Interim report

January – March 2024

HANSA BIOPHARMA

Strong sales performance; solid momentum with the Phase 3 trial in anti-GBM disease; cash runway extended into 2026; Evan Ballantyne joins Hansa Biopharma as Chief Financial Officer

Business highlights for the first quarter of 2024

- **Strong commercial performance**. Total Q1 revenue of SEK 56m including product sales of SEK 47m – sales growth during Q1 2024 was driven by product sales in our largest European markets including France, UK, and Germany, as well as initial sales in Belgium. Represents first time Company has delivered two consecutive quarters of strong growth.
- **IDEFIRIX® has achieved pricing and reimbursement in 75%** of the European kidney transplant market; Ongoing HTA processes in 11 countries including, most recently, in Ireland.
- **Evan Ballantyne joined Hansa Biopharma as Chief Financial Officer** effective March 1, 2024. Previously served as CFO of Gain Therapeutics, Inc., a U.S. based biotech company. Evan brings to Hansa more than 30 years of international experience as a senior financial executive in both public and private life science companies.

Clinical pipeline update

- **US ConfIdeS trial (kidney transplantation**): 122 patients have been enrolled with 49 of 64 targeted patients randomized in this pivotal, Phase 3 U.S. open label, randomized, controlled trial of imlifidase in kidney transplantation.
- **Post Approval Study (kidney transplantation**): 36 patients have been treated (72% completion). The study will support full marketing authorization in Europe and is expected to be completed by 2025.
- **Phase 3 (anti-GBM disease)**: 25 of 50 targeted patients enrolled in global pivotal Phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease. Completion of enrollment is expected in 2025.
- **Investigator-initiated phase 2 trial (ANCA-associated vasculitis**): 3 of 10 targeted patients enrolled.

Events after the closing period

- **Cash runway extended into 2026:** Raised SEK ~372m (USD ~34.6m) in a directed share issue targeting mainly high-quality international healthcare specialist investors.

Financial Summary

SEKm, unless otherwise stated – unaudited	Q1 2024	Q1 2023	FY 2023
Revenue	56.0	24.2	134.1
- thereof: Product sales	47.4	14.3	103.7
SG&A expenses	(91.3)	(103.3)	(450.5)
R&D expenses	(103.0)	(92.8)	(411.3)
Loss from operation	(159.4)	(182.3)	(788.5)
Loss for the period	(218.6)	(205.4)	(831.7)
Net cash used in operations	(189.1)	(207.0)	(755.7)
Cash and short-term investments	541.5	1,286.8	732.1
EPS before and after dilution (SEK)	(4.15)	(3.92)	(15.83)
Number of outstanding shares	52,671,796	52,443,962	52,671,796
Weighted avg. no of shares before and after dilution	52,671,796	52,443,962	52,540,089
No of employees at the end of the period	166	159	168

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

"I am very pleased with the strong commercial performance in the first quarter of 2024 due to new and repeat utilization of IDEFIRIX in leading centers throughout Europe."

Søren Tulstrup
President and CEO, Hansa Biopharma

"I am very pleased with the strong commercial performance in the first quarter of 2024, the second consecutive quarter with solid product sales and a promising start to 2024. This strong sales performance is a continuation of the traction we saw at the end of last year where key large markets such as UK and Germany started to contribute. Our performance continues to be driven by our largest markets underpinned by new and repeat use of IDEFIRIX at leading transplant centers. We have now achieved pricing and reimbursement in 75% of the European kidney transplant market and expect to see utilization in new centers resulting in additional sales growth in 2024.

Our clinical programs in kidney transplantation continue to progress at pace. Enrolment and randomization in our ConfIdeS pivotal US Phase 3 trial is advancing as expected. During the first quarter of 2024 four new sites have been activated and both screening and randomization of eligible patients have recently accelerated. We expect randomization to complete in mid-2024, as previously guided.

We have also made significant progress in the European post approval study – PAES – with more than a doubling of the number of patients treated in the trial in the last couple of quarters. This post approval study is an obligation under the European conditional marketing authorization and will be used to further investigate the long-term graft survival in 50 highly sensitized kidney transplant patients treated with IDEFIRIX. The study will also help generate important clinical experience in leading transplant centers in using IDEFIRIX as a new transformative desensitization therapy in highly sensitized patients.

Beyond kidney transplantation, we continue to advance our imlifidase clinical programs in autoimmunity. In the Phase 3 trial in anti-GBM disease, our lead autoimmune indication, we have reached 50% enrolment in the trial and expect completion in 2025 as previously guided. We also expect to share contextualized efficacy data later this year in our Phase 2 study in Guillain-Barré Syndrome (GBS). This follows promising first high-level data shared in December 2023.

On April 12, 2024, we announced that additional financing had been secured – extending our cash runway into 2026 through a SEK ~372m (USD ~34.6m) directed share issue targeting mainly U.S. and European healthcare specialist investors. I am very pleased to see the strong interest in the Hansa equity story from leading international health specialist investors. This transaction will help finance the preparation of a potential U.S. launch of imlifidase in kidney transplantation, strengthen ongoing product development in autoimmune indications and allow for the continued clinical development of HNSA-5487, the lead candidate from the NiceR program for repeat dosing.

Lastly, I am delighted to welcome Evan Ballantyne as Chief Financial Officer. With his deep international experience and successful track record as a CFO at public and private life science companies I am confident that Evan will be a strong addition to our team and will help drive our financial strategy, deliver on key strategic priorities, and build shareholder value.

We look forward to keeping you updated on our continued progress, with several upcoming important milestones to be achieved across our platform and franchises as we continue the development of new, transformative medicines for patients suffering from serious, rare immunologic diseases.

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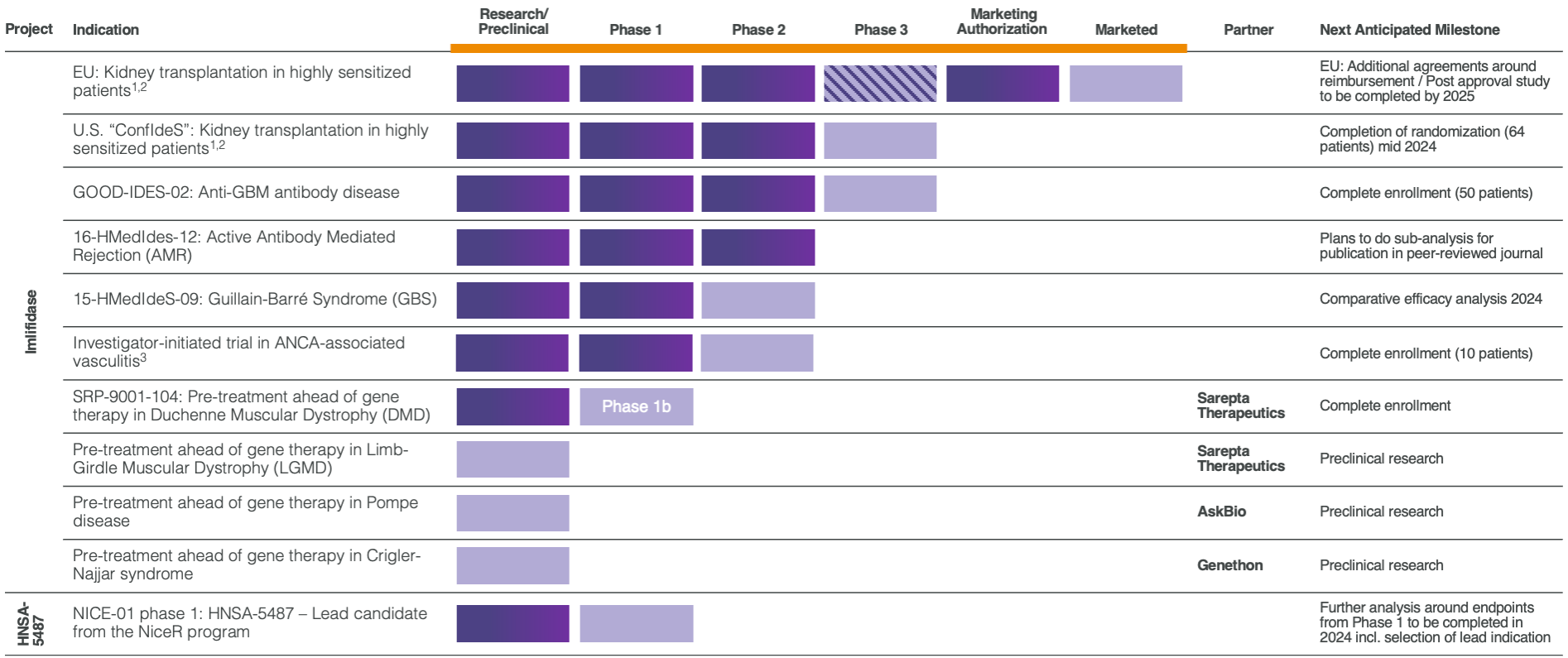
Continued pipeline progress



[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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Imlifidase – Commercial, Clinical and Regulatory progress

EU: Kidney transplantation in highly sensitized patients

In August 2020, IDEFIRIX was granted conditional approval by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

Commercial launch activities and market access efforts for IDEFIRIX (conditionally approved in 2020) in Europe continue to progress as planned – most recently with the positive reimbursement decision received in Slovenia. The product now has commercial access in 14 European countries, including France, U.K., Germany, Italy and Spain.

The clinical community has made significant progress in advancing desensitization strategies and clinical practice frameworks for highly sensitized kidney transplant patients. The creation of clinical guidelines and organ allocation systems that recognize the unmet need in desensitization are key improvements in care for highly sensitized kidney transplant patients.

Importantly, the European Society for Organ Transplantation (ESOT) - leading professional society - issued the first ever guidelines on desensitization in 2022 followed by IDEFIRIX-specific guideline implementation at the national level in key European markets and, the recent Eurotransplant desensitization program is helping identify patients eligible for IDEFIRIX. Eurotransplant is an international allocation system that is responsible for the allocation of donor organs across eight countries including Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, and Slovenia.

20-HMedIdes-19: Post Approval Efficacy Study (PAES)

In parallel to the commercial launch, Hansa is conducting a post-approval efficacy study (PAES) as part of its obligation under European conditional marketing authorization. The study will be used to further investigate the long-term graft survival in 50 highly sensitized kidney transplant patients treated with IDEFIRIX. The study will support full marketing authorization and is expected to be completed by 2025.

20-HMedIdeS-17: U.S. Phase 3 Trial (ConfIdeS)

The ConfIdeS Phase 3 trial is evaluating imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a deceased donor kidney through the U.S. kidney allocation system. A total of 64 highly sensitized (cPRA ≥99.9%) patients on the wait list for kidney transplantation will be 1:1 randomized to either desensitization with imlifidase or Standard of Care (SoC) (SoC is defined as waiting for a matched donor or subject for experimental treatment) at the time of organ offer. Randomization is expected to be completed by mid-2024, while a BLA is expected under the accelerated approval path in 2025.

17-HMedIdeS-14 study: Long-term follow-up trial of kidney transplant patients

Beyond the four completed phase 2 studies in kidney transplantation, Hansa had been conducting 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.

On October 17, 2023, Hansa announced results from the 17-HMedIdeS-14 study - an extended pooled analysis using data from the long-term follow-up study of patients who have received a kidney transplant following desensitization with imlifidase. The data showed sustained positive outcomes out to 5 years in the majority of highly sensitized patients who received an imlifidase-enabled kidney transplant. Patient survival was 90% (death censored) and graft survival was 82%, in line with outcomes seen at 3-years post-transplant. The 5-year extended pooled analysis is a continuation of the analysis at 3-years of crossmatch positive only patients, published in the *American Journal of Transplantation*.

GOOD-IDES-02 phase 3: Anti-Glomerular Basement Membrane (anti-GBM) disease

Solid progress is being made in the Phase 3 trial in anti-GBM. 50% of patients are enrolled in the trial and completion is expected in 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. Completion of enrollment is expected in 2025.

In March 2022, key data from an investigator initiated led trial in anti-GBM disease were published in the *Journal of American Society of Nephrology (JASN)*. The data showed that two-thirds of patients achieved dialysis independence six months after treatment as compared to less than 20% of patients in a historical control cohort. The trial was led by Principal Investigator, Mårten Segelmark, Professor of Nephrology at Lund University, previously Linköping University

Anti-GBM disease is an acute autoimmune disease in which antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM), causing acute injury of kidney and/or lung function. Anti-GBM is an ultrarare and very severe disease that affects approximately 1.6 people per million, annually. A majority of patients lose their kidney function, requiring chronic dialysis and/or kidney transplantation.[1,2]

16-HMedIdes-12 Phase 2 trial: Active Antibody Mediated Rejection (AMR)

In December 2023, Hansa announced full data from its Phase 2 trial in AMR, demonstrating a statistically significantly superior capacity of imlifidase to rapidly reduce levels of DSAs compared to plasma exchange in the five days following the start of the treatment. The secondary endpoint investigated overall kidney function following treatment. The imlifidase arm demonstrated a 74% six-month graft survival and eGFR of 30mL/min/1.73m^2. A 100% six-month graft survival and eGFR of 33mL/min/1.73m^2 was observed in the Plasma Exchange arm.

Given the heterogeneity of the patient population, the trial was not designed nor sufficiently powered to be able show a statistically significant difference in the secondary outcome measures. Patients with an acute AMR and without an additional cellular component of the immune rejection may be best placed to benefit from a rapid and significant reduction in DSA, one of the main goals of any AMR treatment according to existing treatment guidance. Hansa plans to submit the data for publication in a peer-reviewed journal during 2024.

Acute AMR episodes post kidney transplantation occur in 5-7 percent of patients[3] and are a significant challenge to long-term graft survival. There is no approved drug to treat AMR.

[1] Kluth et al.. J Am Soc Nephrol. 1999 Nov;10(11):2446-53
[2] Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12
[3] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.

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

In December 2024, Hansa communicated positive high-level data from the Phase 2 trial in GBS, demonstrating that imlifidase was safe and well tolerated when administered prior to SoC including rapid improvement in disease-related efficacy measures. The trial is an open-label, single arm, multi-center study evaluating the safety, tolerability, and efficacy of imlifidase in GBS patients in combination with SOC intravenous immunoglobulin (IVIg). Further analysis of efficacy data will be conducted in 2024.

GBS is a disease which is caused by an acute autoimmune attack on the peripheral nervous system, which affects approximately 1-2 in 100,000 people annually.[4]

Investigator-initiated phase 2 trial in ANCA-associated vasculitis

Three patients with severe ANCA-associated vasculitis were enrolled as of April 18, 2024, in an Investigator-initiated phase 2 trial in ANCA-associated vasculitis at the Charité – Universitätsmedizin Berlin. The study is targeting 10 patients with severe ANCA-associated vasculitis and acute respiratory distress syndrome ("ARDS") due to pulmonary hemorrhage who will be treated with imlifidase on top of SoC (consisting of standard immunosuppression as per center protocol and intensive support care).

ANCA-associated vasculitis is a group of conditions that affect approximately 30 people in a million annually in the EU and US.[5,6] It is characterized by the presence of IgG anti-neutrophil cytoplasmatic antibodies[7] directed against antigens expressed by the neutrophils, a type of white blood cell involved in the body's immune system response. The action of ANCA antibodies against neutrophils causes blood vessel damage[8] that can affect multiple organs, most frequently lungs and kidneys, where it leads to rapidly deteriorating organ function.

NICE-01 Phase 1 trial (HNSA-5487): Lead candidate from the NiceR program

In October 2023, Hansa announced high-level results from a Phase 1 trial of HNSA-5487. The data showed that it was safe and well tolerated with fast and complete depletion of immunoglobulin G (IgG) antibodies observed in all subjects with increasing doses in all subjects. Pharmacokinetics (PK) were in line with expectations and pharmacodynamics (PD) (efficacy on IgG cleavage) showed a fast and complete cleavage of IgG to $F(ab')_2$ and Fc-fragments with increasing doses. The trial included a total of 36 healthy male and female adult participants. Further analysis of other endpoints will be completed in 2024, including the selection of the first indication to be evaluated clinically.

Hansa is developing novel, IgG-degrading enzymes with the objective of enabling repeat dosing in autoimmune conditions, oncology, gene therapy and transplantation, where patients may benefit from more than one dose of an IgG-modulating enzyme.

SRP-9001-104 Phase 1b trial: Duchenne Muscular Dystrophy (DMD)

In December 2023, a clinical trial using imlifidase as a pre-treatment to Sarepta's ELEVIDYS (SRP-9001) gene therapy in DMD was initiated. ELEVIDYS received US FDA approval in June 2023, as a one-time treatment in ambulatory paediatric patients aged 4 through 5 years suffering from DMD. High-level data from the trial is expected in 2024.

Between 5% and 70% of gene therapy patients carry antibodies against AAV vectors that act as a barrier for treatment eligibility. Up to 20% of patients affected by DMD might not be able to receive treatment due to the presence of anti-AAV antibodies. Imlifidase as pre-treatment to gene therapy may enable up to 14% of patients who are currently suffering from too high titres of neutralizing antibodies against AAVrh74.

In July 2020, Hansa entered into an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment to gene therapy in DMD and LGMD in patients with pre-existing neutralizing antibodies (Nabs) against adeno-associated virus (AAV). Under the terms of the agreement, Hansa received a USD 10 million upfront payment and will book all future sales of imlifidase. Hansa is also eligible for up to USD 397.5 million in development, regulatory and sales milestones, as well as royalties on any Sarepta gene therapy sales enabled through pre-treatment with imlifidase in NAb-positive patients. The program with imlifidase as pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy is still in preclinical research stage. For further information about Sarepta's programs please refer to www.sarepta.com.

[4] McGrogan A, et al. Neuroepidemiology. 2009; 32(2):150-63.

[5] Berti A, et al. *Arthritis Rheum atol.* 2017;69.

[6] Rathmann J, et al. *RMD Open.* 2023;9:e002949.

[7] Jennette JC, et al. 2012 *Arthritis and rheumatism.* 2013;65(1):1-11.

[8] Falk RJ, Jennette JC. *The New England journal of medicine.* 1988;318(25):1651-7.

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Preclinical programs

Pre-treatment ahead of gene therapy in Pompe disease (partnered with AskBio)

In January 2022, Hansa and AskBio announced a collaboration agreement designed to evaluate the potential use of imlifidase as a pre-treatment, prior to the administration of AskBio's gene therapy in Pompe disease, in a preclinical and clinical feasibility study aimed at enabling gene therapy for patients with pre-existing neutralizing antibodies against the adeno-associated viral vector used in AskBio's gene therapy.

Additional pre-clinical data evaluating the potential use of imlifidase as a pre-treatment prior to the administration of gene therapy have been generated under the Hansa-AskBio Option Product Collaboration Agreement and will be presented at an upcoming scientific congress.

For further information regarding AskBio's programs please refer to www.askbio.com.

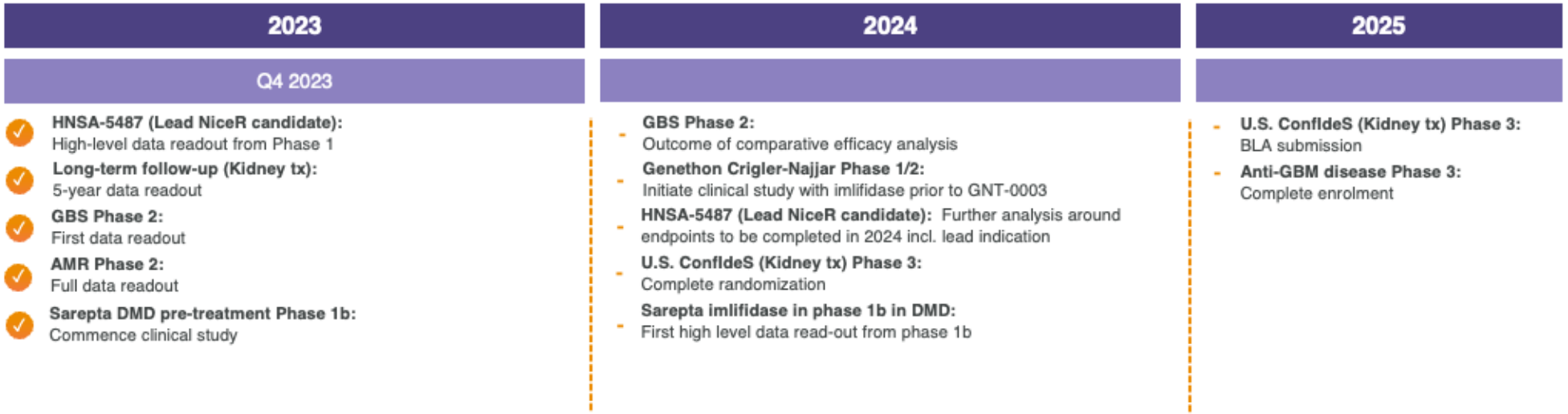
Pre-treatment ahead of gene therapy in Crigler-Najjar (partnered with Genethon)

On April 27, 2023, Hansa announced a collaboration agreement with Genethon, a French non-profit organization and pioneer in the discovery and development of gene therapies for rare diseases.

The collaboration will, in a clinical study, 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 Crigler-Najjar syndrome in patients with pre-existing NAbs to adeno-associated virus serotype 8 (AAV8).

GNT-0003 is currently being evaluated in a pivotal clinical study in France, Italy, and the Netherlands and has received PRIME (PRIority MEdicines) status from the EMA. Through this collaboration, patients with Crigler-Najjar syndrome and pre-formed neutralizing antibodies will be enrolled in a study where imlifidase is evaluated as a pre-treatment to enable gene therapy treatment with GNT-0003. This study is planned to commence in 2024.

Achieved and upcoming milestones



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Financial review January – March 2024

Revenue

Revenue for the first quarter of 2024 amounted to SEK 56.0m (Q1'23: SEK 24.2m) consisting of IDEFIRIX® product sales of SEK 47.4m (Q1'23: SEK 14.3m) and contract revenue of SEK 8.5m (Q1'23: SEK 9.9m) consisting mainly of recognized revenue from the upfront payment the Company received according to the Sarepta agreement.

SG&A expenses

Sales, general and administrative expenses for the first quarter of 2024 amounted to SEK 91.3m (Q1'23: SEK 103.3m). SG&A expenses has been affected by a re-structuring reserve amounting to SEK 3.5m. The impact of re-structuring activities has reduced the total SG&A expenses as compared to previous quarters. Recorded non-cash costs for the Company's employee long-term incentive programs, included in the above SG&A expenses, amounted to SEK 8.9m for the first quarter 2024 (Q1'23: SEK 11.5m).

R&D expenses

Research and development expenses for the first quarter of 2024 amounted to SEK 103.0m (Q1'23: SEK 92.8m). R&D expenses has been affected by re-structuring reserve amounting to SEK 2.2m. The increase compared to corresponding quarter in 2023 is mainly driven by the ongoing U.S. ConfIdeS study, progressing the EMA post-approval commitments, the ongoing anti-GBM phase 3 clinical study as well as the clinical program and CMC development for HNSA-5487. Recorded non-cash costs for the Company's employee long-term incentive programs, included in the above R&D expenses, amounted to SEK 4.1m for the first quarter 2024 (Q1'23: SEK 5.5m).

Other operating income/expenses and financial income/expenses

Other operating income/expenses, net, for the first quarter of 2024 amounted to a loss of SEK 3.0m (Q1'23: loss of SEK 0.8m). Other operating income/expenses consist mainly of effects from exchange rates on operational items.

Financial expenses, net, for the first quarter of 2024, amounted to SEK 59.1m (Q1'23: expense of SEK 22.7m). The difference compared to 2023 is mainly driven by exchange effects on Hansa's USD long-term loan (see Note 4 below) due to a higher exchange rate for USD. The increased financial expenses are partly offset by positive exchange effects related to USD bank deposits.

Financial results

The loss from operations for the first quarter 2024 amounted to SEK 159.4m (Q1'23: SEK 182.3m). The decrease in loss compared to first quarter 2023 is mainly driven by the increased sales. The loss for the first quarter 2024 amounted to SEK 218.6m (Q1'23: SEK 205.4m).

Cash flow, cash and investments

Net cash used in operating activities for the first quarter of 2024 amounted to SEK 189.1m (Q1'23: SEK 207.0m). The change as compared to the corresponding quarter 2023 is driven by a mix of positive impact on lower cash flow related expenses (SEK 39.3m) on one hand, and a negative impact concerning changes in working capital (SEK 19.8m) on the other hand.

Cash and cash equivalents amounted to SEK 541.5m on March 31, 2024, as compared to SEK 732.1m as of December 31, 2023.

Parent Company

The parent company's revenue for the first quarter of 2024 amounted to SEK 56.0m (Q1'23: SEK 24.2m).

Loss for the parent company for the first quarter 2024 amounted to SEK 247.1m (Q1'23: SEK 205.3m).

The parent company's shareholders' equity amounted to SEK 981.3m as of March 31, 2024, as compared to SEK 1,216.9m on 31 December 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. As per March 31, 2024, Hansa Biopharma Inc. had twelve employees, Hansa Biopharma Ltd six employees and Hansa Biopharma S.r.l. four employees.

Long-term incentive programs

Hansa Biopharma's past Annual General Meetings have resolved to adopt share-based long-term incentive programs (LTIPs). As of March 31, 2024, the Company incurred equity-based compensation expenses under the following programs: LTIP 2020, LTIP 2021, LTIP 2022 and LTIP 2023.

The respective costs related to such ongoing programs are indicated 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 2020	LTIP 2021	LTIP 2022	LTIP 2023
Maximum number of issuable shares*	633,776	1,093,642	1,075,490	1,443,055
Number of allocated and outstanding share rights and options	487,520	841,263	827,300	1,123,000
Number of acquired and outstanding warrants	-	-	-	-
Estimated total cost including social contributions, KSEK	94,906	61,812	54,448	26,080
Total cost per program, including social contributions, as of March 31, 2024, YTD, KSEK	297	5,489	4,902	2,232

*As of March 31, 2024, including issuable shares to cover estimated social contributions under the LTIP.

Total costs, including social contributions, as of March 31, 2024, YTD, KSEK	12,920

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 also consider these risks.

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.

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.

Hansa's Board of Directors and senior management reviews, on a regular basis, 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.

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Other information

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Legal disclaimer

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

Financial calendar 2024

April 18, 2024	Interim Report January – March 2024
June 27, 2024	2024 Annual General Meeting in Lund, Sweden
July 18, 2024	Half-year Report January – June 2024
October 24, 2024	Interim Report for January – September 2024

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares March 31, 2024[1]	55,034,241 (52,671,796 A-shares and 2,362,445 C-shares)
Market Cap March 31, 2024	SEK ~1.75bn (USD ~164m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of March 31, 2024

Name	Number of shares	Ownership in pct
Redmile Group, LLC	9,647,747	18.3%
Nexttobe AB	2,155,379	4.1%
Jeansson, Theodor	2,150,000	4.1%
Olausson, Thomas	1,917,000	3.6%
Försäkrings AB Avanza Pension	1,799,517	3.4%
Fjärde AP-Fonden (AP 4)	1,700,000	3.2%
Tredje AP-Fonden (AP 3)	1,389,650	2.6%
Braidwell, L.P.	867,530	1.6%
VOB & T Trading AB	644,800	1.2%
Max Mitteregger Kapitalförvaltning AB	600,000	1.1%
Other	29,800,173	56.6%
Total	52,671,796	100.0%

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 March 31, 2024.

1. Following execution of a directed share issue on April 12, 2024, the number of outstanding shares will increase to 67,814,241 shares.

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Assurance

The Board of Directors and the CEO 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 April 18, 2024

Peter Nicklin
Chairman of the Board

Hilary Malone
Board member

Eva Nilsagård
Board member

Mats Blom
Board member

Andreas Eggert
Board member

Anders Gersel Pedersen
Board member

Søren Tulstrup
President & CEO

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Unaudited condensed financial statements

Unaudited condensed consolidated statement of financial position

KSEK	Note	March 31 2024	March 31 2023	December 31 2023
ASSETS				
Non-current assets				
Intangible assets	5	147,502	72,346	135,817
Property and equipment		6,003	8,072	6,343
Right-of-use assets		18,839	25,845	20,730
Total non-current assets		**172,344**	**106,263**	**162,890**
Current assets				
Inventories		1,201	1,037	1,513
Trade receivables & unbilled revenues		72,596	47,221	78,025
Current receivables, non-interest bearing		42,944	58,346	43,553
Cash and cash equivalents		541,465	1,286,820	732,060
Total current assets		**658,206**	**1,393,424**	**855,151**
TOTAL ASSETS		**830,550**	**1,499,687**	**1,018,041**
EQUITY AND LIABILITIES				
Shareholders' equity		**(374,209)**	**414,666**	**(167,876)**
Non-current liabilities				
Long-term loan	4	927,116	797,685	844,903
Deferred tax liabilities		375	402	367
Provisions		5,899	5,109	4,454
Lease liabilities		12,466	19,512	14,362
Deferred revenue		-	20,625	-
Contingent consideration	3	909	786	843
Total non-current liabilities		**946,765**	**844,119**	**864,929**
Current liabilities				
Tax liabilities		1,534	757	1,599
Lease liabilities		7,540	7,211	7,503
Current liabilities, non-interest bearing		62,662	61,115	86,966
Deferred revenue		36,458	41,024	41,473
Refund liabilities		52,851	34,986	49,266
Accrued expenses		96,949	95,809	134,181
Total current liabilities		**257,994**	**240,902**	**320,988**
TOTAL EQUITY AND LIABILITIES		**830,550**	**1,499,687**	**1,018,041**

Unaudited condensed consolidated income statement

KSEK	Note	Q1 2024	Q1 2023	Full year 2023
Revenue	2	55,981	24,194	134,094
Cost of revenue		(18,158)	(9,646)	(63,143)
Sales, general and administration expenses		(91,250)	(103,292)	(450,492)
Research and development expenses	5	(102,965)	(92,791)	(411,332)
Other operating income/(expenses), net		(2,999)	(813)	2,377
Loss from operations		**(159,391)**	**(182,348)**	**(788,496)**
Financial income		5,236	2,674	63,204
Financial expenses	4	(64,363)	(25,391)	(105,520)
Loss before tax		**(218,518)**	**(205,065)**	**(830,812)**
Tax		(61)	(356)	(908)
Loss for the period		**(218,579)**	**(205,421)**	**(831,720)**
Loss for the period attributable to owners of the parent		(218,579)	(205,421)	(831,720)
Loss per share, basic and diluted (SEK)		(4.15)	(3.92)	(15.83)
Other comprehensive income/(loss)				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences		771	100	(422)
Other comprehensive income/(loss) for the period		**771**	**100**	**(422)**
Total comprehensive income/(loss)		**(217,808)**	**(205,321)**	**(832,142)**

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Unaudited condensed consolidated statements of changes in shareholder's equity

KSEK	January-March 2024	January-March 2023	Full year 2023
Opening balance of shareholders' equity	**(167,876)**	**602,912**	**602,912**
Result for the period	(218,579)	(205,421)	(831,720)
Translation reserve	771	100	(422)
Net comprehensive income/(loss)	**(217,808)**	**(205,321)**	**(832,142)**
Transactions with the group's owner			
Long term incentive programs	11,475	17,075	61,354
Total transactions with the group's owner	**11,475**	**17,075**	**61,354**
Closing balance of shareholders' equity	**(374,209)**	**414,666**	**(167,876)**

Unaudited condensed consolidated statement of cash flow

KSEK	Q1 2024	Q1 2023	Full year 2023
Cash Flows from Operating Activities			
Loss for the period	(218,579)	(205,421)	(831,720)
Adjustment for items not included in cash flow	81,613	29,147	37,793
Interest received and paid, net	455	2,361	26,970
Income taxes paid	(146)	(356)	(133)
Cash flow from operations before change in working capital	**(136,657)**	**(174,269)**	**(767,090)**
Changes in working capital	(52,486)	(32,691)	11,436
Net cash used in operating activities	**(189,143)**	**(206,960)**	**(755,654)**
Investing activities			
Acquisition of property and equipment	(116)	(534)	(284)
Cash flow from investing activities	**(116)**	**(534)**	**(284)**
Financing activities			
Payment of lease liabilities	(1,859)	(1,768)	(7,545)
Cash flow from financing activities	**(1,859)**	**(1,768)**	**(7,545)**
Net change in cash	(191,118)	(209,261)	(763,483)
Cash and cash equivalents at beginning of period	732,060	1,496,179	1,496,179
Currency exchange variance, cash and cash equivalents	523	(98)	(636)
Cash and cash equivalents, end of period	**541,465**	**1,286,820**	**732,060**

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Parent company – Unaudited condensed statement of financial position

KSEK	Note	March 31 2024	March 31 2023	December 31 2023
ASSETS				
Non-current assets				
Intangible assets	5,6	1,486,124	70,222	1,504,277
Property and equipment		6,003	8,072	6,343
Right-of-use assets		18,839	25,845	20,730
Investment in subsidiaries		31,754	25,486	30,044
Total non-current assets		**1,542,720**	**129,625**	**1,561,394**
Current assets				
Inventories		1,201	1,037	1,513
Trade receivables & unbilled revenues		72,596	47,221	78,025
Current receivables, non-interest bearing		42,504	58,088	43,205
Cash and cash equivalents		537,441	1,272,639	715,538
Total current assets		**653,742**	**1,378,985**	**838,281**
TOTAL ASSETS		**2,196,462**	**1,508,610**	**2,399,675**
EQUITY AND LIABILITIES				
Shareholders' equity	6	**981,304**	**427,609**	**1,216,945**
Non-current liabilities				
Long-term loan	4	927,116	797,685	844,903
Provisions		5,899	5,109	4,454
Lease liabilities		12,466	19,512	14,362
Deferred revenue		-	20,626	-
Contingent consideration	3	909	757	843
Total non-current liabilities		**946,390**	**843,689**	**864,562**
Current liabilities				
Tax liabilities		1,334	786	1,409
Lease liabilities		7,540	7,211	7,503
Liabilities, group companies		17,360	2,448	7,089
Current liabilities, non-interest bearing		60,411	60,709	86,966
Deferred revenue		36,458	41,024	41,473
Refund liabilities		52,851	34,986	49,266
Accrued expenses		92,814	90,148	124,462
Total current liabilities		**268,768**	**237,312**	**318,168**
TOTAL EQUITY AND LIABILITIES		**2,196,462**	**1,508,610**	**2,399,675**

Parent company – Unaudited condensed income statement

KSEK	Note	Q1 2024	Q1 2023	Full year 2023
Revenue	2	55,981	24,194	134,094
Cost of revenue		(47,949)	(9,646)	(122,726)
Sales, general and administration expenses		(89,713)	(103,160)	(448,133)
Research and development expenses	5	(103,255)	(92,936)	(412,404)
Other operating income/(expenses), net		(2,988)	(813)	2,200
Loss from operations		**(187,924)**	**(182,360)**	**(846,969)**
Financial income		5,236	2,674	63,181
Financial expenses	4	(64,364)	(25,397)	(105,519)
Loss before tax		**(247,052)**	**(205,083)**	**(889,307)**
Income tax	6	(71)	(182)	293,771
Loss for the period		**(247,123)**	**(205,265)**	**(595,536)**
Other comprehensive income/(loss) for the period		-	-	-
Total comprehensive income/(loss) for the period		**(247,123)**	**(205,265)**	**(595,536)**

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

KSEK	Q1 2024	Q1 2023	Full year 2023
Opening balance of shareholders' equity	**1,216,945**	**615,799**	**615,799**
Result for the period	(247,123)	(205,265)	(595,536)
Other comprehensive income/(loss) for the period	-	-	-
Net comprehensive income/(loss)	**(247,123)**	**(205,265)**	**(595,536)**
IP write-up, net	-	-	1,135,421
Long term incentive programs	11,482	17,075	61,261
Total other transactions	**11,482**	**17,075**	**1,196,682**
Closing balance of shareholders' equity	**981,304**	**427,609**	**1,216,945**

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Financial notes

Note 1 Basis of preparation and accounting policies

This consolidated interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting, and recommendation RFR2 of the Swedish Reporting Board, Accounting for Legal entities. The same accounting principles have been used as in the latest annual report except for what is stated below. Hansa's Annual Report 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	Q1		Full year
KSEK	2024	2023	2023
Group			
Revenue			
Product sales	47,448	14,306	103,712
Contract revenue, Axis-Shield agreement	651	644	2,575
Cost reimbursement, Axis-Shield agreement	501	286	388
Contract revenue, Sarepta, AskBio agreement	7,381	8,958	27,419
	55,981	**24,194**	**134,094**
Parent Company			
Revenue			
Product sales	47,448	14,306	103,712
Contract revenue, Axis-Shield agreement	651	644	2,575
Cost reimbursement, Axis-Shield agreement	501	286	388
Contract revenue, Sarepta, AskBio agreement	7,381	8,958	27,419
	55,981	**24,194**	**134,094**

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 on March 31, 2024 amounted to SEK 0.9 million (Dec'23: SEK 0.8 million) 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 USD 70.0 million funding agreement with NovaQuest. The funding was accounted for as liability classified debt as the Company has an unavoidable obligation to settle the funding in cash. The debt will be accounted for at amortized cost.

The net proceeds from the funding were USD 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 debt, the Company will make quarterly mid-single-digit royalty payments to NovaQuest on future worldwide annual net sales of imlifidase, commencing upon approval in the U.S. of imlifidase in kidney transplantation or anti-GBM. In addition, Hansa will make certain milestone payments to NovaQuest upon U.S. approval of imlifidase in kidney transplantation or anti-GBM. The agreement also provides for time-based catch-up payments within the payment cap if specified payment amounts have not been received by NovaQuest by specified dates. The repayment must start latest January 2026, irrespectively whether the above-mentioned approvals were achieved, with the last potential catch-up payment due on December 31, 2028. The company is obligated to repay a total amount of USD 140 million in the form of milestone- or catch-up and royalty payments.

Hansa has also entered into a security agreement under which it pledges and provides 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 forecasted 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 is satisfied.

On March 31, 2024 the loan amounted to SEK 927.1 million, thereof SEK 190.4 million in accrued interest.

Note 5 Intangible assets – Internally generated intangible assets

Expenditure on research activities is recognized as an 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 if, and only if, all of the following 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 expenditure incurred from the date when the intangible asset first meets all the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditures are recognized in the statement of profit and loss and other comprehensive income in the period in which they are incurred.

The Company assessed that with respect to IDEFIRIX® and its conditional approval by EMA in enabling kidney transplantation in highly sensitized patients it does meet all the above criteria as of Q1-2024.

The total capitalized development expenses related to performing its IDEFIRIX® EMA post-approval commitments amounts, as of March 31, 2024, to SEK 135.1 million whereof SEK 15.5 million has been capitlalized during 2024. The capitalized development cost is subject to regular amortization over its useful life which is estimated to be up until end of 2032. Total accumulated amortization amounts to SEK 10.2 million.

Note 6 Intangible assets – Recognition of write-up

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

The write-up relates to IDEFIRIX®, that 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. After the write-up, the asset will have a gross value of 1,500.0 million SEK in the financial statements of Hansa Biopharma AB. The write-up increased the restricted shareholder equity in Hansa Biopharma AB by SEK 1,430.0 million. The write-up resulted in a taxable temporary difference for which a deferred tax liability of SEK 294.6 million was recognized, with a corresponding decrease in restricted shareholder equity. As a result of recognizing the deferred tax liability Hansa recognized a deferred tax asset of SEK 294.6 million 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 useful life of estimated 12 years.

As of March 31, 2024 the Company in its statutory financial statements has recorded an accumulated amortisation of SEK 89.4 million in cost of revenue thereby reducing the previously recorded intangible asset by the same amount. In addition, as a result of the amortization, the Company has recorded an adjustment of SEK 18.4 million to its previously recorded deferred tax assets and tax liabilities.

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
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.

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