# Year-end report

## January – December 2022

HANSA BIOPHARMA

# Total 2022 revenue of SEK 155m; Cash runway extended into 2025; Market Access obtained in four of the five largest European markets; Reported positive phase 2 top-line data in AMR; Decision made to initiate clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in 2023

## Business highlights for the fourth quarter of 2022

- Total Q4 revenue of SEK 31m including SEK 20m in product sales and SEK 11m, mainly under the agreements with Sarepta and AskBio.
- Positive reimbursement decisions received in Italy and Czech Republic for Idefirix® in highly sensitized kidney transplant patients. Market access now secured in 11 European countries including four of the five largest European markets.
- Hansa and partner Sarepta Therapeutics announced plans to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in Duchenne Muscular Dystrophy (DMD) during 2023.
- Positive topline data from the imlifidase phase 2 study in antibody mediated rejection (AMR) post kidney transplantation announced, showing statistical superiority over plasma exchange.
- Raised SEK 416m (USD ~40m) in a directed share issue expanding cash runway into 2025.

### Clinical pipeline update

- U.S. ConfIdeS: As of February 1, 2023, 51 patients, 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 aims to complete enrollment in the first half 2023, while completion of randomization is expected in the second half 2023 targeting a Biologics License Application (BLA) submission under the accelerated approval pathway in 2024, as previously guided.
- AMR: Topline data from the imlifidase phase 2 study in antibody mediated rejection (AMR) post kidney transplantation demonstrates a statistically significantly superior capacity of imlifidase to rapidly reduce levels of donor-specific antibodies (DSAs) compared to plasma exchange (standard of care) in the five days following the start of treatment. Hansa plans to publish the full dataset in the second half of 2023.
- Anti-GBM: Hansa's pivotal phase 3 study in anti-Glomerular Basement Membrane (anti-GBM) disease commenced mid-December 2022 with the first sites activated.
- GBS: As of February 1, 2023, 25 patients, out of a target of 30 patients in the Guillain Barré Syndrome (GBS) phase 2 trial, have been enrolled and Hansa expects to complete enrollment in the first half of 2023, as previously guided, with the first high level data read-out expected H2 2023.

### Clinical pipeline update, continued

- NiceR program (lead candidate HNSA-5487) progressing, with Investigational New Drug (IND) enabling toxicology studies completed and Clinical Trial Application (CTA) approved to initiate clinical study in the first half of 2023.
- Gene Therapy: Following successful pre-clinical work completed by Hansa and Sarepta, plans were announced to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in Duchenne Muscular Dystrophy (DMD) during 2023.

### Events after the closing period

- On January 30, 2023, it was announced that Christian Kjellman, Chief Scientific Officer (CSO) and Chief Operating Officer (COO), has decided to leave the company in 2024. Effective immediately, Commercial Operations will report directly to President and CEO Søren Tulstrup and a search is underway for a new CSO.

## Financial Summary

| SEKm, unless otherwise stated – unaudited | Q4 2022 | Q4 2021 | 12M 2022 | 12M 2021 |
|---|---|---|---|---|
| Revenue | 30.8 | 15.4 | 154.5 | 33.9 |
| SG&A expenses | (82.1) | (103.2) | (336.2) | (327.3) |
| R&D expenses | (92.1) | (68.2) | (346.1) | (230.8) |
| Loss from operation | (144.7) | (162.8) | (587.0) | (547.0) |
| Loss for the period | (147.1) | (163.4) | (609.6) | (548.3) |
| Net cash used in operations | (111.7) | (116.3) | (504.4) | (481.2) |
| Cash and short-term investments | 1,496.2 | 889.0 | 1,496.2 | 889.0 |
| Shareholders' equity | 605.9 | 757.6 | 605.9 | 757.6 |
| EPS before and after dilution (SEK) | (3.19) | (3.67) | (13.57) | (12.33) |
| Number of outstanding shares | 52,443,962 | 44,473,452 | 52,443,962 | 44,473,452 |
| Weighted avg. number of shares before and after dilution | 46,128,829 | 44,473,452 | 44,923,998 | 44,473,452 |
| Number of employees at the end of the period | 150 | 133 | 150 | 133 |

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

***"2022 was a successful year at Hansa with solid performance and strong progress across the organization. I'm pleased with the forward momentum we continue to make across R&D, Commercial and Operation.***

***In Europe, we are very pleased to have secured Market Access in 11 countries including four of the five largest markets, while we continue to drive progress across our pipeline"***

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

"2022 was a successful year at Hansa with solid performance and strong progress across the organization. I'm pleased with the forward momentum we continue to make across R&D, Commercial and Operations. In Europe, we are very pleased to have secured Market Access in 11 countries including four of the five largest markets.

In August, the first medical guidelines for desensitization treatment of highly sensitized kidney transplant patients were published. These guidelines are the first to include Idefirix® and represent the first international consensus on a management pathway for kidney transplant patients with high unmet need. This underscores the important role that Idefirix® can play as a new, transformative therapy to enable kidney transplantation and is an important step in ensuring its use as a potential new Gold Standard in desensitization protocols.

On the development side, we continued to drive progress across our pipeline. In November, we presented topline data from our phase 2 program in AMR, post transplantation, demonstrating significantly superior capacity of imlifidase to rapidly reduce DSA levels in comparison to plasma exchange in the five days following the start of the treatment.

In 2022 we initiated two new phase 3 studies, namely the European Post Approval Efficacy Study in kidney transplantation and the pivotal, global phase 3 study in anti-GBM disease. Both studies will target 50 patients and involve a significant number of clinics as we broaden our experience with imlifidase to become a potential new standard of care in both transplantation and acute autoimmune diseases.

Patient enrolment continues to progress in the ConfIdeS trial - our pivotal, phase 3 trial in kidney transplantation in the US - with 51 out of a target of 64 patients enrolled. In the GBS phase 2 program, 25 out of a target of 30 patients have been enrolled. We aim to add more clinics to increase capacity and accelerate enrollment in both trials. Enrollment completion for both trials is expected in the first half 2023, while completion of randomization in the US ConfIdeS trial is expected in the second half 2023. We are targeting submission of a Biologics License Application (BLA), under the accelerated approval pathway, in 2024, as previously guided.

I am also very pleased with the achievements made in the preclinical development programs, specifically, in the DMD program with Sarepta in gene therapy and in the NiceR program, which is exploring utilisation of second-generation enzymes for repeat dosing. In DMD, imlifidase is being investigated as a potential pre-treatment in patients with pre-existing IgG antibodies to Sarepta's SRP-9001. To date, the data looks promising, and plans have been announced to initiate a clinical study in 2023. We completed IND enabling toxicology studies at the end of last year in the NiceR program for the lead candidate HNSA 5487. A CTA approval has since been obtained and we expect to start a clinical trial in the first half 2023.

An important pillar in our overall strategy is to progress select collaborations. I'm pleased to share that we announced our second collaboration in gene therapy with AskBio, in Pompe disease. Meanwhile, we continue to receive a steady flow of interest from other gene therapy companies, looking to collaborate with us, using our antibody cleaving enzyme technology platform.

We are pleased to have secured financing – giving us runway into 2025 -- through two financing events in 2022. In July, we raised USD 70m through a non-dilutive financing transaction with NovaQuest and in December, raised USD 40m in a directed share issue targeting U.S. and other international healthcare specialist investors. Together these transactions will help finance preparations for a potential U.S. launch of imlifidase in kidney transplantation, strengthen ongoing product development activities and expand the Company's R&D pipeline.

We anticipate an exciting year ahead, with several key milestones across our platform and therapy areas, as we continue the development of new, transformative medicines for patients suffering from serious, rare immunologic diseases."

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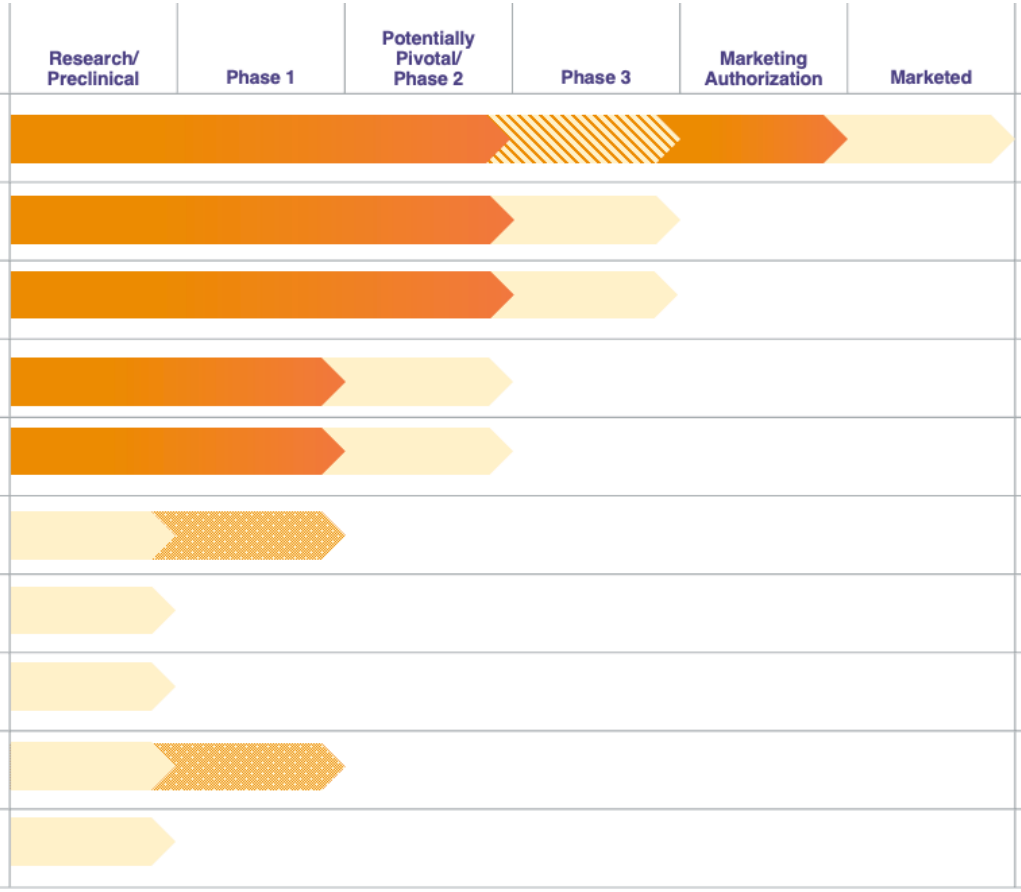
# Continued pipeline progress

| Candidate/ Project | Indication | 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) | Completion of enrollment (30 patients) H1'23 |
| | 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 |
| NiceR | Recurring treatment in autoimmune disease, transplantation and oncology | Initiate Phase I study of HNSA-5487 (Lead NiceR candidate) H1 2023 |
| 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 continued to progress, as planned, during 2022. Commercial access has been obtained in 11 European countries, including four of the five largest markets i.e. Germany, U.K., France (through a reimbursed Early Access Program) and Italy. Additional market access procedures are ongoing in nine countries including Spain, Portugal, and Switzerland.

In spring 2022, Swissmedic (the Swiss 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.

On July 11, 2022, Hansa announced that the first patient was treated in the post approval efficacy study (PAES). The PAES is an obligation under the European conditional marketing authorization and will be used to further investigate the long-term graft survival in 50 highly sensitized kidney transplant patients treated with Idefirix® and support the commercial development as well. The PAES is ongoing and is expected to be completed by 2025, at the latest.

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

As of February 1, 2023, 51 patients have been enrolled for randomization to imlifidase treatment or standard of care. Currently, 13 clinics are open for enrollment and new clinics are continuously added, aiming for approximately 20, to further increase the enrollment capacity and accelerate the study.

Completion of enrollment in the study is expected in the first half of 2023, while randomization is aimed for completion by the second half of 2023. Following a 12-month follow-up period, results are expected to support a BLA under the accelerated approval pathway in 2024, as previously guided.

## 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 patents demonstrate graft survival of 84% 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%, graft survival was 92% 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, when the five-year data is expected.

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

Anti-GBM is an acute autoimmune disease where 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 *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 typically two-thirds of patients losing their kidney function and ending up on dialysis after six months. These positive results mark an important milestone for the expansion of imlifidase outside transplantation and into autoimmune diseases.

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

The first sites have been initiated in a pivotal global phase 3 study in anti-GBM disease, with the first patient expected to be treated in the first half 2023. The study targets 50 patients with anti-GBM disease across the U.S. U.K. and EU.

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

Acute AMR episodes post kidney transplantation occur in 5-7% of patients[1] and is a significant challenge to long-term graft survival. There is no approved drug in AMR.

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

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 donor-specific antibodies (DSAs) compared to plasma exchange in the five days following the start of the treatment. The full data set is expected to be announced 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 in 100,000 people. 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 standard of care intravenous immunoglobulin (IVIg).

As of February 1, 2023, 25 out of a target of 30 patients with GBS have been enrolled at 10 centers across France, the U.K. and the Netherlands.

The widespread impact of the COVID-19 pandemic and the emergence of new variants have impacted the availability of staff across a number of our GBS trial centers and a shortage of IVIg has affected the enrollment rate at a subset of participating hospitals. During the second quarter and over the summer 2022, Hansa worked on mitigating these hurdles through implementation a number of significant initiatives including adding additional sites in the U.K. and the Netherlands. We continue to implement additional measures to increase capacity and accelerate recruitment. Completion of enrollment in the GBS trail is anticipated H1 2023, as previously guided.

### 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 transplantation2. Based on these findings a new single center study will be initiated to evaluate if a combination of bortezomib and belatacept can reduce the risk for AMR following desensitization with imlifidase. The study aims at including 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 Associate Professor Vasishta Tatapudi, MD and Program Director at the NYU Langone Transplant Institute.

# Preclinical programs

### HNSA5487 - lead candidate in the NiceR program for repeat dosing

Hansa is developing novel, IgG-degrading enzymes with the objective of enabling repeat dosing in autoimmune conditions, oncology 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, which Hansa intends to advance into clinical development. In line with previous guidance, IND enabling toxicology studies were completed at the end of 2022 and a CTA was subsequently approved. Hansa expects to initiate a clinical trial for HNSA- 5487during the first half 2023.

### EnzE – Enzyme-based antibody Enhancement

Published findings demonstrate how pre-treatment with imlifidase in tumor animal 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 the 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, can 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 USD 10 million as an 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 been progressing, as planned, and is ongoing with preclinical investigations with imlifidase as a potential pre-treatment to Sarepta's gene therapies.

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. This followed an earlier release from Sarepta Therapeutics in September 2022, in which Sarepta Therapeutics announced that it had submitted a BLA to the U.S. FDA for the accelerated approval of SRP-9001 to treat ambulant patients with DMD. 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

### 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 was initiated during the first quarter of 2022. It 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.

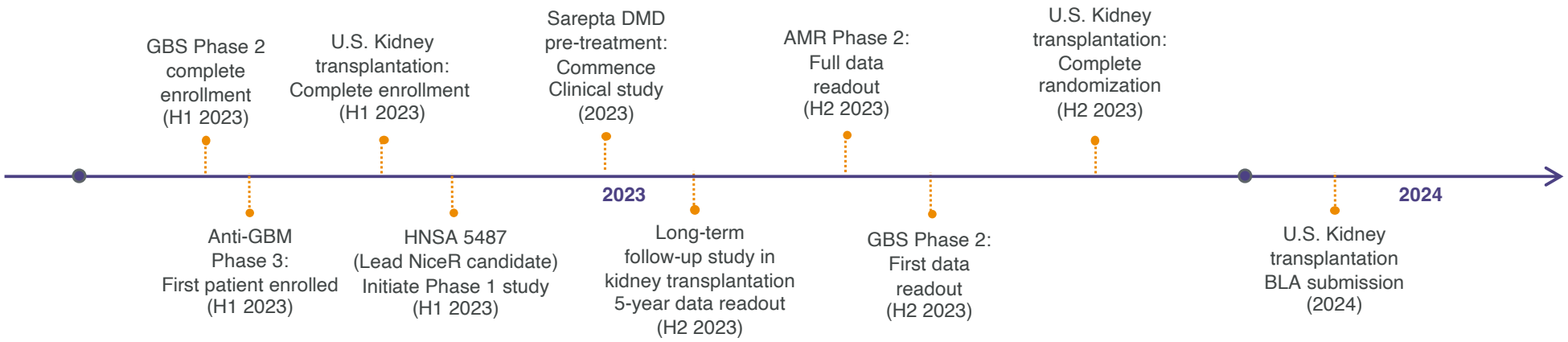
Under terms of the agreement, Hansa received a USD 5 million payment upon execution of the agreement and AskBio has the exclusive option to negotiate a full development and commercialization agreement following evaluation of the results from an initial phase 1/2 study. For further information regarding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

The collaboration is progressing as planned, currently at a preclinical stage.

### Preclinical research collaboration with argenx BV

In March 2021, Hansa announced a preclinical research collaboration agreement with argenx BV to explore the potential of combining imlifidase, and efgartigimod, argenx's FcRn antagonist, to potentially unlock additional therapeutic value in both the acute and chronic setting of autoimmune diseases and transplantation.

# Upcoming milestones

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# Financial review Year-end Report January – December 2022

## Revenue

Revenue for the fourth quarter of 2022 amounted to SEK 30.8m (Q4 ’21: SEK 15.4m) including Idefirix® product sales of SEK 20.3m (Q4 ’21: SEK 9.0m) and contract revenue of SEK 10.5m (Q4 ’21: SEK 6.4m), mainly from the upfront payments the Company received under the Sarepta and AskBio Agreements.

Revenue for the full year of 2022 amounted to SEK 154.5m (full year ’21: SEK 33.9m), mainly comprised of Idefirix® product sales of SEK 86.7m (full year ’21: SEK 15.0m), and contract revenue of SEK 67.8m (full year ’21: SEK 18.9m), chiefly related to revenue recognition of SEK 64.3m (full year ’21: SEK 15.7m) from the upfront payments the Company received under the Sarepta and AskBio Agreements.

## SG&A expenses

Sales, general and administrative expenses for the fourth quarter of 2022 amounted to SEK 82.1m (Q4 ’21: SEK 103.2m) and to SEK 336.2m for the full year of 2022 (full year ’21: SEK 327.3m). The increase in full year expenses mainly reflects Hansa’s broadened commercial activities and organizational expansion related to the launch of Idefirix® in Europe. Recorded non-cash costs for the Company’s employee long-term incentive programs, included in the above SG&A expenses, amounted to SEK 39.8m for the full year 2022 (full year ’21: SEK 37.5m).

## R&D expenses

Research and development expenses for the fourth quarter of the year 2022 amounted to SEK 92.1m (Q4 ’21: SEK 68.2m) and to SEK 346.1m for the full year of 2022 (full year ’21: SEK 230.8m). The increase over the respective 2021 periods is mainly driven by the ongoing U.S. ConfIdeS study, as well as progressing the EMA post-approval commitments and the initiation of the anti-GBM phase 3 program. Recorded non-cash costs for the Company’s employee long-term incentive programs, included in the above R&D expenses, amounted to SEK 18.5m for the full year 2022 (full year ’21: SEK 19.2m).

## Other operating income/expenses and financial expenses

Other operating income/expenses for the fourth quarter of 2022 amounted to an income of SEK 3.2m (Q4 ’21: expense of SEK 3.1m) and to an expense of SEK 20.8m for the full year of 2022 (full year ’21: expense of SEK 7.4m). The increase over the respective 2021 full-year period is mainly driven by a one-off settlement payment the Company made related to arbitration proceedings as further described in Note 2 below, as well as the impact of the US dollar exchange rate appreciation 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 fourth quarter of 2022, amounted to SEK 1.9m (Q4 ’21: SEK 0.5m) and to SEK 21.4m for the full year of 2022 (full year ’21: SEK 1.2m). The increase over the respective 2021 periods is mainly driven by accrued interest related to Hansa’s long-term loan (see Note 4 below).

## Financial results

The loss from operations for the fourth quarter of 2022 amounted to SEK 144.7m (Q4 ’21: SEK 162.8m) and to SEK 587.0m for the full year of 2022 (full year ’21: SEK 547.0m). The increase as compared to full year 2021 is mainly driven by Hansa’s broadened R&D pipeline activities partly off-set by increased revenues in 2022 as compared to 2021.

The loss for the fourth quarter of 2022 amounted to SEK 147.1m (Q4 ’21: SEK 163.4m) and to SEK 609.6m for the full year of 2022 (full year ’21: SEK 548.3m).

## Cash flow, cash and investments

Net cash used in operating activities for the fourth quarter of 2022 amounted to SEK 111.7m (Q4 ’21: SEK 116.3m) and to SEK 504.4m for the full year of 2022 (full year ’21 SEK 481.2m). The change as compared to the previous year periods is driven by increased operating expense levels mainly due to Hansa’s broadened R&D activities, partly compensated by higher revenue in 2022. Additionally, in Q1 2022, Hansa received a USD 5m (SEK 45.8m) upfront payment related to its agreement with AskBio.

Cash and cash equivalents, including short-term investments, amounted to SEK 1,496.2m on December 31, 2022, as compared to SEK 889.0m at year-end 2021. 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 1,126.0m in proceeds net of transaction cost, partly off-set by cash used in operations.

## Shareholders' equity

On December 31, 2022, shareholders' equity amounted to SEK 605.9m as compared to SEK 757.6m at the end of the year 2021.

## Parent Company

The parent company's revenue for the fourth quarter of 2022 amounted to SEK 30.8 (Q4 '21: SEK 15.4m) and to SEK 154.5 for the full year of 2022 (full year '21: SEK 33.9m).

Loss for the period for the parent company for the fourth quarter of 2022 amounted to SEK 131.9m (Q4 '21:
SEK 163.6m) and to SEK 595.2m for the full year of 2022 (full year '21: SEK 549.1m).

The parent company's equity amounted to SEK 618.8m as of December 31, 2022, as compared to SEK 755.9m at the end of the year 2021.

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 five employees at the end of December 2022. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of December 2022.

## Long-term incentive programs

Hansa Biopharma's past Annual General Meetings have resolved to adopt share-based long-term incentive programs (LTIPs). As of December 31, 2022, the following LTIPs were ongoing: LTIP 2019, 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 2021 Annual Report which can be found at www.hansabiopharma.com.

## Long term incentive programs

| Ongoing programs | LTIP 2018 | LTIP 2019 | LTIP 2020 | LTIP 2021 | LTIP 2022 |
|---|---|---|---|---|---|
| **Maximum number of issuable shares*** | - | 193 892 | 1 151 580 | 1 275 642 | 1 400 389 |
| Number of allocated and outstanding share rights and options | - | 149 148 | 885 831 | 981 263 | 927 000 |
| Number of acquired and outstanding warrants | - | - | - | - | - |
| Estimated total cost including social contributions, KSEK | - | 33 | 92 999 | 55 515 | 66 838 |
| Total cost per program, including social contributions, as of December 31, 2022 YTD, KSEK | 294 | 4 467 | 29 414 | 13 839 | 10 211 |

*As of 31 December 2022, including issuable shares to cover estimated social contributions under the LTIP.

| | |
|---|---|
| **Total costs, including social contributions, as of December 31, 2022 YTD, KSEK** | **58 226** |

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.

On February 24, 2022, Russia invaded Ukraine. Hansa does not have any operations in nor collaborations with any third-party service providers from either Ukraine or Russia. Therefore, Hansa's operational activities are not directly affected by the conflict. However, the conflict does have and is expected to continue to have general negative impacts on the global economy, stock markets, exchange rates, energy prices, global supply, and free trade, and, as such, does indirectly negatively impact Hansa's business.

In the 2021 Annual Report (pages 102-105 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 2021 Annual Report have been identified as of the date of this quarterly report.

## Other information

### Contacts

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### Legal disclaimer

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

### Financial calendar 2023

| | |
|---|---|
| March 30, 2023 | 2022 Annual Report |
| 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 December 31, 2022 | SEK ~2.7bn (USD ~261m) |
| Ticker | HNSA |
| ISIN | SE0002148817 |

### Top 10 shareholders as of December 31, 2022

| Name | Number of shares | Ownership in pct |
|---|---|---|
| Redmile Group, LLC | 10 896 553 | 20.8% |
| Försäkrings AB Avanza Pension | 2 209 783 | 4.2% |
| 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% |
| Handelsbanken Asset Management | 908 266 | 1.7% |
| C WorldWide Asset Management | 799 749 | 1.5% |
| Heights Capital Management, Inc. | 667 169 | 1.3% |
| Other | 28 318 488 | 54.0% |
| 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 19,000 shareholders as of December 31, 2022.

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

# Assurance

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

Lund February 2, 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 | December 31 2022 | December 31 2021 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible assets | 5 | 46 866 | 28 761 |
| Property and equipment | | 8 113 | 6 432 |
| Leased assets | | 27 723 | 35 273 |
| **Total non-current assets** | | **82 702** | **70 466** |
| **Current assets** | | | |
| Inventories | | 973 | 242 |
| Trade receivables & contract assets | | 42 959 | 9 712 |
| Current receivables, non-interest bearing | | 64 593 | 43 427 |
| Short-term investments | | - | 237 619 |
| **Cash and cash equivalents** | | 1 496 179 | 651 342 |
| **Total current assets** | | **1 604 704** | **942 342** |
| **TOTAL ASSETS** | | **1 687 406** | **1 012 808** |
| **EQUITY AND LIABILITIES** | | | |
| Shareholders' equity | | 605 909 | 757 573 |
| **Non-current liabilities** | | | |
| Long-term loan | 4 | 762 601 | - |
| Deferred tax liabilities | | 405 | 426 |
| Provisions | | 5 192 | 7 357 |
| Lease liabilities | | 21 326 | 28 491 |
| Deferred revenue | | 29 500 | 47 020 |
| Contingent consideration | 3 | 757 | 722 |
| **Total non-current liabilities** | | **819 781** | **84 016** |
| **Current liabilities** | | | |
| Tax liability | | 604 | - |
| Lease liabilities | | 7 165 | 6 888 |
| Current liabilities, non-interest bearing | | 80 754 | 66 908 |
| Deferred revenue | | 40 430 | 24 961 |
| Contract liabilities | | 27 013 | - |
| Accrued expenses and deferred income | | 105 750 | 72 462 |
| **Total current liabilities** | | **261 716** | **171 219** |
| **TOTAL EQUITY AND LIABILITIES** | | **1 687 406** | **1 012 808** |

## Consolidated income statement

| KSEK | Note | Q4 2022 | Q4 2021 | January-December 2022 | January-December 2021 |
|---|---|---|---|---|---|
| Revenue | 2 | 30 766 | 15 398 | 154 525 | 33 878 |
| Cost of revenue | | (4 535) | (3 623) | (38 477) | (15 425) |
| Sales, general and administration expenses | | (82 073) | (103 167) | (336 242) | (327 269) |
| Research and development expenses | 5 | (92 091) | (68 241) | (346 060) | (230 764) |
| Other operating income (expenses) | | 3 229 | (3 124) | (20 794) | (7 398) |
| **Loss from operations** | | **(144 704)** | **(162 757)** | **(587 048)** | **(546 978)** |
| Financial income (expenses), net | 4 | (1 888) | (452) | (21 365) | (1 152) |
| **Loss for the period before tax** | | **(146 592)** | **(163 209)** | **(608 413)** | **(548 130)** |
| Tax | | (516) | (181) | (1 155) | (152) |
| **Loss for the period** | | **(147 108)** | **(163 390)** | **(609 568)** | **(548 282)** |
| Attributable to: | | | | | |
| Parent company shareholders | | (147 108) | (163 390) | (609 568) | (548 282) |
| Earnings per share (EPS) | | | | | |
| Before dilution (SEK) | | (3,19) | (3,67) | (13,57) | (12,33) |
| After dilution (SEK) | | (3,19) | (3,67) | (13,57) | (12,33) |
| Other comprehensive income | | | | | |
| Items that have been, or may be reclassified to profit or loss for the period | | | | | |
| Translation differences | | (396) | 120 | (132) | 264 |
| **Other comprehensive income for the period** | | **(396)** | **120** | **(132)** | **264** |
| **Total net comprehensive income** | | **(147 504)** | **(163 270)** | **(609 700)** | **(548 018)** |

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-December 2022 | 2021 |
|---|---|---|
| **Opening balance of shareholders' equity as reported** | **757 573** | **1 242 124** |
| Result for the period | (609 568) | (548 282) |
| Other comprehensive income for the period | (132) | 264 |
| **Net comprehensive income** | **(609 700)** | **(548 018)** |
| **Transactions with the group's owner** | | |
| Proceeds from new share issuance, net [1] | 397 646 | - |
| Long term incentive programs | 60 391 | 63 467 |
| **Total transactions with the group's owner** | **458 037** | **63 467** |
| **Closing balance of shareholders' equity** | **605 909** | **757 573** |

1) Total share issue cost amounted to SEK 18,303k

## Consolidated statement of cash flow

| KSEK | Q4 2022 | Q4 2021 | January-December 2022 | January-December 2021 |
|---|---|---|---|---|
| Cash Flows from Operating Activities | | | | |
| Loss for the period | (147 108) | (163 390) | (609 568) | (548 282) |
| Adjustment for items not included in cash flow [1] | (7 021) | 23 085 | 83 240 | 64 998 |
| Interest received and paid, net | 5 318 | (213) | 5 101 | (627) |
| Income taxes paid | (866) | (70) | (1 565) | (143) |
| **Cash flow from operations before change in working capital** | **(149 677)** | **(140 588)** | **(522 792)** | **(484 053)** |
| Changes in working capital | 37 956 | 24 330 | 18 435 | 2 886 |
| **Net cash used in operating activities** | **(111 721)** | **(116 258)** | **(504 357)** | **(481 167)** |
| Investing activities | | | | |
| Proceeds from sale of short-term investments | - | - | 232 644 | - |
| Acquisition of property and equipment | (3 017) | - | (3 157) | (2 399) |
| **Cash flow from investing activities** | **(3 017)** | **-** | **229 487** | **(2 399)** |
| Financing activities | | | | |
| Proceeds long-term loan, net of transaction cost [2] | - | - | 728 373 | - |
| Proceeds from new share issue, net of transaction cost [3] | 397 646 | - | 397 646 | - |
| Repayment of lease liabilities | (1 734) | (1 216) | (6 888) | (4 857) |
| **Cash flow from financing activities** | **395 912** | **(1 216)** | **1 119 131** | **(4 857)** |
| Net change in cash | 281 174 | (117 474) | 844 261 | (488 423) |
| Cash and cash equivalents, beginning of period | 1 215 282 | 768 614 | 651 342 | 1 139 362 |
| Currency exchange variance, cash and cash equivalents | (277) | 200 | 576 | 403 |
| **Cash and cash equivalents, end of period** | **1 496 179** | **651 342** | **1 496 179** | **651 342** |

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 18,303k

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.

## Parent company – Statement of financial position

| KSEK | Note | December 31 2022 | December 31 2021 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible assets | 5 | 44 718 | 26 518 |
| Property, plant and equipment | | 8 113 | 6 432 |
| Leased assets | | 27 723 | 35 273 |
| Investment in subsidiaries | | 24 264 | 5 095 |
| Receivables, group companies | | - | 2 203 |
| **Total non-current assets** | | **104 818** | **75 521** |
| **Current assets** | | | |
| Inventories | | 973 | 242 |
| Trade receivables & contract assets | | 42 959 | 9 712 |
| Current receivables, non-interest bearing | | 64 368 | 43 201 |
| Short-term investments | | - | 237 619 |
| Cash and cash equivalents | | 1 486 502 | 644 975 |
| **Total current assets** | | **1 594 802** | **935 749** |
| **TOTAL ASSETS** | | **1 699 620** | **1 011 270** |
| **EQUITY AND LIABILITIES** | | | |
| **Shareholders' equity** | | **618 799** | **755 948** |
| **Non-current liabilities** | | | |
| Long-term loan | 4 | 762 601 | - |
| Provisions | | 5 192 | 7 357 |
| Lease liabilities | | 21 326 | 28 491 |
| Deferred revenue | | 29 500 | 47 020 |
| Contingent consideration | 3 | 757 | 722 |
| **Total non-current liabilities** | | **819 376** | **83 590** |
| **Current liabilities** | | | |
| Tax liability | | 604 | - |
| Lease liabilities | | 7 165 | 6 888 |
| Liabilities, group companies | | 5 738 | 3 901 |
| Current liabilities, non-interest bearing | | 80 225 | 66 598 |
| Deferred revenue | | 40 430 | 24 961 |
| Contract liabilities | | 27 013 | - |
| Accrued expenses and deferred income | | 100 270 | 69 384 |
| **Total current liabilities** | | **261 445** | **171 732** |
| **TOTAL EQUITY AND LIABILITIES** | | **1 699 620** | **1 011 270** |

## Parent company – Income statement

| KSEK | Note | Q4 2022 | Q4 2021 | January-December 2022 | January-December 2021 |
|---|---|---|---|---|---|
| Revenue | 2 | 30 766 | 15 398 | 154 525 | 33 878 |
| Cost of revenue | | (4 535) | (3 623) | (38 477) | (15 425) |
| Sales, general and administration expenses | | (74 383) | (102 515) | (328 521) | (327 031) |
| Research and development expenses | 5 | (84 745) | (69 110) | (340 192) | (231 974) |
| Other operating income (expenses) | | 3 488 | (3 123) | (20 532) | (7 395) |
| **Loss from operations** | | **(129 409)** | **(162 973)** | **(573 197)** | **(547 947)** |
| Result from financial items: | | | | | |
| Finance income | | 27 945 | 67 | 30 683 | 67 |
| Finance costs | 4 | (29 857) | (675) | (52 067) | (1 218) |
| **Loss for the period before tax** | | **(131 321)** | **(163 581)** | **(594 581)** | **(549 098)** |
| Income tax benefit/expense | | (604) | - | (604) | - |
| **Loss for the period** | | (131 925) | (163 581) | (595 185) | (549 098) |
| **Other comprehensive income for the period** | | - | - | - | - |
| **Total comprehensive income for the period** | | **(131 925)** | **(163 581)** | **(595 185)** | **(549 098)** |

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

| KSEK | January-December 2022 | January-December 2021 |
|---|---|---|
| **Opening shareholders' equity as reported** | **755 948** | **1 241 578** |
| **Result for the period** | **(595 185)** | **(549 098)** |
| Other comprehensive income for the period | - | - |
| **Net comprehensive income** | **(595 185)** | **(549 098)** |
| Proceeds from new share issuance, net [1] | 397 646 | - |
| Long term incentive programs | 60 391 | 63 467 |
| **Total transactions with the group's owner** | **458 037** | **63 467** |
| **Closing shareholders' equity** | **618 799** | **755 948** |

1) Total share issue cost amounted to SEK 18,303k

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 2021 was published on April 6, 2022 and is available at www.hansabiopharma.com. Disclosures in accordance with IAS 34.16A are as applicable in the notes or on the pages before the consolidated income statement.

## Note 2 Revenue

| Income per significant category of income | Q4 | | January-December | |
|---|---|---|---|---|
| KSEK | 2022 | 2021 | 2022 | 2021 |
| Group | | | | |
| Revenue | | | | |
| Product sales | 20 337 | 8 991 | 86 735 | 15 017 |
| Contract revenue, Axis-Shield agreement | 1 176 | 1 056 | 2 892 | 2 624 |
| Cost reimbursement, Axis-Shield agreement | 87 | 61 | 624 | 527 |
| Contract revenue, Sarepta, AskBio agreement | 9 165 | 5 290 | 64 273 | 15 710 |
| | **30 766** | **15 398** | **154 525** | **33 878** |
| Parent company | | | | |
| Revenue: | | | | |
| Product sales | 20 337 | 8 991 | 86 735 | 15 017 |
| Contract revenue, Axis-Shield agreement | 1 176 | 1 056 | 2 892 | 2 624 |
| Cost reimbursement, Axis-Shield agreement | 87 | 61 | 624 | 527 |
| Contract revenue, Sarepta, AskBio agreement | 9 165 | 5 290 | 64 273 | 15 710 |
| | **30 766** | **15 398** | **154 525** | **33 878** |

The Company is a party to two separate royalty agreements (the "Royalty Agreements") with certain inventors and an affiliated entity (collectively, the "Counterparties") of certain patents related to methods of use of imlifidase. Under each agreement, in consideration of the assignment of these patents, the Counterparties are entitled to receive a low single-digit royalty percentage of the Company's net income related to the utilization of the patents, in each case as defined in the applicable agreement, and a low-teens percentage of any once-only considerations, milestones, royalties, license income, consideration for transfer of patents, patent applications and other intellectual property rights and other payments received by the Company related to the exploitation of rights related to these patents, in each case subject to certain specified reductions. As the Company has received conditional regulatory approval for Idefirix® (imlifidase) in the EU for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor in August 2020 and the Company has initiated the commercial launch of Idefirix® in the EU, above-mentioned compensation obligations under the Royalty Agreements have become effective during 2022.

On April 20, 2021, the Company received a request for arbitration from the Counterparties claiming they were entitled to 10% of the upfront payment the Company received under its 2020 collaboration agreement with Sarepta as well as entitlement to participate in payments the Company may receive under the Sarepta agreement in the future. The Company has settled these arbitration proceedings with the Counterparties during 3rd quarter 2022. The settlement includes a one-off settlement payment and the entitlement of the Counterparties to low single-digit royalties on net sales as well as mid-single-digit participation in any once-only consideration received by Hansa in respect of imlifidase. This settlement includes all compensation obligations under the Royalty Agreements.

## Note 3 Fair value of financial instruments

The Group measures its investments in interest funds and its financial liability for contingent consideration at fair value. The fair value of the financial liability for contingent consideration on December 31, 2022 amounted to SEK 0.8 million (Year-end'21: SEK 0.7 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 the period – 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 December 2022, the loan amounted to SEK 762.6 million, thereof SEK 41.2 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. Therefore, the Company for this period and going forward does capitalize development cost related to Idefirix in the conditionally approved indication.

For Q4-2022 and the year ending December 31, 2022 the Company capitalized development cost in the amount of SEK 20.8 million related to performing its Idefirix® EMA post-approval commitments.

# 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.