

Year-end Report

January – December 2024



Hansa delivers strong 2024 sales performance; positive results from Phase 2 trial in Guillain-Barré Syndrome (15-HMedIdeS-09); completed enrolment in Phase 3 trial in anti-GBM (GOOD-IDES-02)

Business Update

- > **Strong full year IDEFIRIX sales performance.** Q4 2024 product sales of IDEFIRIX totaled 25.6 MSEK (43.3 MSEK). Excluding the impact of a provision taken to reflect retroactive discounts and rebates since launch in 2020 (49.6 MSEK) full year IDEFIRIX sales totaled 189.7 MSEK representing an 83% increase over prior year (103.7 MSEK). Full year 2024 revenue for IDEFIRIX totaled 140.1 MSEK inclusive of the provision representing a 35 percent increase over the prior year (103.7 MSEK).
- > **Full year and Q4 total revenue.** Full year Total Revenue for 2024 was 171.3 MSEK representing a 28% increase over prior year (134.1 MSEK). Q4 Total Revenue was 32.3 MSEK. It's important to recognize that despite strong full year 2024 sales of IDEFIRIX, quarterly sales continue to fluctuate as a direct result of variations in European kidney allocation systems.
- > **Successful conversion of special early access program** to full reimbursement completed. In previous quarters, the Company recorded a provision totaling 49.6 MSEK to reflect a one-time retroactive price adjustment associated with IDEFIRIX sales since launch in 2020 under a successful early access program. No further material provisions are anticipated at this time.

Clinical Pipeline Update

- > **GOOD-IDES-02 Phase 3 trial (anti-GBM disease):** Enrolment completed in the GOOD-IDES-02 trial, a global pivotal Phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease. Imlifidase has been granted orphan drug designation for the treatment of anti-GBM disease by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
- > **NICE-01 study and 12-month analysis:** Results from the 12-month analysis demonstrated that HNSA-5487, the Company's next generation IgG cleaving molecule, can very robustly and rapidly reduce IgG levels, has redosing potential, and a favorable safety and tolerability profile. The Company will look to align with regulatory agencies on a development pathway in neuro-autoimmune diseases in 1H 2025.
- > **15-HMedIdeS-09 (GBS):** The Company announced positive data from the 15-HMedIdeS-09 Phase 2 trial in Guillain Barre Syndrome (GBS) and indirect treatment comparison to the International Guillain-Barré Syndrome Outcome Study (IGOS), demonstrating the potential of imlifidase, the Company's first-generation IgG cleaving molecule, to address a significant unmet need in GBS.
- > **Genethon:** Genethon and Hansa announced the initiation of GNT-018-IDES, a Phase 2 trial in patients with Crigler-Najjar syndrome with pre-existing antibodies against adeno-associated virus (AAV) vectors. The trial will evaluate the efficacy and safety of a single intravenous administration 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).
- > **US ConfldeS trial (kidney transplantation):** The US Phase 3 pivotal trial for imlifidase completed randomization of 64 patients in May 2024. Management expects a data read out from the trial in the third quarter of 2025. Data read out of the pivotal US Phase 3 ConfldeS trial for imlifidase and submission of a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) in 2H 2025
- > **Post Authorization Efficacy and Safety Phase 3 Study (PAES) (kidney transplantation):** The study is 96 percent enrolled (48 of targeted 50) and is intended to support full marketing authorization in Europe.
- > **Sarepta:** Enrolment continues in Sarepta Therapeutic's Phase 1b trial evaluating the use of imlifidase as a pre-treatment in its Duchenne Muscular Dystrophy gene therapy program.

Subsequent Events

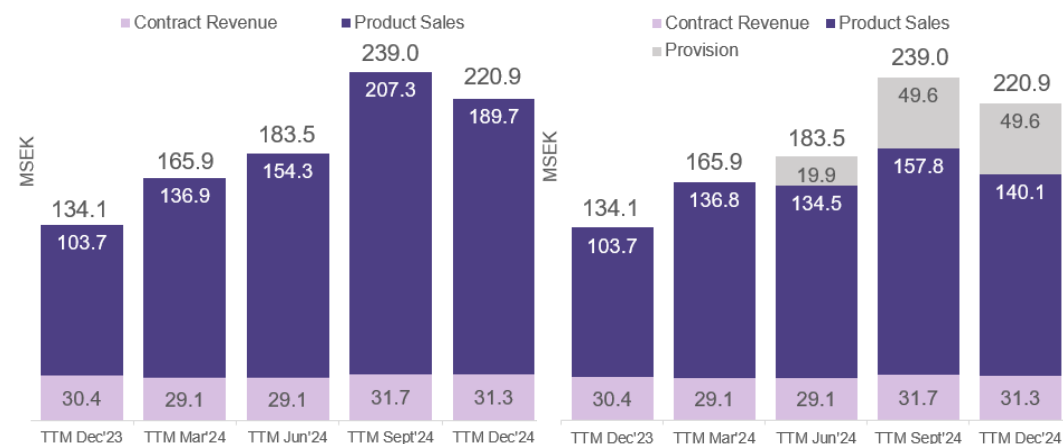
- > In January 2025, *Transplant International* published an international consensus on the appropriate use of imlifidase in clinical practice for highly sensitized kidney transplant patients.
- > IDEFIRIX received reimbursement in Austria, Estonia, and Portugal as a desensitization treatment for adult kidney transplant patients with a positive crossmatch against an available deceased donor.

Financial Summary

MSEK, unless otherwise stated – unaudited	Q4 2024	Q4 2023	12M 2024	12M 2023
Total Revenue	32.3	50.4	220.9	134.1
Provision ¹	-	-	(49.6)	-
Net revenue after provision	32.3	50.4	171.3	134.1
SG&A expenses	(88.5)	(106.0)	(343.8)	(450.5)
R&D expenses	(101.4)	(108.3)	(375.7)	(411.3)
Loss from operations	(173.7)	(175.5)	(637.4)	(788.5)
Loss for the period	(276.4)	(124.5)	(806.7)	(831.7)
Net cash used in operations	(206.8)	(172.9)	(733.9)	(755.7)
Cash and short-term investments	405.3	732.1	405.3	732.1
EPS before and after dilution (SEK)	(4.08)	(2.36)	(12.84)	(15.83)
Number of outstanding shares	67,814,241	52,671,796	67,814,241	52,671,796
Weighted average number of shares before and after dilution	67,814,241	52,671,796	62,834,848	52,540,089
No of employees at the end of the period	135	168	135	168

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. Including the provision, year to date product sales totaled 140.1 MSEK.

Quarter on Quarter Performance, Trailing 12 Months (TTM)



Quarter on Quarter Performance, Net of Provision, Trailing 12 Months



“Over the course of 2024, the Company achieved key pipeline milestones across its three core therapy areas – Autoimmune, Gene Therapy and Transplantation. We had strong year on year sales growth with an 83% increase as compared to previous year. Q4 2024 IDEFIRIX product sales were 25.6 MSEK and despite strong full year sales, quarterly product sales continue to fluctuate given the unpredictable nature of the European kidney allocation systems and availability of organs. Of note, enrolment in the ConfIdes Phase 3 US trial and GOOD-IDES-09 Phase 3 trial in anti-GBM has been completed and we look forward to sharing data later in 2025. Additionally, positive results from both the 15-HMedIdeS-09 Phase 2 trial of imlifidase and indirect treatment comparison to IGOS in GBS and 12-month analysis of NICE-01 study of HNSA-5487 mark exciting progress in Autoimmune. In addition, we continue to make significant progress in collaboration with our gene therapy partners to advance studies exploring the potential of imlifidase as a pre-treatment to gene therapy in patients with anti-AAV antibodies.”

Søren Tulstrup
President and CEO, Hansa Biopharma

In 2024, Hansa Biopharma delivered on several critical priorities, including advancing our pipeline across our core therapeutic areas – Autoimmune, Gene Therapy and Transplantation – with both imlifidase, the Company’s first-in-class IgG cleaving enzyme, and HNSA-5487, a next-generation molecule that can very rapidly and robustly reduce IgG and additionally, the potential for redosing in chronic autoimmune diseases.

The Company delivered strong sales performance for IDEFIRIX in 2024 including the highest quarter of sales performance (Q3 2024) since launch. To date, there have been five consecutive quarters of strong IDEFIRIX sales performance. In Q4 2024, product sales totaled 25.6 MSEK. Excluding the impact of a provision taken to reflect retroactive discounts since launch in 2020 (49.6 MSEK), full year IDEFIRIX sales totaled approximately 189.7 MSEK. Including the provision, full year 2024 product sales totaled 140.1 MSEK and represents a 35 percent increase over the prior year (103.7 MSEK).

The performance reflects the strong launch execution and growing utilization of IDEFIRIX in key clinics across Europe. Further, the performance is underscored by an increase in the overall number of clinics utilizing IDEFIRIX as a desensitization strategy in highly sensitized kidney transplant patients and repeat utilization in many of these clinics. Solid market access and adoption of IDEFIRIX in local and international organ allocation systems remains a foundational pillar of IDEFIRIX launch progress. As mentioned previously, the organ allocation market is unpredictable and directly reflects our quarterly sales.

Importantly, the clinical and scientific community published international consensus in January of 2025 on appropriate utilization of imlifidase in kidney transplantation for highly sensitized kidney transplant patients. These clinical practice guidelines were published in *Transplant International* and will help further enhance patient outcomes and support the development of center-specific infrastructure and guidelines.

In Q4 the Company finalized pricing negotiations in certain markets where a successful early access program enabled Hansa to deliver IDEFIRIX prior to the conclusion of reimbursement negotiations. In previous quarters, the Company recorded provisions (49.6 MSEK) to account for a one-time retroactive pricing adjustment. The Company does not anticipate further material provisions at this time.

The Company announced notable progress in Q4 in Autoimmune, including positive results from the 15-HMedIdeS-09 Phase 2 study in Guillain-Barré Syndrome (GBS) and indirect treatment comparison to the International Guillain-Barré Syndrome Outcome Study (IGOS). The study results demonstrated rapid overall improvement in functional status for severe GBS patients and the indirect treatment comparison concluded that patients in the study returned to independently walking six weeks sooner than those in the IGOS real-world comparator group. We are also pleased to have completed enrolment in the GOOD-IDES-02 Phase 3 study in anti-GBM and expect a data read out in 2025.

Our collaborations in gene therapy continue to progress. In Q4 2024, we announced the initiation of 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 in patients with severe Crigler-Najjar syndrome and pre-formed antibodies to AAV serotype 8 (AAV8).

Positive results from a 12-month analysis of NICE-01, the first in-human trial of HNSA-5487, demonstrated the molecule can very robustly and rapidly reduce IgG levels, has clear redosing potential, and a favorable safety and tolerability profile. We believe HNSA-5487 has a highly differentiated profile compared to published data from studies with other IgG-targeted therapies. We plan to focus initial clinical development of HNSA-5487 in myasthenia gravis (MG).

Imlifidase: Commercial, Clinical and Regulatory Update

Commercial Update

EU: Kidney transplantation in highly sensitized patients

The European launch of IDEFIRIX continues to progress and in 2024 drove overall strong commercial performance for the Company. Market access remains strong with commercial access across Europe including France, Germany, Italy, Spain, and the UK. IDEFIRIX was granted conditional approval by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch antibodies against an available deceased donor in August 2020.

The clinical and scientific community continue to collaborate to improve overall kidney transplant patient outcomes as evidenced by a growing body of data, real-world evidence and published consensus on the utilization of imlifidase as a desensitization strategy for highly sensitized kidney transplant patients.

In 2024, 53 patients eligible for IDEFIRIX were identified by transplant centers in countries participating in Eurotransplant's Desensitization Program. Eurotransplant is an international allocation system responsible for the allocation of donor organs across eight countries: Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, and Slovenia. Real-world evidence was published in *Kidney International Reports* (July 2024), demonstrating that the use of imlifidase in highly sensitized kidney transplant can have an acceptable short-term efficacy and safety profile in select patients.¹ This data was also presented at the American Society of Transplantation's annual congress in June 2024.

Finally, in January 2025, *Transplant International* published international consensus on the appropriate use of imlifidase in clinical practice. The consensus provides clinical practice guidance on imlifidase use in the management of highly sensitized kidney transplant patients and supports the development and integration of center-specific guidelines.²

Pipeline Update

Post Authorization Efficacy and Safety Study (PAES) - 20-HMedIdeS-19

Current enrolment for the 20-HMedIdeS-19 post authorization efficacy and safety study (PAES) is at 96 percent (48 out of 50 targeted). This study is part of the Company's obligation under the European conditional marketing authorization following conditional approval. The study will be used to further investigate long-term graft survival in 50 highly sensitized kidney transplant patients treated with IDEFIRIX and is expected to support full marketing authorization. Enrolment is expected to be completed in the first half of 2025.

ConfIdeS US Phase 3 Trial - 20-HMedIdeS-17

As previously reported, randomization of the 20-HMedIdeS-17 study (ConfIdeS), the Company's pivotal Phase 3 trial, was completed in May 2024. The trial evaluates imlifidase as a potential desensitization therapy compared to treatment according to standard of care (SoC) to enable kidney transplantation in highly sensitized patients. Data read out of the pivotal US Phase 3 ConfIdeS trial for imlifidase and submission of a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) in 2H 2025.

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

Pooled five-year data including data from the 17-HMedIdeS-14 study was published in *American Journal of Transplantation*.³ This data was also presented at the American Society of Transplantation's annual congress and SITO in June and October, respectively.

17-HMedIdeS-14 trial data pooled with data from four Phase 2 trials showed sustained positive outcomes out to five years in most highly sensitized patients who received an imlifidase-enabled kidney transplant. Patient survival was 90 percent (death censored) and graft survival was 82 percent and in line with SoC outcomes seen at three years post-transplant. The five-year extended pooled analysis is a continuation of the analysis at three years of crossmatch positive only patients.

The 17-HMedIdeS-14 trial is a prospective, observational, long-term follow-up study of patients treated with imlifidase prior to kidney transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration.

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

The GOOD-IDES-02 Phase 3 trial is completely enrolled (50 of 50 patients). The data readout remains on track for the second half of 2025. The trial is an open label, controlled, randomized, multi-center trial evaluating renal function in patients with severe anti-GBM disease using imlifidase plus SoC versus SoC only.

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

The Company announced positive full results from the 15-HMedIdeS-09 single arm Phase 2 study of imlifidase in GBS and an indirect treatment comparison of the 15-HMedIdeS-09 study data to the International Guillain-Barré Syndrome Outcome Study (IGOS), a worldwide prospective study by the Inflammatory Neuropathy Consortium on prognosis and biomarkers of GBS.

Data from the 15-HMedIdeS-09 study demonstrated that severe GBS patients treated with a single dose of imlifidase (0.25 mg/kg) plus intravenous immunoglobulin (IVIg) had rapid overall improvement in functional status including expedited recovery of muscle strength, fast return to independently walking, and a median time to independently walk (e.g., reaching Guillain-Barré Syndrome Disability Scale (GBS DS) 2 or less) by 16 days.

The indirect treatment comparison concluded that patients in the 15-HMedIdeS-09 study treated with imlifidase plus IVIg returned to independently walking 6 weeks sooner when compared to severe GBS patients in the IGOS real-world comparator group treated with IVIg. Additionally, patients in the 15-HMedIdeS-09 study experienced statistically significant improvement across several clinically meaningful measures at multiple time points as compared to the IGOS real-world comparator group including 6.4 times more likely at week 1, and 4.2 times more likely at week 4 to walk independently.

1. Kamar, Nassim et al. Imlifidase in Highly Sensitized Kidney Transplant Recipients With a Positive Crossmatch Against a Deceased Donor. *Kidney International Reports*, Volume 9, Issue 10, 2927 – 2936
2. Furián, Lucrezia & Heemann, Uwe & Bengtsson, Mats & Bestard, Oriol & Binet, Isabelle & Böhmig, Georg & Boletis, John & Briggs, David & Claas, Frans & Couzi, Lionel & Cozzi, Emanuele & Crespo, Marta & de Vries, Aiko & Diekmann, Fritz & Durlik, Magdalena & Glotz, Denis & Helantera, Ilkka & Jackson, Annette & Jordan, Stanley & Naesens, Maarten. (2025). Desensitization With Imlifidase for HLA-Incompatible Deceased Donor Kidney Transplantation: A Delphi International Expert Consensus. *Transplant International*. 37. 10.3389/ti.2024.13886
3. Jordan, Stanley C, Maldonado, Angela Q, Lonze, Bonnie E, Sjöholm, Kristoffer Lagergren, Anna Montgomery, Robert A, Runström, Anna Desai, Niraj M, Legendre, Christophe Lundgren, Torbjörn von Zur Mühlen, Bengt Vo, Ashley A, Tollemar, Jan Lefèvre, Paola Lorant, Tomas et al. Long-term outcomes at 5 years posttransplant in imlifidase-desensitized kidney transplant patients. *American Journal of Transplantation*, Volume 0, Issue 0

Pipeline Update (continued)

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

In December 2024, Genethon and Hansa announced initiation of GNT-018-IDES, a Phase 2 trial in patients with Crigler-Najjar syndrome with pre-existing antibodies against adeno-associated virus (AAV) vectors. The trial is evaluating the efficacy and safety of a single intravenous administration 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).

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

Enrolment continues in the SRP-9001-104 Phase 1b trial evaluating the use of imlifidase as a pre-treatment to Sarepta Therapeutic's (Sarepta) ELEVIDYS (delandistrogene moxeparvec) gene therapy in Duchenne Muscular Dystrophy (DMD). ELEVIDYS is FDA approved as a one-time treatment in individuals with DMD with a confirmed mutation in the DMD gene who are at least four years old.

Preclinical Update

AskBio - pre-treatment ahead of gene therapy in Pompe disease

AskBio and Hansa announced a collaboration agreement in January 2022 to evaluate the use of imlifidase as a pre-treatment for AskBio's gene therapy in Pompe disease. In May 2024, AskBio presented pre-clinical data as part of the Hansa-AskBio partnership at the American Society of Gene and Cell Therapy's (ASGCT) annual meeting. The data demonstrated that imlifidase can help keep AAVs in circulation for a longer time period increasing the window for gene therapy transduction. For further information regarding AskBio's programs please visit www.askbio.com.

HNSA-5487: Clinical and Regulatory Update

HNSA-5487 Phase 1 Trial – NICE-01

Results of a 12-month follow up analysis from the NICE-01 trial of HNSA-5487, the Company's next generation IgG-cleaving molecule were announced on October 7, 2024. The analysis assessed IgG recovery, immunogenicity and the potential for redosing HNSA-5487 in chronic autoimmune diseases.

High-level results from the NICE-01 trial demonstrated that HNSA-5487 was safe and well tolerated with rapid depletion of IgG observed with increasing doses in all healthy study subjects. Pharmacokinetics (PK) and pharmacodynamics (PD) were in line with expectations. The trial included a total of 36 healthy male and female adult participants. The Company will focus initial clinical development activities in chronic autoimmune diseases where IgG plays a role in disease pathology with recurring attacks. The Company will align with regulatory agencies on a development pathway in neuro-autoimmune diseases with an initial focus in myasthenia gravis (MG) in first half 2025.

Broad clinical pipeline



	Preclinical	Phase 1	Phase 2	Phase 3	Marketing authorization	Marketed	Partner	Status	Next anticipated milestone
Imlifidase									
EU: Kidney transplantation in highly sensitized patients ^{1,2}								Commercialization ongoing ● Post approval Clinical Phase 3 ongoing	EU: Additional agreements around reimbursement / Post authorization study to be completed by end of 2025
U.S. "ConfIdeS": Kidney transplantation in highly sensitized patients ^{1,2}								Clinical Phase 3 ongoing	Data readout in 2H 2025
GOOD-IDES-02: Anti-GBM antibody disease								Clinical Phase 3 ongoing	Data readout in 2025
16-HMedIdeS-12: Active Antibody Mediated Rejection (AMR)								Clinical Phase 2 completed	
15-HMedIdeS-09: Guillain-Barré Syndrome (GBS)								Clinical Phase 2 completed	Publication in peer-reviewed journal Preparation of Phase 3 trial
Investigator-initiated trial in ANCA-associated vasculitis ³								Clinical Phase 2 ongoing	Complete enrollment (10 patients)
SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)								Clinical Phase 1b ongoing	Complete enrollment
Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)								Preclinical research ongoing	Preclinical research
Pre-treatment ahead of gene therapy in Pompe disease								Preclinical research ongoing	Preclinical research
Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome								Clinical Phase 2 ongoing	Complete enrollment
HNSA-5487									
NICE-01: HNSA-5487 – Lead candidate from the NiceR program								Clinical Phase 1 completed	Alignment with regulatory authorities on clinical development pathway in neuro-autoimmune diseases

¹ Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)
² Lorant et al., American Journal of Transplantation and 03+04 studies (Jordan et al., New England Journal of Medicine)
³ Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

Financial Review 2024: Fourth Quarter & Year to Date

Revenue

Revenue for the fourth quarter 2024 totaled 32.3 MSEK (Q4 2023: 50.4 MSEK) consisting of IDEFIRIX product sales of 25.6 MSEK (Q4 2023: 43.3 MSEK) and contract revenue of 6.7 MSEK (Q4 2023: 7.1 MSEK) primarily related to the recognition of an upfront payment the Company received under its partnership agreement with Sarepta.

Revenue for full year 2024, totaled 171.3 MSEK (full year 2023: 134.1 MSEK) consisting of IDEFIRIX product sales of 140.1 MSEK (full year 2023: 103.7 MSEK) and contract revenue of 31.2 MSEK (full year 2023: 30.4 MSEK) primarily from an upfront payment the Company received under its partnership agreement with Sarepta. Product sales in 2024 were offset by a provision of 49.6 MSEK.

Sales General & Administrative (SG&A) expenses

SG&A expenses for the fourth quarter 2024 totaled 88.5 MSEK (Q4 2023: 106.0 MSEK) and 343.8 MSEK for the full year 2024 (full year 2023: 450.5 MSEK). SG&A expenses include a restructuring reserve totaling 6.2 MSEK in the year 2024. Restructuring activities reduced total SG&A expenses compared to prior quarters. Non-cash expenses for the Company's long-term incentive programs (LTIP) were included in SG&A costs and totaled 21.7 MSEK for full year 2024 (full year 2023: 39.4 MSEK).

Research & Development (R&D) expenses

R&D expenses for the fourth quarter of 2024 totaled 101.4 MSEK (Q4 2023: 108.3 MSEK) and 375.7 MSEK for full year 2024 (full year 2023: 411.3 MSEK). R&D expenses include a restructuring reserve totaling 6.6 MSEK in 2024. Compared to 2023, the decrease in expense was primarily driven by savings associated with restructuring activities offset by the ongoing US Phase 3 ConfldeS 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 10.0 MSEK for full year 2024 (full year 2023: 21.2 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 fourth quarter 2024, the Company recorded expense of 2.6 MSEK, compared to 6.4 MSEK in income in the fourth quarter of 2023. For the full year 2024, the Company recorded expense of 5.7 MSEK compared to an income of 2.4 MSEK for the full year 2023. The change in expenses is primarily due to fluctuations in the US dollar exchange rate against the Swedish Krona, affecting deferred revenue as well as accounts payable and receivable positions on the balance sheet.

Financial income/expenses, net, for the fourth quarter of 2024, totaled 99.9 MSEK of expense (Q4 2023 income of 51.3 MSEK). The financial expenses for the fourth quarter were negative due to the development of the foreign exchange rate in US dollar and the accrued interest for the loan. For the full year 2024 the financial income/expenses, net totaled 166.3 MSEK of expense (full year 2023 expense of 42.3 MSEK). In 2024, financial expenses included non-cash interest expense associated with the NovaQuest loan totaling 134.1 MSEK (full year 2023: 115.9 MSEK), unfavorable foreign exchange fluctuations associated with the NovaQuest loan of 85.7 MSEK (In 2023 full year foreign exchange fluctuations were favorable: 32.6 MSEK), and other favorable items totaling 32.6 MSEK (full year 2023: 12.9 MSEK) (see Note 4).

Financial results

The loss from operations for the fourth quarter 2024 totaled 173.7 MSEK (Q4 2023: 175.5 MSEK) and 637.4 MSEK for the full year 2024 (full year 2023: 788.5 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 fourth quarter loss totaled 276.4 MSEK (Q4 2023: 124.5 MSEK) and for the full year 2024 the loss totaled 806.7 MSEK (full year 2023: 831.7 MSEK).

Cash flow, cash and investments

Net cash used in operating activities for the fourth quarter 2024 totaled 206.8 MSEK (Q4 2023: 172.9 MSEK) and 733.9 MSEK for the full year 2024 (full year 2023: 755.7 MSEK). The change compared to the prior year was driven by higher sales and lower operating expenses offset by the negative impact associated with changes in working capital. The Company completed a share issue during Q2 increasing cash and cash equivalents by 354.3 MSEK net of transaction costs.

Cash and cash equivalents totaled 405.3 MSEK at December 31, 2024, compared to 732.1 MSEK at December 31, 2023.

Parent Company

The parent company's revenue for the fourth quarter of 2024 totaled 32.3 MSEK (Q4 2023: 50.4 MSEK) and for the full year 2024 171.3 MSEK (full year 2023: 134.1 MSEK).

During the fourth quarter 2024 the parent company loss totaled 306.6 MSEK (Q4 2023: 147.1 MSEK) and for the full year 2024 the loss totaled 926.4 MSEK (full year 2023: loss of 595.5 MSEK). The parent company loss for 2023 was affected by a deferred tax income credit of 287.9 MSEK related to the write-up of Intellectual Property (IP) in the second quarter of 2023.

The parent company shareholders' equity at December 31, 2024 totaled 674.4 MSEK compared to 1,216.9 MSEK at December 31, 2023.

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, 2024, Hansa Biopharma Inc. had thirteen employees, Hansa Biopharma Ltd seven employees and Hansa Biopharma S.r.l. three employees.

Financial Review 2024: 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, 2024, the Company incurred non-cash equity-based compensation expense under the following LTIP programs: 2019, 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 2023 Annual Report which can be found at www.hansabiopharma.com.

Ongoing programs	LTIP 2019	LTIP 2020	LTIP 2021	LTIP 2022	LTIP 2023	LTIP 2024
Maximum number of issuable shares*	193,892	633,776	325,000	819,904	1,037,327	1,744,600
Number of allocated outstanding share rights and options	149,148	487,520	250,000	630,695	797,944	1,342,000
Estimated total cost including social contributions for outstanding share rights and options, KSEK	-	97,319	62,467	44,266	19,065	50,741
Total cost per program, including social contributions, recognized in profit/loss as of December 31, 2024, YTD, KSEK	-	322	7,699	10,973	6,303	6,392
Total costs, including social contributions, recognized in profit/loss as of December 31, 2024, YTD, KSEK						31,689

*As of December 31, 2024, the table includes shares issued to cover estimated social contributions under the LTIP.

Risks and uncertainties

Hansa's business is influenced by a number of factors, the effects of which on the Company's earnings and financial position in certain respects cannot be controlled by the Company at all, or in part. In an assessment of the Company's future development, it is important, alongside the possibilities for growth in earnings, to consider these risks.

Since Q4 2022 Hansa has capitalized development costs related to IDEFIRIX in connection with the conditional approval the Company received from the EMA (see Note 5). Based on the conditional approval from the EMA, the parent company of the group also revalued the underlying intangible asset related to IDEFIRIX in 2023 (see Note 6). Both the assessment to start capitalizing development costs and the write up of the intangible assets in the parent company was based on the assessment that Hansa will eventually receive a final approval from EMA for the sale of IDEFIRIX. The current conditional approval from EMA requires Hansa to conduct two clinical trials to secure a final approval:

- a five-year follow-up clinical study on previously performed Phase II studies of treatment in 46 patients. This concerns a follow-up on patients that have been treated with IDEFIRIX. This clinical study was finalized and submitted to EMA in December 2023. In 2024 EMA finalized its review and the study was approved.
- a post-authorization efficacy and safety study (PAES), of 50 transplanted patients treated with IDEFIRIX with a reference group of 50 transplant patients not treated with IDEFIRIX which is the standard treatment for kidney transplants. After finalizing the treatment, the patients will be monitored for one year to analyze the long-term effect of the drug. The objective is to see if the treatment of highly sensitized patients with IDEFIRIX are as successful as the standard treatment. As of December 31, 2024, 43 of the targeted 50 patients were enrolled in the study. The study is expected to be finalized in 2025. Hansa currently has no indication that the study would be unsuccessful.

Based on the fact that the follow-up study is already approved and that there are no current indications that the PAES study would be unsuccessful, Hansa considers the risk of not being able to fulfill EMA's conditions for final approval to be remote.

Risk factors include, among others, uncertainties with regard to clinical trials and regulatory approvals, collaboration and partnerships, intellectual property issues, dependence on key products, market and competition, manufacturing, purchasing and pricing, as well as dependence on key persons and financial risks.

The Board of Directors and management remain focused on cash flow and work continuously to ensure long-term and sustainable financing of current and planned development projects. There are a number of possible alternatives to secure the financing for the Company and the Board and management will continue to evaluate financing opportunities. Within the next 12-months, the Company plans to raise capital through a financing event or other means and is actively exploring options. There can be no assurances that these efforts will be successful. Risks and uncertainties which are considered to have greatest significance for Hansa Biopharma are described in more detail in the English version of the Company's 2023 Annual Report (pages 53-56).

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 2023 Annual Report have been identified as of the date of this quarterly report.

Financial Review December 2024: Fourth Quarter & Year to Date continued

Other information

Contacts

Evan Ballantyne, Chief Financial Officer
Hansa Biopharma
E-mail: ir@hansabiopharma.com

Stephanie Kenney, VP Global Corporate Affairs
Hansa Biopharma
E-mail: media@hansabiopharma.com

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 2024.

Financial calendar 2024/2025

March 21, 2025	Annual and Sustainability Report for 2024
April 17, 2025	Interim Report for January – March 2025
July 17, 2025	Half-year Report for January – June 2025
October 23, 2025	Interim Report for January – September 2025

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares December 31, 2024	67,814,241
Market Cap December 31, 2024	~2.66 BSEK (USD ~\$241M)
Ticker	HNSA
ISIN	SE0002148817

Top 10 Shareholders as of December 31, 2024

Shareholder Name	Number of Shares	Ownership %
Redmile Group LLC	13,156,700	19.40%
Braidwell LP	8,247,600	12.16%
Avanza Pension	2,691,744	3.97%
Theodor Jeansson Jr.	2,654,041	3.91%
Hansa Biopharma AB	2,204,667	3.25%
Handelsbanken Fonder	2,181,579	3.22%
Nexttobe AB	2,155,379	3.18%
Fourth Swedish National Pension Fund (AP4)	2,094,000	3.09%
Thomas Olausson	1,917,000	2.83%
Sphera Funds Management	1,107,000	1.63%
All other	29,404,531	43.36%
Total Shares Outstanding	67,814,241	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, 2024.

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, February 5, 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

Søren Tulstrup
President & CEO

Unaudited Condensed Financial Statements

Unaudited condensed consolidated statement of financial position

KSEK	Note	December 31	
		2024	2023
ASSETS			
Non-current assets			
Intangible assets	5	197,333	135,817
Property and equipment		4,682	6,343
Right-of-use assets		13,198	20,730
Total non-current assets		215,213	162,890
Current assets			
Inventories		2,610	1,513
Trade receivables & unbilled revenues		144,965	78,025
Current receivables, non-interest bearing		32,574	43,553
Cash and cash equivalents		405,280	732,060
Total current assets		585,429	855,151
TOTAL ASSETS		800,642	1,018,041
EQUITY AND LIABILITIES			
Shareholders' equity			
		(589,315)	(167,876)
Non-current liabilities			
Long-term loan	4	1,064,645	844,903
Deferred tax liabilities		168	367
Provisions		4,259	4,454
Lease liabilities		6,678	14,362
Refund liabilities		59,038	-
Contingent consideration	3	-	843
Total non-current liabilities		1,134,788	864,929
Current liabilities			
Tax liabilities		2,705	1,599
Lease liabilities		7,684	7,503
Current liabilities, non-interest bearing		55,492	108,748
Deferred revenue		16,334	41,473
Refund liabilities		64,484	49,266
Accrued expenses		108,470	112,399
Total current liabilities		255,169	320,988
TOTAL EQUITY AND LIABILITIES		800,642	1,018,041

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

KSEK	Note	Q4		12 Months	
		2024	2023	2024	2023
Revenue	2	32,337	50,411	171,316	134,094
Cost of revenue		(13,488)	(18,126)	(83,554)	(63,143)
Sales, general and administration expenses		(88,497)	(105,992)	(343,773)	(450,492)
Research and development expenses	5	(101,442)	(108,251)	(375,709)	(411,332)
Other operating income/(expenses), net		(2,580)	6,417	(5,654)	2,377
Loss from operations		(173,670)	(175,541)	(637,374)	(788,496)
Financial income		3,844	63,204	20,834	63,204
Financial expenses	4	(103,762)	(11,908)	(187,165)	(105,520)
Loss before tax		(273,588)	(124,245)	(803,705)	(830,812)
Tax		(2,833)	(214)	(3,034)	(908)
Loss for the period		(276,421)	(124,459)	(806,739)	(831,720)
Loss for the period attributable to owners of the parent		(276,421)	(124,459)	(806,739)	(831,720)
Loss per share, basic and diluted (SEK)		(4.08)	(2.36)	(12.84)	(15.83)
Other comprehensive income/(loss)					
Items that have been, or may be reclassified to profit or loss for the period:					
Translation differences		1,196	(1,297)	1,363	(422)
Other comprehensive income/(loss) for the period		1,196	(1,297)	1,363	(422)
Total comprehensive loss		(275,225)	(125,756)	(805,376)	(832,142)

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

KSEK	January-December	
	2024	2023
Opening balance of shareholders' equity	(167,876)	602,912
Result for the period	(806,739)	(831,720)
Translation reserve	1,363	(422)
Net comprehensive loss	(805,376)	(832,142)
Transactions with the group's owner		
Proceeds from new share issuance, net ¹	354,308	-
Long term incentive programs	29,629	61,354
Total transactions with the group's owner	383,937	61,354
Closing balance of shareholders' equity	(589,315)	(167,876)

¹ Total share issue cost amounted to SEK 17,845 KSEK.

Unaudited condensed consolidated statement of cash flow

KSEK	Q4		12 Months	
	2024	2023	2024	2023
Cash Flows from Operating Activities				
Loss for the period	(276,421)	(124,459)	(806,739)	(831,720)
Adjustment for items not included in cash flow ¹	106,543	(77,269)	180,890	37,793
Interest received and paid, net	18,350	26,827	19,108	26,970
Income taxes paid	(2,711)	(21)	(3,611)	(133)
Cash flow from operations before change in working capital	(154,239)	(174,922)	(610,352)	(767,090)
Changes in working capital	(52,599)	1,977	(123,570)	11,436
Net cash used in operating activities	(206,838)	(172,945)	(773,922)	(755,654)
Investing activities				
Acquisition of property and equipment	-	405	(116)	(284)
Cash flow from investing activities	-	405	(116)	(284)
Financing activities				
Proceeds from new share issue, net of transaction cost ²	-	-	354,308	-
Refund liabilities non-current	59,038	-	59,038	-
Payment of lease liabilities	(1,876)	(2,195)	(7,503)	(7,545)
Cash flow from financing activities	57,162	(2,195)	405,843	(7,545)
Net change in cash	(149,676)	(174,735)	(328,195)	(763,483)
Cash and cash equivalents at beginning of period	553,544	908,176	732,060	1,496,179
Currency exchange variance, cash and cash equivalents	1,412	(1,381)	1,415	(636)
Cash and cash equivalents, end of period	405,280	732,060	405,280	732,060

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 amounted to SEK 17,845 KSEK.

Unaudited Condensed Financial Statements continued

Parent Company – Unaudited condensed statement of financial position

KSEK	Note	December 31	
		2024	2023
ASSETS			
Non-current assets			
Intangible assets	5,6	1,446,684	1,504,277
Property and equipment		4,682	6,343
Right-of-use assets		13,198	20,730
Investment in subsidiaries		34,194	30,044
Total non-current assets		1,498,758	1,561,394
Current assets			
Inventories		2,610	1,513
Trade receivables & unbilled revenues		144,965	78,025
Current receivables, non-interest bearing		31,160	43,205
Cash and cash equivalents		385,103	715,538
Total current assets		563,838	838,281
TOTAL ASSETS		2,062,596	2,399,675
EQUITY AND LIABILITIES			
Shareholders' equity			
	6	674,449	1,216,945
Non-current liabilities			
Long-term loan	4	1,064,645	844,903
Provisions		4,259	4,454
Lease liabilities		6,678	14,362
Refund liabilities		59,038	-
Contingent consideration	3	-	843
Total non-current liabilities		1,134,620	864,562
Current liabilities			
Tax liabilities		1,119	1,409
Lease liabilities		7,684	7,503
Liabilities, group companies		11,480	7,089
Current liabilities, non-interest bearing		55,448	108,045
Deferred revenue		16,334	41,473
Refund liabilities		64,484	49,266
Accrued expenses		96,978	103,383
Total current liabilities		253,527	318,168
TOTAL EQUITY AND LIABILITIES		2,062,596	2,399,675

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

KSEK	Note	Q4		12 Months	
		2024	2023	2024	2023
Revenue	2	32,337	50,411	171,316	134,094
Cost of revenue		(43,280)	(47,917)	(202,721)	(122,726)
Sales, general and administration expenses		(93,238)	(103,941)	(346,455)	(448,133)
Research and development expenses	5	(99,109)	(109,034)	(375,351)	(412,404)
Other operating income/(expenses), net		(3,005)	6,239	(6,242)	2,200
Loss from operations		(206,295)	(204,242)	(759,453)	(846,969)
Financial income		3,867	54,003	20,848	63,181
Financial expenses	4	(103,760)	(2,729)	(187,164)	(105,519)
Loss before tax		(306,188)	(152,968)	(925,769)	(889,307)
Income tax	6	(383)	5,871	(607)	293,771
Loss for the period		(306,571)	(147,097)	(926,376)	(595,536)
Other comprehensive loss for the period		-	-	-	-
Total comprehensive loss for the period		(306,571)	(147,097)	(926,376)	(595,536)

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

KSEK	December 31	
	2024	2023
Opening balance of shareholders' equity	1,216,945	615,799
Result for the period	(926,376)	(595,536)
Other comprehensive income/(loss) for the period	-	-
Net comprehensive loss	(926,376)	(595,536)
IP write-up, net	-	1,135,421
Proceeds from new share issuance, net ¹	354,308	-
Long term incentive programs	29,572	61,261
Total other transactions	383,880	1,196,682
Closing balance of shareholders' equity	674,449	1,216,945

¹ Total share issue cost amounted to SEK 17,845 KSEK.

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 2023 was published on March 21, 2024, 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 KSEK	Q4		12 Months	
	2024	2023	2024	2023
Group				
Revenue				
Product sales ¹	25,633	43,337	140,111	103,712
Contract revenue, Axis-Shield agreement	652	644	2,605	2,575
Cost reimbursement, Axis-Shield agreement	59	102	640	388
Contract revenue, Sarepta, AskBio agreement	5,993	6,328	27,960	27,419
	32,337	50,411	171,316	134,094
Parent Company				
Revenue				
Product sales ¹	25,633	43,337	140,111	103,712
Contract revenue, Axis-Shield agreement	652	644	2,605	2,575
Cost reimbursement, Axis-Shield agreement	59	102	640	388
Contract revenue, Sarepta, AskBio agreement	5,993	6,328	27,960	27,419
	32,337	50,411	171,316	134,094

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, year to date 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 December 31, 2024 totaled 0.0 MSEK (December 31, 2023: 0.8 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 funding agreement.

The net proceeds from the funding agreement totaled US \$69.2 million after the deduction of transaction costs. The transaction costs were capitalized and offset against the carrying value of the debt and will be amortized over the term of the debt.

Under the terms of the funding agreement, the Company was required to make quarterly mid-single-digit royalty payments to NovaQuest on future worldwide annual net sales of imlifidase, commencing upon approval by the US FDA of imlifidase in kidney transplantation or anti-GBM. In addition, Hansa will make certain milestone payments to NovaQuest upon FDA approval of imlifidase in kidney transplantation or anti-GBM disease. The agreement also provides for time-based catch-up payments if specified payment amounts have not been received by NovaQuest by specified dates. Under the agreement, repayments must begin no later than January 31, 2026, regardless of whether the aforementioned approvals were achieved, with the final potential catch-up payment due on January 31, 2029. The company is obligated to repay a total of US \$140.0 million in the form of milestones, royalty payments and/or catch-up payments.

Hansa has also entered into a security agreement under which the Company has pledged and provided a broad security interest to NovaQuest in, and to, certain assets, proceeds and IP rights related to imlifidase in kidney transplantation in highly sensitized patients and anti-GBM disease.

The Company will record 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, 2024, the loan totaled 1,064.6 MSEK, including 292.5 MSEK in 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.

Financial Notes continued

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, 2024, the total capitalized development expenses related to fulfilling the IDEFIRIX EMA post-approval commitments amount to 199.7 MSEK, with 80.1 MSEK capitalized during 2024. 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, 2024 was 22.8 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 has 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 will have 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 decrease 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 will be subject to regular amortization over its estimated useful life of 12 years.

As of December 31, 2024, the Company recorded accumulated amortization of 178.7 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 36.8 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.