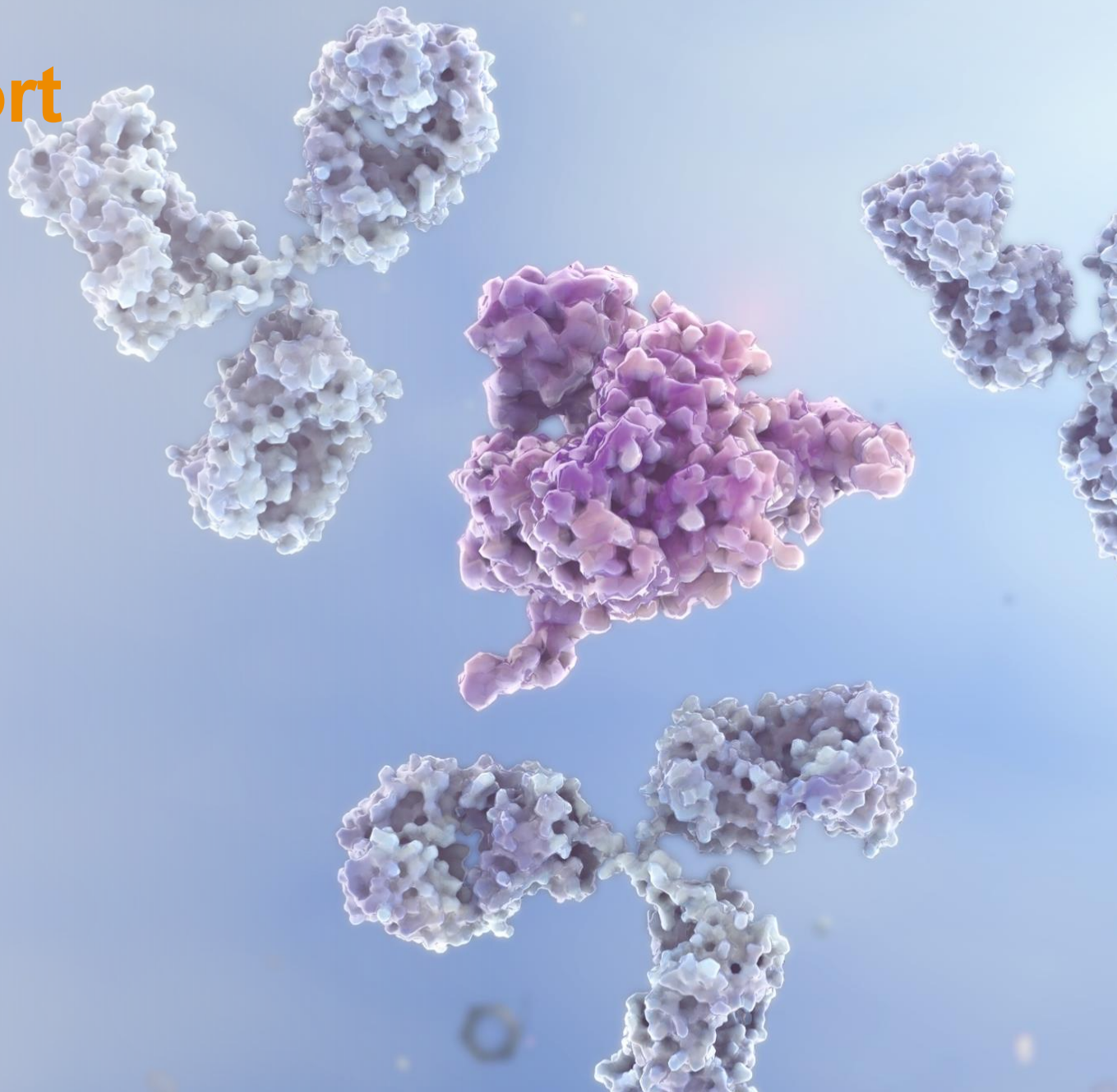
Half Year Report

January - July 2025

HANSA BIOPHARMA



Hansa secures directed cash share issue of approximately 232 MSEK/US $24.3M and restructures NovaQuest debt; as compared to prior year Q2 IDEFIRIX product sales increased 76%

Business Update

- **Completion of directed cash share issue totaling 232 MSEK / US $24.3M.** In Q2 2025, Hansa completed a successful capital raise with the support of new and existing shareholders. The funding will support two Phase 3 trial readouts in the second half of 2025 including the ConfIdeS US pivotal trial in kidney transplantation and GOOD-IDES-02 trial in anti-GBM.
- **Hansa has restructured its existing debt agreement with NovaQuest entered in July 2022.** As part of a directed share issue, Hansa and NovaQuest entered into an amended debt agreement in which the Company offset US $14.9M of outstanding debt through the issue of new shares (equity). The remaining debt will be paid in fixed cash payments in June 2027, June 2028 and June 2029. In addition, a true-up payment of approximately US $14.9M is due on January 31, 2026, which may be settled in cash or equity at the Company's discretion.
- **IDEFIRIX quarterly sales revenue increased by 76% as compared to previous year same time**. IDEFIRIX Q2 product revenues increased by 76% as compared to the same period last year. In Q2 2025, the Company delivered 47.8 MSEK in IDEFIRIX sales reflecting an increase of 76% as compared to previous year (27.2 MSEK) for the same time period. For the 1H 2025, IDEFIRIX sales amounted to 113.5 MSEK representing a 52% increase in product sales over 1H 2024, which represents approximately 80% of full year product sales for 2024.
- **Maria Törnsén appointed Chief Operating Officer (COO) and President U.S**. Törnsén joined the Company with more than 20 years' experience across global and US operations, where she held multiple senior commercial leadership roles. Most recently, she held the position of President North America at Calliditas Therapeutics, where she was responsible for the US commercial and medical affairs organization, until it was acquired by Asahi Kasei Corporation of Japan in September 2024.
- **Subsequent Event**: Dr. Richard Philipson appointed Chief Medical Officer and joined the Company 14 July.

Financial Summary

MSEK, unless otherwise stated – unaudited	Q2 2025	Q2 2024	1H 2025	1H 2024
Revenue	49.1	34.3	115.5	90.3
- thereof: Product sales[1]	47.8	27.2	113.5	74.7
SG&A expenses	(90.5)	(88.2)	(166.5)	(179.5)
R&D expenses	(95.8)	(91.7)	(160.1)	(194.6)
Loss from operations	(154.8)	(187.4)	(248.2)	(346.8)
Loss for the period	(178.9)	(207.9)	(216.0)	(426.5)
Net cash used in operations	(111.7)	(189.2)	(263.6)	(378.3)
Cash and short-term investments	354.4	705.0	354.4	705.0
EPS before and after dilution (SEK)	(2.53)	(3.30)	(3.13)	(7.38)
Number of outstanding shares	84,763,222	67,814,241	84,763,222	67,814,241
Weighted average number of shares before and after dilution	70,802,763	62,929,675	68,937,930	57,800,736
No of employees at the end of the period	140	146	140	146

[1] *Product sales in the second quarter 2024 totaled 47.1 MSEK. Sales were offset by a provision totaling 19.9 MSEK for potential credits associated with volume discounts and potential refunds. First half 2024 product sales totaled 94.6 MSEK and were offset by the provision totaling 19.9 MSEK. Net of the provision, first half product sales totaled 74.7 MSEK.*

Clinical Pipeline Update

- **U.S. ConfIdeS trial (kidney transplantation**): The Company remains on track to report data from the 20-HMedIdeS-17 study (ConfIdeS), a pivotal Phase 3 trial evaluating imlifidase as a potential desensitization therapy compared to standard of care (SoC) for enabling kidney transplantation in highly sensitized patients. Patient randomization was completed in May 2024 and a Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) is expected in second half 2025, following.
- **15-HMedIdeS-09 in Guillain Barré Syndrome (GBS):** Positive data from the 15-HMedIdeS-09 Phase 2 trial including an indirect treatment comparison to the International Guillain-Barré Syndrome Outcome Study (IGOS) was presented at the Peripheral Nerve Society (PNS) annual meeting in May.
- **SRP-9001-104 in Duchenne Muscular Dystrophy:** Several patients have been enrolled in Sarepta Therapeutic's Phase 1b trial evaluating the use of imlifidase as a pre-treatment in its Duchenne Muscular Dystrophy gene therapy program. Recruitment and dosing are temporarily halted in several ELEVYDIS studies following a safety update in March. An independent data monitoring committee concurred that the overall risk-benefit profile remains favorable and there should be no material impact to timelines.

Upcoming Key Catalysts – 2H 2025

Desensitization: Transplantation and Gene Therapy

- **Phase 3 Top Line Data Readout:** pivotal US trial in kidney transplantation (ConfIdeS)
- **Phase 1b Initial Data Readout:** global trial in Duchenne Muscular Dystrophy with Sarepta (SRP-9001-104)
- **Phase 2 Top Line Data Readout:** global trial in Crigler Najjar with Genethon (GNT-018-IDES)

Autoimmune Disease

- **Phase 3 Top Line Data Readout:** global trial in anti-GBM (GOOD-IDES-02)
- **Phase 2 Data Publication:** single arm trial in GBS (15-HMedIdeS-09)

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 three strategic therapeutic areas – transplantation, autoimmune diseases and gene therapy – 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

"In Q2 2025, the Company successfully secured additional financing and restructured its existing debt agreement with NovaQuest, ensuring the ability to report out data on two key Phase 3 programs in kidney transplantation and anti-GBM. With a cash runway now extending into Q2 2026, we can focus on near term catalysts, strategic pipeline decisions and driving the continued commercialization of IDEFIRIX in Europe. Following nearly 90 days in the role, I am impressed by the capabilities of the innovative platform, the deep scientific expertise and the potential to create value across indications and geographies. As we move forward, we will evaluate options to crystallize value and drive our strategic agenda to ensure that our resources are directed toward the most promising programs with the highest unmet medical need and potential return."

Renee Aguiar-Lucander
CEO, Hansa Biopharma

In Q2 2025, the Company secured necessary financing (232 MSEK/US $24.3M) and in parallel restructured the current debt agreement with NovaQuest. The debt restructuring provides the Company with the ability to offset a portion of the debt payment for new shares in the Company and pay the remaining debt in three fixed cash payments beginning in mid-2027.

Together, these actions will extend the cash runway into Q2 2026 and importantly support the readout of several key catalysts including two Phase 3 trials (ConfIdeS in kidney transplantation and GOOD-IDES-09 in anti-GBM).

Financial performance in Q2 2025 remained on track. Product sales totalling 47.8 MSEK representing a 76% increase over prior year (Q2 2024: 27.2 MSEK). In 1H 2025 product sales were 113.5 MSEK, an increase of 52% as compared to 1H 2024 (74.7 MSEK).

During Q2, the Company secured reimbursement for IDEFIRIX in both Australia and Switzerland further expanding the number of markets with established pricing and reimbursement agreements.

Additional regional level agreements were also secured. Following the completed enrolment in the Post Authorization Efficacy and Safety (PAES) Phase 3 study, 65% of centers that participated in the trial are utilizing IDEFIRIX commercially some with repeat utilization.

In May, Belgian consensus guidelines were published online in *Transplant* outlining patient eligibility criteria for IDEFIRIX treatment in alignment with Eurotransplant allocation rules. The guidelines also incorporate post-transplant management strategies for highly sensitized kidney transplant patients. To date, consensus guidelines have been published in nine countries, supporting the use of IDEFIRIX as a desensitization strategy and reinforcing its potential to become the SoC in kidney transplantation for highly sensitized patients.

In Germany the Eurotransplant desensitization program was closed earlier this year which had a negative impact on Q2 revenues from Germany. This is a prioritization program for highly sensitized kidney transplant patients to ensure access to kidney transplantation and is active in seven other European countries.

While German physicians can use IDEFIRIX through the standard allocation system, the lack of access to the focused desensitization program has impacted the utilization of IDEFIRIX for highly sensitized patients in Germany and created some uncertainty amongst physicians as to how best to proceed. Hansa therefore expects this to continue to have a negative impact over the near term and continues to work with the clinical, patient and public health communities to more fully understand the potential impact on commercialization of IDEFIRIX in Germany longer term as well as impact to overall patient care.

In the second half of 2025, the Company will report data from two Phase 3 trials - the U.S. ConfIdeS Phase 3 study in kidney transplantation and the GOOD-IDES-02 Phase 3 study in anti-GBM. Both studies remain on track, and we look forward to sharing the results.

Following the positive data read out of the 15-HMedIdes-09 Phase 2 study in GBS and indirect treatment comparison to the IGOS database, the data was presented at the PNS annual meeting in May. The Company held an investor webcast featuring two prominent KOLs in June providing a deeper dive into the unmet medical need in GBS and the potential role for imlifidase in halting the progression of the disease.

Our focus in gene therapy continue with ongoing enrolment in GNT-018-IDES, a Phase 2 trial in Crigler Najjar to evaluate the efficacy and safety of Genethon's gene therapy, GNT-0003 following pre-treatment with imlifidase. The Phase 1b trial SRP-9001-104 with Sarepta remains on track for an initial data readout later this year.

The Company added to its leadership with the addition of Maria Törnsén as Chief Operating Officer and President, US and Richard Philipson as Chief Medical Officer.

Imlifidase Commercial and Pipeline Update

Commercial Update

EU: Kidney transplantation in highly sensitized patients

The launch of IDEFIRIX continues to advance with strong commercial performance in the first half of 2025. Product sales in the first half of 2025 were 52% higher as compared to product sales over the same period in 2024. Further, Q2 2025 product sales of IDEFIRIX were 76% higher than in the same period a year ago (Q2 2024). This represents an increase in overall adoption of IDEFIRIX as a critical desensitization strategy for highly sensitized kidney transplant patients.

The Company has secured pricing and reimbursement in 20 countries across Europe. In June, IDEFIRIX was granted reimbursement in Australia and Switzerland. IDEFIRIX received conditional approval from the European Commission in August 2020 for the desensitization treatment of highly sensitized kidney transplant patients with positive crossmatch antibodies against a deceased donor organ.

The Company continues to see a growing body of clinical data, real-world evidence and published consensus supporting the use of imlifidase as a desensitization strategy for highly sensitized kidney transplant patients.

In Q2, Belgian consensus guidelines were published online in *Transplant* under the title, "*Belgian Consensus Guidelines Within Eurotransplant on Imlifidase-enabled Deceased Donor Kidney Transplantation in Highly Sensitized Patients*".[1] The guidelines outlined patient eligibility criteria for imlifidase treatment in alignment with Eurotransplant allocation rules and included post-transplant management strategies for highly sensitized patients. These guidelines are intended to be dynamic and will be reviewed and updated regularly to reflect changes in Eurotransplant policies and the evolving use of imlifidase.

In Q1, *Transplant International* published an international consensus outlining the appropriate use of imlifidase in the management of highly sensitized kidney transplant patients, supports the development and implementation of center-specific guidelines.[3] Additionally, in January 2025, the *Spanish Guide to Kidney Transplantation in Highly Sensitized Patients with Anti-HLA Antibody* was published offering detailed recommendations for the management of renal transplantation in highly sensitized patients with donor-specific anti-HLA antibodies.[4]

Enrolment for the trial was completed in January 2025 with a data readout expected in mid-2026. This study fulfils a key post-approval commitment under the European conditional marketing authorization for IDEFIRIX and is expected to support the transition to full marketing approval. The trial involves 22 centers, highlighting the clinical community's sustained interest in gaining experience with IDEFIRIX. Most of these centers now have established protocols and firsthand clinical experience in treating highly sensitized kidney transplant patients.

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

As previously reported, randomization of the ConfIdeS study, the Company's pivotal Phase 3 trial, was completed in May 2024. The trial is evaluating imlifidase as a potential desensitization therapy compared to existing SoC to enable kidney transplantation in highly sensitized patients. The Company remains on track for data read out in the second half 2025.

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

In June 2025, data from the 17-HMedIdeS-14 trial was presented at the European Society of Transplantation annual meeting in London. Previously, these findings were published in the February issue of Transplantation Direct demonstrating that donor-specific antibodies (DSA) rebound is common, antibody strength diminishes over time and persistence of DSAs did not result in premature graft failure.5

Pooled five-year data–including results from the 17-HMedIdeS-14 study was presented at the American Society of Transplantation's annual congress in June and at the SITO congress in October. The data had previously been published in American Journal of Transplantation.6 which demonstrated sustained positive outcomes up to five years in the majority of highly sensitized patients who received an imlifidase-enabled kidney transplant. Patient survival (death censored) was 90%, and graft survival reached 82% consistent with SoC outcomes observed three years post-transplant. The five-year extended analysis builds on the previous three-year evaluation of crossmatch-positive patients.

The 17-HMedIdeS-14 trial is a prospective, observational, long-term follow-up study designed to access graft survival in patients who underwent kidney transplantation following treatment with imlifidase.

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

Enrollment for the GOOD-IDES-02 Phase 3 trial was completed with data readout expected in the second half of 2025. This is an open label, controlled, randomized,

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multi-center study evaluating renal function outcomes in patients with severe anti-GBM disease treated with imlifidase in combination with SoC versus SoC alone.

Phase 2 Guillain-Barré Syndrome (GBS) Study - 15-HMedIdeS-09

Positive full results from the 15-HMedIdeS-09 single arm Phase 2 study of imlifidase in GBS was presented at the PNS annual meeting in May 2025. A peer reviewed publication of the study results, along with the indirect treatment comparison is planned for 2025.

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

In December 2024, Genethon and Hansa announced the initiation of GNT-018-IDES, a Phase 2 trial in patients with Crigler-Najjar syndrome who have pre-existing antibodies against adeno-associated virus (AAV) vectors. The study is assessing the efficacy and safety of a single intravenous dose of Genethon's gene therapy GNT-0003 following pre-treatment with imlifidase in patients with severe Crigler-Najjar syndrome and pre-formed antibodies to AAV serotype 8 (AAV8). The Companies remain on track to report data in the second half of 2025.

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

The SRP-9001-104 Phase 1b trial is evaluating the use of imlifidase as a pre-treatment to Sarepta gene therapy ELEVIDYS (delandistrogene moxeparvovec), in patients with DMD. Following a safety update for ELEVIDYS in March, several clinical trials–including SRP-9001-104–were temporarily halted at the request of EU reference member state authorities.

An independent data monitoring committee has since affirmed that the overall risk-benefit profile supports the continuation of dosing without changes to study protocols. This assessment will be submitted to EU regulators as requested. No material impact on study timelines is anticipated. ELEVIDYS is approved by the FDA as a one-time treatment for in individuals with DMD who have a confirmed mutation in the DMD gene and who are at least four years of age.

Focused pipeline in Desensitization and Autoimmune Diseases

	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Partner	Upcoming Milestone
idefirix (imlifidase)	Desensitization Kidney Transplantation						2026: EU Ph 3 PAES data read out
	Desensitization Kidney Transplantation						2H 2025: ConfIdeS US Phase 3 data read out
	Desensitization Gene Therapy (Crigler Najjar)					GENETHON	2025: GNT-018-IDES complete enrolment
	Desensitization Gene Therapy (DMD)					SAREPTA	2025: SRP-9001-104 data read out
	Desensitization Gene Therapy (LGMD)					SAREPTA	Preclinical Research
	Autoimmune GBS						2025:15-HMedIdeS-09 data publication
	Autoimmune anti-GBM						2025: GOOD-IDES-02 data read out
	Autoimmune ANCA (Investigator Initiated Trial)[1]						2025: Complete enrolment

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

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Financial Review 2025: Second Quarter & Year to Date

Revenue

Revenue for the second quarter 2025 totaled 49.1 MSEK (Q2 2024: 34.3 MSEK) consisting of IDEFIRIX product sales of 47.8 MSEK (Q2 2024: 27.2 MSEK) and contract revenue of 1.3 MSEK (Q2 2024: 7.1 MSEK) related to revenue from the Axis-Shield agreement, the 2024 number mainly consisted of revenue from the Sarepta agreement. Revenue for the six months ended June 30, 2025, totaled 115.5 MSEK (1H 2024: 90.3 MSEK) consisting of IDEFIRIX product sales of 113.5 MSEK (1H 2024: 74.7 MSEK) and contract revenue of 2.0 MSEK (1H 2024: 15.6 MSEK).

Sales General & Administrative (SG&A) expenses

SG&A expenses for the second quarter 2025 totaled 90.5 MSEK (Q2 2024: 88.2 MSEK) and 166.5 MSEK for the first half of 2025 (1H 2024: 179.5 MSEK). SG&A expenses were impacted by the restructuring reserve totaling 20.6 MSEK. The restructuring costs have resulted in increased SG&A expenses compared to the same quarter in the prior year, but a small decrease compared to the first six months of 2024. Non-cash expenses for the Company's long-term incentive programs (LTIP) were included in SG&A and totaled 4.1 MSEK for the first half of 2025 (1H 2024: 16.0 MSEK).

Research & Development (R&D) expenses

R&D expenses for the second quarter of 2025 totaled 95.8 MSEK (Q2 2024: 91.7 MSEK) and 160.1 MSEK for the first half of 2025 (1H 2024: 194.6 MSEK). R&D expenses include a restructuring reserve totaling 3.4 MSEK. Compared to the first half 2024, the decrease in expense was primarily driven by savings associated with the restructuring activities done in 2024, offset by the ongoing U.S. Phase 3 ConfIdeS study, EMA post-approval commitments, the ongoing anti-GBM Phase 3 clinical study and CMC development expense for HNSA-5487. Non-cash expenses for the Company's LTIP program were included in R&D expense and totaled 3.4 MSEK for the first half of 2025 (1H 2024: 6.5 MSEK).

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. In the second quarter 2025, the Company recorded income of 0.7 MSEK, compared to 1.3 MSEK in expense in the second quarter of 2024. The change is primarily due to a strengthening in the exchange rate of the Swedish Krona versus primarily US dollar and EUR, affecting deferred revenue as well as accounts payable and receivable positions on the balance sheet.

Financial income/expenses, net, for the second quarter of 2025, totaled 23.3 MSEK of loss (Q2 2024 expense of 20.5 MSEK). For the first half of 2025, the income totaled 33.4 MSEK compared to an expense of 79.7 MSEK for the first half of 2024. The financial expenses for the second quarter developed negatively by a non-cash loss in the restructuring of the loan to NovaQuest. Besides this the finance net developed positively due to the strengthening of the Swedish Krona compared to the US dollar and impacted the accrued interest for the loan. The second quarter 2025 financial expenses included non-cash interest expense associated with the NovaQuest loan restructuring of 66.9 MSEK (Q2 2024: 62.3 MSEK), a non-cash loss of 59,4 MSEK (Q2 2024: 0) from the loan restructuring modification, favourable foreign exchange fluctuations associated with the NovaQuest loan to 48.4 MSEK (Q2 2024 unfavourable: 18.8 MSEK), and other items (see Note 4).

Financial results

The loss from operations for the second quarter 2025 totaled 154.8 MSEK (Q2 2024: 187.4 MSEK) and 248.2 MSEK for the first half of 2025 (1H 2024: 346.8 MSEK). The decrease in Hansa's operating loss compared to the prior period was driven by increased sales as well as lower overall expenses.

The second quarter loss for the period totaled 178.0 MSEK (Q2 2024: 207.9 MSEK) and for the first half of 2025 the loss for the period totaled 216.0 MSEK (1H 2024: 426.5 MSEK).

Cash flow, cash and investments

Net cash used in operating activities for the second quarter 2025 totaled 111.7 MSEK (Q2 2024: 189.1 MSEK) and 263.6 MSEK for the first half of 2025 (1H 2024: 378.3 MSEK). The change, compared to the prior year, was driven by higher sales, lower operating expenses and a positive change in working capital balance sheet accounts. The share issue completed during Q2 increased cash balances by 218.5 MSEK net of transaction costs.

Cash and cash equivalents totaled 354.4 MSEK at June 30, 2025, compared to 405.3 MSEK at December 31, 2024.

Parent Company

The parent company's revenue for the second quarter of 2025 totaled 49.1 MSEK (Q2 2024: 34.3 MSEK) and for the first half of 2025 to 115.5 (1H 2025: 90.3 MSEK). The second quarter 2025 the parent company loss for the period totaled 209.7 MSEK (Q1 2024: 238.7 MSEK) and for the first half of 2025 the loss for the period was 278.1 MSEK (1H 2024: 485.8 MSEK). Year to date

The parent company shareholders' equity at June 30, 2025, totaled 763.2 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 June 30, 2025, Hansa Biopharma Inc. had fourteen employees, Hansa Biopharma Ltd eight employees and Hansa Biopharma S.r.l. three employees.

Financial Review 2025: Second 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 June 30, 2025, the Company incurred non-cash equity-based compensation expense under the following LTIP programs: 2020, 2021, 2022, 2023 and 2024.

The respective non-cash costs related to the ongoing LTIP programs are summarized in the table below. 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
Maximum number of issuable shares*	633,776	299,000	727,022	809,278	1,463,322
Number of allocated outstanding share rights and options	487,520	230,000	559,248	629,788	1,138,772
Estimated total cost including social contributions for outstanding share rights and options, KSEK	25,863	15,473	39,988	13,899	34,939
Total cost per program, including social contributions as of June 30, 2025 YTD, KSEK	0	-1	1,283	256	1,589
Total costs, including social contributions, as of June 30, 2025 YTD, KSEK					**3,127**

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 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 Q4 2022, Hansa has capitalized development costs related to IDEFIRIX following the conditional approval granted by the EMA (see Note 5). In 2023, based on the conditional approval, the parent company also revalued the underlying intangible asset related to IDEFIRIX (see Note 6). 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 has 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. Following the recent capital raise and the new NovaQuest debt restructuring agreement, the Company expects its current cash position to support operations into late Q1 or early Q2 2026. 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: Second Quarter & Year to Date (continued)

Other information

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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.

Financial Calendar 2025

October 23, 2025	Interim Report for January – September 2025
February 5, 2026	Full Year 2025 Report

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares June 30, 2025	84,763,222
Market Cap June 30, 2025	~2.22 BSEK (USD ~$233 M)
Ticker	HNSA
ISIN	SE0002148817

Top 10 Shareholders as of June 30, 2025

Shareholder Name	Number of Shares	Ownership %
Redmile Group LLC	16,309,214	19.24%
Braidwell LP	6,706,171	7.91%
NovaQuest Capital Management LLC	6,398,981	7.55%
Theodor Jeansson Jr.	3,520,000	4.15%
Avanza Pension	2,886,177	3.40%
Fourth Swedish National Pension Fund (AP4)	2,619,000	3.09%
Hansa Biopharma AB	2,204,667	2.60%
Thomas Olausson	1,917,000	2.26%
Handelsbanken Fonder	1,867,997	2.20%
Nexttobe AB	1,355,379	1.60%
All other	38,978,636	45.99%
Total Shares Outstanding	84,763,222	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 June 30, 2025.

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.

Assurance

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

Lund, Sweden, July 17, 2025

Peter Nicklin
Chairman of the Board

Hilary Malone
Board member

Eva Nilsagård
Board member

Mats Blom
Board member

Florian Reinaud
Board member

Anders Gersel Pedersen
Board member

Jonas Wikström
Board member

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Unaudited Condensed Financial Statements

Unaudited condensed consolidated statement of financial position

KSEK	Note	June 30 2025	June 30 2024	Dec 31 2024
ASSETS				
Non-current assets				
Intangible assets	5	244,497	166,363	197,333
Property and equipment		3,812	5,551	4,682
Right-of-use assets		10,049	16,949	13,198
Total non-current assets		**258,358**	**188,863**	**215,213**
Current assets				
Inventories		2,944	2,117	2,610
Trade receivables & unbilled revenues		181,319	99,329	144,965
Current receivables, non-interest bearing		40,232	34,068	32,574
Cash and cash equivalents		354,416	704,999	405,280
Total current assets		**578,911**	**840,513**	**585,429**
TOTAL ASSETS		**837,269**	**1,029,376**	**800,642**
EQUITY AND LIABILITIES				
Shareholders' equity		**(441,057)**	**(218,794)**	**(589,833)**
Non-current liabilities				
Long-term loan	4	753,636	956,352	1,064,645
Deferred tax liabilities		136	364	168
Provisions		4,313	4,173	4,259
Lease liabilities		3,041	10,554	6,678
Refund liabilities		95,130	-	59,038
Contingent consideration	3	-	930	-
Total non-current liabilities		**856,256**	**972,373**	**1,134,788**
Current liabilities				
Short-term part of loan		141,472	-	-
Tax liabilities		2,104	1,420	2,705
Lease liabilities		8,058	7,576	7,684
Current liabilities, non-interest bearing		56,162	54,927	55,491
Deferred revenue		14,125	30,015	16,334
Refund liabilities		62,964	86,167	64,484
Accrued expenses		137,185	95,692	108,989
Total current liabilities		422,070	**275,797**	**255,687**
TOTAL EQUITY AND LIABILITIES		**837,269**	**1,029,376**	**800,642**

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

KSEK	Note	Q2 2025	Q2 2024	1H 2025	1H 2024
Revenue	2	49,122	34,334	115,471	90,315
Cost of revenue		(18,266)	(40,528)	(38,796)	(58,686)
Sales, general and administration expenses		(90,522)	(88,207)	(166,514)	(179,457)
Research and development expenses	5	(95,836)	(91,678)	(160,100)	(194,643)
Other operating income/(expenses), net		734	(1,306)	1,755	(4,305)
Loss from operations		**(154,768)**	**(187,385)**	**(284,184)**	**(346,776)**
Financial income		49,495	5,970	135,659	11,206
Financial expenses	4	(13,320)	(26,514)	(42,806)	(90,877)
Non-cash loss on loan restructuring		(59,447)	-	(59,447)	-
Loss before tax		**(178,040)**	**(207,929)**	**(214,778)**	**(426,447)**
Tax		(842)	(14)	(1,179)	(75)
Loss for the period		**(178,882)**	**(207,943)**	**(215,957)**	**(426,522)**
Loss for the period attributable to owners of the parent		(178,882)	(207,943)	(215,957)	(426,522)
Loss per share, basic and diluted (SEK)		(2.53)	(3.30)	(3.13)	(7.38)
Other comprehensive income/(loss)					
Items that have been, or may be reclassified to profit or loss for the period:					
Translation differences		(606)	(39)	(2,179)	732
Other comprehensive income/(loss) for the period		**(606)**	**(39)**	**(2,179)**	**732**
Total comprehensive loss		**(179,488)**	**(207,982)**	**(218,136)**	**(425,790)**

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Unaudited condensed consolidated statement of changes in shareholders' equity

	January-June		Full Year
KSEK	**2025**	**2024**	**2024**
Opening balance of shareholders' equity	**(589,833)**	**(167,876)**	**(167,876)**
Result for the period	(215,957)	(426,522)	(807,243)
Translation reserve	(2,179)	732	1,350
Net comprehensive loss	**(218,136)**	**(425,790)**	**(805,893)**
Transactions with the group's owner			
Proceeds from new share issuance, net[1]	218,492	354,308	354,308
Proceeds from restructuring of debt	141,472		
Long term incentive programs	6,948	20,564	29,629
Total transactions with the group's owner	**366,912**	**374,872**	**383,937**
Closing balance of shareholders' equity	**(441,057)**	**(218,794)**	**(589,833)**

[1] Total share issue cost as of 30th of June 2025 amounted to SEK 13,608 KSEK, total share issue cost 2024 amounted to 17,845 KSEK.

Unaudited condensed consolidated statement of cash flow

	Q2		1H	
KSEK	**2025**	**2024**	**2025**	**2024**
Cash Flows from Operating Activities				
Loss for the period	(178,882)	(207,943)	(215,957)	(426,522)
Adjustment for non-cash items [1]	5,435	14,144	(66,580)	95,757
Interest received and paid, net	(47)	437	32	892
Income taxes paid	(941)	(137)	(1,655)	(283)
Cash flow from operations before change in working capital	**(174,435)**	**(193,499)**	**(284,160)**	**(330,156)**
Changes in working capital	62,734	4,359	20,586	(48,127)
Net cash used in operating activities	**(111,701)**	**(189,140)**	**(263,574)**	**(378,283)**
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]	218,492	354,308	218,492	354,308
Payment of lease liabilities	(1,961)	(1,876)	(3,891)	(3,735)
Cash flow from financing activities	**216,531**	**352,432**	**214,601**	**350,573**
Net change in cash	104,830	163,292	(48,973)	(27,826)
Cash and cash equivalents at beginning of period	250,200	514,465	405,280	732,060
Currency exchange variance, cash and cash equivalents	(614)	242	(1,891)	765
Cash and cash equivalents, end of period	**354,416**	**704,999**	**354,416**	**704,999**

[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 5).

[2] Total share issue cost 2025 as of 30th of June amounted to SEK 13,608 KSEK. Total share issue cost 2024 amounted to SEK 17,845 KSEK.

Parent Company – Unaudited condensed statement of financial position

KSEK	Note	June 30 2025	June 30 2024	12 Months 2024
ASSETS				
Non-current assets				
Intangible assets	5,6	1,434,482	1,475,250	1,446,684
Property and equipment		3,812	5,552	4,682
Right-of-use assets		10,049	16,949	13,198
Investment in subsidiaries		34,363	33,646	34,194
Total non-current assets		**1,482,706**	**1,531,397**	**1,498,758**
Current assets				
Inventories		2,944	2,117	2,610
Trade receivables & unbilled revenues		181,319	99,329	144,965
Current receivables, non-interest bearing		39,230	33,744	31,160
Cash and cash equivalents		342,206	689,395	385,103
Total current assets		**565,699**	**824,585**	**563,838**
TOTAL ASSETS		**2,048,405**	**2,355,982**	**2,062,596**
EQUITY AND LIABILITIES				
Shareholders' equity	6	**763,200**	**1,105,982**	**674,449**
Non-current liabilities				
Long-term loan	4	753,636	956,352	1,064,645
Provisions		4,313	4,173	4,259
Lease liabilities		3,041	10,554	6,678
Refund liabilities		95,130	-	59,038
Contingent consideration	3	-	930	-
Total non-current liabilities		**856,120**	**972,009**	**1,134,620**
Current liabilities				
Short-term part of loan		141,472	-	-
Tax liabilities		1,091	1,221	1,119
Lease liabilities		8,058	7,577	7,684
Liabilities, group companies		16,232	9,851	11,480
Current liabilities, non-interest bearing		56,168	55,433	55,448
Deferred revenue		14,125	30,015	16,334
Refund liabilities		62,964	86,167	64,484
Accrued expenses		128,975	87,727	96,978
Total current liabilities		**429,085**	**277,991**	**253,527**
TOTAL EQUITY AND LIABILITIES		**2,048,405**	**2,355,982**	**2,062,596**

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

KSEK	Note	Q2 2025	Q2 2024	1H 2025	1H 2024
Revenue	2	49,122	34,334	115,471	90,315
Cost of revenue		(48,057)	(70,320)	(98,379)	(118,269)
Sales, general and administration expenses		(92,960)	(87,472)	(170,988)	(177,185)
Research and development expenses	5	(94,691)	(93,548)	(158,384)	(196,803)
Other operating income/(expenses), net		596	(1,159)	1,314	(4,147)
Loss from operations		**(185,990)**	**(218,165)**	**(310,966)**	**(406,089)**
Financial income		49,495	5,960	135,659	11,196
Financial expenses	4	(13,309)	(26,502)	(42,793)	(90,866)
Non-cash loss on loan restructuring		(59,447)		(59,447)	
Loss before tax		**(209,251)**	**(238,707)**	**(227,547)**	**(485,759)**
Income tax	6	(490)	(16)	(561)	(87)
Loss for the period		**(209,741)**	**(238,723)**	**(278,108)**	**(485,846)**
Other comprehensive loss for the period		-	-	-	-
Total comprehensive loss for the period		**(209,741)**	**(238,723)**	**(278,108)**	**(485,846)**

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

KSEK	June 30 2025	June 30 2024	12 Months 2024
Opening balance of shareholders' equity	**674,449**	**1,216,945**	**1,216,945**
Result for the period	(278,108)	(485,846)	(926,376)
Other comprehensive income/(loss) for the period	-	-	-
Net comprehensive loss	**(278,108)**	**(485,846)**	**(926,376)**
Proceeds from new share issuance, net[1]	218,492	354,308	354,308
Proceeds from restructuring of debt	141,472		
Long term incentive programs	6,895	20,575	29,572
Total other transactions	**366,859**	**374,883**	**383,880**
Closing balance of shareholders' equity	**763,200**	**1,105,982**	**674,449**

[1] Total share issue cost 2025 amounted to SEK 13,608 KSEK. Total share issue cost 2024 amounted to SEK 17,845 KSEK.

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.

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	Q2		January-June	
KSEK	2025	2024	2025	2024
Group				
Revenue				
Product sales[1]	47,772	27,219	113,450	74,667
Contract revenue, Axis-Shield agreement	673	651	1,344	1,302
Cost reimbursement, Axis-Shield agreement	677	80	677	581
Contract revenue, Sarepta, AskBio agreement	-	6,384	-	13,765
	49,122	**34,334**	**115,471**	**90,315**
Parent Company				
Revenue				
Product sales[1]	47,772	27,219	113,450	74,667
Contract revenue, Axis-Shield agreement	673	651	1,344	1,302
Cost reimbursement, Axis-Shield agreement	677	80	677	581
Contract revenue, Sarepta, AskBio agreement	-	6,384	-	13,765
	49,122	**34,334**	**115,471**	**90,315**

[1] *Actual product sales for the full year 2024 totaled 189.7 MSEK. Sales were offset by a provision totaling 49.6 MSEK associated with volume discounts and rebates. Net of the provision, 2024 product sales totaled 140.1 MSEK.*

Note 3 Fair value of financial instruments

The Group measures its investments in interest funds and its financial liability for contingent consideration at fair value. The fair value of the financial liability for contingent consideration at June 30, 2025 totaled 0.0 MSEK (Q1, 2024: 0.9 MSEK) and belongs to Level 3 in the fair value hierarchy. The Group does not currently hold any interest funds. All other financial instruments are measured at amortized cost. The carrying values of those instruments are considered reasonable approximations of their fair values.

Note 4 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 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 shall also pay NovaQuest US $14.875 million (Second Tranche), either in ordinary shares or in cash, at the Company's discretion. If paid in shares, the subscription price will be the lower of (i) the subscription price in the Directed Share Issue or (ii) the volume-weighted average price (VWAP) of the Company's ordinary shares on Nasdaq Stockholm during the ten trading days immediately preceding the day before the resolution of the share issue.

NovaQuest has 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.

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 will result in modification of the original debt agreement. As a result, the debt will be remeasured based on the net present value of the revised cash flows, discounted using a fair value effective interest rate. This remeasured amount will be compared to the previous carrying value of the original debt, with any difference recognized as a gain or loss in the financial statements. Transaction costs incurred in connection with the new amendment will also be 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 June 30, 2025, the loan totaled 895.1 MSEK, including 362.4 MSEK in total accrued interest.

Note 5 Intangible assets – Internally-generated intangible assets

Expenditures related to research activities are recognized as expense in the period in which it is 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 June 30, 2025, the total capitalized development expenses related to fulfilling the IDEFIRIX EMA post-approval commitments amount to 260.7 MSEK, with 61.0 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 June 30, 2025 was 35.2 MSEK.

Note 6 Intangible assets – Recognition of write-up

As of June 30, 2023, Hansa recognized a write-up of 1,430.0 MSEK in intangible assets in the statutory financial statements of the parent company Hansa Biopharma AB, in accordance with Chapter 4, Section 6 of the Swedish Annual Accounts Act (1995:1554) and RFR 2.

The write-up relates to IDEFIRIX, which received a conditional market authorization in the European Union (EU)/EEA and United Kingdom for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Following the write-up, the asset got a gross value of 1,500.0 MSEK in Hansa Biopharma AB's financial statements. The write-up increased the restricted shareholder equity in Hansa Biopharma AB by 1,430.0 MSEK. It also created a taxable temporary difference, leading to the recognition of a deferred tax liability of 294.6 MSEK, which decreased restricted shareholder equity. As a result of recognizing the deferred tax liability, Hansa recognized a deferred tax asset of 294.6 MSEK in its profit or loss statement, increasing unrestricted shareholder equity, related to previously unrecognized tax losses.

The intangible asset is subject to regular amortization over its estimated useful life of 12 years.

As of June 30, 2025, the Company recorded accumulated amortization of 238.3 MSEK in its statutory financial statements, thereby reducing the previously recorded intangible asset by the same amount. As a result, the Company has recorded an adjustment of 49.1 MSEK to its previously recorded deferred tax assets and tax liabilities due to amortization.

The write-up and subsequent amortization of the intangible asset does not impact the consolidated IFRS financial statements of the Hansa Group.

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.

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.