Year-end report

January – December 2023

HANSA BIOPHARMA

Strong revenue generation in Q4 2023; Encouraging results from first-in-human trial of HNSA-5487; Initiation of phase 1b trial of imlifidase as pre-treatment to Sarepta's SRP-9001 in DMD

Business highlights for the fourth quarter of 2023

- Strong commercial performance. Total Q4 revenue of SEK 50m including SEK 43m in product sales and SEK 7m under our agreement mainly with Sarepta. Idefirix® sales were driven by growth in new markets such as U.K., Germany, and Spain.
- Medical guidelines and recommendations including use of Idefirix® implemented on a national level in Italy and Germany.
- NICE-01 phase 1 (HNSA-5487): Following positive results from the first-in-human trial of HNSA-5487, the lead candidate from the NiceR program for repeat dosing, an analysis of additional exploratory endpoints on IgG recovery and immunogenicity is being conducted for completion in 2024.
- AMR (antibody-mediated transplant rejection) phase 2: Full data published in December 2023. Imlifidase met the primary endpoint; explorative secondary outcome measures were not designed nor sufficiently powered to show statistical significance versus the control arm.
- GBS (Guillain-Barré Syndrome) phase 2: Positive high-level data announced in December 2023 as imlifidase demonstrated positive safety, tolerability, and early efficacy outcomes. Further analysis will contextualize the efficacy data.
- SRP-9001-104 phase 1b trial (Duchenne Muscular Dystrophy, DMD): The first clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD was initiated mid-December 2023. First patient is expected to be dosed in early 2024.
- On October 17, 2023, Hansa announced 5-year data from the long-term follow-up study of imlifidase, demonstrating 90% patient survival and 82% graft survival in extended pooled analysis with data from the 17-HMedIdeS-14 study.
- On December 5, 2023, Hansa announced plans to restructure the organization to better align and focus on key clinical development and commercial priorities. The planned restructuring should result in an approximately 20-25% reduction in the current workforce and will provide approximately SEK 75-85 million in annual savings, when fully implemented.

Clinical pipeline update

- US ConfIdeS phase 3 trial (kidney transplantation): 104 patients have been enrolled with 40 of 64 targeted patients randomized in this pivotal U.S. open label, randomized, controlled trial of imlifidase in kidney transplantation.
- GOOD-IDES-02 phase 3 (anti-GBM disease): 18 of 50 targeted patients enrolled in this global pivotal phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease. Completion of enrollment is expected in 2025.

Clinical pipeline update continued

- Investigator-initiated phase 2 trial (ANCA-associated vasculitis): 3 of 10 targeted patients enrolled.

Events after the closing period

- On January 6, 2024, Hansa and NewBridge Pharmaceuticals announced their partnership to enable supply of Idefirix® to kidney transplant patients in the Middle East and North Africa (MENA).
- On February 1, 2024, Hansa Biopharma and Medison Pharma announced positive reimbursement decision in Slovenia for Idefirix® in highly sensitized kidney transplant patients. With this, commercial access to Idefirix® has now been obtained in 14 European countries.
- First patient treated in the new Eurotransplant Desensitization Program, under the Acceptable Mismatch Program, which is intended to transform desensitization across eight European member countries including Germany, the Benelux and select Eastern European countries.

Financial Summary

SEKm, unless otherwise stated – unaudited	Q4 2023	Q4 2022	FY 2023	FY 2022
Revenue	50.4	30.8	134.1	154.5
- thereof: Product sales	43.3	20.3	103.7	86.7
SG&A expenses	(106.0)	(83.7)	(450.5)	(337.9)
R&D expenses	(108.3)	(92.3)	(411.3)	(346.2)
Loss from operation	(175.5)	(146.2)	(788.5)	(588.6)
Loss for the period	(124.5)	(148.7)	(831.7)	(611.1)
Net cash used in operations	(172.9)	(110.1)	(755.7)	(502.7)
Cash and short-term investments	732.1	1,496.2	732.1	1,496.2
EPS before and after dilution (SEK)	(2.36)	(3.22)	(15.83)	(13.60)
Number of outstanding shares	52,671,796	52,443,962	52,671,796	52,443,962
Weighted avg. no of shares before and after dilution	52,671,796	46,128,829	52,540,089	44,923,998
No of employees at the end of the period	168	150	168	150

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, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

CEO comments

"Hansa enters 2024 in a strong position to successfully execute on our key priorities. I am encouraged by the strong commercial performance of Idefirix® against key launch metrics in the fourth quarter of 2023 and the continued progress we have achieved across our pipeline development activities."

Søren Tulstrup
President and CEO, Hansa Biopharma

"Hansa enters 2024 in a strong position to successfully execute on our key priorities. I am encouraged by the strong commercial performance of Idefirix® against key launch metrics and the continued progress we have achieved across our pipeline development activities.

I am particularly excited about the encouraging first results from the first-in-human trial of HNSA-5487, Hansa's lead candidate in the NiceR program. It is our aim with this new enzyme to enable repeated infusions and thereby target diseases and conditions where either a prolonged IgG-free window or intermittent therapy is desirable. If successful, this new approach could enable innovative treatment approaches in a broad range of indications, including chronic auto-immune diseases.

In kidney transplantation, we continue to see good commercial progress in Europe, including the implementation of treatment guidelines in both Italy and Germany and continued growth in the number of hospitals with desensitization protocols in place, while sales were supported by growth in key new markets such as U.K., Germany, and Spain.

During the fourth quarter, we also saw increased patient identification through organ allocation systems such as Eurotransplant where both a first and second wave patient assessment took place with the new Desensitization Program. This new pilot program, under the Acceptable Mismatch Program, is intended to transform desensitization across eight European member countries including Germany, the Benelux and select Eastern European countries.

In the U.S., we continue enrollment in the phase 3 ConfIdeS trial in kidney transplantation to accelerate randomization of patients. As previously guided, completion of randomization is expected by mid-2024, with a BLA submission expected in 2025 following a 12-month follow-up on kidney function, measured through the mean estimated glomerular filtration rate (eGFR).

Beyond our core markets, we continue to expand access to imlifidase for highly sensitized kidney transplant patients through a new commercial partnership with NewBridge Pharmaceuticals in the MENA region. The new collaboration is rooted in the existing European conditional marketing authorization for Idefirix® and pending applications for marketing authorization in the respective MENA markets.

Further, I am also pleased to see positive data from our long-term follow-up study further supporting the clinical benefit of imlifidase in kidney transplantation out to year five. The five-year data demonstrate graft survival in line with outcomes seen at 3-years post-transplant.

Beyond kidney transplantation, we shared data read-outs from two phase 2 programs in AMR and GBS. In the AMR phase 2 trial (16-HMedIdes-12), imlifidase met the primary endpoint demonstrating statistically significant reduction in donor-specific antibodies (DSAs) observed among imlifidase patients within five days of treatment as compared to plasma exchange which is a common part of a standard of care treatment. While we are encouraged to have met the primary endpoint, it is important to note that the secondary endpoints were not met as the trial was not designed nor sufficiently powered to show a statistically significant difference between the two arms given the heterogeneity of patients, involving many patients with an additional cellular component of the immune rejection, and the small number of patients enrolled. Patients with an acute AMR may be best placed to benefit from a rapid and significant reduction in DSA levels.

In the GBS phase 2 study (15-HMedIdeS-09), high level data was announced in December 2024 demonstrating that imlifidase was safe and well tolerated when administered prior to standard of care, including rapid improvement in disease-related efficacy measures. Further analysis of efficacy data will be conducted this year.

In our pivotal phase 3 program in anti-glomerular basement membrane (anti-GBM) disease (GOOD-IDES-02), we continue to see good progress, with 18 of 50 targeted patients enrolled as of February 2, 2024. Completion of enrollment is expected in 2025.

Further, I am happy to report that the first clinical study with imlifidase in gene therapy was recently commenced by our partners from Sarepta Therapeutics. In the phase 1b study, imlifidase is being investigated as a pre-treatment to Sarepta's FDA approved SRP-9001 (Elevidys) gene therapy in Duchenne Muscular Dystrophy (DMD). First patient is expected to be dosed in due course.

Lastly, we recently announced plans to restructure the organisation to better align and focus on key clinical development and commercial priorities. This is expected to result in an approximate 20-25% reduction in the current workforce and will yield approximately 75-85 million SEK in annual savings when fully implemented.

While we firmly believe this initiative is a necessary action to help us deliver on our important mission, it was obviously a difficult decision to take as it impacts our most valuable asset – our people. We are grateful for the commitment and relentless efforts of our colleagues who have worked tirelessly to advance potentially lifesaving medicines for people suffering from serious immunological diseases and conditions and we remain committed to supporting those colleagues impacted by the restructure.

I look forward to keeping you updated on our continued progress, with several upcoming important milestones to be achieved across our platform and franchises in 2024.

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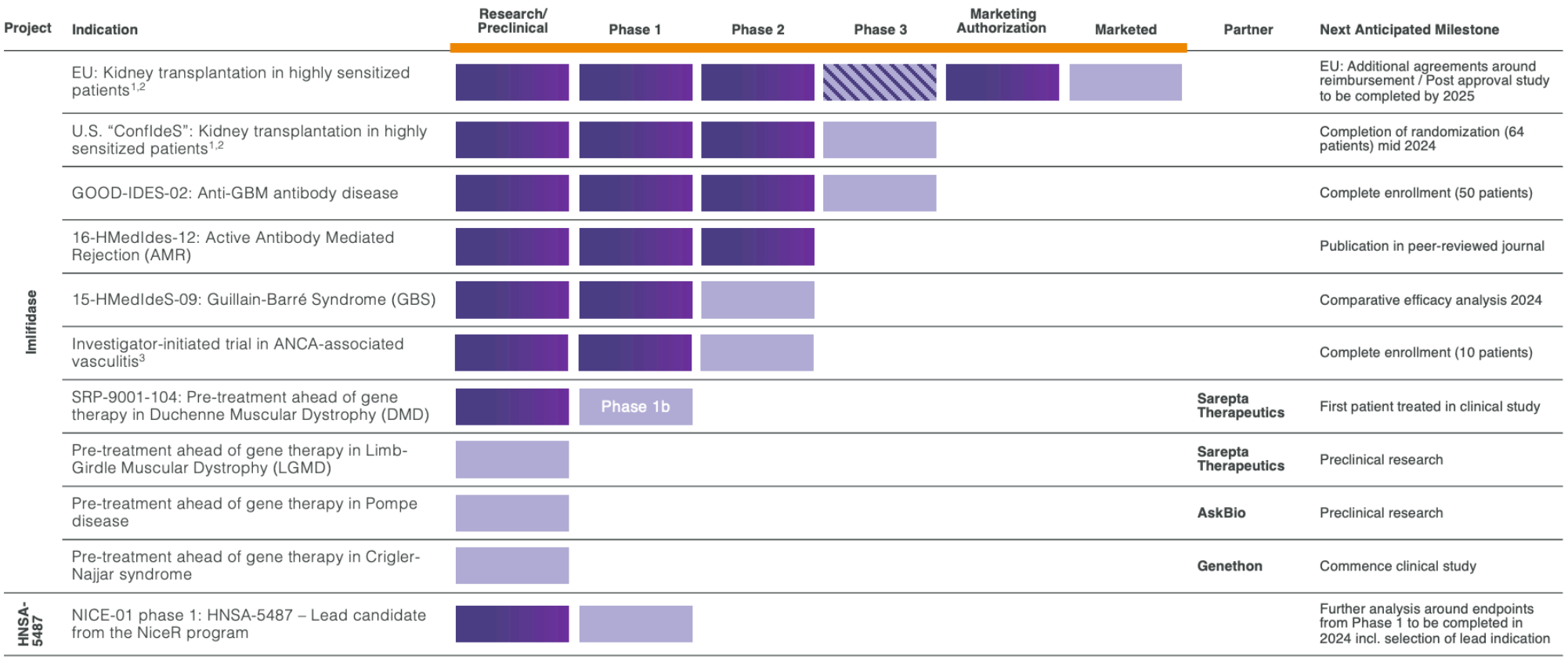
Continued pipeline progress

Project	Indication	Partner	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients[1,2]		EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	U.S. "ConfIdeS": Kidney transplantation in highly sensitized patients[1,2]		Completion of randomization (64 patients) mid 2024
	GOOD-IDES-02: Anti-GBM antibody disease		Complete enrollment (50 patients)
	16-HMedIdes-12: Active Antibody Mediated Rejection (AMR)		Publication in peer-reviewed journal
	15-HMedIdeS-09: Guillain-Barré Syndrome (GBS)		Comparative efficacy analysis 2024
	Investigator-initiated trial in ANCA-associated vasculitis[3]		Complete enrollment (10 patients)
	SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)	**Sarepta Therapeutics**	First patient treated in clinical study
	Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)	**Sarepta Therapeutics**	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease	**AskBio**	Preclinical research
	Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome	**Genethon**	Commence clinical study
HNSA-5487	NICE-01 phase 1: HNSA-5487 – Lead candidate from the NiceR program		Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication



[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® in Europe continue to progress as planned – most recently with the positive reimbursement decision received in Slovenia. Commercial access has been obtained in 14 European countries, including France, U.K., Germany, Italy and Spain.

Following the publication of the first guidelines in *Transplant International* by European Society for Organ Transplantation's (ESOT) in August 2022 for desensitization treatment of highly sensitized kidney transplant patients, Idefirix-specific guidelines have been implemented on a national level in several countries including U.K., Finland, France, Belgium, the Netherlands and more recently Italy and Germany. These guidelines provide a new clinical practice framework for healthcare professionals on a management pathway for highly sensitized patients.

In June 2023, a new Eurotransplant desensitization program was launched as a pilot. 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. The new Eurotransplant Desensitization Program is a subprogram of the Acceptable Mismatch Program (priority program for Highly Sensitized Patients) and is initially targeting 20 imlifidase-eligible patients. A first and second wave of patient identification was carried out during the fourth quarter 2023 and patients are now waiting for an organ from a deceased donor.

In parallel to the commercial launch, Hansa is also carrying out a post-approval efficacy study (PAES). The PAES is an obligation under 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 PAES will support full marketing authorization and is expected to be completed by 2025. As of February 2, 2024, 28 patients (56% completion) were treated in PAES.

U.S. Randomized Controlled Trial "ConfIdeS"

The ConfIdeS study 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 waiting list for kidney transplantation in the U.S. will be 1:1 randomized to either desensitization with imlifidase or SoC Standard of Care;i.e., 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 was 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 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, showing 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

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]

In March 2022, Hansa announced that key data from an investigator-initiated phase 2 trial (GoodIdeS) of imlifidase to treat anti-GBM disease were published in the *Journal of American Society of Nephrology (JASN)*. The study, led by Principal Investigator, Mårten Segelmark, Professor of Nephrology at Lund University, previously Linköping University, 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.

In May 2023, the first patient was enrolled in a pivotal phase 3 trial with imlifidase in 50 anti-GBM patients to evaluate kidney function after six months. This study is an open label, controlled, randomized, multi-center phase 3 trial evaluating renal function in patients with severe anti-GBM disease imlifidase plus SoC versus SoC. Completion of enrollment is expected in 2025.

[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

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

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.

In 2019, Hansa initiated a randomized, open-label, multi-center, controlled phase 2 study, designed to evaluate the safety and efficacy of imlifidase in eliminating donor-specific antibodies (DSA) in the treatment of active episodes of acute and chronic acute AMR in kidney transplant patients, in comparison to plasma exchange (SoC).

On December 14, 2023, Hansa announced full data from the imlifidase phase 2 study 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.

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

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] In 2019, Hansa initiated 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).

On December 7, 2024, Hansa presented positive high-level data from the 15-HMedIdeS-09 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. Further analysis of efficacy data will be conducted in 2024.

Investigator-initiated phase 2 trial in ANCA-associated vasculitis

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.

An Investigator-initiated phase 2 trial in ANCA-associated vasculitis was commenced in the summer 2023 at Charité - Universitätsmedizin Berlin targeting 10 patients with severe ANCA-associated vasculitis and acute respiratory distress syndrome ("ARDS") due to pulmonary hemorrhage will be treated with imlifidase on top of SoC (consisting of standard immunosuppression as per center protocol and intensive support care).

As of February 2, 2023, three patients with severe ANCA-associated vasculitis have been enrolled.

NICE-01 phase 1 (HNSA-5487) – Lead candidate from the NiceR program

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. The Company has developed and patented several novel immunoglobulin cysteine endopeptidases.

High-level results from the lead candidate HNSA-5487 were published October 9, 2023, demonstrating that the molecule 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.

SRP-9001-104 phase 1b trial (Duchenne Muscular Dystrophy, DMD)

In July 2020, Hansa entered into an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment prior to the administration of 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. In addition, Hansa will be 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.

On June 22, 2023, Sarepta's product Elevidys (SRP-9001), received U.S. FDA approval as a one-time treatment in ambulatory paediatric patients aged 4 through 5 years, suffering from Duchenne Muscular Dystrophy. In combination with imlifidase, additional treatment may potentially be enabled in up to 14% of patients who are currently suffering from too high titres of neutralizing antibodies against AAVrh74.

The first clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD was initiated mid-December 2023. The first patient is expected to be dosed in due course, with first high level data read-out from the phase 1b study expected later this year.

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.

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[3] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.

[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

2023

Q4 2023

- **HNSA-5487 (Lead NiceR candidate):** High-level data readout from Phase 1
- **Long-term follow-up (Kidney tx):** 5-year data readout
- **GBS Phase 2:** First data readout
- **AMR Phase 2:** Full data readout
- **Sarepta DMD pre-treatment Phase 1b:** Commence clinical study

2024

- **GBS Phase 2:** Outcome of comparative efficacy analysis
- **Genethon Crigler-Najjar Phase 1/2:** Initiate clinical study with imlifidase prior to GNT-0003
- **HNSA-5487 (Lead NiceR candidate):** Further analysis around endpoints to be completed in 2024 incl. lead indication
- **U.S. ConfIdeS (Kidney tx) Phase 3:** Complete randomization
- **Sarepta imlifidase in phase 1b in DMD:** First high level data read-out from phase 1b

2025

- **U.S. ConfIdeS (Kidney tx) Phase 3:** BLA submission
- **Anti-GBM disease Phase 3:** Complete enrolment

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Financial review January – December 2023

Revenue

Revenue for the fourth quarter of 2023 amounted to SEK 50.4 million (Q4'22: SEK 30.8m) consisting of Idefirix® product sales of SEK 43.3m (Q4'22: SEK 20.3m) and contract revenue of SEK 7.1m (Q4'22: SEK 10.4m) mainly from the upfront payment the Company received under the Sarepta agreement.

Revenue for the full year 2023 amounted to SEK 134.1m (FY '22 SEK 154.5m) mainly comprising of Idefirix® product sales of SEK 103.7m (FY '22: SEK 86.7m) and contract revenue of SEK 30.4m (FY '22: SEK 67.8m) mainly from the upfront payment the Company received under the Sarepta agreement.

The change in revenue is driven by higher product sales amounting to SEK 17.0m and lower contract revenue amounting to SEK 36.7m from a non-recurring recognition of contract revenue under the AskBio agreement.

SG&A expenses

Sales, general and administrative expenses for the fourth quarter of 2023 amounted to SEK 106.0m (Q4'22: SEK 83.7m) and to SEK 450.5m for the FY 2023 (FY '22 SEK 337.9m). The increase in expenses mainly reflects Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix® in Europe. Recorded non-cash costs for the Company's employee long-term incentive programs, included in the above SG&A expenses, amounted to SEK 39.4m for the full year 2023 (FY '22: SEK 39.8m).

R&D expenses

Research and development expenses for the fourth quarter of 2023 amounted to SEK 108.3m (Q4'22: SEK 92.3m) and to SEK 411.3m for the full year 2023 (FY '22: SEK 346.2m). The increase over the 2023 periods 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 21.2m for the full year 2023 (FY '22: SEK 18.5m).

Other operating income/expenses and financial income/expenses

Other operating income/expenses for the fourth quarter of 2023 amounted to an income of SEK 6.4m (Q4 '22: income of SEK 3.5m) and to an income of SEK 2.4m for the full year 2023 (FY '22: expense of SEK 20.5m). The difference compared to the full year 2022 is mainly driven by a a one-off settlement payment the Company made related to arbitration proceedings in Q3-2022 and US dollar exchange rate changes against the Swedish Krona on the deferred revenue positions as well as the accounts payable/accounts receivables positions in the balance sheet.

Financial income, net, for the fourth quarter of 2023, amounted to SEK 51.3m (Q4 '22: expense of SEK 1.9m) and to an expense of SEK 42.3m for the full year 2023 (FY '22: expense of SEK 21.4m). The difference compared to 2022 is mainly driven by accrued interest related to Hansa's USD long-term loan (see Note 4 below) with a positive FX-effect related to that loan, which is partly offset by negative FX changes related to USD bank deposits.

Financial results

The loss from operations for the fourth quarter 2023 amounted to SEK 175.5m (Q4 '22: SEK 146.2m) and to SEK 788.5m for the full year 2023 (FY '22: SEK 588.6m). The increase as compared to previous year periods is mainly driven by Hansa's broadened commercial and R&D pipeline activities.

The loss for the fourth quarter 2023 amounted to SEK 124.5m (Q4'22: SEK 148.7m) and to SEK 831.7m for the full year 2023 (FY '22: SEK 611.1m).

Cash flow, cash and investments

Net cash used in operating activities for the fourth quarter of 2023 amounted to SEK 172.9m (Q4 '22: SEK 110.1m) and to SEK 755.7m for the full year 2023 (FY '22: SEK 502.7m). The change as compared to the previous full year is driven by increased operating expense levels mainly due to Hansa's broadened commercial and R&D activities and a USD 5m (SEK 45.8m) upfront payment related to its agreement with AskBio positively impacting 2022 cash-flow.

Cash and cash equivalents amounted to SEK 732.1m on December 31, 2023, as compared to SEK 1,496.2m as of December 31, 2022.

Parent Company

The parent company's revenue for the fourth quarter of 2023 amounted to SEK 50.4m (Q4 '22: SEK 30.8m) and to SEK 134.1m for the full year 2023 (FY '22: SEK 154.5m).

Loss for the parent company for the fourth quarter 2023 amounted to SEK 159.4m (Q4'22: SEK 133.5m) and to SEK 607.8m for the full year 2023 (FY '22: SEK 596.7).

The parent company's shareholders' equity amounted to SEK 1,216.9m as of December 31, 2023, as compared to SEK 615.8m on 31 December 2022. The increase in equity is driven by the recognition of a write-up of SEK 1,430 million in intangible assets related to Idefirix (please see Note 6 below for further information).

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. Hansa Biopharma Italy S.r.l. was registered in July 2023 to support commercialization in Italy. The subsidiary had no employees as of December 31, 2023. Hansa Biopharma Inc. had ten employees at the end of December 2023. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had seven employees at the end of December 2023.

Long-term incentive programs

Hansa Biopharma's past Annual General Meetings have resolved to adopt share-based long-term incentive programs (LTIPs). As of December 31, 2023, 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 2022 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*	654,576	1,093,642	1,075,490	1,443,055
Number of allocated and outstanding share rights and options	503,520	841,263	827,300	1,123,000
Number of acquired and outstanding warrants	-	-	-	-
Estimated total cost including social contributions, KSEK	97,175	61,419	50,474	24,443
Total cost per program, including social contributions, as of December 31, 2023, YTD, KSEK	21,479	23,589	14,550	1,019

*As of December 31, 2023, including issuable shares to cover estimated social contributions under the LTIP.

Total costs, including social contributions, as of December 31, 2023, YTD, KSEK	60,637

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, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

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 2022 Annual Report (pages 91-94 ENG), 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 2022 Annual Report have been identified as of the date of this quarterly report.

Other information

Contacts

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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

March 20, 2024	Annual Report 2023
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	55,034,241 (52,671,796 A-shares and 2,362,445 C-shares)
Market Cap December 31, 2023	SEK ~1.45bn (USD ~140m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of December 31, 2023

Name	Number of shares	Ownership in pct
Redmile Group, LLC	9,653,214	18.3%
Nexttobe AB	2,155,379	4.1%
Jeansson, Theodor	2,100,000	3.7%
Olausson, Thomas	1,917,000	3.6%
Försäkrings AB Avanza Pension	1,765,506	3.4%
Fjärde AP-Fonden (AP 4)	1,700,000	3.2%
Tredje AP-Fonden (AP 3)	1,389,650	2.6%
Max Mitteregger Kapitalförvaltning AB	725,000	1.4%
VOB & T Trading AB	644,800	1.2%
BWG Invest SARL	600,000	1.1%
Other	30,021,247	57.0%
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 December 31, 2023.

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, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

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 February 2, 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

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, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

Unaudited condensed financial statements

Unaudited condensed consolidated statement of financial position

KSEK	Note	December 31 2023	2022
ASSETS			
Non-current assets			
Intangible assets	5	135,817	46,866
Property and equipment		6,343	8,113
Leased assets		20,730	27,723
Total non-current assets		**162,890**	**82,702**
Current assets			
Inventories		1,513	973
Trade receivables & unbilled revenues		78,025	42,959
Current receivables, non-interest bearing		43,553	64,593
Cash and cash equivalents		732,060	1 496,179
Total current assets		**855,151**	**1,604,704**
TOTAL ASSETS		**1,018,041**	**1,687,406**
EQUITY AND LIABILITIES			
Shareholders' equity		**(167,876)**	**602,912**
Non-current liabilities			
Long-term loan	4	844,903	762,601
Deferred tax liabilities		367	405
Provisions		4,454	5,192
Lease liabilities		14,362	21,326
Deferred revenue		-	29,500
Contingent consideration	3	843	757
Total non-current liabilities		**864,929**	**819,781**
Current liabilities			
Tax liability		1,599	604
Lease liabilities		7,503	7,165
Current liabilities, non-interest bearing		86,966	80,754
Deferred revenue		41,473	40,430
Refund liabilities		49,266	27,013
Accrued expenses and deferred income		134,181	108,747
Total current liabilities		**320,988**	**264,713**
TOTAL EQUITY AND LIABILITIES		**1,018,041**	**1,687,406**

Unaudited condensed consolidated income statement

KSEK	Note	Q4 2023	Q4 2022	January-December 2023	January-December 2022
Revenue	2	50,411	30,766	134,094	154,525
Cost of revenue		(18,126)	(4,535)	(63,143)	(38,477)
Sales, general and administration expenses		(105,992)	(83,692)	(450,492)	(337,861)
Research and development expenses	5	(108,251)	(92,275)	(411,332)	(346,244)
Other operating income/(expenses), net		6,417	3,491	2,377	(20,532)
Loss from operations		**(175,541)**	**(146,245)**	**(788,496)**	**(588,588)**
Financial income/(expenses), net	4	51,296	(1,914)	(42,316)	(21,391)
Loss for the period before tax		**(124,245)**	**(148,159)**	**(830,812)**	**(609,979)**
Tax		(214)	(516)	(908)	(1,155)
Loss for the period		**(124,459)**	**(148,675)**	**(831,720)**	**(611,134)**
Attributable to:					
Parent company shareholders		(124,459)	(148,675)	(831,720)	(611,134)
Earnings per share (EPS)					
Before dilution (SEK)		(2.36)	(3.22)	(15.83)	(13.60)
After dilution (SEK)		(2.36)	(3.22)	(15.83)	(13.60)
Other comprehensive income/(loss)					
Items that have been, or may be reclassified to profit or loss for the period					
Translation differences		(1,297)	(378)	(422)	(114)
Other comprehensive income/(loss) for the period		(1,297)	(378)	(422)	(114)
Total net comprehensive income/(loss)		**(125,756)**	**(149,053)**	**(832,142)**	**(611,248)**

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, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

Unaudited condensed consolidated statements of changes in shareholder's equity

KSEK	January-December 2023	2022
Opening balance of shareholders' equity as reported	**602,912**	**757,573**
Result for the period	(831,720)	(611,134)
Other comprehensive income/(loss) for the period	(422)	(114)
Net comprehensive income/(loss)	**(832,142)**	**(611,248)**
Transactions with the group's owner		
Proceeds from new share issuance, net [1]	-	396,196
Long term incentive programs	61,354	60,391
Total transactions with the group's owner	**61,354**	**456,587**
Closing balance of shareholders' equity	**(167,876)**	**602,912**

1) Total share issue cost amounted to KSEK 19,754

Unaudited condensed consolidated statement of cash flow

KSEK	Q4 2023	Q4 2022	January-December 2023	January-December 2022
Cash Flows from Operating Activities				
Loss for the period	(124,459)	(148,674)	(831,720)	(611,134)
Adjustment for items not included in cash flow [1]	(77,269)	(6,828)	37,793	83,433
Interest received and paid, net	26,827	5,318	26,970	5,101
Income taxes paid	(21)	(866)	(133)	(1,565)
Cash flow from operations before change in working capital	**(174,922)**	**(151,050)**	**(767,090)**	**(524,165)**
Changes in operating related assets and liabilities	1,977	40,953	11,436	21,432
Net cash used in operating activities	**(172,945)**	**(110,097)**	**(755,654)**	**(502,733)**
Investing activities				
Proceeds from sale of short-term investments	-	-	-	232,644
Acquisition of property and equipment	405	(3,191)	(284)	(3,331)
Cash flow from investing activities	**405**	**(3,191)**	**(284)**	**229,313**
Financing activities				
Proceeds long-term loan, net of transaction cost [2]	-	(8,027)	-	728,373
Proceeds from new share issue, net of transaction cost [3]	-	404,223	-	396,196
Repayment of lease liabilities	(2,195)	(1,734)	(7,545)	(6,888)
Cash flow from financing activities	**(2,195)**	**394,462**	**(7,545)**	**1,117,681**
Net change in cash	(174,735)	281,174	(763,483)	844,261
Cash and cash equivalents, beginning of period	908,176	1,215,282	1,496,179	651,342
Currency exchange variance, cash and cash equivalents	(1,381)	(277)	(636)	576
Cash and cash equivalents, end of period	**732,060**	**1,496,179**	**732,060**	**1,496,179**

[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] The sale is to cover withholding tax of participants under the LTIP 2019 program.
[3] Total share issue cost amounted to SEK 19,754k.

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Parent company – Unaudited condensed statement of financial position

KSEK	Note	December 31 2023	2022
ASSETS			
Non-current assets			
Intangible assets	5,6	1,504,277	44,718
Property, plant and equipment		6,343	8,113
Leased assets		20,730	27,723
Investment in subsidiaries		30,044	24,264
Receivables, group companies		-	-
Total non-current assets		**1,561,394**	**104,818**
Current assets			
Inventories		1,513	973
Trade receivables & unbilled revenue		78,025	42,959
Current receivables, non-interest bearing		43,205	64,368
Cash and cash equivalents		715,538	1,486,502
Total current assets		**838,281**	**1,594,802**
TOTAL ASSETS		**2,399,675**	**1,699,620**
EQUITY AND LIABILITIES			
Shareholders' equity	6	**1,216,945**	**615,799**
Non-current liabilities			
Long-term loan	4	844,903	762,601
Provisions		4,454	5,192
Lease liabilities		14,362	21,326
Deferred revenue		-	29,500
Contingent consideration	3	843	757
Total non-current liabilities		**864,562**	**819,376**
Current liabilities			
Tax liability		1,409	604
Lease liabilities		7,503	7,165
Liabilities, group companies		7,089	5,738
Current liabilities, non-interest bearing		86,966	80,225
Deferred revenue		41,473	40,430
Refund liabilities		49,266	27,013
Accrued expenses and deferred income		124,462	103,270
Total current liabilities		**318,168**	**264,445**
TOTAL EQUITY AND LIABILITIES		**2,399,675**	**1,699,620**

Parent company – Unaudited condensed income statement

KSEK	Note	Q4 2023	2022	January-December 2023	2022
Revenue	2	50,411	30,766	134,094	154,525
Cost of revenue		(47,917)	(4,535)	(122,726)	(38,477)
Sales, general and administration expenses		(103,941)	(75,933)	(448,133)	(330,071)
Research and development expenses	5	(109,034)	(84,745)	(412,404)	(340,192)
Other operating income/(expenses), net		6,239	3,488	2,200	(20,532)
Loss from operations		**(204,242)**	**(130,959)**	**(846,969)**	**(574,747)**
Result from financial items:					
Finance income		18,892	24,507	28,070	27,245
Finance costs	4	32,382	(26,419)	(70,408)	(48,629)
Loss for the period before tax		**(152,968)**	**(132,871)**	**(889,307)**	**(596,131)**
Income tax benefit/(expense)	6	(6,403)	(604)	281,497	(604)
Loss for the period		**(159,371)**	**(133,475)**	**(607,810)**	**(596,735)**
Other comprehensive income/(loss) for the period		-	-	-	-
Total comprehensive income/(loss) for the period		**(159,371)**	**(133,475)**	**(607,810)**	**(596,735)**

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

KSEK	Note	January-December 2023	2022
Opening balance of shareholders' equity as reported		**615,799**	**755,948**
Result for the period		(607,810)	(596,735)
Other comprehensive income/(loss) for the period		-	-
Net comprehensive income/(loss)		**(607,810)**	**(596,735)**
IP Write up	6	1,430,000	-
IP Write up - Deferred tax liability	6	(282,305)	-
Proceeds from new share issuance, net [1]		-	396,196
Long term incentive programs		61,261	60,391
Total transactions with the group's owner		**1,208,956**	**456,587**
Closing balance of shareholders' equity		**1,216,945**	**615,799**

1) Total share issue cost amounted to KSEK 19,754

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, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

Financial notes

Note 1 Basis of preparation and accounting policies

This consolidated interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting, and recommendation RFR2 of the Swedish Reporting Board, Accounting for Legal entities. The same accounting principles have been used as in the latest annual report except for what is stated below. Hansa's Annual Report 2022 was published on March 30, 2023 and is available at www.hansabiopharma.com. Disclosures in accordance with IAS 34.16A are as applicable in the notes or on the pages before the consolidated income statement.

Note 2 Revenue

Income per significant category of income	Q4		January-December	
KSEK	2023	2022	2023	2022
Group				
Revenue				
Product sales	43,337	20,337	103,712	86,735
Contract revenue, Axis-Shield agreement	644	1,176	2,575	2,892
Cost reimbursement, Axis-Shield agreement	102	87	388	624
Contract revenue, Sarepta, AskBio agreement	6,328	9,166	27,419	64,273
	50,411	**30,766**	**134,094**	**154,525**
Parent Company				
Revenue				
Product sales	43,337	20,337	103,712	86,735
Contract revenue, Axis-Shield agreement	644	1,176	2,575	2,892
Cost reimbursement, Axis-Shield agreement	102	87	388	624
Contract revenue, Sarepta, AskBio agreement	6,328	9,166	27,419	64,273
	50,411	**30,766**	**134,094**	**154,525**

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 December 31, 2023 amounted to SEK 0.8 million ('22: 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.

The debt is secured by certain of the Company's intellectual property and assets.

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. Total payments by Hansa to NovaQuest are capped at USD 140 million. 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, with the last potential catch-up payment due on December 31, 2028.

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 31 December 2023, the loan amounted to SEK 844.9 million, thereof SEK 149.8 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 Q4-2023.

During the full year 2023 and 2022 the Company capitalized development cost related to performing its Idefirix® EMA post-approval commitments in the amount of SEK 97.7 million and SEK 20.9 million, respectively. The capitalized development cost is subject to regular amortization over its useful life which is estimated to be up until end of 2032.

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 December 31, 2023 the Company in its statutory financial statements recorded an amortisation expense of SEK 59.6 million in cost of revenue thereby reducing the previously recorded intangible asset by the same amount. In addition, the Company recorded an adjustment of SEK 12.3 million to its previously recorded deferred tax assets and tax liabilities in connection with the amortization charge.

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.