Interim Report

January – September 2024

HANSA BIOPHARMA

Company records highest ever quarterly in market IDEFIRIX® sales performance; GOOD-IDES-02 trial in anti-GBM at 86% patient enrolment; US ConfIdeS trial remains on track for data readout in H2 2025

Business Update

- **Highest ever quarterly IDEFIRIX sales performance**. Third quarter 2024 in market product sales of IDEFIRIX totaled 69.5 MSEK, marking the highest ever quarterly sales performance. This represents a 321 percent increase versus the prior year and was the fourth consecutive quarter of strong sales growth. Year-to-date (YTD) revenue for IDEFIRIX totaled 164.1 MSEK. This represents a 171 percent increase over the prior year.
- **Successful conversion of special early access program to full reimbursement expected soon**. In Q3 the company recorded a provision totaling 29.7 MSEK to account for discounts and a one-time retroactive price adjustment. The adjustment is associated with IDEFIRIX sales since launch (2020) under a successful early access program that ensured patients and clinicians had access to IDEFIRIX prior to the conclusion of final pricing negotiations. This provision reflects an updated estimate based on near final pricing negotiations.

  Of the total provision only 4.9 MSEK is related to Q3 sales. Net the provision, Q3 2024 IDEFIRIX sales were 39.8 MSEK and total YTD IDEFIRIX sales were 114.5 MSEK. In Q2, the Company recorded a provision of 19.9 MSEK, whereof 2.0 MSEK was related to sales in Q2 2024. Of the total provision taken in Q2 and Q3, 42.7 MSEK relates to previous periods since launch in 2020.

Clinical Pipeline Update

- **US ConfIdeS trial (kidney transplantation**): The US Phase 3 pivotal trial for imlifidase completed randomization of all 64 patients in May. The trial continues to progress and data from the study is expected to provide the basis for submission of a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) in the second half of 2025 to seek accelerated approval.
- **GOOD-IDES-02 Phase 3 trial (anti-GBM disease):** 86 percent of patients have been enrolled in this global trial (43 of targeted 50) for anti-glomerular basement membrane (anti-GBM) disease. Data readout is expected in the second half of 2025.
- **Post Authorization Efficacy Study (PAES) (kidney transplantation)**: 78 percent of patients have been enrolled in this post approval, Phase 3 study in kidney transplantation (39 of targeted 50). The study is intended to support full marketing authorization in Europe with a data readout planned in 2025.

Subsequent Events

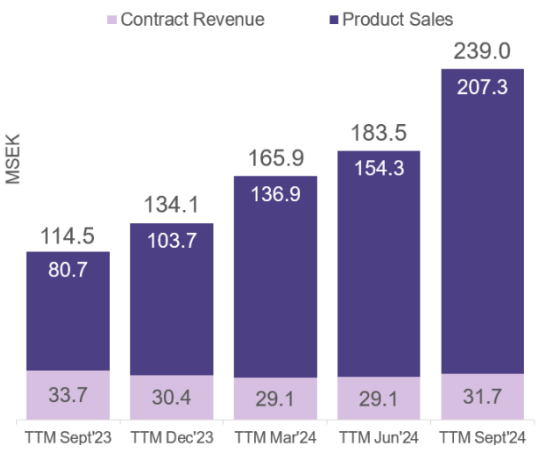
- **The Company announced (7 October) the results of NICE-01 and a 12-month analysis that demonstrated that HNSA-5487, the Company's next generation IgG cleaving molecule** can very robustly and rapidly reduce IgG levels, has redosing potential, and was safe and well tolerated. The Company will focus initial clinical development activities in chronic autoimmune diseases where IgG plays a role in disease pathology with recurring attacks. Initial clinical development of HNSA-5487 will focus in neuromyelitis optica (NMO), myelin oligodendrocyte glycoprotein antibody disease (MOGAD), and myasthenia gravis (MG).

Financial Summary

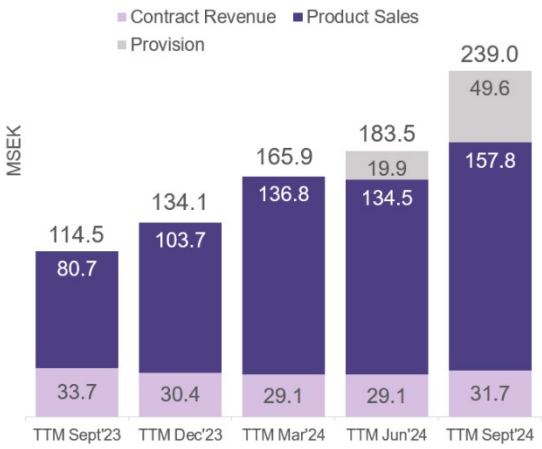
MSEK, unless otherwise stated – unaudited	Q3 2024	Q3 2023	9M 2024	9M 2023
Total Revenue	78.4	22.8	188.6	83.7
Provision[1]	(29.7)	-	(49.6)	-
Net revenue after provision	48.7	22.8	139.0	83.7
SG&A expenses	(75.8)	(111.7)	(255.3)	(344.5)
R&D expenses	(79.6)	(95.6)	(274.3)	(303.1)
Loss from operations	(116.9)	(202.2)	(463.7)	(613.0)
Loss for the period	(103.8)	(250.7)	(530.3)	(707.3)
Net cash used in operations	(148.8)	(193.8)	(527.1)	(582.7)
Cash and short-term investments	553.5	908.2	553.5	908.2
EPS before and after dilution (SEK)	(1.53)	(4.78)	(8.67)	(13.49)
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	52,597,502	61,162,934	52,495,705
No of employees at the end of the period	135	168	135	168

[1] *Product sales in the third quarter 2024 totaled 69.5 MSEK. Sales were offset by a provision totaling 29.7 MSEK for potential credits associated with volume discounts and rebates. Year to date 2024 IDEFIRIX product sales totaled 164.1 MSEK and were offset by a provision totaling 49.6 MSEK. Net of the provision, year-to-date 2024 product sales totaled 114.5 MSEK.*

Quarter on Quarter Performance, Trailing 12 Months (TTM)



Quarter on Quarter Performance Net of Provision, Trailing 12 Months



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.

CEO Comments

"Q3 2024 marks the highest ever IDEFIRIX sales performance to date and the fourth consecutive quarter of strong sales performance. We are encouraged by the growing uptake in leading transplant clinics across Europe and the repeat usage by key clinics in new patients based on successful first outcomes. We are also very encouraged by the positive results from the HNSA-5487 First-in-Human trial and the continued strong momentum in patient recruitment in the pivotal Phase 3 anti-GBM trial."

Søren Tulstrup
President and CEO, Hansa Biopharma

Q3 2024 marks the highest quarter of sales performance for IDEFIRIX since launch in 2020 and the fourth consecutive quarter of strong sales performance. Product sales for Q3 totaled 69.5 MSEK, representing a growth of 48 percent vs. Q2 2024 and 321 percent vs. same quarter last year. Year-to-date sales totaled 164.1 MSEK, a growth of 171 percent vs. same period last year.

The strong growth reflects the continued launch execution and increasing uptake in leading transplant clinics across Europe, including growing repeat usage by key clinics based on initial successful patient outcomes. To date, 32 clinics across Europe have clinical experience with IDEFIRIX with the majority of these having repeat utilization. Launch progress is underpinned by strong market access across Europe (15 countries) and the adoption of IDEFIRIX in local and international organ allocation systems. For example, countries participating in the Eurotransplant program have identified 53 patients for IDEFIRIX enabled transplants. This underscores an increased demand for IDEFIRIX-designated organs. We have also made solid progress in the Post Authorization Efficacy and Safety (PAES) study with almost 80 percent enrolment.

As we communicated last quarter, we are negotiating final pricing in certain markets where a successful early access program enabled Hansa to deliver IDEFIRIX prior to the conclusion of reimbursement negotiations. The expected successful conversion of this early access program into full reimbursement will entail a retroactive one-time discount of accumulated sales since launch in 2020. A provision of 19.9 MSEK was taken in Q2 2024. We have applied a new best estimate of the one-time retroactive adjustment based on recent advancement of pricing negotiations. To that end, we have taken an additional one-time provision of 29.7 MSEK in Q3 2024. Of this, only 4.9 MSEK relates to sales in Q3 2024. Pricing negotiations are expected to conclude in the near future.

Beyond kidney transplantation, we are pleased with the continued advancement of our two ongoing trials in autoimmune diseases. The Phase 3 GOOD-IDES-02 study in anti-GBM is already 86 percent enrolled, with an expected data read out in 2025. Further efficacy data from the 15-HMedIdes-09 Phase 2 trial in Guillain-Barré Syndrome (GBS) is scheduled to read out by the end of 2024. This is important progress in two disease areas where there is high unmet medical need and advanced therapies are needed.

We also remain excited about our collaborations with three leading gene therapy companies – Sarepta, AskBio and Genethon - and look forward to providing an update in 2025 on the progress we make together.

Finally, just after quarter end, we communicated positive results from the 12-month analysis of NICE-01, the first in-human trial of HNSA-5487, our next generation IgG-cleaving enzyme for redosing. The analysis demonstrates that HNSA-5487 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. Our intention is to focus initial clinical development of HNSA-5487 in neuromyelitis optica (NMO), myelin oligodendrocyte glycoprotein antibody disease (MOGAD), and myasthenia gravis (MG).

Imlifidase – Commercial, Clinical & Regulatory Update

EU: Kidney transplantation in highly sensitized patients

The European launch of IDEFIRIX continues to progress and drive overall strong commercial performance for the company. Market access remains strong with commercial access in 15 markets 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.

Following a consensus paper published by the European Society of Organ Transplantation (ESOT) recommending imlifidase as a desensitization strategy for deceased kidney transplantation in selected patients for whom no other treatment options are available, clinical utilization of IDEFIRIX alongside the adoption of new desensitization strategies has continued to increase.

53 patients eligible for IDEFIRIX have been 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.

Additionally, real-world evidence including data from nine highly sensitized kidney transplant patients was published in the July 2024 issue of *Kidney International Reports,* 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.

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 78 percent (39 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. Data readout is expected in 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 is evaluating imlifidase as a potential desensitization therapy compared to treatment according to standard of care (SoC) to enable kidney transplantation in highly sensitized patients. The Company is on track to submit a BLA to the FDA in the second half of 2025 seeking accelerated approval.

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

Pooled five-year data including data from 17-HMedIdeS-14 has been submitted to a peer reviewed journal for publication. This data was presented at the American Society of Transplantation's annual congress in June 2024.

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 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-GBM Trial - GOOD-IDES-02

The GOOD-IDES-02 Phase 3 trial has enrolled 86 percent of patients (43 out of 50 targeted). 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.

Global Phase 2 AMR trial - 16-HMedIdeS-12

Data from the 16-HMedIdeS-12 Phase 2 trial in antibody mediated rejection (AMR) was published in *Clinical Transplantation* in July 2024 and will be presented at an upcoming medical congress later this year.

Data from the trial, announced in December 2023, demonstrated a statistically significant and superior reduction of donor-specific antibodies (DSAs) by imlifidase compared to plasma exchange in the five days following the start of the treatment. The secondary endpoint investigated overall kidney function following treatment.

Phase 2 GBS Trial - 15-HMedIdeS-09

Further analysis of the 15-HMedIdeS-09 Phase 2 trial in GBS will be communicated by the end of 2024. The analysis will contextualize efficacy data from the study through a comparison to data from patients receiving SoC treatment in the International Guillain-Barré Syndrome Outcome Study (IGOS) database. Positive high-level data from the trial (communicated in December 2023) demonstrated that imlifidase was safe and well tolerated when administered prior to the SoC including rapid improvement in disease-related efficacy measures.

Sarepta SRP-9001-104 Phase 1b Trial

Enrolment in the SRP-9001-104 Phase 1b trial continues. The trial is evaluating the use of imlifidase as a pre-treatment to Sarepta Therapeutic's (Sarepta) ELEVIDYS (delandistrogene moxeparvovec) gene therapy in Duchenne Muscular Dystrophy (DMD). The companies expect to share preliminary data from the trial in 2025. 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.

Sarepta and Hansa entered into an exclusive agreement in July 2020 to develop imlifidase as a potential pre-treatment to gene therapy in DMD and Limb-Girdle Muscular Dystrophy (LGMD) in patients with antibodies against the vector AAVrh74. The program with imlifidase as pre-treatment ahead of gene therapy in LGMD is still in preclinical research stage. For further information about Sarepta's programs please visit www.sarepta.com.

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

HNSA-5487 – Clinical 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 redosing potential for HNSA-5487.

High-level results from the NICE-01 trial demonstrated HNSA-5487 was safe and well tolerated with rapid depletion of IgG observed with increasing doses in all subjects. Pharmacokinetics (PK) and pharmacodynamics (PD) were in line with expectations. The trial included a total of 36 healthy male and female adult participants and demonstrated that 5487 can robustly and rapidly reduce IgG levels, has redosing potential, and is safe and well tolerated. The Company will focus initial clinical development activities in chronic autoimmune diseases where IgG plays a role in disease pathology with recurring attacks. Initial clinical development of HNSA-5487 will focus in neuromyelitis optica (NMO), myelin oligodendrocyte glycoprotein antibody disease (MOGAD), and myasthenia gravis (MG).

Preclinical Update

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

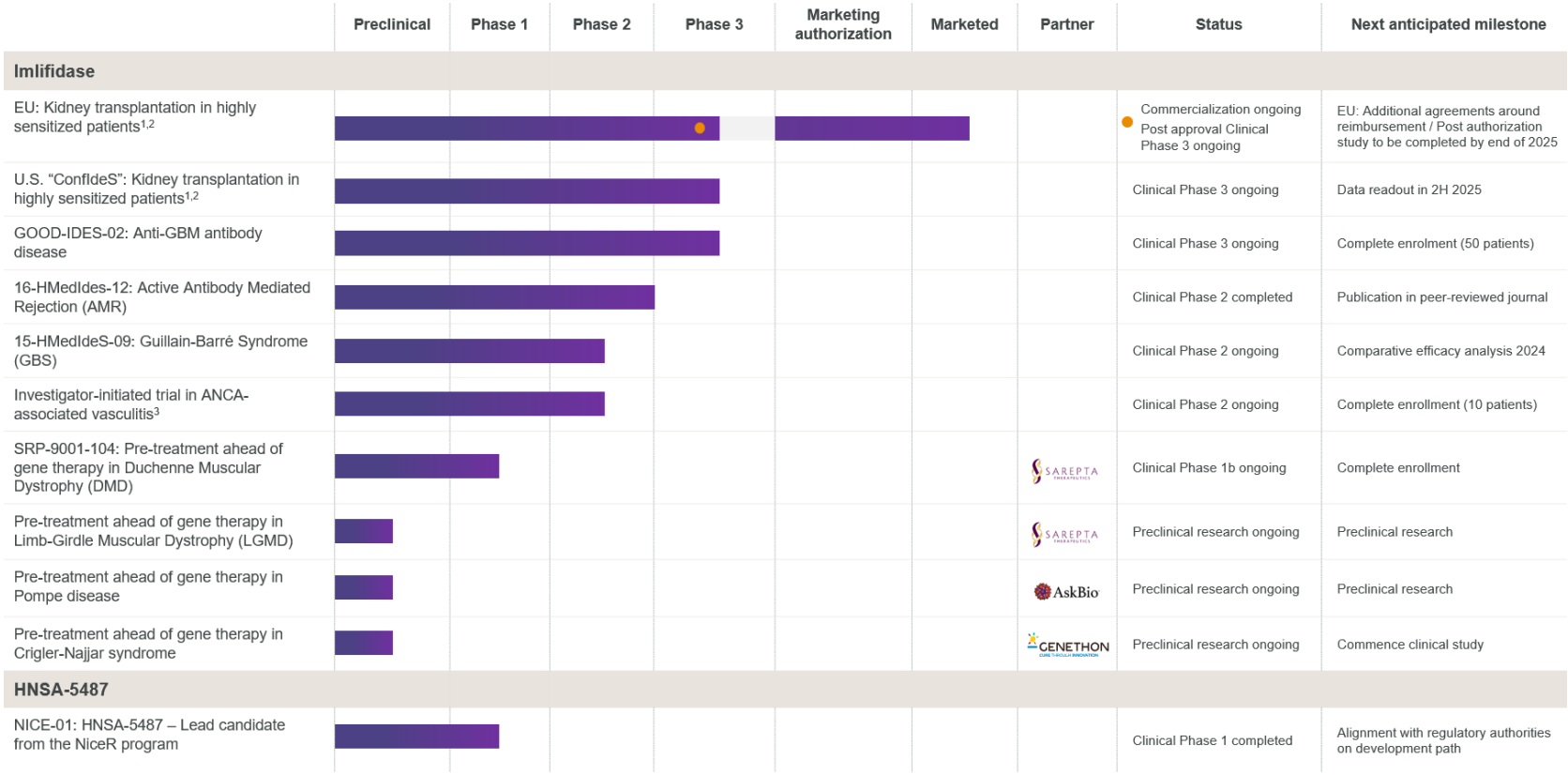
AskBio and Hansa announced a collaboration agreement in January 2022 to evaluate the use of imlifidase as a pre-treatment for AskBio's gene therapy in Pompe disease. In May 2024, AskBio presented pre-clinical data as part of the Hansa-AskBio partnership at the American Society of Gene and Cell Therapy's (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.

Genethon - pre-treatment ahead of gene therapy in Crigler-Najjar syndrome

Genethon and Hansa announce a collaboration agreement in April 2023 to evaluate the safety and efficacy of Hansa's antibody cleaving enzyme, imlifidase, as a pre-treatment prior to the administration of Genethon's gene therapy product candidate, GNT-0003, in patients with Crigler-Najjar syndrome and pre-formed antibodies to adeno-associated virus serotype 8 (AAV8). The study is on track to begin in 2024.

Pipeline Update



[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

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Financial Review 2024: Third Quarter & Year to Date

Revenue

Revenue excluding a retroactive provision for the third quarter 2024 totaled 78.4 MSEK (Q3 2023: 22.8 MSEK) consisting of IDEFIRIX product sales of 69.5 MSEK (Q3 2023: 16.5 MSEK) and contract revenue of 8.9 MSEK (Q3 2023: 6.3 MSEK) primarily related to the recognition of an upfront payment the Company received under its partnership agreement with Sarepta. Product sales were offset by a provision of 29.7 MSEK. Including the provision, total revenue and product sales were 48.7 MSEK and 39.8 MSEK, respectively. The provision was established to account for potential credits related to volume discounts and rebates related to sales in previous periods in European markets since the launch of IDEFIRIX in 2020.

Revenue, excluding a retroactive provision, for the nine months ended September 30, 2024, totaled 188.6 MSEK (nine months 2023: 83.7 MSEK) consisting of IDEFIRIX product sales of 164.1 MSEK (nine months 2023: 60.4 MSEK) and contract revenue of 24.5 MSEK (nine months 2023: 23.3 MSEK) primarily from an upfront payment the Company received under its partnership agreement with Sarepta. Product sales were offset by a provision of 49.6 MSEK, as described in the previous section. Total revenue and product sales for the nine months ended September 30, 2024 were 139.0 MSEK and 114.5 MSEK, respectively.

Sales General & Administrative (SG&A) expenses

SG&A expenses for the third quarter 2024 totaled 75.8 MSEK (Q3 2023: 111.7 MSEK) and 255.3 MSEK for the first nine months of 2024 (nine months 2023: 344.5 MSEK). SG&A expenses include a restructuring reserve totaling 6.2 MSEK. 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 18.3 MSEK for the first nine months of 2024 (nine months 2023: 28.7 MSEK).

Research & Development (R&D) expenses

R&D expenses for the third quarter of 2024 totaled 79.6 MSEK (Q3 2023: 95.6 MSEK) and 274.3 MSEK for the first nine months of 2024 (nine months 2023: 303.1 MSEK). R&D expenses include a restructuring reserve totaling 6.6 MSEK. Compared to the same period in 2023, the decrease in expense was primarily driven by the savings associated with restructuring activities offset by the ongoing US 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 7.9 MSEK for the first nine months of 2024 (nine months 2023: 12.5 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 third quarter 2024, the Company recorded income of 1.2 MSEK, compared to 1.0 MSEK in expense in the third quarter of 2023. For the first nine months of 2024, the Company recorded expense of 3.1 MSEK compared to 4.0 MSEK in the first nine months of 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 third quarter of 2024, totaled 13.3 MSEK of income, compared to an expense of 48.3 MSEK in the third quarter 2023. The financial expenses for the third quarter were positive due to that the foreign exchange rate effect in US dollar on the NovaQuest loan was higher than the accrued interest for the loan in the quarter. For the first nine months of 2024, the expense totaled 66.4 MSEK compared to 93.6 MSEK for the first nine months of 2023. The difference compared to the prior period was mainly driven by positive foreign exchange variances associated with Hansa's US dollar denominated long-term loan (see Note 4 below), partially offset by negative foreign exchange variances on bank deposits.

Financial results

The loss from operations for the third quarter 2024 totaled 116.9 MSEK (Q3 2023: 202.2 MSEK) and 463.7 MSEK for the first nine months 2024 (nine months 2023: 613.0 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 third quarter loss totaled 103.8 MSEK (Q3 2023: 250.7 MSEK) and for the first nine months 2024 the loss totaled 530.3 MSEK (nine months 2023: 707.3 MSEK).

Cash flow, cash and investments

Net cash used in operating activities for the third quarter 2024 totaled 148.8 MSEK (Q3 2023: 192.9 MSEK) and 527.1 MSEK for the first nine months of 2024 (nine months 2023: 582.7 MSEK). The change compared to the prior period was driven by higher sales and lower operating expenses offset by the negative impact associated with changes in working capital. The share issue completed during Q2 increased cash balances by 354.3 MSEK net of transaction costs.

Cash and cash equivalents totaled 553.5 MSEK at September 30, 2024, compared to 732.1 MSEK at December 31, 2023.

Parent Company

The parent company's revenue for the third quarter of 2024 totaled 48.7 MSEK (Q3 2023: 22.8 MSEK) and for the first nine months of 2024 139.0 MSEK (nine months 2023: 83.7 MSEK).

During the third quarter 2024 the parent company loss totaled 134.0 MSEK (Q3 2023: 286.9 MSEK) and for the first nine months of 2024 the loss totaled 619.8 MSEK (nine months 2023: loss of 448.4 MSEK). The parent company loss for the first nine months 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.

Parent company shareholders' equity at September 30, 2024 totaled 975.2 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 September 30, 2024, Hansa Biopharma Inc. had thirteen employees, Hansa Biopharma Ltd seven employees and Hansa Biopharma S.r.l. four employees.

Financial Review 2024: Third 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 September 30, 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	878,404	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	-	97,322	65,512	45,624	21,075	45,950
Total cost per program, including social contributions, recognized in profit/loss as of September 30, 2024, YTD, KSEK	-	324	7,739	9,907	5,300	2,992

*As of September 30, 2024, the table includes shares issued to cover estimated social contributions under the LTIP.

Total costs, including social contributions, recognized in profit/loss as of September 30, 2024, YTD, KSEK	**26,262**

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 asset 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) 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 has been finalized and was submitted to EMA in December 2023. In 2024 EMA finalized its review of the follow-up study and the study was approved.

b) 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 i.e. 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 September 30, 2024, 39 of the targeted 50 patients were enrolled in the study. The study is expected to be finalized in 2025. Hansa currently has no indications 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 as 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 have a continuous focus on cash flow and work continuously to ensure long-term and sustainable financing of ongoing and planned development projects and assesses that there are a number of possible alternatives to secure the financing of the Company. In the 2023 Annual Report (pages 53-56 English version), the risks and uncertainties which are considered to have greatest significance for Hansa Biopharma are described in more detail.

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.

Other information

Contacts

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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. The original Swedish version of this report takes precedence and is reviewed by the company's auditors. This is a translated version of the Swedish original.

Financial calendar 2024/2025

February 6, 2025	Full-year Report for January – December 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 September 30, 2024[1]	67,814,241
Market Cap September 30, 2024	~2.72 BSEK (USD ~$260M)
Ticker	HNSA
ISIN	SE0002148817

Top 10 Shareholders as of September 30, 2024

Shareholder Name	Number of Shares	Ownership %
Redmile Group LLC	13,156,700	19.40%
Braidwell LP	8,247,600	12.16%
Theodor Jeansson Jr.	2,720,000	4.01%
Hansa Biopharma AB	2,204,667	3.25%
Nexttobe AB	2,155,379	3.18%
Fjärde AP-fonden (AP4)	2,094,000	3.09%
Thomas Olausson	1,917,000	2.83%
Avanza Pension	1,906,416	2.81%
Handelsbanken Fonder	1,724,561	2.54%
Sphera Funds Management	1,107,000	1.63%
All other	30,580,918	45.10%
Total Shares Outstanding	67,814,241	100.00%

Source: S&P Global 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 September 30, 2024.

1. Following execution of a directed share issue in the second quarter 2024, the number of outstanding shares increased to 67,814,241 shares.

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 been reviewed by the company's auditors.

Lund Sweden, October 17, 2024

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	September 30 2024	September 30 2023	December 31 2023
ASSETS				
Non-current assets				
Intangible assets	5	174,844	117,504	135,817
Property and equipment		5,117	7,139	6,343
Right-of-use assets		15,058	22,088	20,730
Total non-current assets		**195,019**	**146,731**	**162,890**
Current assets				
Inventories		1,976	3,120	1,513
Trade receivables & unbilled revenues		144,645	65,506	78,025
Current receivables, non-interest bearing		45,491	47,515	43,553
Cash and cash equivalents		553,544	908,176	732,060
Total current assets		**745,656**	**1,024,317**	**855,151**
TOTAL ASSETS		**940,675**	**1,171,048**	**1,018,041**
EQUITY AND LIABILITIES				
Shareholders' equity		**(319,959)**	**(62,207)**	**(167,876)**
Non-current liabilities				
Long-term loan	4	942,950	906,675	844,903
Deferred tax liabilities		174	407	367
Provisions		4,701	5,117	4,454
Lease liabilities		8,624	15,837	14,362
Deferred revenue		-	7,601	-
Contingent consideration	3	-	887	843
Total non-current liabilities		**956,449**	**936,524**	**864,929**
Current liabilities				
Tax liabilities		1,121	1,412	1,599
Lease liabilities		7,614	7,304	7,503
Current liabilities, non-interest bearing		51,617	67,862	108,748
Deferred revenue		20,552	45,206	41,473
Refund liabilities		132,499	52,726	49,266
Accrued expenses		90,782	122,221	112,399
Total current liabilities		**304,185**	**296,731**	**320,988**
TOTAL EQUITY AND LIABILITIES		**940,675**	**1,171,048**	**1,018,041**

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

		Q3		9M	
KSEK	Note	2024	2023	2024	2023
Revenue	2	48,664	22,837	138,979	83,683
Cost of revenue		(11,380)	(16,656)	(70,066)	(45,017)
Sales, general and administration expenses		(75,819)	(111,738)	(255,276)	(344,500)
Research and development expenses	5	(79,624)	(95,554)	(274,267)	(303,081)
Other operating income/(expenses), net		1,231	(1,045)	(3,074)	(4,040)
Loss from operations		**(116,928)**	**(202,156)**	**(463,704)**	**(612,955)**
Financial income		5,784	(5,927)	16,990	-
Financial expenses	4	7,474	(42,356)	(83,403)	(93,612)
Loss before tax		**(103,670)**	**(250,439)**	**(530,117)**	**(706,567)**
Tax		(126)	(219)	(201)	(694)
Loss for the period		**(103,796)**	**(250,658)**	**(530,318)**	**(707,261)**
Loss for the period attributable to owners of the parent		(103,796)	(250,658)	(530,318)	(707,261)
Loss per share, basic and diluted (SEK)		(1.53)	(4.78)	(8.67)	(13.49)
Other comprehensive income/(loss)					
Items that have been, or may be reclassified to profit or loss for the period:					
Translation differences		(565)	386	167	875
Other comprehensive income/(loss) for the period		**(565)**	**386**	**167**	**875**
Total comprehensive loss		**(104,361)**	**(250,272)**	**(530,151)**	**(706,386)**

Unaudited condensed consolidated statement of changes in shareholder's equity

KSEK	January-September 2024	January-September 2023	Full year 2023
Opening balance of shareholders' equity	**(167,876)**	**602,912**	**602,912**
Result for the period	(530,318)	(707,261)	(831,720)
Translation reserve	167	875	(422)
Net comprehensive loss	**(530,151)**	**(706,386)**	**(832,142)**
Transactions with the group's owner			
Proceeds from new share issuance, net[1]	354,308	-	-
Long term incentive programs	23,760	41,267	61,354
Total transactions with the group's owner	**378,068**	**41,267**	**61,354**
Closing balance of shareholders' equity	**(319,959)**	**(62,207)**	**(167,876)**

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

Unaudited condensed consolidated statement of cash flow

KSEK	Q3 2024	Q3 2023	9M 2024	9M 2023
Cash Flows from Operating Activities				
Loss for the period	(103,796)	(250,658)	(530,318)	(707,261)
Adjustment for items not included in cash flow[1]	(21,410)	49,815	74,347	115,062
Interest received and paid, net	(134)	(243)	758	143
Income taxes paid	(617)	(90)	(900)	(112)
Cash flow from operations before change in working capital	**(125,957)**	**(201,176)**	**(456,113)**	**(592,168)**
Changes in working capital	(22,844)	8,308	(70,971)	9,459
Net cash used in operating activities	**(148,801)**	**(192,868)**	**(527,084)**	**(582,709)**
Investing activities				
Acquisition of property and equipment	-	-	(116)	(689)
Cash flow from investing activities	**-**	**-**	**(116)**	**(689)**
Financing activities				
Proceeds from new share issue, net of transaction cost[2]	-	-	354,308	-
Payment of lease liabilities	(1,892)	(1,799)	(5,627)	(5,350)
Cash flow from financing activities	**(1,892)**	**(1,799)**	**348,681**	**(5,350)**
Net change in cash	(150,693)	(194,667)	(178,519)	(588,748)
Cash and cash equivalents at beginning of period	704,999	1,102,514	732,060	1,496,179
Currency exchange variance, cash and cash equivalents	(762)	329	3	745
Cash and cash equivalents, end of period	**553,544**	**908,176**	**553,544**	**908,176**

[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.

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.

Parent Company – Unaudited condensed statement of financial position

KSEK	Note	September 30 2024	September 30 2023	December 31 2023
ASSETS				
Non-current assets				
Intangible assets	5,6	1,453,976	1,515,545	1,504,277
Property and equipment		5,117	7,139	6,343
Right-of-use assets		15,058	22,088	20,730
Investment in subsidiaries		34,593	27,820	30,044
Total non-current assets		**1,508,74**	**1,572,59**	**1,561,394**
Current assets				
Inventories		1,976	3,120	1,513
Trade receivables & unbilled revenues		144,645	65,506	78,025
Current receivables, non-interest bearing		45,203	47,164	43,205
Cash and cash equivalents		534,273	893,729	715,538
Total current assets		**726,097**	**1,009,51**	**838,281**
TOTAL ASSETS		**2,234,84**	**2,582,11**	**2,399,675**
EQUITY AND LIABILITIES				
Shareholders' equity	6	**975,218**	**1,350,13**	**1,216,945**
Non-current liabilities				
Long-term loan	4	942,950	906,675	844,903
Provisions		4,701	5,118	4,454
Lease liabilities		8,624	15,837	14,362
Deferred revenue		-	7,601	-
Contingent consideration	3	-	887	843
Total non-current liabilities		**956,275**	**936,118**	**864,562**
Current liabilities				
Tax liabilities		1,187	1,164	1,409
Lease liabilities		7,614	7,304	7,503
Liabilities, group companies		8,614	7,860	7,089
Current liabilities, non-interest bearing		51,133	67,514	108,046
Deferred revenue		20,552	45,205	41,473
Refund liabilities		132,499	52,726	49,266
Accrued expenses		81,749	114,083	103,383
Total current liabilities		**303,348**	**295,856**	**318,168**
TOTAL EQUITY AND LIABILITIES		**2,234,84**	**2,582,11**	**2,399,675**

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

KSEK	Note	Q3 2024	Q3 2023	9M 2024	9M 2023
Revenue	2	48,664	22,837	138,979	83,683
Cost of revenue		(41,172)	(46,448)	(159,441)	(74,809)
Sales, general and administration		(76,032)	(112,836)	(253,217)	(344,192)
Research and development expenses	5	(79,439)	(94,856)	(276,242)	(303,370)
Other operating income/(expenses), net		910	(1,043)	(3,237)	(4,039)
Loss from operations		**(147,069)**	**(232,346)**	**(553,158)**	**(642,727)**
Financial income		5,785	3,251	16,981	9,178
Financial expenses	4	7,462	(51,534)	(83,404)	(102,790)
Loss before tax		**(133,822)**	**(280,629)**	**(619,581)**	**(736,339)**
Income tax	6	(137)	(6,302)	(224)	287,900
Loss for the period		**(133,959)**	**(286,931)**	**(619,805)**	**(448,439)**
Other comprehensive loss for the period		-	-	-	-
Total comprehensive loss for the period		**(133,959)**	**(286,931)**	**(619,805)**	**(448,439)**

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

KSEK	Q3 2024	Q3 2023	Full year 2023
Opening balance of shareholders' equity	**1,216,945**	**615,799**	**615,799**
Result for the period	(619,805)	(448,439)	(595,536)
Other comprehensive income/(loss) for the period	-	-	-
Net comprehensive loss	**(619,805)**	**(448,439)**	**(595,536)**
IP write-up, net	-	1,141,557	1,135,421
Proceeds from new share issuance, net[1]	354,308	-	-
Long term incentive programs	23,770	41,220	61,261
Total other transactions	**378,078**	**1,182,777**	**1,196,682**
Closing balance of shareholders' equity	**975,218**	**1,350,137**	**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 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	Q3		9M	
KSEK	2024	2023	2024	2023
Group				
Revenue				
Product sales[1]	39,811	16,493	114,478	60,375
Contract revenue, Axis-Shield agreement	651	643	1,953	1,931
Cost reimbursement, Axis-Shield agreement	-	-	581	286
Contract revenue, Sarepta, AskBio agreement	8,202	5,701	21,967	21,091
	48,664	**22,837**	**138,979**	**83,683**
Parent Company				
Revenue				
Product sales	39,811	16,493	114,478	60,375
Contract revenue, Axis-Shield agreement	651	643	1,953	1,931
Cost reimbursement, Axis-Shield agreement	-	-	581	286
Contract revenue, Sarepta, AskBio agreement	8,202	5,701	21,967	21,091
	48,664	**22,837**	**138,979**	**83,683**

[1] *Actual product sales in Q3 2024 amounted to 69.5 MSEK. Sales were offset by a provision totaling 29.7 MSEK for expected credits associated with volume discounts and potential rebates.Year to date 2024 IDEFIRIX product sales totaled 164.1 MSEK and were offset bya provision totaling 49.6 MSEK. Net of the provision, year to date product sales totaled 114.5 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 September 30, 2024 totaled 0.0 MSEK (December 31, 2023: 0.8 MSEK) and belongs to Level 3 in the fair value hierarchy. The Group does currently not 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 will 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 September 30, 2024, the loan totaled 943.0 MSEK, including 255.8 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.

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 September 30, 2024, the total capitalized development expenses related to fulfilling the IDEFIRIX EMA post-approval commitments amount to 171.6 MSEK, with 52.0 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 September 30, 2024 was 17.9 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 (UK) 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 through profit or loss, 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 September 30, 2024, the Company recorded accumulated amortization of 148.9 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 30.7 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 organsation which overlooks how transplantations are structured and streamlined.

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

Guillian-Barré syndrome
Guillian-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.