834
Financial expenses	3	(64,594)	(103,762)	(117,630)	(187,165)
Non-cash loss on loan restructuring		-	-	(59,447)	-
Loss before tax		**(164,643)**	**(274,092)**	**(526,984)**	**(804,209)**
Tax		(396)	(2,833)	(2,268)	(3,034)
Loss for the period		**(165,039)**	**(276,925)**	**(529,252)**	**(807,243)**
Loss for the period attributable to owners of the parent		(165,039)	(276,925)	(529,252)	(807,243)
Loss per share, basic and diluted (SEK)		(1.62)	(4.08)	(6.52)	(12.85)
Other comprehensive income/(loss)					
Items that have been, or may be reclassified to profit or loss for the period:					
Translation differences		(503)	1,183	(2,970)	1,350
Other comprehensive income/(loss) for the period		**(503)**	**1,183**	**(2,970)**	**1,350**
Total comprehensive loss		**(165,542)**	**(275,742)**	**(532,222)**	**(805,893)**

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabiopharma.com.

Unaudited condensed consolidated statement of changes in shareholders' equity

	January-December	
KSEK	**2025**	**2024**
Opening balance of shareholders' equity	**(589,833)**	**(167,876)**
Result for the period	(529,252)	(807,243)
Translation reserve	(2,970)	1,350
Net comprehensive loss	**(532,222)**	**(805,893)**
Transactions with the group's owner		
Proceeds from new share issuance, net[1]	847,216	354,308
Proceeds from restructuring of debt	141,472	-
Long term incentive programs	30,848	29,629
Long term incentive program option contribution[2]	18,385	-
Total transactions with the group's owner	**1,037,921**	**383,937**
Closing balance of shareholders' equity	**(84,134)**	**(589,833)**

[1] Total share issue costs in Q2 2025 amounted to SEK 14,703 and in Q4 2025 to 41,681 KSEK, total share issue cost 2024 amounted to 17,845 KSEK.

[2] In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants.

Unaudited condensed consolidated statement of cash flow

	Q4		12 Months	
KSEK	**2025**	**2024**	**2025**	**2024**
Cash Flows from Operating Activities				
Loss for the period	(165,041)	(276,925)	(529,252)	(807,243)
Adjustment for non-cash items [1]	57,159	106,543	13,742	180,890
Interest received and paid, net	6,397	18,349	6,328	19,107
Income taxes paid	(567)	(2,711)	(2,383)	(3,611)
Cash flow from operations before change in working capital	**(102,052)**	**(154,744)**	**(511,565)**	**(610,857)**
Changes in working capital	(75,484)	6,944	(37,607)	(64,027)
Net cash used in operating activities	**(177,536)**	**(147,800)**	**(549,172)**	**(674,884)**
Investing activities				
Acquisition of property and equipment	-	-	-	(116)
Cash flow from investing activities	**-**	**-**	**-**	**(116)**
Financing activities				
Proceeds from new share issue, net of transaction cost[2]	**629,819**	**-**	847,216	354,308
Proceeds from incentive program option contribution			18,385	
Restructuring costs long-term loan	-	-	(9,530)	-
Payment of lease liabilities	(2,240)	(1,876)	(8,109)	(7,503)
Cash flow from financing activities	**627,579**	**(1,876)**	**847,962**	**346,805**
Net change in cash	450,043	(149,676)	298,790	(328,195)
Cash and cash equivalents at beginning of period	252,072	553,544	405,280	732,060
Currency exchange variance, cash and cash equivalents	(1,032)	1,412	(2,987)	1,415
Cash and cash equivalents, end of period	**701,083**	**405,280**	**701,083**	**405,280**

[1] Values are mainly costs of share-based incentive programs including social contributions and depreciation, partly offset by certain capitalized development costs (see further in Note 4).

[2] Total share issue costs in Q2 2025 amounted to SEK 14,703 and in Q4 2025 to 41,681 KSEK. Total share issue cost 2024 amounted to SEK 17,845 KSEK.

Parent Company - Unaudited condensed statement of financial position

KSEK	Note	December 31 2025	2024
ASSETS			
Non-current assets			
Intangible assets	4,5	1,361,141	1,446,684
Property and equipment		2,945	4,682
Right-of-use assets		10,401	13,198
Trade receivables & unbilled revenues	2	126,249	118,186
Investment in subsidiaries		43,224	34,194
Total non-current assets		**1,543,960**	**1,616,944**
Current assets			
Inventories		6,132	2,610
Trade receivables & unbilled revenues	2	53,872	26,779
Current receivables, non-interest bearing		32,715	31,160
Cash and cash equivalents		681,145	385,103
Total current assets		**773,864**	**445,652**
TOTAL ASSETS		**2,317,824**	**2,062,596**
EQUITY AND LIABILITIES			
Shareholders' equity		**1,067,000**	**674,449**
Non-current liabilities			
Long-term loan	3	785,676	1,064,645
Provisions		8,838	4,259
Lease liabilities		2,995	6,678
Deferred revenue		1,606	-
Refund liabilities		40,868	59,038
Total non-current liabilities		**839,983**	**1,134,620**
Current liabilities			
Short-term part of loan		136,869	-
Tax liabilities		358	1,119
Lease liabilities		8,276	7,684
Liabilities, group companies		12,979	11,480
Current liabilities, non-interest bearing		66,168	55,448
Deferred revenue		-	16,334
Refund liabilities		76,264	64,484
Accrued expenses		109,927	96,978
Total current liabilities		**410,841**	**253,527**
TOTAL EQUITY AND LIABILITIES		**2,317,824**	**2,062,596**

Parent Company - Unaudited condensed statement of profit or loss and other comprehensive income (loss)

KSEK	Note	Q4 2025	Q4 2024	12 Months 2025	12 Months 2024
Revenue	2	75,990	32,337	222,265	171,316
Cost of revenue		(54,446)	(43,280)	(202,725)	(202,721)
Sales, general and administration expenses		(100,889)	(93,238)	(360,154)	(346,455)
Research and development expenses	4	(68,900)	(99,109)	(294,390)	(375,351)
Other operating income/(expenses), net		(4,157)	(3,005)	(2,913)	(6,242)
Loss from operations		**(152,402)**	**(206,295)**	**(637,917)**	**(759,453)**
Financial income		24,858	3,867	170,796	20,848
Financial expenses	3	(64,593)	(103,760)	(117,615)	(187,164)
Non-cash loss on loan restructuring		-	-	(59,447)	-
Loss before tax		**(192,137)**	**(306,188)**	**(644,183)**	**(925,769)**
Income tax		-	(383)	(320)	(607)
Loss for the period		**(192,137)**	**(306,571)**	**(644,503)**	**(926,376)**
Other comprehensive loss for the period		-	-	-	-
Total comprehensive loss for the period		**(192,137)**	**(306,571)**	**(644,503)**	**(926,376)**

Parent Company - Unaudited condensed statement of changes in shareholders' equity

KSEK	January-December 2025	2024
Opening balance of shareholders' equity	**674,449**	**1,216,945**
Result for the period	(644,503)	(926,376)
Other comprehensive income/(loss) for the period	-	-
Net comprehensive loss	**(644,503)**	**(926,376)**
Proceeds from new share issuance, net[1]	847,216	354,308
Proceeds from restructuring of debt	141,472	-
Long term incentive programs	29,981	29,572
Long term incentive program option contribution[2]	18,385	-
Total other transactions	**1,037,054**	**383,880**
Closing balance of shareholders' equity	**1,067,000**	**674,449**

1 Total share issue costs in Q2 2025 amounted to SEK 14,703 and in Q4 2025 to 41,681 KSEK. Total share issue cost 2024 amounted to SEK 17,845 KSEK.

2 In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants

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Financial Notes

Note 1 Basis of preparation and accounting policies

This consolidated interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting, and recommendation RFR2 of the Swedish Reporting Board, Accounting for Legal entities. The same accounting principles have been used as in the latest annual report except for what is stated below. Hansa's Annual Report for 2024 was published on March 21, 2025, and is available at www.hansabiopharma.com. Disclosures in accordance with IAS 34.16A are as applicable in the notes or on the pages before the consolidated income statement.

Note 2 Revenue

Income per significant category of income	Q4		12M	
KSEK	2025	2024	2025	2024
Group				
Revenue				
Product sales	61,148	25,633	204,731	140,111
Contract revenue, Axis-Shield agreement	672	652	2,687	2,605
Cost reimbursement, Axis-Shield agreement	84	59	761	640
Contract revenue, Sarepta, AskBio agreement	14,086	5,993	14,086	27,960
	75,990	**32,337**	**222,265**	**171,316**
Parent Company				
Revenue				
Product sales	61,148	25,633	204,731	140,111
Contract revenue, Axis-Shield agreement	672	652	2,687	2,605
Cost reimbursement, Axis-Shield agreement	84	59	761	640
Contract revenue, Sarepta, AskBio agreement	14,086	5,993	14,086	27,960
	75,990	**32,337**	**222,265**	**171,316**

Variable Consideration

For healthcare facilities where payment for imlifidase is contingent upon product usage in a kidney transplant, and where there is no established payment history, the Company recognizes product revenue at the transaction price upon transfer of control of the product.

Variable consideration related to vials that may not ultimately be used in a transplant is estimated using the expected value method, based on the median wait time for a kidney transplant of highly sensitized patients on a wait list. Due to the extended duration of transplant wait times, the Company does not initially record variable consideration at the time revenue is recognized.

Variable consideration, with a corresponding reserve, is recorded when it becomes probable that the healthcare facility will not use the product, resulting in a reduction of product revenue and the recognition of a liability in the consolidated balance sheets. The estimate of variable consideration is reassessed at each reporting date, and any changes are recognized on a cumulative catch-up basis.

Trade Receivables

In certain European markets, payment is contingent on when the healthcare facility uses imlifidase in a successful transplantation of a highly sensitized patient and may be subject to outcome-based or post-transplant reconciliation with healthcare authorities. In these situations, patients typically experience extended waiting periods for kidney transplantation, which may be in excess of one year. Accordingly, a portion of the Company's trade receivable balances are classified as non-current. The Company reassesses the classification of trade receivable at each reporting date based on updated expectations regarding the timing of transplantation and payment.

Significant Financing Component

The Company does not recognize a significant financing component due to the uncertainty of the expected period between customer payment and the transfer of imlifidase at contract inception.

Note 3 Long-term loan

On July 18, 2022, the Company entered into a US $70.0 million funding agreement with NovaQuest. The funding was accounted for as a liability and classified as debt because the Company has an unavoidable obligation to settle the agreement in cash. The debt will be accounted for over the life of the agreement.

The net proceeds from the funding agreement totaled US $69.2 million after the deduction of transaction costs.

In June 2025, Hansa and NovaQuest entered into agreements to restructure their existing debt agreement. As part of the restructuring, and in connection with the Q2 2025 Directed Share Issue, Hansa offset approximately US $14.875 million of its outstanding debt through the issuance of new shares at the same price as in the Directed Share Issue (the "First Tranche"). The First Tranche was resolved by the Company's Board of Directors under the authorization granted at the Annual General Meeting held on June 27, 2024, and with deviation from the shareholders' preferential rights.

On January 31, 2026, Hansa paid NovaQuest US $14.875 million (Second Tranche) in relation to the June 2025 agreement.

NovaQuest agreed to a lock-up for each share issue, restricting the sale or disposition of shares for a period of 180 calendar days from the respective issue date, subject to customary exceptions and the Company's prior written consent.

The remaining debt will be paid in three fixed cash payments scheduled for June 2027, June 2028 and January 2029. In addition, previously agreed approval-related payments will be eliminated. Under the restructured terms, total payments from Hansa to NovaQuest will be capped at US $150.5 million, an increase from the original agreement cap of US $140.0 million. The accounting assessment of the NovaQuest debt restructuring actions were deemed to be non-substantial.

An updated version of the original security agreement entered into under the initial debt agreement remains in place under which the Company has granted NovaQuest a broad security interest in certain assets, proceeds and intellectual property rights related to imlifidase for use in kidney transplantation in highly sensitized patients and in the treatment of anti-GBM disease.

The new debt amendment resulted in modification of the original debt agreement. As a result, the debt was remeasured based on the net present value of the revised cash flows, discounted using a fair value effective interest rate. This remeasured amount was compared to the previous carrying value of the original debt, with the difference recognized as a non-cash loss of 59.4 MSEK in the financial statements. Transaction costs incurred in connection with the new amendment were also recognized as part of a gain or loss calculation on the modification.

The Company records the difference between the principal and the total payments as interest expense over the term of the debt by applying the effective-interest-rate method. Based on the progress of the payments, the Company will recalculate the effective interest each reporting period until the debt obligation has been satisfied.

On December 31, 2025, the loan totaled 922.5 MSEK, including 420.6 MSEK in total accrued interest.

Note 4 Intangible assets - Internally-generated intangible assets

Expenditures related to research activities are recognized as expense in the period in which they are incurred. An internally-generated intangible asset arising from development (or from the development phase of an internal project) is recognized only if all the following criteria have been demonstrated in accordance with IAS 38:

- *The technical feasibility of completing the intangible asset so that it will be available for use or sale;*
- *The intention to complete the intangible asset and use or sell it;*
- *The ability to use or sell the intangible asset;*
- *How the intangible asset will generate probable future economic benefits;*
- *The availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and*
- *The ability to measure reliably the expenditure attributable to the intangible asset during its development.*

The amount initially recognized for internally-generated intangible assets is the sum of the expenditures incurred from the date when the intangible asset first meets all the recognition criteria listed above. Development expenses, for which no internally-generated intangible asset can be identified, are expensed in the statement of profit and loss and other comprehensive income in the period in which they are incurred.

The Company determined that IDEFIRIX and its conditional approval by EMA to enable kidney transplantation in highly sensitized patients met all the above criteria as of Q4 2022.

As of December 31, 2025, the total capitalized development expenses related to fulfilling the IDEFIRIX EMA post-approval commitments amount to 262.3 MSEK, with 62.6 MSEK capitalized during 2025. These capitalized development costs are subject to regular amortization over their useful life, which is projected to extend until the end of 2032. Total accumulated amortization at December 31, 2025 was 49.2 MSEK.

Note 5 Non-cash adjustments - Capitalized development costs

Subsequent to the issuance of the Company's third quarter report for the period ended on September 30, 2025, the Company determined that its accounting related to interest for capitalized development costs required an adjustment. The amount of interest capitalized exceeded the amount allowable based on the effective interest rate and the development costs incurred for the first, second and third quarter periods of 2025. To reflect this change, the Company is making the following adjustments to intangible assets (capitalized development costs) and financial expenses for the impacted periods:

Non-cash adjustments	**Q1**		**Q2**		**Q3**	
KSEK	**Before Adjustment**	**Adjusted**	**Before Adjustment**	**Adjusted**	**Before Adjustment**	**Adjusted**
Balance Sheet						
Non-Current Intangible Assets	213,579	211,805	244,497	224,631	265,440	230,014
Profit & Loss						
Cost of revenue	(20,530)	(20,513)	(18,266)	(18,016)	(20,108)	(19,344)
Loss from operations	(93,416)	(93,399)	(154,768)	(154,518)	(147,612)	(146,848)
Financial expenses	(29,486)	(31,277)	(13,320)	(31,662)	(10,230)	(26,554)
Loss for the period	(37,075)	(38,849)	(178,882)	(196,975)	(147,563)	(163,816)

There is no adjustment to the fourth quarter results, the 12-month 2025 results or the comparative periods for 2024.

Glossary

Adeno-associated virus (AAV)
AAV is a versatile viral vector technology that can be engineered for very specific functionality in gene therapy applications.

Allogeneic hematopoietic stem cell transplantation (HSCT)
Allogeneic HSCT, also known as “bone-marrow” transplantation, involves transferring the stem cells from a healthy person (the donor) to the patient’s body after high-intensity chemotherapy or radiation. The donated stem cells can come from either a related or an unrelated donor.

AMR
Antibody mediated transplant rejection.

Antibody
One type of protein produced by the body’s immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM.

Anti-GBM disease (Goodpasture syndrome)
Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

Autoimmune disease
Diseases that occur when the body’s immune system reacts against the body’s own structures.

Biologics License Application (BLA)
A Biologics License Application (BLA) is submitted to the Food and Drug Administration (FDA) to obtain permission for distribution of a biologic product across the United States.

CD20
B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

Clinical studies
Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical phase 1
The first time a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical phase 2
Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical phase 3
Trials that involve many patients and often continue for a longer time; they are intended to identify the drug’s effects and side effects during ordinary but still carefully controlled conditions.

DSA
Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

EMA
The European Medicines Agency (EMA) is an EU agency for the evaluation of medicinal products.

Enzyme
A protein that accelerates or starts a chemical reaction without itself being consumed.

ESOT
The European Society for Organ Transplantation (ESOT) is an umbrella organisation which overlooks how transplantations are structured and streamlined.

FDA or US FDA
U.S. Food and Drug Administration.

Guillain-Barré syndrome
Guillain-Barré syndrome (GBS), is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

HBP
Heparin Binding Protein is a naturally occurring protein that is produced by certain immune cells, i.e. neutrophilic granulocytes, to direct immune cells from the bloodstream into the tissues.

HLA
Human Leukocyte Antigen is a protein complex found on the surface of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

IgG
IgG, Immunoglobulin G, is the predominant type of antibody in serum.

Imlifidase
Imlifidase, is the immunoglobulin G-degrading enzyme of Streptococcus pyogenes, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

IND
Investigational New Drug (IND) application is required to get approval from the FDA to administer an investigational drug or biological product to humans.

INN
International Nonproprietary Name (INN) is a generic and non-proprietary name to facilitate the identification of a pharmaceutical substances or active pharmaceutical ingredient.

In vitro
Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

In vivo
Term within biomedical science to indicate that experiments or observations are made in living organisms.

IVD
IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Marketing Authorization Application (MAA)
A Marketing Authorization Application (MAA) is an application submitted to the European Medicines Agency (EMA) to market a medicinal product in the EU member states.

Neutralizing Antibodies (NAbs)
NAb is an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically.

Pivotal trial
A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat life threatening or severely debilitating conditions.

Panel Reactive Antibody (PRA)
PRA is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

Preclinical development
Testing and documentation of a pharmaceutical candidate’s properties (e.g. safety and feasibility) before initiation of clinical trials.

Prescription Drug User Fee Act (PDUFA)
The Prescription Drug User Fee Act (PDUFA), established by the U.S. Congress in 1992, authorizes the FDA to collect fees from companies that manufacture certain human drug and biological products.

Randomized Control Trial (RCT)
RCT is a study design where the trial subject is randomly allocated to one of two or more study cohorts to test a specific intervention against other alternatives, such as placebo or standard of care.

Streptococcus pyogenes
A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

Standard of Care (SOC)
Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals.