Interim report

January – June 2023

HANSA BIOPHARMA

Solid product sales in Q2 2023; Collaboration announced in gene therapy with Genethon in Crigler-Najjar syndrome; New Eurotransplant desensitization program implemented in June; First patient treated in new investigator-initiated Phase 2 study in ANCA-associated vasculitis

Business highlights for the second quarter of 2023

- Total Q2 revenue of SEK 36.7m consisting of SEK 29.6m in product sales and SEK 7.1m in revenue recognition mainly under the agreement with Sarepta.
- Positive reimbursement decision received in Belgium bringing access to Idefirix to a total of 13 European markets.
- Medical guidelines and recommendations including use of Idefirix® implemented on a national level in U.K., Finland, France, Belgium and the Netherlands.
- New Eurotransplant desensitization program launched as a pilot in June 2023 initially targeting 20 imlifidase-eligible patients under the Acceptable Mismatch Program.
- Hansa and Genethon entered collaboration to develop imlifidase as pre-treatment to gene therapy in Crigler-Najjar syndrome.
- Pre-clinical data in non-human primates presented at ASGCT conference confirms ability of imlifidase to remove antibodies against AAVrh74 and supports the upcoming clinical study combining imlifidase with SRP-9001.
- First patient enrolled in an investigator-initiated phase 2 trial of 10 patients with imlifidase in ANCA-associated vasculitis at Charité - Universitätsmedizin Berlin.

Clinical pipeline update

- U.S. ConfIdeS: As of July 19, 2023, 76 patients have been enrolled at fourteen sites. Hansa will continue to enroll and add additional centers up to a total of approximately 20 in order to accelerate the randomization of 64 patients.
- Guillain-Barré Syndrome (GBS): First high-level data read-out expected H2 2023. Results of a comparative efficacy analysis matched to a cohort from the International GBS Outcome Study (IGOS) expected in 2024.

Clinical pipeline continued

- Anti-GBM disease: As of July 19, four patients have been enrolled in a pivotal phase 3 trial. The study targets 50 patients with anti-GBM disease across 30-40 sites in the U.S., U.K., and EU.
- HNSA 5487: Enrollment in the phase 1 study in healthy volunteers is completed. Once the Phase 1 data has been analyzed, we will decide on next steps for further clinical development.

Events after reporting period

- On July 11, 2023, Idefirix received provisional approval in Australia as desensitization treatment in highly sensitized patients prior to kidney transplantation from both living and deceased donors. The provisional approval has a duration of two years and was based on data from Hansa's phase 2 studies.

Financial Summary

SEKm, unless otherwise stated – unaudited	Q2 2023	Q2 2022	H1 2023	H1 2022
Revenue	36.7	26.4	60.8	56.7
SG&A expenses	(129.5)	(90.3)	(232.8)	(170.7)
R&D expenses	(114.7)	(92.7)	(207.5)	(163.6)
Loss from operation	(228.5)	(167.8)	(410.8)	(302.9)
Loss for the period	(251.2)	(170.1)	(456.6)	(308.5)
Net cash used in operation	(182.0)	(135.6)	(388.9)	(266.1)
Cash and short-term investments	1,102.5	616.5	1,102.5	616.5
EPS before and after dilution (SEK)	(4.79)	(3.82)	(8.71)	(6.94)
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	44,491,093	52,443,962	44,482,321
Number of employees at the end of the period	162	145	162	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

"I am pleased with the solid performance in the second quarter. The launch of Idefirix® in Europe continues to track well against the key launch metrics, and we have also seen good progress in our efforts to advance a valuable pipeline of drug candidates in all our four priority therapy areas."

Søren Tulstrup
President and CEO, Hansa Biopharma

"I am pleased with the solid performance in the second quarter. The launch of Idefirix® in Europe continues to track well against the key launch metrics, and we have also seen good progress in our efforts to advance a valuable pipeline of drug candidates in all our four priority therapy areas.

Our progress this quarter is underscored by encouraging changes in the transplantation clinical community, including implementation of national medical guidelines in key European markets and a new desensitization program by Eurotransplant targeting Idefirix®-eligible patients. The ongoing evolution of the transplantation ecosystem reflects the important role Idefirix® is playing in advancing transplantation care and potentially helping even more kidney transplant patients.

During the last 15 months, we have received, positive reimbursement decisions in several key markets. In June, we secured positive reimbursement in Belgium where more than 1,100 patients are waiting for a kidney transplant and approximately one in ten are classified as highly sensitized, with limited or no access to a suitable donor organ.

In April, we announced an important collaboration with Genethon to develop imlifidase as pre-treatment to gene therapy in Crigler-Najjar syndrome patients with anti-AAV antibodies. Genethon is a pioneer in research and development of gene therapies for rare diseases. This research collaboration further validates our commitment in gene therapy and in advancing the science in rare disease to bring better medical care options to patients with unmet medical need.

Additionally, during this year's American Society of Gene and Cell Therapy Conference, our partner Sarepta presented data in non-human primates confirming the ability of imlifidase to remove antibodies against AAVrh74. This supports the upcoming clinical study combining imlifidase with Sarepta's product, Elevidys (SRP-9001), which received U.S. FDA approval in June 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 have too high titers of neutralizing antibodies against AAVrh74.

We also continue to drive progress across the early and late-stage pipelines. In the U.S, we will continue enrolment of patients in the pivotal ConfIdeS trial in kidney transplantation. As previously guided, we expect to complete randomization in the second half of 2023. As of July 19, 2023, 76 patients were enrolled at fourteen sites, and we continue to add centers with a goal of approximately 20 in order to accelerate the randomization of 64 patients.

In anti-GBM disease, we have enrolled four patients as of July 19, 2023, in the global pivotal phase 3 study. The study will enroll 50 patients across 30-40 centers in the U.S., U.K., and EU.

We are also happy to report that we successfully completed enrollment of healthy volunteers in a phase 1 study for HNSA-5487, our lead molecule from the second-generation IgG antibody cleaving enzyme program, NiceR. HNSA-5487 may represent an opportunity to substantially expand the number of potential indications for our antibody-cleaving enzyme platform, including in areas where more than one dose of an IgG-modulating enzyme is beneficial. Data is being evaluated to determine relevant indications to pursue in clinical development.

Beyond our exciting programs we are very excited to announce the first patient treated with imlifidase in an investigator-initiated phase 2 trial in ANCA-associated vasculitis to assess efficacy and safety of imlifidase together with standard of care in the treatment of patients with pulmonary haemorrhage due to severe ANCA-associated vasculitis. The trial is a single center, single arm study in 10 patients led by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité - Universitätsmedizin Berlin. This is an important step in advancing the science around ANCA-associated vasculitis as there are very few treatment options that can achieve rapid control of disease activity.

Lastly, we applaud the decision from the Australian Therapeutic Goods Administration (TGA) for being the first regulatory body to approve the use of Idefirix in transplants from both living and deceased donors, thus ensuring comprehensive access for highly sensitized patients in Australia to this important therapy.

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

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Continued pipeline progress

Candidate/ Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	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) H2 2023
	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 (Partnered with Sarepta)		Phase 1b					Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)							Preclinical research
	Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome (Partnered with Genethon)							Preclinical research
HNSA-5487	Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)							Completion of phase 1 (H2 2023)

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, guidelines are being implemented on a national level in a number of 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 acts as a mediator between donor hospitals and transplant centers across eight counties including Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, and Slovenia. The new desensitization program will initially be targeting 20 imlifidase-eligible patients under the Acceptable Mismatch 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)

On December 29, 2021, Hansa announced the first patient in the pivotal U.S. open label, randomized, controlled trial, "ConfIdeS," was enrolled at the Columbia University Medical Center in New York. 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.

As of July 19, 2023, 76 patients have been enrolled/consented at fourteen sites in our pivotal U.S. open label, randomized, controlled trial of imlifidase in kidney transplant. Hansa will continue the enrollment and add additional centers up to a total of approximately 20 to accelerate randomization. Completion of randomization is anticipated in the second half of 2023.

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.

The three-year follow-up data in highly sensitized kidney transplant patients demonstrates graft survival of 84 percent after imlifidase treatment and transplantation and a mean eGFR of 55 mL/min/1.73 m2 (61 ml/min/m2 for those without AMR). Data is in line with expectations in imlifidase treated transplant patients compared to outcomes in patients undergoing HLA-incompatible transplantation. For a subgroup of 13 patients with cPRA of ≥ 99.9 percent, graft survival was 92 percent and data showed improved kidney function for patients with a mean eGFR at 60ml/min/1.73 m2, after year three. The three-year data from the follow-up study was published in the *American Journal of Transplantation* in July 2021. The next read-out, five-year data, is expected in the second half 2023.

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. The publication recognized the significance of the study in autoimmune diseases as it suggested that deactivation of autoantibodies could alter the course of an autoimmune disease, allowing restoration of kidney function.

As of July 19, 2023, the first four patients have been enrolled in our pivotal phase 3 study in anti-GBM disease. The study targets 50 patients with anti-GBM disease across the U.S., U.K. and EU. Twelve sites are currently active and open for enrollment.

[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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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 second half 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 second half 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).

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.

The lead program HNSA-5487 is progressing according to plan and enrollment in the phase I study in healthy volunteers is completed. Data analysis is underway to evaluate relevant indications to pursue in clinical development.

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.

On November 2, 2022, Hansa Biopharma and Sarepta Therapeutics announced plans to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in 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 regarding Sarepta's gene therapy programs in DMD and LGMD, 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

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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 gene therapy programs in Pompe disease, 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

H1 2023

- ✓ **U.S. ConfIdeS (Kidney tx) Phase 3:** Complete enrollment
- ✓ **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

H2 2023

- **U.S. ConfIdeS (Kidney tx) Phase 3:** Complete randomization
- **GBS Phase 2:** First data readout
- **AMR Phase 2:** Full data readout
- **Long-term follow-up (Kidney tx):** 5-year data readout
- **Sarepta DMD pre-treatment Phase 1b:** Commence clinical study
- **HNSA-5487 (Lead NiceR candidate):** Completion of Phase 1 study

2024

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

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Financial review January – June 2023

Revenue

Revenue for the second quarter of 2023 amounted to SEK 36.7m (Q2'22: SEK 26.4m) consisting of Idefirix® product sales of SEK 29.6m (Q2'22: SEK 19.5m) and contract revenue of SEK 7.1m (Q2'22: SEK 6.9m) mainly from the upfront payment the Company received under the Sarepta agreement.

Revenue for the first HY 2023 amounted to SEK 60.8m (H1'22 SEK 56.7m) mainly comprising of Idefirix® product sales of SEK 43.9mm H1'22: SEK 43.7m) and contract revenue of SEK 17.0m (H1'22: SEK 13.0m) mainly from the upfront payment the Company received under the Sarepta agreement.

SG&A expenses

Sales, general and administrative expenses for the second quarter of 2023 amounted to SEK 129.5m (Q2'22: SEK 90.3m) and to SEK 232.8m for the first half of 2023 (H1'22 SEK 170.7m). 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 24.1m for the first half of the year 2023 (H1'22: SEK 21.2m).

R&D expenses

Research and development expenses for the second quarter of the year 2023 amounted to SEK 114.7m (Q2 '22: SEK 92.7m) and to SEK 207.5m for the first HY 2023 (H1'22 SEK 163.6m). The increase over the 2023 period is mainly driven by the ongoing U.S. ConfIdeS study, progressing the EMA post-approval commitments, the initiation of the anti-GBM phase 3 program as well as the clinical program 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 11.3m for the first half of the year 2023 (H1 '22: SEK 10.3m).

Other operating income/expenses and financial expenses

Other operating income/expenses for the second quarter of 2023 amounted to an expense of SEK 2.2m (Q2 '22: expense of SEK 6.2m) and to SEK 3.0m for the first half-year of 2023 (H1'22 SEK 8.9m). The decrease in expenses is mainly driven by 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 second quarter of 2023, amounted to SEK 22.6m (Q2 '22: SEK 2.2m) and to SEK 45.3m for the first half of 2023 (H1'22: 5.5m). The increase as compared to 2022 periods is mainly driven by accrued interest related to Hansa's long-term loan, partly offset by FX changes of USD bank deposits (see Note 4 below).

Financial results

The loss from operations for the second quarter of 2023 amounted to SEK 228.5m (Q2 '22: SEK 167.8m) and to SEK 410.8m for the first HY 2023 (H1'22 SEK 302.9m). 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 second quarter of 2023 amounted to SEK 251.2m (Q2'22: SEK 170.1m) and to SEK 456.6m for the first half of 2023 (H1'22 SEK 308.5m).

Cash flow, cash and investments

Net cash used in operating activities for the second quarter of 2023 amounted to SEK 182.0m (Q2 '22: SEK 135.6m) and to SEK 388.9 for the first HY 2023 (H1'22 SEK 266.1m). 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, including short-term investments, amounted to SEK 1,102.5m on June 30, 2023, as compared to SEK 616.5m end of Q2 2022. The increase in Hansa's cash position is mainly driven by its non-dilutive debt-financing of USD 70m completed in July 2022 and the equity financing of approximately USD 40m completed in December 2022 which together contributed SEK 1,124.6m in proceeds net of transaction cost, partly off-set by cash used in operations.

Parent Company

The parent company's revenue for the second quarter of 2023 amounted to SEK 36.7m (Q2 '22: SEK 26.4m) and to SEK 60.8m for the first HY 2023 (H1'22: 56.7m).

Loss for the period for the parent company for the second quarter of 2023 amounted to SEK 228.0m (Q2'22: SEK 168.4m) and to SEK 410.4m for the first half of 2023 (H1'22: 303.9).

The parent company's shareholders' equity amounted to SEK 1,625.1m as of June 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 billion 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. and Hansa Biopharma Australia PTY LTD. Hansa Biopharma Inc. had ten employees at the end of June 2023. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had six employees at the end of June 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 June 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*	1 151 580	1 275 642	1 400 389
Number of allocated and outstanding share rights and options	885 831	981 263	910 194
Number of acquired and outstanding warrants	-	-	-
Estimated total cost including social contributions, KSEK	93 829	54 767	66 992
Total cost per program, including social contributions, as of June 30, 2023 YTD, KSEK	16 022	8 733	10 630

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

Total costs, including social contributions, as of June 30, 2023 YTD, KSEK	35 385

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

October 18, 2023	Interim Report for January - September 2023
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 June 30, 2023	SEK ~2.4bn (USD ~228m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of June 30, 2023

Name	Number of shares	Ownership in pct
Redmile Group, LLC	10,626,131	20.3%
Försäkrings AB Avanza Pension	2,382,092	4.5%
Fjärde AP-Fonden (AP 4)	2,207,397	4.2%
Nexttobe AB	2,155,379	4.1%
Olausson, Thomas	1,917,000	3.7%
Tredje AP-Fonden (AP 3)	1,389,650	2.6%
Handelsbanken Asset Management	879,183	1.7%
Jeansson, Theodor	860,000	1.6%
C WorldWide Asset Management	799,749	1.5%
VOB & T Trading AB	644,800	1.2%
Other	28,582,581	54.6%
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 20,000 shareholders as of June 30, 2023.

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Assurance

The Board of Directors and the CEO affirm that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and give a fair view of the group's financial position and results. The interim report has been prepared in accordance with generally accepted accounting principles for the group and the parent company and gives a fair overview of the development of the group's and the parent company's operations, financial positions, and results. This Report has not been reviewed by the company's auditors.

Lund July 20, 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

Consolidated statement of financial position

KSEK	Note	June 30 2023	June 30 2022	December 31 2022
ASSETS				
Non-current assets				
Intangible assets	5	95 938	27 400	46 866
Property and equipment		7 666	5 797	8 113
Leased assets		23 966	31 476	27 723
Total non-current assets		**127 570**	**64 673**	**82 702**
Current assets				
Inventories		2 501	377	973
Trade receivables & unbilled revenues		70 557	55 590	42 959
Current receivables, non-interest bearing		59 381	47 817	64 593
Short-term investments	3	-	99 269	-
Cash and cash equivalents		1 102 514	517 203	1 496 179
Total current assets		**1 234 953**	**720 256**	**1 604 704**
TOTAL ASSETS		**1 362 523**	**784 929**	**1 687 406**
EQUITY AND LIABILITIES				
Shareholders' equity		182 183	481 999	602 912
Non-current liabilities				
Long-term loan	4	840 908	-	762 601
Deferred tax liabilities		418	418	405
Provisions		5 531	5 053	5 192
Lease liabilities		17 683	24 940	21 326
Deferred revenue		13 347	40 124	29 500
Contingent consideration	3	862	781	757
Total non-current liabilities		**878 749**	**71 316**	**819 781**
Current liabilities				
Tax liability		981	-	604
Lease liabilities		7 257	7 003	7 165
Current liabilities, non-interest bearing		57 267	54 960	80 754
Deferred revenue		42 955	79 000	40 430
Refund liabilities		47 907	12 124	27 013
Accrued expenses and deferred income		145 224	78 527	108 747
Total current liabilities		**301 591**	**231 614**	**264 713**
TOTAL EQUITY AND LIABILITIES		**1 362 523**	**784 929**	**1 687 406**

Consolidated income statement

KSEK	Note	Q2 2023	Q2 2022	H1 2023	H1 2022
Revenue	2	36 652	26 396	60 846	56 676
Cost of revenue		(18 715)	(5 075)	(28 361)	(16 309)
Sales, general and administration expenses		(129 470)	(90 306)	(232 762)	(170 690)
Research and development expenses	5	(114 736)	(92 684)	(207 527)	(163 591)
Other operating income (expenses)		(2 182)	(6 162)	(2 995)	(8 940)
Loss from operations		**(228 451)**	**(167 831)**	**(410 799)**	**(302 854)**
Financial income (expenses), net	4	(22 612)	(2 154)	(45 329)	(5 511)
Loss for the period before tax		**(251 063)**	**(169 985)**	**(456 128)**	**(308 365)**
Tax		(119)	(87)	(475)	(144)
Loss for the period		**(251 182)**	**(170 072)**	**(456 603)**	**(308 509)**
Attributable to:					
Parent company shareholders		(251 182)	(170 072)	(456 603)	(308 509)
Earnings per share (EPS)					
Before dilution (SEK)		(4,79)	(3,82)	(8,71)	(6,94)
After dilution (SEK)		(4,79)	(3,82)	(8,71)	(6,94)
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the period					
Translation differences		439	96	489	219
Other comprehensive income for the period		**439**	**96**	**489**	**219**
Total net comprehensive income		**(250 743)**	**(169 976)**	**(456 114)**	**(308 290)**

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Consolidated statements of changes in shareholder's equity

KSEK	January-June 2023	January-June 2022	Year 2022
Opening balance of shareholders' equity as reported	**602 912**	**757 573**	**757 573**
Result for the period	(456 603)	(308 509)	(611 134)
Other comprehensive income for the period	489	219	(114)
Net comprehensive income	**(456 114)**	**(308 290)**	**(611 248)**
Transactions with the group's owner			
Proceeds from new share issuance, net [1]	-	-	396 196
Long term incentive programs	35 385	32 714	60 391
Total transactions with the group's owner	**35 385**	**32 714**	**456 587**
Closing balance of shareholders' equity	**182 183**	**481 999**	**602 912**

1) Total share issue cost amounted to SEK 19,754k

Consolidated statement of cash flow

KSEK	Q2 2023	Q2 2022	H1 2023	H1 2022
Cash Flows from Operating Activities				
Loss for the period	(251 182)	(170 072)	(456 603)	(308 509)
Adjustment for items not included in cash flow [1]	41 580	19 322	70 727	37 609
Interest received and paid, net	3 566	344	5 927	5
Income taxes paid	(140)	-	(496)	-
Cash flow from operations before change in working capital	**(206 176)**	**(150 406)**	**(380 445)**	**(270 894)**
Changes in operating related assets and liabilities	24 196	14 784	(8 495)	4 759
Net cash used in operating activities	**(181 980)**	**(135 622)**	**(388 940)**	**(266 135)**
Investing activities				
Proceeds from sale of short-term investments	-	132 853	-	132 853
Acquisition of property and equipment	(155)	-	(689)	(140)
Cash flow from investing activities	**(155)**	**132 853**	**(689)**	**132 713**
Financing activities				
Proceeds from the sale of treasury shares [2]	-	2 243	-	2 243
Repayment of lease liabilities	(1 783)	(1 733)	(3 551)	(3 436)
Cash flow from financing activities	**(1 783)**	**510**	**(3 551)**	**(1 193)**
Net change in cash	(183 918)	(2 259)	(393 180)	(134 617)
Cash and cash equivalents, beginning of period	1 286 819	519 136	1 496 179	651 342
Currency exchange variance, cash and cash equivalents	(387)	327	(485)	478
Cash and cash equivalents, end of period	**1 102 514**	**517 203**	**1 102 514**	**517 203**

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 – Statement of financial position

KSEK	Note	June 30 2023	June 30 2022	Year 2022
ASSETS				
Non-current assets				
Intangible assets	5,6	1 523 720	25 191	44 718
Property, plant and equipment		7 666	5 797	8 113
Leased assets		23 966	31 476	27 723
Investment in subsidiaries		27 107	5 095	24 264
Receivables, group companies		-	2 446	-
Total non-current assets		**1 582 459**	**70 005**	**104 818**
Current assets				
Inventories		2 501	377	973
Trade receivables & unbilled revenue		70 557	58 280	42 959
Current receivables, non-interest bearing		59 059	47 491	64 368
Short-term investments	3	-	99 269	-
Cash and cash equivalents		1 086 007	508 978	1 486 502
Total current assets		**1 218 124**	**714 396**	**1 594 802**
TOTAL ASSETS		**2 800 583**	**784 401**	**1 699 620**
EQUITY AND LIABILITIES				
Shareholders' equity	6	**1 625 097**	**479 269**	**615 799**
Non-current liabilities				
Long-term loan	4	840 908	-	762 601
Provisions		5 531	5 053	5 192
Lease liabilities		17 683	24 940	21 326
Deferred revenue		13 347	40 124	29 500
Contingent consideration	3	862	781	757
Total non-current liabilities		**878 331**	**70 899**	**819 376**
Current liabilities				
Tax liability		981	-	604
Lease liabilities		7 256	7 003	7 165
Liabilities, group companies		2 086	3 275	5 738
Current liabilities, non-interest bearing		56 841	54 184	80 225
Deferred revenue		42 955	79 000	40 430
Refund liabilities		47 907	14 814	27 013
Accrued expenses and deferred income		139 129	75 957	103 270
Total current liabilities		**297 155**	**234 233**	**264 445**
TOTAL EQUITY AND LIABILITIES		**2 800 583**	**784 401**	**1 699 620**

Parent company – Income statement

KSEK	Note	Q2 2023	Q2 2022	H1 2023	H1 2022
Revenue	2	36 652	26 396	60 846	56 676
Cost of revenue		(18 715)	(5 075)	(28 361)	(16 309)
Sales, general and administration expenses		(128 196)	(90 347)	(231 356)	(170 800)
Research and development expenses	5	(115 578)	(93 227)	(208 514)	(164 517)
Other operating income (expenses)		(2 183)	(6 162)	(2 996)	(8 939)
Loss from operations		**(228 019)**	**(168 415)**	**(410 381)**	**(303 889)**
Result from financial items:					
Finance income		3 253	-	5 927	-
Finance costs	4	(25 859)	(2 146)	(51 256)	(5 503)
Loss for the period before tax		**(250 625)**	**(170 561)**	**(455 710)**	**(309 392)**
Income tax benefit/expense	6	294 384	-	294 202	-
Loss for the period		43 759	(170 561)	(161 508)	(309 392)
Other comprehensive income for the period		-	-	-	-
Total comprehensive income for the period		**43 759**	**(170 561)**	**(161 508)**	**(309 392)**

Parent company – Statement of changes in shareholders' equity

KSEK	Note	Q2 2023	Q2 2022	Year 2022
Opening shareholders' equity as reported		**615 799**	**755 948**	**755 948**
Result for the period		**(161 508)**	**(309 392)**	**(596 735)**
Other comprehensive income for the period		-	-	-
Net comprehensive income		**(161 508)**	**(309 392)**	**(596 735)**
IP Write up	6	1 430 000	-	-
IP Write up - Deferred tax liability	6	(294 580)	-	-
Proceeds from new share issuance, net [1]		-	-	396 196
Long term incentive programs		35 385	32 714	60 391
Total transactions with the group's owner		**1 170 806**	**32 714**	**456 587**
Closing shareholders' equity		**1 625 097**	**479 269**	**615 799**

1) Total share issue cost amounted to SEK 19,754k

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	Q2		January-June	
KSEK	2023	2022	2023	2022
Group				
Revenue				
Product sales	29 576	19 458	43 882	43 695
Contract revenue, Axis-Shield agreement	644	763	1 288	1 144
Cost reimbursement, Axis-Shield agreement	-	-	286	450
Contract revenue, Sarepta, AskBio agreement	6 432	6 175	15 390	11 387
	36 652	**26 396**	**60 846**	**56 676**
Parent company				
Revenue:				
Product sales	29 576	19 458	43 882	43 695
Contract revenue, Axis-Shield agreement	644	763	1 288	1 144
Cost reimbursement, Axis-Shield agreement	-	-	286	450
Contract revenue, Sarepta, AskBio agreement	6 432	6 175	15 390	11 387
	36 652	**26 396**	**60 846**	**56 676**

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 June 30, 2023 amounted to SEK 0.9 million (Q2 '22: SEK 0.8 million) and belongs to level 3 in the fair value hierarchy. All other financial instruments are measured at amortized cost. The carrying values of those instruments are considered reasonable approximations of their fair values. The Group sold all its investments in interest funds during 2022 – see further information in the Cash Flow Statement.

Note 4 Long-term loan

On July 18, 2022, the Company entered into a $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 $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 $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 June 2023, the loan amounted to SEK 840.9 million, thereof SEK 98.6 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 Q4-2022.

During H1-2023 and H1-2022 the Company capitalized development cost related to performing its Idefirix® EMA post-approval commitments in the amount of SEK 52.4 million and SEK 0.0 million, respectively.

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Note 6 Intangible assets – Recognition of write-up

As of June 30, 2023, Hansa recognized a write-up of SEK 1.43 billion 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 billion SEK in the financial statements of Hansa Biopharma AB. The write-up will increase the restricted shareholder equity in Hansa Biopharma AB by SEK 1.430 billion. The write-up results in a taxable temporary difference for which a deferred tax liability of SEK 0.295 billion is recognized, with a corresponding decrease in restricted shareholder equity. As a result of recognizing the deferred tax liability Hansa has recognized a deferred tax asset of SEK 0.295 billion 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, currently expected to be at least 10 years.

The write-up of the intangible asset will not impact the consolidated IFRS financial statements of the Hansa Group.

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.

Glossary

Adeno-associated virus (AAV)
AAV is a versatile viral vector technology that can be engineered for very specific functionality in gene therapy applications.

Allogeneic hematopoietic stem cell transplantation (HSCT)
Allogeneic HSCT, also known as "bone-marrow" transplantation, involves transferring the stem cells from a healthy person (the donor) to the patient's body after high-intensity chemotherapy or radiation. The donated stem cells can come from either a related or an unrelated donor.

AMR
Antibody mediated transplant rejection.

Antibody
One type of protein produced by the body's immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM.

Anti-GBM disease (Goodpasture syndrome)
Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

Autoimmune disease
Diseases that occur when the body's immune system reacts against the body's own structures.

Biologics License Application (BLA)
A Biologics License Application (BLA) is submitted to the Food and Drug Administration (FDA) to obtain permission for distribution of a biologic product across the United States.

CD20
B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

Clinical studies
Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical phase 1
The first time a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical phase 2
Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical phase 3
Trials that involve many patients and often continue for a longer time; they are intended to identify the drug's effects and side effects during ordinary but still carefully controlled conditions.

DSA
Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

EMA
The European Medicines Agency (EMA) is an EU agency for the evaluation of medicinal products.

Enzyme
A protein that accelerates or starts a chemical reaction without itself being consumed.

ESOT
The European Society for Organ Transplantation (ESOT) is an umbrella organsation which overlooks how transplantations are structured and streamlined.

FDA
U.S. Food and Drug Administration.

Guillian-Barré syndrome
Guillian-Barré syndrome (GBS), is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

HBP
Heparin Binding Protein is a naturally occurring protein that is produced by certain immune cells, i.e. neutrophilic granulocytes, to direct immune cells from the bloodstream into the tissues.

HLA
Human Leukocyte Antigen is a protein complex found on the surface of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

IgG
IgG, Immunoglobulin G, is the predominant type of antibody in serum.

Imlifidase
Imlifidase, is the immunoglobulin G-degrading enzyme of Streptococcus pyogenes, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

IND
Investigational New Drug (IND) application is required to get approval from the FDA to administer an investigational drug or biological product to humans.

INN
International Nonproprietary Name (INN) is a generic and non-proprietary name to facilitate the identification of a pharmaceutical substances or active pharmaceutical ingredient.

In vitro
Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

In vivo
Term within biomedical science to indicate that experiments or observations are made in living organisms.

IVD
IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Marketing Authorization Application (MAA)
A Marketing Authorization Application (MAA) is an application submitted to the European Medicines Agency (EMA) to market a medicinal product in the EU member states.

Neutralizing Antibodies (NAbs)
NAb is an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically.

Pivotal trial
A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat life threatening or severely debilitating conditions.

Panel Reactive Antibody (PRA)
PRA is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

Preclinical development
Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

Randomized Control Trial (RCT)
RCT is a study design where the trial subject is randomly allocated to one of two or more study cohorts to test a specific intervention against other alternatives, such as placebo or standard of care.

Streptococcus pyogenes
A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

Standard of Care (SOC)
Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals.

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