# Interim report

## January – March 2023

HANSA BIOPHARMA

# Positive reimbursement decision in Spain expands market access to include the five largest European markets; Enrollment in phase 2 study of imlifidase in Guillain-Barré Syndrome (GBS) completed; HNSA-5487: Phase 1 clinical study started in healthy volunteers

## Business highlights for the first quarter of 2023

- Total Q1 revenue of SEK 24.2m including SEK 14.3m in product sales and SEK 9.9m in revenue recognition mainly under the agreement with Sarepta.
- Received positive reimbursement decision in Spain, completing market access in the five largest European markets. Market access has now been secured in 12 European countries. Market Access procedures are ongoing in additional eight countries including Portugal, Belgium, and Switzerland.
- Expanded commercialization partnership with Medison Pharma for Idefirix® for kidney transplantation to cover the Baltics.
- Announced completion of enrollment in phase 2 study of imlifidase in Guillain-Barré Syndrome (GBS).
- Initiated clinical trial of HNSA-5487 with dosing in the first healthy volunteers.
- Appointed Matthew Shaulis as Chief Commercial Officer and U.S. President of Hansa Biopharma.

### Clinical pipeline update

- U.S. ConfIdeS: As of April 20, 2023, 62, out of a target of 64 patients, have been enrolled in our pivotal U.S. open label, randomized controlled trial of imlifidase in kidney transplantation. Hansa continues to see strong interest among clinics and will continue enrollment to accelerate randomization. We expect to add further centers up to a total of 20.
- On March 31, 2023, Hansa announced completion of enrollment in the phase 2 study of imlifidase in GBS. The first high level data read-out is expected in the second half 2023.
- Anti-GBM: Hansa's pivotal phase 3 study in anti-GBM disease has been initiated with the first sites being activated at end of 2022 and several more sites to be activated before summer 2023. The study will target 50 patients with anti-GBM disease across the U.S., U.K. and EU, as previously communicated.
- HNSA-5487, the second-generation lead molecule, is progressing. A new clinical phase 1 trial has started with dosing of the first healthy volunteers.

## Financial Summary

| SEKm, unless otherwise stated – unaudited | Q1 2023 | Q1 2022 | 12M 2022 |
|---|---|---|---|
| Revenue | 24.2 | 30.3 | 154.5 |
| SG&A expenses | (103.3) | (80.4) | (337.9) |
| R&D expenses | (92.8) | (70.9) | (346.2) |
| Loss from operation | (182.3) | (135.0) | (588.6) |
| Loss for the period | (205.4) | (138.4) | (611.1) |
| Net cash used in operations | (207.0) | (130.5) | (502.7) |
| Cash and short-term investments | 1,286.8 | 753.7 | 1,496.2 |
| Shareholders' equity | 414.7 | 636.0 | 602.9 |
| EPS before and after dilution (SEK) | (3.92) | (3.11) | (13.60) |
| Number of outstanding shares | 52,443,962 | 44,473,452 | 52,443,962 |
| Weighted avg. number of shares before and after dilution | 52,443,962 | 44,473,452 | 44,923,998 |
| Number of employees at the end of the period | 159 | 141 | 150 |

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

# CEO comments

***"We continue to make solid strides in delivering on our mission of developing innovative, life-saving and life-altering immunomodulating therapies by leveraging our unique IgG-cleaving enzyme technology platform for people with rare diseases"***

**Søren Tulstrup**
**President and CEO, Hansa Biopharma**

"Hansa's commercial efforts for Idefirix® in Europe continue to progress as planned. During the first quarter of 2023, we were pleased to announce a positive reimbursement decision in Spain, where more than 3,000 kidney transplantations are performed annually with approximately 90 percent of transplanted organs coming from deceased donors and where one in five on the kidney waitlist are classified as highly sensitized.

With Spain secured, Idefirix® now has market access in the five largest markets in Europe, representing approximately 15,000 kidney transplants per year. This is great news for the thousands of people who are in urgent need of more personalized and innovative desensitization options like Idefirix® which can enable incompatible kidney transplantation.

Our goal in kidney transplantation is to change the approach to desensitization and organ allocation by integrating Idefirix® into clinical practice as a new standard-of-care (SOC) for highly sensitized patients. With this novel therapy, we are changing the transplantation ecosystem and advancing a treatment regime from one that has been solely focused on compatibility, to one that is more patient-centric – accommodating transplants for incompatible patients, who previously had no other choice than to wait and hope.

On the development side, we continue to drive progress across our pipeline. At the end of March, we announced the completion of enrollment in our phase 2 study of imlifidase in Guillain-Barré Syndrome (GBS). GBS is an acute autoimmune attack on the peripheral nervous system, which affects approximately one to two patients per 100,000 people, annually. The first high-level data read-out is expected in the second half of 2023, while the outcome of the comparative efficacy analysis to an externally matched cohort from the International GBS Outcome Study (IGOS) database is expected to be shared in 2024.

Patient enrollment in the U.S. continues to progress in our pivotal ConfIdeS trial in kidney transplantation. As of April 20, 2023, a total of 62 out of a targeted 64 patients were enrolled. Hansa continues to see strong interest among clinics and will continue enrollment to accelerate randomization and add additional centers up to a total of 20. This will help build valuable, real-world clinical experience in desensitization of highly sensitized patients among key transplantation centers and specialists in preparation for a planned launch in the market.

Lastly, I am pleased to announce we have dosed the first healthy volunteers with HNSA-5487, our lead molecule from our second-generation IgG antibody cleaving enzyme program. Moving HNSA-5487 into the clinic is a major accomplishment of our R&D team and an important milestone for the Company. HNSA-5487 represents an opportunity to substantially expand the potential indications in rare immunologic diseases that can be targeted, including indications where patients may benefit from more than one dose of an IgG-modulating enzyme.

On the organizational side, we are very excited to welcome Matthew Shaulis as the new Chief Commercial Officer and U.S. President. Matthew joins Hansa from Pfizer, where he held several senior executive roles including President, Inflammation and Immunology for the International Developed Markets; President, North America Oncology; and, most recently, Senior Vice President responsible for the company's global commercial and medical go-to-market model transformation. With over 20 years of international experience in the pharmaceutical industry, Matthew will further strengthen our commercial and in-market leadership team and create a U.S.-focused organization that will help deliver our goal of bringing imlifidase to patients and clinicians in the U.S.

We continue to make solid strides in delivering on our mission of developing innovative, life-saving and life-altering immunomodulating therapies by leveraging our unique IgG-cleaving enzyme technology platform for people with rare diseases who have limited to no treatment options available."

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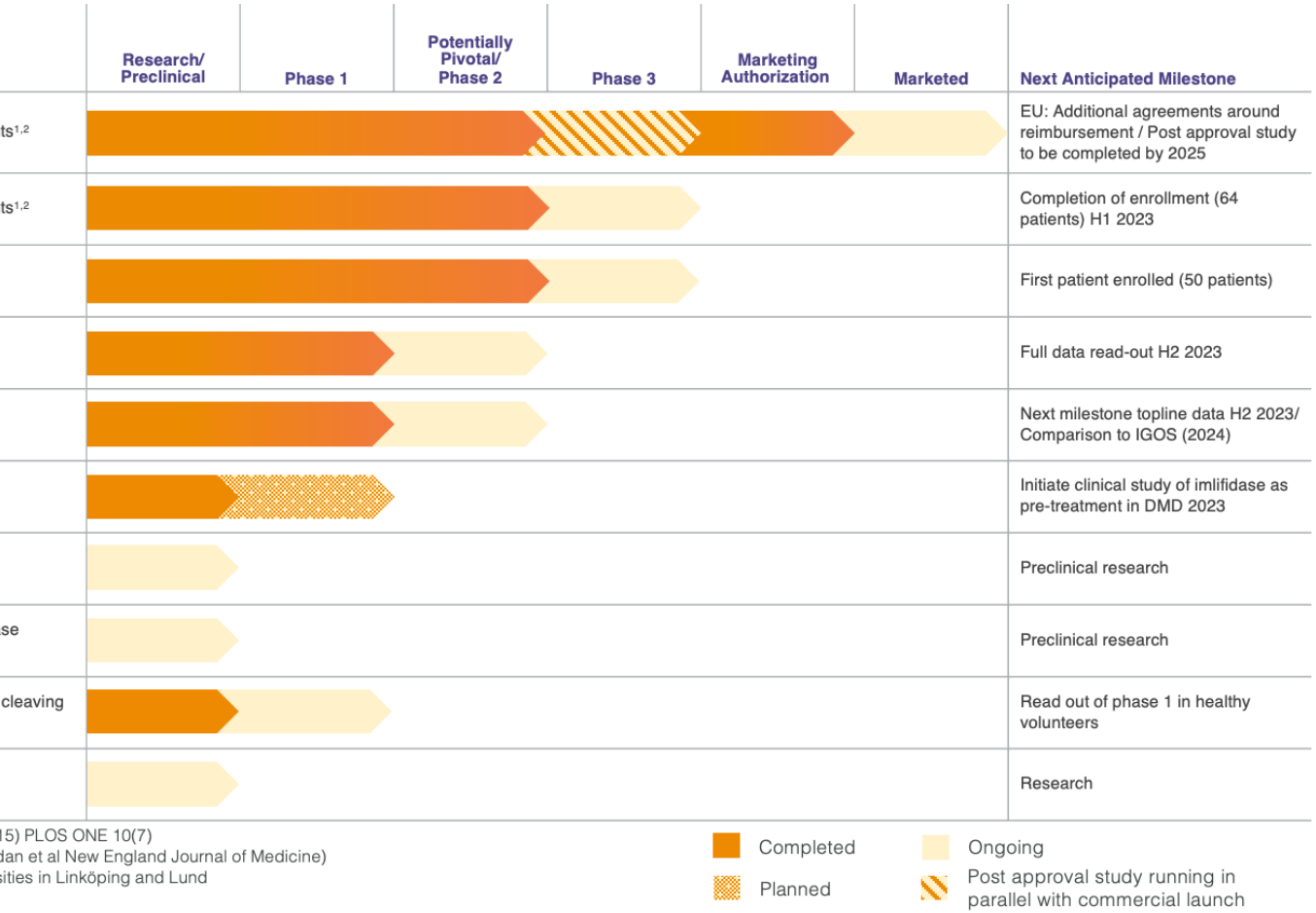
# Continued pipeline progress

| Candidate/ Project | Indication | 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 enrollment (64 patients) H1 2023 |
| | Anti-GBM antibody disease[3] | First patient enrolled (50 patients) |
| | Antibody mediated kidney transplant rejection (AMR) | Full data read-out H2 2023 |
| | Guillain-Barré syndrome (GBS) | Next milestone topline data H2 2023/ Comparison to IGOS (2024) |
| | Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta) | 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 |
| HNSA-5487 | Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR) | Read out of phase 1 in healthy volunteers |
| EnzE | Cancer immunotherapy | Research |




[1] Results from the Phase 1 study have been published, Winstedt el 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

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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. Commercial access has been obtained in 12 European countries, including the five largest markets – Spain, Germany, U.K., France (through a funded Early Access Program) and Italy. Additional market access procedures are ongoing in eight countries including Portugal, Belgium, and Switzerland. In Spring 2022, Swissmedic (the Swiss Regulatory Agency for Therapeutic Products) granted temporary marketing authorization for Idefirix® in adult kidney transplant patients with a positive crossmatch against an available organ from a diseased donor. In addition, Hansa and Medison Pharma obtained marketing authorization in Israel for Idefirix® in 2022. The Medison collaboration covers select countries in Eastern Europe and Israel, as well as the Baltics, which were recently added to the agreement.

On July 11, 2022, Hansa announced the first patient was treated in the 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® and will support the commercial development. The PAES is ongoing and is expected to be completed by 2025.

On August 11, 2022, the European Society for Organ Transplantation's (ESOT) guidelines for desensitization treatment of highly sensitized kidney transplant patients was published in *Transplant International*. The guidelines, which are the first to include imlifidase, provide a new clinical practice tool for healthcare professionals and represent the first international consensus on a management pathway for highly sensitized patients.

## 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 April 20, 2023, 62 patients have been enrolled in this trial. Hansa will continue enrollment due to strong interest among centers to participate. Hansa continues to see strong interest among clinics and will continue enrollment to accelerate randomization and add additional centers up to a total of 20. Completion of enrollment in the study is expected in the first half of 2023, while completion of randomization is anticipated by 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 in order 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 data from the three-year follow-up study was published in the *American Journal of Transplantation* in July 2021. The next read-out on the long-term follow-up trial is expected in the second half 2023.

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

Anti-GBM 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.

On March 8, 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 two-thirds of patients losing kidney function and starting dialysis after six months. The publication recognized the study's significance in autoimmune diseases as it suggested that deactivation of autoantibodies could alter the course of an autoimmune disease, allowing restoration of kidney function. These positive results mark an important milestone for the expansion of imlifidase outside transplantation into autoimmune disease.

The first sites have been initiated and several more sites will be added before summer 2023. The study will target 50 patients with anti-GBM disease across the U.S., U.K. and EU as previously communicated.

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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[1] 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 an acute autoimmune attack on the peripheral nervous system, which affects approximately 1-2 in 100,000 people annually. 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).

At the end of the first quarter of 2023, Hansa announced completion of enrollment in the phase 2 study of imlifidase in GBS. The first high-level data read-out is expected in the second half of 2023.

Following database lock of the single arm study, efficacy parameters from patients treated with imlifidase and SOC will be compared with an external matched cohort from the International GBS Outcome Study (IGOS) database at the Erasmus Medical Centre, Rotterdam, Netherlands. The outcome of the comparative efficacy analysis between the two cohorts is expected to be shared in 2024.

### 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[2]. 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.

# Preclinical programs

### HNSA-5487 - lead candidate in the NiceR program (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.

HNSA-5487, part of the Company's NiceR program, has been selected as the lead IgG-eliminating enzyme candidate for repeat dosing. In line with previous guidance, Hansa has recently initiated a new clinical phase 1 trial for HNSA-5487 with dosing of the first healthy volunteers.

### EnzE – Enzyme-based antibody Enhancement

Published findings demonstrate how pre-treatment with imlifidase in animal tumor models can increase the efficacy of currently available antibody-based cancer therapies. This treatment concept is currently being investigated under the project name, EnzE, Enzyme-based antibody Enhancement.

The research results demonstrate the potential of an IgG-cleaving agent as a pre-treatment for cancer therapy. High levels of plasma IgG have been shown to limit the efficacy of therapeutic antibodies, as plasma IgG can saturate the receptors of a patient's immune cells, preventing them from efficiently killing the tumor cells. Removing the inhibiting IgG antibodies with imlifidase, or a novel IgG-clearing enzyme prior to dosing the patient with a therapeutic antibody, could potentially increase the efficacy of the given cancer therapy.

### Pre-treatment ahead of gene therapy in Limb-Girdle (LGMD) & Duchenne (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 NAbs to 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. The partnership has progressed, as planned.

On November 2, 2022, Hansa Biopharma and Sarepta Therapeutics announced plans to, based on results from pre-clinical research, initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in 2023.

The FDA has accepted and granted priority review to Sarepta BLA for SRP-9001 for treating DMD with a PDUFA date set for May 29, 2023. For further information regarding Sarepta's gene therapy programs in DMD and LGMD, please refer to www.sarepta.com.

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

[2] 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), a fully integrated AAV gene therapy company dedicated to developing medicines that improve the quality of life for patients with genetic diseases.

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 NAbs to the adeno-associated viral vector used in AskBio's gene therapy.

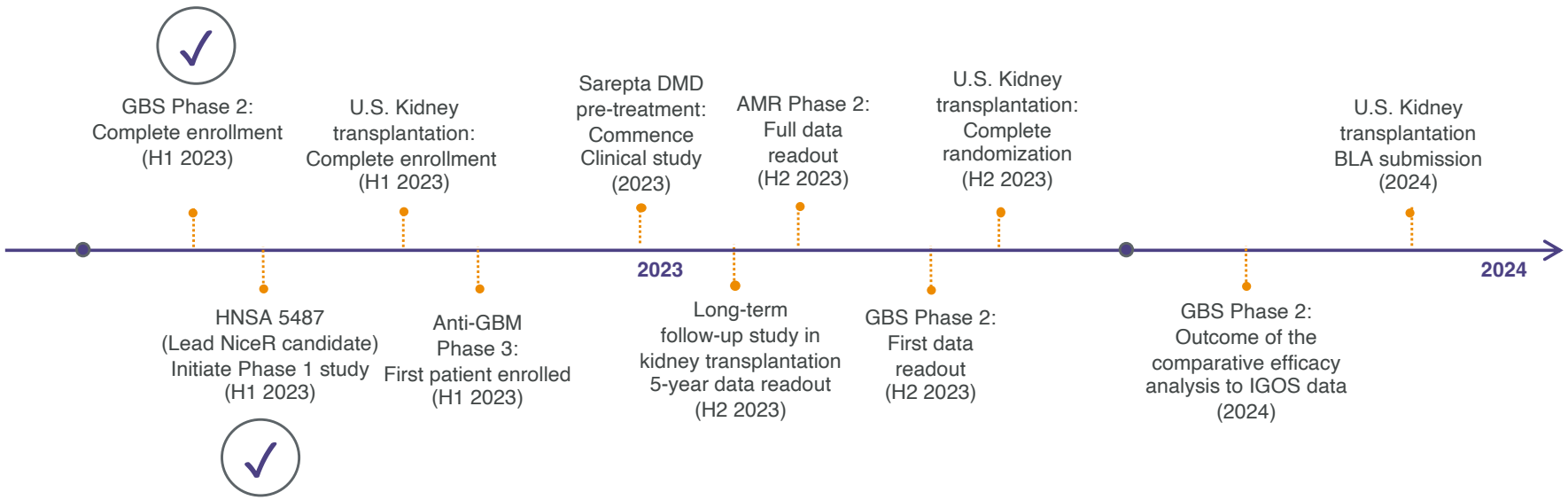
Under terms of the agreement, Hansa received a USD 5 million upfront payment and AskBio has the exclusive option to negotiate a full development and commercialization agreement following evaluation of the results from an initial phase 1/2 study. For further information regarding AskBio's gene therapy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

The collaboration is currently at a preclinical stage.

### Preclinical research collaboration with argenx BV

Hansa and argenx BV have been evaluating the therapeutic potential of combining imlifidase and efgartigimod, argenx's FcRn antagonist. A combination of imlifidase and efgartigimod or other FcRn antagonists could potentially be used in both the acute and the chronic setting of autoimmune diseases and transplantation. Any potential next steps will be evaluated.

# Upcoming milestones

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# Financial review Year-end Report January – March 2023

## Revenue

Revenue for the first quarter of 2023 amounted to SEK 24.2m (Q1 '22: SEK 30.3m) including Idefirix® product sales of SEK 14.3m (Q1 '22: SEK 24.2m) and contract revenue of SEK 9.9m (Q1 '22: SEK 6.0m) mainly from the upfront payments the Company received under the Sarepta agreement.

## SG&A expenses

Sales, general and administrative expenses for the first quarter of 2023 amounted to SEK 103.3m (Q1 '22: SEK 80.4m). 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 11.5m for the first quarter of the year 2023 (Q1 '22: SEK 10.2m).

## R&D expenses

Research and development expenses for the first quarter of the year 2023 amounted to SEK 92.8m (Q1 '22: SEK 70.9m). The increase over the 2022 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 5.5m for the first quarter of the year 2023 (Q1 '22: SEK 5.0m).

## Other operating income/expenses and financial expenses

Other operating income/expenses for the first quarter of 2023 amounted to an expense of SEK 0.8m (Q1 '22: expense of SEK 2.8m). 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 first quarter of 2023, amounted to SEK 22.7m (Q1 '22: SEK 3.4m). The increase as compared to Q1 2022 is mainly driven by accrued interest related to Hansa's long-term loan, partly offset by changes of USD bank deposits (see Note 4 below).

## Financial results

The loss from operations for the first quarter of 2023 amounted to SEK 182.3m (Q1 '22: SEK 135.0m). The increase as compared to Q1 2022 is mainly driven by Hansa's broadened commercial and R&D pipeline activities.

The loss for the first quarter of 2023 amounted to SEK 205.4m (Q1 '22: SEK 138.4m).

## Cash flow, cash and investments

Net cash used in operating activities for the first quarter of 2023 amounted to SEK 207.0m (Q1 '22: SEK 130.5m). The change as compared to the previous year period 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 Q1-2022 cash-flow.

Cash and cash equivalents, including short-term investments, amounted to SEK 1,286.8m on March 31, 2023, as compared to SEK 753.7m in Q1 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.

## Shareholders' equity

On March 31, 2023, shareholders' equity amounted to SEK 414.7m as compared to SEK 636.0m at the end of Q1 2022.

## Parent Company

The parent company's revenue for the first quarter of 2023 amounted to SEK 24.2m (Q1 '22: SEK 30.3m).

Loss for the period for the parent company for the first quarter of 2023 amounted to SEK 205.3m (Q1 '22: SEK 138.8m).

The parent company's equity amounted to SEK 427.6m as of March 31, 2023, as compared to SEK 633.8m at the end of the first quarter 2022.

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 eight employees at the end of March 2023. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had six employees at the end of March 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 March 31, 2023, the following LTIPs were ongoing: 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.

## Long term incentive programs

| 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** | **927 000** |
| Number of acquired and outstanding warrants | **-** | **-** | **-** |
| Estimated total cost including social contributions, KSEK | **92 753** | **55 061** | **69 180** |
| Total cost per program, including social contributions, as of March 31, 2023 YTD, KSEK | **7 478** | **4 349** | **5 248** |

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

| | |
|---|---|
| **Total costs, including social contributions, as of March 31, 2023 YTD, KSEK** | **17 075** |

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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Hansa Biopharma
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E-mail: klaus.sindahl@hansabiopharma.com

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E-mail: stephanie.kenney@hansabiopharma.com

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

| | |
|---|---|
| April 20, 2023 | Interim Report for January-March 2023 |
| June 14, 2023 | 2023 Annual General Meeting |
| July 20, 2023 | Half-year Report for January-June 2023 |
| October 18, 2023 | Interim Report for January-September 2023 |

## 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 March 31, 2023 | SEK ~2.8bn (USD ~269m) |
| Ticker | HNSA |
| ISIN | SE0002148817 |

### Top 10 shareholders as of March 31, 2023

| Name | Number of shares | Ownership in pct |
|---|---|---|
| Redmile Group, LLC | 10,896,553 | 20.8% |
| Försäkrings AB Avanza Pension | 2,509,535 | 4.8% |
| 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% |
| Braidwell, L.P. | 974,528 | 1.9% |
| C WorldWide Asset Management | 799,749 | 1.5% |
| Heights Capital Management, Inc. | 667,169 | 1.3% |
| VOB & T Trading AB | 644,800 | 1.2% |
| Other | 28,282,202 | 53.9% |
| Total | 52,443,962 | 100% |

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 March 31, 2023.

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

# Assurance

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

Lund April 19, 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

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.

# Condensed unaudited financial statements

## Consolidated statement of financial position

| KSEK | Note | March 2023 | March 2022 | December 31 2022 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| Intangible assets | 5 | 72 346 | 28 111 | 46 866 |
| Property and equipment | | 8 072 | 6 186 | 8 113 |
| Leased assets | | 25 845 | 33 380 | 27 723 |
| **Total non-current assets** | | **106 263** | **67 677** | **82 702** |
| **Current assets** | | | | |
| Inventories | | 1 037 | 184 | 973 |
| Trade receivables & unbilled revenues | | 47 221 | 28 825 | 42 959 |
| Current receivables, non-interest bearing | | 58 346 | 39 065 | 64 593 |
| Short-term investments | 3 | - | 234 612 | - |
| **Cash and cash equivalents** | | 1 286 820 | 519 136 | 1 496 179 |
| **Total current assets** | | **1 393 424** | **821 822** | **1 604 704** |
| **TOTAL ASSETS** | | **1 499 687** | **889 499** | **1 687 406** |
| **EQUITY AND LIABILITIES** | | | | |
| Shareholders' equity | | 414 666 | 635 986 | 602 912 |
| **Non-current liabilities** | | | | |
| Long-term loan | 4 | 797 685 | - | 762 601 |
| Deferred tax liabilities | | 402 | 427 | 405 |
| Provisions | | 5 109 | 5 866 | 5 192 |
| Lease liabilities | | 19 512 | 26 723 | 21 326 |
| Deferred revenue | | 20 625 | 66 937 | 29 500 |
| Contingent consideration | 3 | 786 | 761 | 757 |
| **Total non-current liabilities** | | **844 119** | **100 714** | **819 781** |
| **Current liabilities** | | | | |
| Tax liability | | 757 | 265 | 604 |
| Lease liabilities | | 7 211 | 6 953 | 7 165 |
| Current liabilities, non-interest bearing | | 61 115 | 32 548 | 80 754 |
| Deferred revenue | | 41 024 | 49 610 | 40 430 |
| Refund liabilities | | 34 986 | 4 047 | 27 013 |
| Accrued expenses and deferred income | | 95 809 | 59 376 | 108 747 |
| **Total current liabilities** | | **240 902** | **152 799** | **264 713** |
| **TOTAL EQUITY AND LIABILITIES** | | **1 499 687** | **889 499** | **1 687 406** |

## Consolidated income statement

| KSEK | Note | Q1 2023 | Q1 2022 | Year 2022 |
|---|---|---|---|---|
| Revenue | 2 | 24 194 | 30 280 | 154 525 |
| Cost of revenue | | (9 646) | (11 234) | (38 477) |
| Sales, general and administration expenses | | (103 292) | (80 384) | (337 861) |
| Research and development expenses | 5 | (92 791) | (70 907) | (346 244) |
| Other operating income (expenses) | | (813) | (2 778) | (20 532) |
| **Loss from operations** | | **(182 348)** | **(135 023)** | **(588 588)** |
| Financial income (expenses), net | 4 | (22 717) | (3 357) | (21 391) |
| **Loss for the period before tax** | | **(205 065)** | **(138 380)** | **(609 979)** |
| Tax | | (356) | (57) | (1 155) |
| **Loss for the period** | | **(205 421)** | **(138 437)** | **(611 134)** |
| Attributable to: | | | | |
| Parent company shareholders | | (205 421) | (138 437) | (611 134) |
| Earnings per share (EPS) | | | | |
| Before dilution (SEK) | | (3,92) | (3,11) | (13,60) |
| After dilution (SEK) | | (3,92) | (3,11) | (13,60) |
| Other comprehensive income | | | | |
| Items that have been, or may be reclassified to profit or loss for the period | | | | |
| Translation differences | | 100 | 123 | (114) |
| **Other comprehensive income for the period** | | **100** | **123** | **(114)** |
| **Total net comprehensive income** | | **(205 321)** | **(138 314)** | **(611 248)** |

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.

## Consolidated statements of changes in shareholder's equity

| KSEK | January-March 2023 | January-March 2022 | Year 2022 |
|---|---|---|---|
| **Opening balance of shareholders' equity as reported** | **602 912** | **757 573** | **757 573** |
| Result for the period | (205 421) | (138 437) | (611 134) |
| Other comprehensive income for the period | 100 | 123 | (114) |
| **Net comprehensive income** | **(205 321)** | **(138 314)** | **(611 248)** |
| **Transactions with the group's owner** | | | |
| Proceeds from new share issuance, net [1] | - | - | 396 196 |
| Long term incentive programs | 17 075 | 16 726 | 60 391 |
| **Total transactions with the group's owner** | **17 075** | **16 726** | **456 587** |
| **Closing balance of shareholders' equity** | **414 666** | **635 986** | **602 912** |

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

## Consolidated statement of cash flow

| KSEK | Q1 2023 | Q1 2022 | Year 2022 |
|---|---|---|---|
| Cash Flows from Operating Activities | | | |
| Loss for the period | (205 421) | (138 437) | (611 134) |
| Adjustment for items not included in cash flow [1] | 29 147 | 18 287 | 83 433 |
| Interest received and paid, net | 2 361 | (339) | 5 101 |
| Income taxes paid | (356) | - | (1 565) |
| **Cash flow from operations before change in working capital** | **(174 269)** | **(120 489)** | **(524 165)** |
| Changes in operating related assets and liabilities | (32 691) | (10 025) | 21 432 |
| **Net cash used in operating activities** | **(206 960)** | **(130 514)** | **(502 733)** |
| Investing activities | | | |
| Proceeds from sale of short-term investments | - | - | 232 644 |
| Acquisition of property and equipment | (534) | (140) | (3 331) |
| **Cash flow from investing activities** | **(534)** | **(140)** | **229 313** |
| Financing activities | | | |
| Proceeds long-term loan, net of transaction cost [2] | - | - | 728 373 |
| Proceeds from new share issue, net of transaction cost [3] | - | - | 396 196 |
| Repayment of lease liabilities | (1 768) | (1 703) | (6 888) |
| **Cash flow from financing activities** | **(1 768)** | **(1 703)** | **1 117 681** |
| Net change in cash | (209 261) | (132 357) | 844 261 |
| Cash and cash equivalents, beginning of period | 1 496 179 | 651 342 | 651 342 |
| Currency exchange variance, cash and cash equivalents | (98) | 151 | 576 |
| **Cash and cash equivalents, end of period** | **1 286 820** | **519 136** | **1 496 179** |

1) Values are mainly costs of share based incentive programs including social contributions and depreciation, partly offset by certain capitalized development costs (see furter in note 5)

2) Total long-term loan transaction cost amounted to SEK 8,027k

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

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## Parent company – Statement of financial position

| KSEK | Note | March 31 2023 | March 31 2022 | Year 2022 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| Intangible assets | 5 | 70 222 | 25 855 | 44 718 |
| Property, plant and equipment | | 8 072 | 6 186 | 8 113 |
| Leased assets | | 25 845 | 33 380 | 27 723 |
| Investment in subsidiaries | | 25 486 | 5 095 | 24 264 |
| Receivables, group companies | | - | 2 271 | - |
| **Total non-current assets** | | **129 625** | **72 787** | **104 818** |
| **Current assets** | | | | |
| Inventories | | 1 037 | 184 | 973 |
| Trade receivables & unbilled revenue | | 47 221 | 28 825 | 42 959 |
| Current receivables, non-interest bearing | | 58 088 | 38 864 | 64 368 |
| Short-term investments | 3 | - | 234 612 | - |
| Cash and cash equivalents | | 1 272 639 | 510 861 | 1 486 502 |
| **Total current assets** | | **1 378 985** | **813 346** | **1 594 802** |
| **TOTAL ASSETS** | | **1 508 610** | **886 133** | **1 699 620** |
| **EQUITY AND LIABILITIES** | | | | |
| **Shareholders' equity** | | **427 609** | **633 843** | **615 799** |
| **Non-current liabilities** | | | | |
| Long-term loan | 4 | 797 685 | - | 762 601 |
| Provisions | | 5 109 | 5 866 | 5 192 |
| Lease liabilities | | 19 512 | 26 723 | 21 326 |
| Deferred revenue | | 20 626 | 66 937 | 29 500 |
| Contingent consideration | 3 | 757 | 761 | 757 |
| **Total non-current liabilities** | | **843 689** | **100 288** | **819 376** |
| **Current liabilities** | | | | |
| Tax liability | | 786 | - | 604 |
| Lease liabilities | | 7 211 | 6 953 | 7 165 |
| Liabilities, group companies | | 2 448 | 2 655 | 5 738 |
| Current liabilities, non-interest bearing | | 60 709 | 32 482 | 80 225 |
| Deferred revenue | | 41 024 | 49 610 | 40 430 |
| Refund liabilities | | 34 986 | 4 047 | 27 013 |
| Accrued expenses and deferred income | | 90 148 | 56 255 | 103 270 |
| **Total current liabilities** | | **237 312** | **152 002** | **264 445** |
| **TOTAL EQUITY AND LIABILITIES** | | **1 508 610** | **886 133** | **1 699 620** |

## Parent company – Income statement

| KSEK | Note | Q1 2023 | Q1 2022 | Year 2022 |
|---|---|---|---|---|
| Revenue | 2 | 24 194 | 30 280 | 154 525 |
| Cost of revenue | | (9 646) | (11 234) | (38 477) |
| Sales, general and administration expenses | | (103 160) | (80 453) | (330 071) |
| Research and development expenses | 5 | (92 936) | (71 290) | (340 192) |
| Other operating income (expenses) | | (813) | (2 777) | (20 532) |
| **Loss from operations** | | **(182 360)** | **(135 474)** | **(574 747)** |
| Result from financial items: | | | | |
| Finance income | | 2 674 | - | 27 245 |
| Finance costs | 4 | (25 397) | (3 357) | (48 629) |
| **Loss for the period before tax** | | **(205 083)** | **(138 831)** | **(596 131)** |
| Income tax benefit/expense | | (182) | - | (604) |
| **Loss for the period** | | (205 265) | (138 831) | (596 735) |
| **Other comprehensive income for the period** | | - | - | - |
| **Total comprehensive income for the period** | | **(205 265)** | **(138 831)** | **(596 735)** |

## Parent company – Statement of changes in shareholders' equity

| KSEK | Q1 2023 | Q1 2022 | Year 2022 |
|---|---|---|---|
| **Opening shareholders' equity as reported** | **615 799** | **755 948** | **755 948** |
| **Result for the period** | **(205 265)** | **(138 831)** | **(596 735)** |
| Other comprehensive income for the period | - | - | - |
| **Net comprehensive income** | **(205 265)** | **(138 831)** | **(596 735)** |
| Proceeds from new share issuance, net [1] | - | - | 396 196 |
| Long term incentive programs | 17 075 | 16 726 | 60 391 |
| **Total transactions with the group's owner** | **17 075** | **16 726** | **456 587** |
| **Closing shareholders' equity** | **427 609** | **633 843** | **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 | Q1 | | Year |
|---|---|---|---|
| KSEK | 2023 | 2022 | 2022 |
| Group | | | |
| Revenue | | | |
| Product sales | 14 306 | 24 237 | 86 735 |
| Contract revenue, Axis-Shield agreement | 644 | 381 | 2 892 |
| Cost reimbursement, Axis-Shield agreement | 286 | 450 | 624 |
| Contract revenue, Sarepta, AskBio agreement | 8 958 | 5 212 | 64 273 |
| | **24 194** | **30 280** | **154 525** |
| Parent company | | | |
| Revenue: | | | |
| Product sales | 14 306 | 24 237 | 86 735 |
| Contract revenue, Axis-Shield agreement | 644 | 381 | 2 892 |
| Cost reimbursement, Axis-Shield agreement | 286 | 450 | 624 |
| Contract revenue, Sarepta, AskBio agreement | 8 958 | 5 212 | 64 273 |
| | **24 194** | **30 280** | **154 525** |

## Note 3 Fair value of financial instruments

The Group measures its investments in interest funds and its financial liability for contingent consideration at fair value. The fair value of the financial liability for contingent consideration on March 31, 2023 amounted to SEK 0.8 million (Q1 '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 31 March 2023, the loan amounted to SEK 797.7 million, thereof SEK 68.6 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 Q1-2023 and Q1-2022 the Company capitalized development cost related to performing its Idefirix® EMA post-approval commitments in the amount of SEK 26.9 million and SEK 0.0 million, respectively.

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# 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.

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.