Interim report

January – September 2023

HANSA BIOPHARMA

Encouraging high-level results for first-in-human trial of HNSA-5487; well attended Hansa-sponsored symposium at ESOT focusing on first patient experiences; Dr. Hitto Kaufmann appointed new CSO

Business highlights for the third quarter of 2023

- Total Q3 revenue of SEK 22.8m including SEK 16.5m in product sales and SEK 5.7m under our agreement with Sarepta.
- Several new agreements secured with leading transplantation centers in key markets such as U.K. and Germany. Ongoing patient identification through organ allocation systems such as Eurotransplant, which should translate into increased commercial sales in Q4 2023, as previously guided.
- European Society of Organ Transplantation (ESOT) Congress in Athens: Held well-attended Hansa-sponsored symposium *"Crossing DSA Barriers to Transplant Today"* focusing on patient experiences with Idefirix.
- First patients treated with imlifidase in an investigator-initiated Phase 2 study in ANCA-associated vasculitis.
- Dr. Hitto Kaufmann appointed Chief Scientific Officer (CSO) of Hansa Biopharma responsible for all research, early development, translational and manufacturing activities.
- Great Place to Work® certification received for the fourth consecutive year. The 2023 certification is based on a company-wide survey completed with 100% participation from Hansa employees.

Clinical pipeline update

- Anti-GBM disease: Positive momentum in the pivotal phase 3 study in anti-GBM disease, five patients were enrolled during Q3, while number of active sites expanded from 12 to 25 in the past quarter. A total of 9 patients out of a target of 50 patients have been enrolled across centers in the U.S., U.K. and EU.
- U.S. ConfIdeS trial: As of October 26, 2023, 87 patients have been enrolled at 16 centers in this pivotal U.S. open label, randomized, controlled trial of imlifidase in kidney transplant. Despite an acceleration in the number of patients being randomized this summer following the initiation of more centers, the allocation of organs to patients on the study remain highly variable and difficult to predict. Randomization is expected to complete by mid 2024 with, a BLA submission expected in 2025.
- ANCA-associated vasculitis: An investigator-initiated single center, single arm study was launched in the first half 2023 by Charité Universitätsmedizin in Berlin. The study is targeting 10 patients with pulmonary haemorrhage due to severe ANCA-associated vasculitis. As of October 26, 2023, three patients have been treated with imlifidase.

Events after the closing period

- On October 9, 2023, Hansa announced first high-level results from the first-in-human trial for HNSA-5487. Data showed the molecule was safe and well tolerated with fast and complete depletion of immunoglobulin G (IgG) antibodies observed in all subjects with increasing doses.
- On October 17, 2023, Hansa announced results from the 5-year long-term study demonstrating 90% patient survival and 82% graft survival. 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.

Financial Summary

SEKm, unless otherwise stated – unaudited	Q3 2023	Q3 2022	9M 2023	9M 2022
Revenue	22.8	67.1	83.7	123.8
SG&A expenses	(111.7)	(83.5)	(344.5)	(254.2)
R&D expenses	(95.6)	(90.4)	(303.1)	(254.0)
Loss from operation	(202.2)	(139.5)	(613.0)	(442.3)
Loss for the period	(250.7)	(154.0)	(707.3)	(462.5)
Net cash used in operations	(193.8)	(128.7)	(582.7)	(392.6)
Cash and short-term investments	908.2	1,215.3	908.2	1,215.3
Shareholders' equity	(62.2)	344.8	(62.2)	344.8
EPS before and after dilution (SEK)	(4,78)	(3.45)	(13.49)	(10.39)
Number of outstanding shares	52,443,962	44,588,118	52,443,962	44,588,118
Weighted avg. number of shares before and after dilution	52,443,962	44,588,118	52,443,962	44,517,974
Number of employees at the end of the period	168	145	168	145

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

"Our commitment to creating paradigm shifts in clinical care resulting in significantly better patient outcomes remains strong. Ongoing progress with the commercialization of Idefirix continues, and our pipeline of drug candidates, underpinned by exciting science, is progressing steadily."

Søren Tulstrup
President and CEO, Hansa Biopharma

"Our commitment to creating paradigm shifts in clinical care resulting in significantly better patient outcomes remains strong. Ongoing progress with the commercialisation of Idefirix continues, and our pipeline of drug candidates, underpinned by exciting science, is progressing steadily.

We continue to see steady growth in the number of key transplant centers readied for utilisation of Idefirix and patients identified and waitlisted for desensitization across Europe. We are also encouraged by the fact that a growing number of transplant centers now have experience with Idefirix and that positive first outcomes have led to repeat usage in a number of hospitals. Idefirix is a disrupter in the kidney transplant and desensitization treatment ecosystem requiring significant changes in both transplant protocols and organ allocation systems. With this in mind, the adaptation of new approaches to care takes time. While, given the significant unmet need and the demonstrated ability of Idefirix to enable potentially lifesaving kidney transplants, we would like to see a faster uptake, we are pleased with the progress of the launch against key launch metrics and in particular seeing centers gain valuable clinical experience through both the commercially available product and the Post Approval Efficacy Study utilising imlifidase as a desensitization therapy for highly sensitized patients.

During the third quarter we have secured several new agreements with leading transplant centers in Europe and do expect this to translate into increased commercial sales in the coming period, supported by new markets such as U.K., Germany, and Belgium where patient identification is ongoing as organs become available.

On September 16-17 the European Society of Organ Transplantation (ESOT) hosted its annual International Transplant Congress in Athens. At the congress, a Hansa-sponsored symposium *"Crossing DSA Barriers to Transplant Today"* was attended by more than 600 members of the transplantation clinical community - validating the continued interest in Idefirix as a transformative desensitization therapy. The symposium featured KOLs from multiple centers with clinical experience utilizing Idefirix in kidney transplant patients. In some instances, the KOLs had transplanted multiple patients using Idefirix.

I am also pleased to see positive data from our 5-year long follow-up study further supporting the clinical benefit of imlidase in kidney transplantation. Data five years out demonstrate graft survival of 82%, which is in line with outcomes seen at 3-years post-transplant.

In the U.S. we continue to carry out key initiatives to accelerate randomization in the pivotal phase 3 trial, ConfIdeS, in kidney transplantation. Despite several new centers being activated in the last 4-6 months and an acceleration in the number of patients being randomized over the summer, the allocation of organs to patients on the study remain highly variable and difficult to predict. We are expecting randomization to complete by mid 2024 with a BLA submission expected in 2025.

In anti-GBM disease, we have recently seen good uptake in patient enrolment in the global pivotal phase 3 study, with nine patients enrolled out of a target of 50 patients, while our newly started investigator-initiated phase 2 study in ANCA-associated vasculitis now has three patients enrolled out of a target of ten patients.

We are also very pleased to report encouraging high-level data from the first-in-human trial for HNSA-5487, the lead candidate from our NiceR program focused on developing next generation IgG-cleaving enzymes. Results demonstrated the molecule was safe and well tolerated with fast and complete depletion of immunoglobulin G (IgG) antibodies observed at increasing doses in all subjects. These data are highly encouraging as we continue to explore the potential for our next generation enzymes and better understand how this powerful new enzyme could benefit patients with diseases where a prolonged IgG-free window is needed and where repeat dosing would be beneficial.

Further, I am happy to welcome Dr. Hitto Kaufmann as Hansa's new Chief Scientific Officer (CSO), effective December 1, 2023. Dr. Kaufmann brings more than 20 years' experience in R&D from both large pharma and small biotech.

Last, I want to highlight that Hansa Biopharma AB was recently certified as a Great Place to Work® for the fourth consecutive year. This certification reflects our successful efforts over the past years to not only build and maintain a high-performance team, but also to create a rewarding and stimulating workplace for our employees, enabling us to continue to attract and retain the very best people in the industry.

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 the coming period, as we continue our efforts to develop new, transformative medicines for patients suffering from serious, rare immunologic diseases.

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Continued pipeline progress

Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	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
	US: Kidney transplantation in highly sensitized patients[1,2]								Completion of randomization (64 patients) mid 2024
	Anti-GBM antibody disease[3]								Complete enrollment (50 patients)
	Antibody mediated rejection in kidney transplantation (AMR)								Full data read out H2 2023
	Guillain-Barré syndrome (GBS)								Topline data H2 2023 / Comparative efficacy analysis 2024
	ANCA-associated vasculitis[4]								Complete enrollment (10 patients)
	Pre-treatment ahead of gene therapy in Duchenne		Phase 1b					**Sarepta Therapeutics**	Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle							**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**	Preclinical research
HNSA-5487	Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)								Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication

Completed | Ongoing | Planned | Post approval study running in parallel with commercial launch

[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 Mårten Segelmark, Professor at the universities in Linköping and Lund, Sweden
[4] 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 for 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. The EU conditional approval was a landmark milestone for Hansa Biopharma, as Idefirix® is the Company's first approved drug.

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 Belgium in June. Commercial access has been obtained in 13 European countries, including the five largest markets. Additional market access procedures are ongoing in several other European countries, while Hansa and Medison Pharma have established a commercialization partnership covering select countries in Eastern Europe including the Baltics and Israel.

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, and the Netherlands. These guidelines provide a new clinical practice framework for healthcare professionals on a management pathway for highly sensitized patients.

In June a new Eurotransplant desensitization program was launched as a pilot. Eurotransplant 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 the program is initially targeting 20 imlifidase-eligible patients. The new program is set out to increase the likelihood for highly sensitized patients to access a suitable donor in the registry and an assessment is now ongoing for the first patients in the pilot program.

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.

U.S. Randomized Controlled Trial "ConfIdeS" (ClinicalTrials.gov ID: NCT04935177)

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 (i.e., waiting for a matched donor or subject for experimental treatment) at the time of organ offer.

Despite several new centers being activated recently and an acceleration in number of patients being randomized over summer, we are expecting randomization to complete mid 2024 with a BLA submission expected in 2025.

Long-term follow-up trial of kidney transplant patients (ClinicalTrials.gov ID: NCT04711850)

Beyond the four completed phase 2 studies in kidney transplantation, Hansa is 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 5-year 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*. Hansa is continuing to analyze the data from study along with the extended pooled analysis and plans to share further data in 2024.

Anti-Glomerular Basement Membrane (anti-GBM) disease (ClinicalTrials.gov ID: NCT03157037)

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 first patient was enrolled in a pivotal phase 3 trial with imlifidase in 50 anti-GBM patients to evaluate kidney function after six months. The anti-GBM 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.

As October 26, 2023, nine patients out of a target of 50 patients were enrolled in the anti-GBM study, while number of active sites expanded from 12 to 25 with the goal to include a total of approximately 40 sites across the U.S., U.K. and EU to further accelerate enrolment.

[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

Active Antibody Mediated Rejection (AMR) (ClinicalTrials.gov ID: NCT03897205)

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 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 November 28, 2022, Hansa announced topline data from the imlifidase phase 2 study in AMR post kidney transplantation 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 full data set is expected to be published in the fourth quarter of 2023.

Guillain-Barré Syndrome (GBS) (ClinicalTrials.gov ID: NCT03943589)

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).

The first high-level data read-out is expected in the fourth quarter of 2023, while the outcome of a comparative efficacy analysis matched to a cohort from the International GBS Outcome Study (IGOS) is expected in 2024.

ANCA-associated vasculitis (EudraCT Number: 2021-004706-22)

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 cells 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.

A total of 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 standard of care (consisting of standard immunosuppression as per center protocol and intensive support care).

As of October 26, 2023, three patients with severe ANCA-associated vasculitis have been enrolled.

DSA rebound in patients treated with imlifidase prior to transplantation (ClinicalTrials.gov ID: NCT05049850)

Non-clinical data suggest that a combination of bortezomib and belatacept can reduce the levels of DSA and the risk for AMR after incompatible kidney transplantation[9]. Based on these findings a new, single center study has been initiated to evaluate if a combination of bortezomib and belatacept can reduce the risk for AMR following desensitization with imlifidase. The study aims to include 12 patients to assess whether imlifidase, in combination with bortezomib, belatacept, rituximab and IVIg, can suppress DSA and the occurrence of AMR in highly sensitized crossmatch positive patients undergoing living donor transplantation. The study will be run by Vasishta Tatapudi, MD, Associate Professor and Program Director at the NYU Langone Transplant Institute.

HNSA-5487 - next generation enzymes

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.

Preclinical programs

Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD) & Duchenne Muscular Dystrophy (DMD) (partnered with Sarepta)

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.

Hansa Biopharma and Sarepta Therapeutics plan to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in the fourth quarter 2023.

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. For further information about Sarepta's programs please refer to www.sarepta.com.

[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.

[9] Kwun, J., Burghuber, C., Manook, M., Ezekian, B., Park, J., Yoon, J., Yi, J. S., Iwakoshi, N., Gibby, A., Hong, J. J., Farris, A. B., Kirk, A. D., & Knechtle, S. J. (2017). Successful desensitization with proteasome inhibition and costimulation blockade in sensitized nonhuman primates. Blood advances, 1(24), 2115–2119. https://doi.org/10.1182/bloodadvances.2017010991

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

On January 3, 2022, Hansa announced a collaboration agreement with AskBio (subsidiary of Bayer AG). The collaboration is 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 program for patients with pre-existing neutralizing antibodies against the adeno-associated viral vector used in AskBio's gene therapy.

Under terms of the agreement, Hansa received a USD 5 million upfront payment and AskBio has the exclusive option to negotiate a full development and commercialization agreement following evaluation of the results from an initial phase 1/2 study. The collaboration is currently at a preclinical stage. For further information regarding AskBio's programs please refer to www.askbio.com.

Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome (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.

Achieved and upcoming milestones

2023

9M 2023

- ✓ **U.S. ConfIdeS (Kidney tx) Phase 3:** Continued enrollment beyond 64 patients
- ✓ **Anti-GBM disease Phase 3:** First patient enrolled
- ✓ **GBS Phase 2:** Complete enrollment
- ✓ **ANCA-associated vasculitis Phase 2:** First patient enrolled
- ✓ **HNSA-5487 (Lead NiceR candidate):** Initiate Phase 1 study
- ✓ **Genethon Crigler-Najjar:** Initiate preclinical study with imlifidase prior to GNT-0003

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 the comparative efficacy analysis to IGOS data
- - **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

2025

- - **U.S. ConfIdeS (Kidney tx) Phase 3:** BLA submission

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Financial review January – September 2023

Revenue

Revenue for the third quarter of 2023 amounted to SEK 22.8m (Q3'22: SEK 67.1m) consisting of Idefirix® product sales of SEK 16.5m (Q3'22: SEK 22.7m) and contract revenue of SEK 6.3m (Q2'22: SEK 44.3m) mainly from the upfront payment the Company received under the Sarepta agreement.

Revenue for the first nine months of 2023 amounted to SEK 83.7m (nine months '22 SEK 123.8m) mainly comprising of Idefirix® product sales of SEK 60.4m (nine months '22: SEK 66.4m) and contract revenue of SEK 23.0m (nine months '22: SEK 56.8m) mainly from the upfront payment the Company received under the Sarepta agreement.

The change in revenue, both for Q3 as well as on a nine-month basis 2023 compared to 2022, is mainly driven by lower product sales and a non-recurring recognition of contract revenue in the amount of SEK 36.7m under the AskBio agreement in Q3-2022.

SG&A expenses

Sales, general and administrative expenses for the third quarter of 2023 amounted to SEK 111.7m (Q3'22: SEK 83.5m) and to SEK 344.5m for the first nine months of 2023 (nine months '22 SEK 254.2m). 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 28.7m for the first nine months of the year 2023 (nine months '22: SEK 33.5m).

R&D expenses

Research and development expenses for the third quarter of the year 2023 amounted to SEK 95.6m (Q3 '22: SEK 90.4m) and to SEK 303.1m for the first nine months 2023 (nine months '22: SEK 254.0m). The increase over the 2023 periods is mainly driven by the ongoing U.S. ConfIdeS study, progressing the EMA post-approval commitments, 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 12.5m for the first nine months of 2023 (nine months '22: SEK 16.2m).

Other operating income/expenses and financial expenses

Other operating income/expenses for the third quarter of 2023 amounted to an expense of SEK 1.0m (Q3 '22: expense of SEK 15.1m) and to SEK 4.0m for the first nine months of 2023 (nine months '22: SEK 24.0m). The decrease in expenses 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 expenses, net, for the third quarter of 2023, amounted to SEK 48.3m (Q3 '22: SEK 14.0m) and to SEK 93.6m for the first nine months of 2023 (nine months '22: SEK 19.5m). The increase as compared to 2022 periods is mainly driven by accrued interest related to Hansa's USD long-term loan as well as FX-effects related to that loan, partly offset by FX changes of USD bank deposits (see Note 4 below).

Financial results

The loss from operations for the third quarter of 2023 amounted to SEK 202.2m (Q3 '22: SEK 139.5m) and to SEK 613.0m for the first nine months 2023 (nine months '22: SEK 442.3m). 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 third quarter of 2023 amounted to SEK 250.7m (Q3'22: SEK 154.0m) and to SEK 707.3m for the first nine months of 2023 (nine months '22: SEK 462.5m).

Cash flow, cash and investments

Net cash used in operating activities for the third quarter of 2023 amounted to SEK 192.9m (Q3 '22: SEK 128.7m) and to SEK 582.7m for the first nine months 2023 (nine months '22: SEK 392.6m). The change as compared to the previous year periods 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 908.2m on September 30, 2023, as compared to SEK 1,215.3m end of Q3 2022. The change in Hansa's cash position as compared to September 30, 2022, is mainly driven by the equity financing of approximately USD 40m completed in December 2022 contributing SEK 396.2m in proceeds net of transaction cost and cash used in operations.

Parent Company

The parent company's revenue for the third quarter of 2023 amounted to SEK 22.8m (Q3 '22: SEK 67.1m) and to SEK 83.7m for the first nine months 2023 (nine months '22: SEK 123.8m).

Loss for the period for the parent company for the third quarter of 2023 amounted to SEK 286.9m (Q3'22: SEK 153.9m) and to SEK 448.4m for the first nine months of 2023 (nine months '22: SEK 463.3).

The parent company's shareholders' equity amounted to SEK 1,350.1m as of September 30, 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 at the time of this report. Hansa Biopharma Inc. had eleven employees at the end of September 2023. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had seven employees at the end of September 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 September 30, 2023, the Company incurred equity-based compensation expenses under the following programs: LTIP 2020, LTIP 2021 and LTIP 2022.

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
Maximum number of issuable shares*	654 576	1 260 042	1 222 390
Number of allocated and outstanding share rights and options	503 520	969 263	940 300
Number of acquired and outstanding warrants	-	-	-
Estimated total cost including social contributions, KSEK	72 414	45 255	63 944
Total cost per program, including social contributions, as of September 30, 2023 YTD, KSEK	21 180	5 899	14 136

*As of September 30, 2023, including issuable shares to cover estimated social contributions under the LTIP.

Total costs, including social contributions, as of September 30, 2023 YTD, KSEK	41 215

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 Biopharma'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 2023/2024

February 2, 2024	Full-year Report for January – December 2023
March 20, 2024	Annual Report 2023
April 17, 2024	Interim Report January – March 2024
July 17, 2024	Half-year Report January – June 2024
October 23, 2024	Interim Report for January – September 2024

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	55,034,241 (52,443,962 A-shares and 2,590,279 C-shares)
Market Cap September 30, 2023	SEK ~1.9bn (USD ~173m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of September 30, 2023

Name	Number of shares	Ownership in pct
Redmile Group, LLC	10,626,131	20.3%
Nexttobe AB	2,155,379	4.1%
Olausson, Thomas	1,917,000	3.7%
Fjärde AP-Fonden (AP 4)	1,900,000	3.6%
Försäkrings AB Avanza Pension	1,765,506	3.4%
Jeansson, Theodor	1,559,749	3.0%
Tredje AP-Fonden (AP 3)	1,389,650	2.6%
VOB & T Trading AB	644,800	1.2%
BWG Invest SARL	600,000	1.1%
Ålandsbanken Abp (Sweden)	552,249	1.1%
Other	29,333,498	55.9%
Total	52,443,962	100.0%

Source: IHS Markit/IPREO compiled and processed data from various sources, including Euroclear, Morningstar, Factset and the Swedish Financial Supervisory Authority (Finansinspektionen).

Hansa Biopharma had approximately 21,000 shareholders as of September 30, 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 been reviewed by the company's auditors.

Lund October 26, 2023

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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Condensed unaudited financial statements

Unaudited condensed consolidated statement of financial position

KSEK	Note	September 30 2023	September 30 2022	December 31 2022
ASSETS				
Non-current assets				
Intangible assets	5	117 504	26 665	46 866
Property and equipment		7 139	5 408	8 113
Leased assets		22 088	29 602	27 723
Total non-current assets		**146 731**	**61 675**	**82 702**
Current assets				
Inventories		3 120	957	973
Trade receivables & unbilled revenues		65 506	52 481	42 959
Current receivables, non-interest bearing		47 515	50 614	64 593
Cash and cash equivalents		908 176	1 215 282	1 496 179
Total current assets		**1 024 317**	**1 319 334**	**1 604 704**
TOTAL ASSETS		**1 171 048**	**1 381 009**	**1 687 406**
EQUITY AND LIABILITIES				
Shareholders' equity		**(62 207)**	**344 823**	**602 912**
Non-current liabilities				
Long-term loan	4	906 675	760 792	762 601
Deferred tax liabilities		407	403	405
Provisions		5 117	6 560	5 192
Lease liabilities		15 837	23 141	21 326
Deferred revenue		7 601	39 130	29 500
Contingent consideration	3	887	717	757
Total non-current liabilities		**936 524**	**830 743**	**819 781**
Current liabilities				
Tax liability		1 412	-	604
Lease liabilities		7 304	7 083	7 165
Current liabilities, non-interest bearing		67 862	49 103	80 754
Deferred revenue		45 206	42 713	40 430
Refund liabilities		52 726	17 459	27 013
Accrued expenses and deferred income		122 221	89 085	108 747
Total current liabilities		**296 731**	**205 443**	**264 713**
TOTAL EQUITY AND LIABILITIES		**1 171 048**	**1 381 009**	**1 687 406**

Unaudited condensed consolidated income statement

KSEK	Note	Q3 2023	Q3 2022	January-September 2023	January-September 2022
Revenue	2	22 837	67 083	83 683	123 759
Cost of revenue		(16 656)	(17 633)	(45 017)	(33 942)
Sales, general and administration expenses		(111 738)	(83 479)	(344 500)	(254 169)
Research and development expenses	5	(95 554)	(90 378)	(303 081)	(253 969)
Other operating income/expenses, net		(1 045)	(15 083)	(4 040)	(24 023)
Loss from operations		**(202 156)**	**(139 490)**	**(612 955)**	**(442 344)**
Financial income/expenses, net	4	(48 283)	(13 966)	(93 612)	(19 477)
Loss for the period before tax		**(250 439)**	**(153 456)**	**(706 567)**	**(461 821)**
Tax		(219)	(495)	(694)	(639)
Loss for the period		**(250 658)**	**(153 951)**	**(707 261)**	**(462 460)**
Attributable to:					
Parent company shareholders		(250 658)	(153 951)	(707 261)	(462 460)
Earnings per share (EPS)					
Before dilution (SEK)		(4,78)	(3,45)	(13,49)	(10,39)
After dilution (SEK)		(4,78)	(3,45)	(13,49)	(10,39)
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the period					
Translation differences		386	45	875	264
Other comprehensive income for the period		386	45	875	264
Total net comprehensive income		**(250 272)**	**(153 906)**	**(706 386)**	**(462 196)**

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Unaudited condensed consolidated statements of changes in shareholder's equity

	January-September		Year
KSEK	2023	2022	2022
Opening balance of shareholders' equity as reported	**602,912**	**757,573**	**757,573**
Result for the period	(707,261)	(462,460)	(611,134)
Other comprehensive income for the period	875	264	(114)
Net comprehensive income	**(706,386)**	**(462,196)**	**(611,248)**
Transactions with the group's owner			
Proceeds from new share issuance, net [1]	-	-	396,196
Long term incentive programs	41,267	49,444	60,391
Total transactions with the group's owner	**41,267**	**49,444**	**456,587**
Closing balance of shareholders' equity	**(62,207)**	**344,823**	**602,912**

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

Unaudited condensed consolidated statement of cash flow

	Q3		January-September	
KSEK	2023	2022	2023	2022
Cash Flows from Operating Activities				
Loss for the period	(250 658)	(153 951)	(707 261)	(462 460)
Adjustment for items not included in cash flow [1]	49 815	52 652	115 062	90 261
Interest received and paid, net	(243)	(222)	143	(217)
Income taxes paid	(90)	(699)	(112)	(699)
Cash flow from operations before change in working capital	**(201 176)**	**(102 220)**	**(592 168)**	**(373 115)**
Changes in operating related assets and liabilities	8 308	(26 521)	9 459	(19 521)
Net cash used in operating activities	**(192 868)**	**(128 741)**	**(582 709)**	**(392 636)**
Investing activities				
Proceeds from sale of short-term investments	-	99 791	-	232 644
Acquisition of property and equipment	-	-	(689)	(140)
Cash flow from investing activities	**-**	**99 791**	**(689)**	**232 504**
Financing activities				
Proceeds from the sale of treasury shares [2]	-	-	-	-
Proceeds long-term loan, net of transaction cost [2]	-	736 400	-	736 400
Proceeds from new share issue, net of transaction cost [3]	-	(8 027)	-	(8 027)
Repayment of lease liabilities	(1 799)	(1 718)	(5 350)	(5 154)
Cash flow from financing activities	**(1 799)**	**726 655**	**(5 350)**	**723 219**
Net change in cash	(194 667)	697 705	(588 748)	563 087
Cash and cash equivalents, beginning of period	1 102 514	517 203	1 496 179	651 342
Currency exchange variance, cash and cash equivalents	329	375	745	853
Cash and cash equivalents, end of period	**908 176**	**1 215 282**	**908 176**	**1 215 282**

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.

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Parent company – Unaudited condensed statement of financial position

KSEK	Note	September 30 2023	September 30 2022	December 31 2022
ASSETS				
Non-current assets				
Intangible assets	5,6	1 515 545	24 528	44 718
Property, plant and equipment		7 139	5 408	8 113
Leased assets		22 088	29 602	27 723
Investment in subsidiaries		27 820	5 095	24 264
Receivables, group companies		-	2 588	-
Total non-current assets		**1 572 592**	**67 221**	**104 818**
Current assets				
Inventories		3 120	957	973
Trade receivables & unbilled revenue		65 506	52 481	42 959
Current receivables, non-interest bearing		47 164	50 327	64 368
Short-term investments	3	-	-	-
Cash and cash equivalents		893 729	1 206 273	1 486 502
Total current assets		**1 009 519**	**1 310 039**	**1 594 802**
TOTAL ASSETS		**2 582 111**	**1 377 260**	**1 699 620**
EQUITY AND LIABILITIES				
Shareholders' equity	6	**1 350 137**	**342 132**	**615 799**
Non-current liabilities				
Long-term loan	4	906 675	760 792	762 601
Provisions		5 118	6 560	5 192
Lease liabilities		15 837	23 141	21 326
Deferred revenue		7 601	39 130	29 500
Contingent consideration	3	887	717	757
Total non-current liabilities		**936 118**	**830 341**	**819 376**
Current liabilities				
Tax liability		1 164	-	604
Lease liabilities		7 304	7 083	7 165
Liabilities, group companies		7 860	3 620	5 738
Current liabilities, non-interest bearing		67 514	48 433	80 225
Deferred revenue		45 205	42 713	40 430
Refund liabilities		52 726	17 459	27 013
Accrued expenses and deferred income		114 083	85 479	103 270
Total current liabilities		**295 856**	**204 787**	**264 445**
TOTAL EQUITY AND LIABILITIES		**2 582 111**	**1 377 260**	**1 699 620**

Parent company – Unaudited condensed income statement

KSEK	Note	Q3 2023	Q3 2022	January-September 2023	January-September 2022
Revenue	2	22 837	67 083	83 683	123 759
Cost of revenue		(46 448)	(17 633)	(74 809)	(33 942)
Sales, general and administration expenses		(112 836)	(83 338)	(344 192)	(254 138)
Research and development expenses	5	(94 856)	(90 930)	(303 370)	(255 447)
Other operating expenses/income, net		(1 043)	(15 081)	(4 039)	(24 020)
Loss from operations		**(232 346)**	**(139 899)**	**(642 727)**	**(443 788)**
Result from financial items:					
Finance income		3 251	2 738	9 178	2 738
Finance costs	4	(51 534)	(16 707)	(102 790)	(22 210)
Loss for the period before tax		**(280 629)**	**(153 868)**	**(736 339)**	**(463 260)**
Income tax benefit/expense	6	(6 302)	-	287 900	-
Loss for the period		**(286 931)**	**(153 868)**	**(448 439)**	**(463 260)**
Other comprehensive income for the period		-	-	-	-
Total comprehensive income for the period		**(286 931)**	**(153 868)**	**(448 439)**	**(463 260)**

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

KSEK	Note	January-September 2023	January-September 2022	Year 2022
Opening balance of shareholders' equity as reported		**615 799**	**755 948**	**755 948**
Result for the period		(448 439)	(463 260)	(596 735)
Other comprehensive income for the period		-	-	-
Net comprehensive income		**(448 439)**	**(463 260)**	**(596 735)**
IP Write up	6	1 430 000	-	-
IP Write up - Deferred tax liability	6	(288 443)	-	-
Proceeds from new share issuance, net [1]		-	-	396 196
Long term incentive programs		41 220	49 444	60 391
Total transactions with the group's owner		**1 182 777**	**49 444**	**456 587**
Closing balance of shareholders' equity		**1 350 137**	**342 132**	**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	Q3		January-September	
KSEK	2023	2022	2023	2022
Group				
Revenue				
Product sales	16 493	22 703	60 375	66 398
Contract revenue, Axis-Shield agreement	643	572	1 931	1 716
Cost reimbursement, Axis-Shield agreement	-	88	286	538
Contract revenue, Sarepta, AskBio agreement	5 701	43 720	21 091	55 107
	22 837	**67 083**	**83 683**	**123 759**
Parent Company				
Revenue				
Product sales	16 493	22 703	60 375	66 398
Contract revenue, Axis-Shield agreement	643	572	1 931	1 716
Cost reimbursement, Axis-Shield agreement	-	88	286	538
Contract revenue, Sarepta, AskBio agreement	5 701	43 720	21 091	55 107
	22 837	**67 083**	**83 683**	**123 759**

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 September 30, 2023 amounted to SEK 0.9 million (Q3 '22: SEK 0.7 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 30 September 2023, the loan amounted to SEK 906.7 million, thereof SEK 134.0 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 Q3-2023.

During the first nine months of 2023 and 2022 the Company capitalized development cost related to performing its Idefirix® EMA post-approval commitments in the amount of SEK 76.8 million and SEK 0.0 million, respectively.

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 295.0 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 295 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 September 30, 2023 the Company in its statutory financial statements recorded an amortisation expense of SEK 29.8 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 6.1 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.