

# INTERIM REPORT JANUARY-MARCH 2021



## First commercial sales of Idefirix® recorded; New preclinical collaboration with argenx; Encouraging three-year follow-up data in kidney transplantation

### Highlights for the first quarter 2021

- First commercial sales of Idefirix® recorded in Q1 2021 following treatment of the first patients. Commercial launch activities in early launch countries continue to be carried out as planned. National level reimbursement application processes underway and decisions by authorities in the first markets expected from mid-year and onwards.
- First Healthcare Technology Assessment report published in Sweden. The Swedish "TLV" assessment is favorable to the use of Idefirix® in highly sensitized patients incompatible with a deceased donor.
- Hansa Biopharma enters into preclinical research collaboration agreement with argenx BV to evaluate the therapeutic potential of combining the two companies' IgG-modulating technologies for potential use in both the acute and chronic setting of autoimmune diseases and transplantation.
- Encouraging three-year follow-up outcome and safety data in imlifidase treated transplant patients in line with expectations compared to outcomes in patients undergoing HLA-incompatible transplantation. Data expected to be presented later in the year in a peer-reviewed journal.
- Magnus Korsgren, M.D., Ph.D. appointed new Head of R&D. Dr Korsgren will lead research and development activities based on Hansa's proprietary enzyme technology platform as the Company expands into new therapeutic areas.
- Patient recruitment in the phase 2 studies in AMR and GBS ongoing under a risk-based, site-by-site approach due to the COVID-19 pandemic. In the AMR trial, 9 out of a target of 30 patients have been enrolled, and in the GBS trial 8 out of 30 have been enrolled.
- US trial: Hansa continues to be in productive dialogue with the FDA and expects to reach an agreement near-term with the Agency on the protocol for a randomized controlled study in the US. Preparatory work to initiate the trial is ongoing. Hansa expects to initiate the trial over summer and to recruit the first patient in the second half of 2021.
- COVID-19 pandemic: The global COVID-19 pandemic may still adversely impact Hansa Biopharma's operational business and trial activities.

### Events after the end of the reporting period

- Hilary Malone, PhD. in Molecular Neuropharmacology (born 1965, U.S. and UK citizen) proposed as new member of the Board of Directors at the next AGM. Dr. Malone is currently COO and EVP at Valo Health, Inc. (U.S.) and has held global executive positions at Sanofi, Reata Pharmaceuticals, Pfizer, Wyeth and AstraZeneca, among others. Birgit Stattin Norinder has decided not to stand for re-election to the Board of Directors at the next AGM.

### Financial Summary

- Solid cash position of SEK 1,255m at the end of March 2021.
- Investments in SG&A and R&D in the first quarter amounting to SEK 60m (Q1'20: SEK 39m) and SEK 47m (Q1'20: SEK 53m), respectively, in line with plans.
- Cash flow from operating activities for the first quarter ended at SEK -121m (Q1'20: SEK -121m).

SEKm, unless otherwise stated - unaudited	Q1 2021	Q1 2020	FY 2020
Revenue	9.0	0.9	6.1
Gross profit	7.3	0.5	5.1
SG&A expenses	-60.1	-38.7	-203.0
R&D expenses	-47.4	-52.5	-227.2
<b>Operating profit/loss</b>	<b>-103.7</b>	<b>-91.4</b>	<b>-422.8</b>
Net profit/loss	-103.9	-93.4	-420.9
Cash flow from operating activities	-120.9	-121.2	-290.3
Cash and short-term investments	1,254.7	476.9	1,377.5
Shareholders' equity	1,149.8	473.9	1,242.1
EPS before and after dilution (SEK)	-2.34	-2.33	-9.98
Number of outstanding shares	44,473,452	40,026,107	44,473,452
Weighted avg. number of shares before and after dilution	44,473,452	40,026,107	42,176,872
Number of employees	101	78	87

## Søren Tulstrup, President and CEO, comments

*"Hansa Biopharma's evolution into a fully integrated, commercial-stage biopharmaceutical company is now a reality following the Company's first commercial sales of Idefix® and treatments of the first patients.*

*Our long-term objective is to build Hansa into a recognized global leader in rare diseases across multiple broad therapeutic areas through the development of new transformative medicines for patients suffering from rare immunologic diseases. In order to do so, we need to successfully execute on our strategic priorities. This early in 2021, we have already demonstrated clear progress across our business and organization and that we are on track to deliver on our targets for the year.*

*In Europe, our commercial launch activities continue to be rolled out and implemented in early launch countries as planned. As part of this effort, we continue to have close interactions with national reimbursement authorities and leading transplant clinics. Decisions by authorities in the first of the early launch countries can be expected from mid-year and onwards following publication of Healthcare Technology Assessments to evaluate the health-economic impact from using Idefix®. A first such assessment was recently published in Sweden, which was favorable to the use of Idefix® in scenarios representing both high and low mortality assumptions for dialysis patients.*

*On March 29, Hansa entered into a preclinical research collaboration agreement with argenx BV to explore the potential of combining imlifidase, Hansa's IgG antibody-cleaving enzyme, and efgartigimod, argenx's FcRn antagonist. We are pleased to collaborate with argenx, a leader in the field of FcRn-inhibition, as they share our commitment to bringing innovative new medicines to patients suffering from autoimmune diseases. A combination of imlifidase and efgartigimod could potentially be used in both the acute and chronic setting of autoimmune diseases and transplantation and may potentially unlock additional therapeutic value.*

*In the US, Hansa is in productive dialogue with the FDA and we expect to finalize near-term an agreement with the Agency on a protocol for a randomized controlled study in the US. Preparatory work to initiate the trial is already ongoing and we are encouraged by the strong interest shown by leading US transplant centers to participate in the trial. Subject to the expected agreement with FDA on the study protocol in the coming months, we expect study initiation over the summer and the first patient to be enrolled in the second half of 2021.*

*In our ongoing phase 2 programs, GBS and AMR, we see patient enrollment progressing again following a temporary halt in the recruitment process during large parts of 2020 due to the COVID-19 pandemic. In December 2020, patient enrollment was reinitiated in both studies under a risk-based, site-by-site approach. As of April 21, 2021, 9 out of a target of 30 patients have now been enrolled in the AMR study, while 8 out of 30 have been enrolled in the GBS study. Depending on the impact of the COVID-19 pandemic, enrollment is expected to be completed towards the end of 2021, as previously guided.*

*Furthermore, I am pleased to announce that our long-term follow-up study in highly sensitized kidney patients continues to show encouraging outcomes after imlifidase treatment and transplantation. We now have three-year data available, demonstrating follow-up outcomes in line with expectations compared to outcomes in patients undergoing HLA-incompatible transplantation. Data is expected to be published later this year following submission of a manuscript to a peer-reviewed journal.*

*I am also happy to see that we continue to attract the talent and competences needed to build a high-performance organization. In March, we announced the recruitment of Magnus Korsgren, M.D., Ph.D as our new Head of R&D. Dr. Korsgren's extensive international experience in translational medicine and drug*

*development will be very helpful for our continued efforts to build a highly valuable pipeline of drug candidates within transplantation, autoimmune diseases and beyond.*

*Speaking about attracting highly qualified, international competences, I am also very pleased to see Hilary Malone, Ph.D in Molecular Neuropharmacology, being proposed at the next AGM as a new member of the Board of Directors at Hansa Biopharma. Ms. Malone currently holds the position of Executive Vice President and Chief Operating Officer at Valo Health, Inc. in the US and has previously held global executive positions at Sanofi, Reata Pharmaceuticals, Pfizer, Wyeth and AstraZeneca, among others.*

*Hansa is off to a good start in 2021 and I look forward to updating you on our progress as we deliver on our mission to bring lifesaving and life altering therapies to patients with rare diseases who need them while generating value to shareholders and society at large."*



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

# Continuous development in our pipeline activities

Candidate/ Project	Indications	Research/ Preclinical	Phase 1	Potentially Pivotal/ Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
<b>Imlifidase</b>	EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>				→		*)	EU: First national reimbursement agreement Q2/Q3'21
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>				**) )			US: First patient dosed 2H 2021
	Anti-GBM antibody disease <sup>3</sup>							Agreement with regulators on a path forward toward BLA/MAA
	Antibody mediated kidney transplant rejection (AMR)							Complete enrollment of 30 patients in H2 2021
	Guillain-Barré syndrome (GBS)							Complete enrollment of 30 patients in H2 2021
	Pre-treatment ahead of gene therapy in Limb-Girdle (LGMD) & Duchenne (DMD) (Partnered with Sarepta)							Pre-Clinical phase
<b>NiceR</b>	Recurring treatment in autoimmune disease, transplantation and oncology							Initiation of toxicology studies in H1 2021
<b>EnzE</b>	Cancer immunotherapy							Research phase

<sup>1</sup> Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)  
<sup>2</sup> Lorient et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)  
<sup>3</sup> Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund  
 \*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch  
 \*\*) FDA: Hansa continues to be in productive dialogue with the FDA and expects to reach an agreement near-term with the Agency on the protocol for a study in the US. Preparatory work to initiate the trial is ongoing. Hansa expects to initiate the trial over summer and to recruit the first patient in H2 2021

## Imlifidase - Clinical programs and regulatory interactions

### Enabling kidney transplantation for highly sensitized patients

On August 26, 2020 Idefix® (imlifidase) 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 approval served as a landmark milestone for Hansa Biopharma, as Idefix® is the Company's first approved drug.

Commercial launch activities in early launch countries are being carried out as planned and Idefix® is. National level reimbursement application processes are underway as planned, and decisions by authorities in the first of the early launch countries are expected from mid-year and onwards.

In the US, Hansa is in productive dialogue with the FDA and expects to finalize near-term an agreement with the FDA on a protocol for a randomized controlled study in the US. Once an agreement is finalized, Hansa will proceed to set up centers in the US and expects to recruit the first patient in the second half of 2021.

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](http://www.hansabiopharma.com).

Beyond the four completed phase 2 studies in kidney transplantation, Hansa Biopharma is also conducting a prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration. The three-year follow-up data in highly sensitized kidney transplant patents demonstrates follow-up outcome and safety data in line with expectations in imlifidase treated transplant patents compared to outcomes in patients undergoing HLA-incompatible transplantation. Data is expected to be published later this year following submission of a manuscript to a peer-reviewed journal.

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

Anti-GBM is an acute auto-immune disease where antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM) causing acute injury of kidney and/or lung. Anti-GBM is an ultra-rare and very severe disease that annually is affecting approximately 1.6 in a million globally. A majority of patients lose their kidney function<sup>1</sup>, requiring chronic dialysis and kidney transplantation.

On September 24, 2020 positive high-level data was presented from an investigator-initiated phase 2 trial with imlifidase, led by Principal Investigator Mårten Segelmark, Professor at the Universities in Linköping and Lund, to treat anti-GBM disease, showing two-thirds of patients achieving dialysis independence six months after treatment. Normally, two-thirds of patients will lose kidney function and end up on dialysis after six months.

The positive data marks an important milestone for the expansion of imlifidase outside transplantation. Regulatory discussions with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) will be initiated to determine the regulatory path forward for imlifidase in anti-GBM.

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

Active antibody mediated rejection is a serious condition after transplantation that occurs in roughly 10-15% of kidney transplants<sup>2</sup> or approximately 3,200<sup>3</sup> new patients annually<sup>4</sup> and is a significant challenge to long term graft survival.

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

The recruitment process for this phase 2 study was temporarily halted during a large part of 2020 due to the COVID-19 pandemic, but was reinitiated in the fourth quarter of 2020, as previously guided. As of April 21, 2021, 9 of a target of 30 patients with active AMR episodes have been enrolled. Depending on the continued impact of the COVID-19 pandemic, enrollment is expected to be completed in the second half of 2021.

#### 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. In 2019, Hansa Biopharma 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).

The recruitment process for this phase 2 study was temporarily halted during a large part of 2020 due to the COVID-19 pandemic, but reinitiated in the fourth quarter of 2020, as previously guided. As of April 21, 2021 8 of a target of 30 patients with GBS, have been enrolled in this phase 2 study. Depending on the continued impact of the COVID-19 pandemic, enrollment is expected to be completed in the second half of 2021.



<sup>1</sup> Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12

<sup>2</sup> Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.

<sup>3</sup> Jordan et al., British Medical Bulletin, 2015, 114:113-125.

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<sup>4</sup> <http://www.irodat.org>.



## Preclinical programs

### NiceR – Novel Immunoglobulin G (IgG) cleaving enzymes for Repeat dosing

Hansa Biopharma 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.

The first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development has been selected. Development of a GMP-manufacturing process for the lead NiceR candidate has since been initiated and preparations for toxicology studies and a clinical phase 1 study are now ongoing. IND-enabling tox studies are expected to commence in the first half of 2021.

### EnzE – Enzyme-based antibody Enhancement

Published findings<sup>5</sup> 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 (e.g. imlifidase or the selected NiceR-lead) as a pretreatment 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)

On July 2, 2020, Hansa Biopharma announced an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy in Duchenne muscular dystrophy and Limb-Girdle muscular dystrophy in patients with neutralizing antibodies (NABs) to adeno-associated virus (AAV).

Under the terms of the agreement, Hansa received USD 10m as an upfront payment and will book all sales of imlifidase. In addition, Hansa will be eligible for up to USD 397.5m 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.

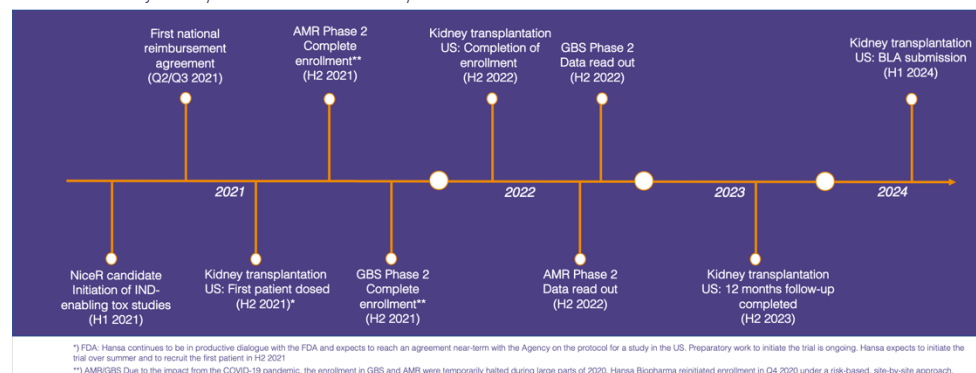
The partnership has been progressing as planned, and during the second half of 2020 Sarepta initiated ongoing pre-clinical investigations with imlifidase as a potential pre-treatment in the gene therapy setting. For further information regarding Sarepta's gene therapy programs in DMD and LGMD please refer to [www.sarepta.com](http://www.sarepta.com).

### Pre-clinical research collaboration with argenx BV

On March 29, Hansa Biopharma announced a preclinical research collaboration agreement with argenx BV to explore the potential of combining imlifidase, Hansa's IgG antibody-cleaving enzyme, 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

*Milestones subject to potential COVID-19 impact*



<sup>5</sup> Järnum et al., "Enzymatic inactivation of endogenous IgG by IdeS enhances therapeutic antibody efficacy", Molecular Cancer Therapeutics, 2017, Sep; 16(9):1887-1897

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# Financial review January – March 2021

## Revenue

Revenue for the first quarter 2021 amounted to SEK 9.0m (Q1'20: SEK 0.9m) and mainly comprises of Idefirix® product sales, revenue recognition from the upfront payment the Company received under the Sarepta Agreement and royalty income from Axis-Shield Diagnostics (Abbott group).

## SG&A expenses

Sales, general and administration expenses for the first quarter 2021 amounted to SEK 60.1m (Q1'20: SEK 38.7m) The increase in expenses mainly reflects Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix® in Europe. Recorded non-cash cost for the Company's employee long-term incentive programs for the first quarter amounted to SEK 1.4m (Q1'20: SEK 2.9m) and is included in the SG&A expenses.

## R&D expenses

Research and development expenses for the first quarter 2021 amounted to SEK 47.4m (Q1'20: SEK 52.5m). Recorded non-cash cost for the Company's employee long-term incentive programs amounting to SEK 0.9m for the first quarter (Q1'20: SEK 1.6m) and is included in the R&D expenses.

## Financial result

The operating result for the first quarter 2021 amounted to SEK -103.7m (Q1'20: SEK -91.4m). The increase as compared to Q1-2020 is mainly driven by Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix in Europe.

Net loss for the first quarter 2021 amounted to SEK -103.9m (Q1'20: SEK -93.4m).

## Cash flow, cash and investments

Cash flow from operating activities for the first quarter 2021 amounted to SEK -120.9m (Q1'20: SEK -121.2m).

Cash and cash equivalents including short term investments amounted to SEK 1,254.7m on March 31, 2021 as compared to SEK 1,377.5m at year-end 2020.

## Shareholders' equity

On March 31, 2021, equity amounted to SEK 1,149.8m as compared to SEK 1,242.1m at the end of the year 2020.

## Parent Company

The parent company's net revenue for the first quarter of 2021 amounted to SEK 9.0m (Q1'20: SEK 0.9m).

Loss for the parent company for the first quarter 2021 amounted to SEK -104.1m (Q1'20: SEK -93.6).

The parent company's equity amounted to SEK 1,149.0m as per March 31, 2021, as compared to SEK 1,241.6m at the end of year 2020.

The Group consists of the parent company Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd and Hansa Biopharma Inc. Hansa Biopharma Inc had three employees at the end of March 2021. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had two employees at the end of March 2021.



## 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, 2020, the following LTIPs were ongoing: LTIP 2018, LTIP 2019 and LTIP 2020.

The respective cost 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 2020 Annual Report which can be found at [www.hansabiopharma.com](http://www.hansabiopharma.com)

Ongoing programs	LTIP 2018	LTIP 2019	LTIP 2020
Maximum number of issuable shares*	789 321	1 154 463	1 011 376
Number of allocated and outstanding share rights and options	223 778	436 703	903 076
Number of acquired and outstanding warrants	6 701	11 000	-
Estimated total cost including social contributions, KSEK	20 294	32 720	98 808
Total cost per program, including social contributions, as of March 31, 2021 YTD, KSEK	-2 272	-1 833	6 311
<i>*Includes issuable shares to cover social contributions under the LTIP</i>			
Total costs, including social contributions, as of March 31, 2021 YTD, KSEK	2 205		

## Risks and uncertainties

Hansa Biopharma'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 regards to clinical trials and regulatory approvals, collaboration and partnerships, intellectual property issues, dependence on key product, market and competition, manufacturing, purchasing and pricing, as well as dependence on key persons and financial risks.

In the Annual Report 2020 (pages 58-60 ENG) the risks which are considered to have greatest significance for Hansa Biopharma's future development are described in more detail.

## Other information

### Contacts

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### Financial calendar 2021

May 12, 2021 - Annual General Meeting 2021

July 15, 2021 - Interim report for Jan - Jun 2021

Oct. 21, 2021 - Interim report for Jan – Sep 2021

### 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 development within research programs.

## Shareholder information

### Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	45,894,909 (44,473,452 A-shares and 1,421,457 C-shares)
Market Cap March 31, 2021	SEK ~7bn (USD ~800m)
Ticker	HNSA
ISIN	SE0002148817

### Top 10 shareholders as of March 31, 2021

Name	Number of shares	Ownership in pct
Redmile Group, LLC	4 625 590	10.4
Nexttobe AB	2 155 379	4.9
Handelsbanken Asset Management*	2 022 706	4.6
Invesco Advisers, Inc.	1 973 164	4.4
Fjärde AP-Fonden (AP 4)	1 972 796	4.4
Olausson, Thomas	1 770 474	4.0
Försäkrings AB Avanza Pension	1 378 840	3.1
Schroder Investment Management, LTD	1 160 946	2.6
The Vanguard Group, Inc.	1 158 198	2.6
Norges Bank Investment Management	1 080 080	2.4
Other	25 175 279	56.6
<b>Outstanding shares in total</b>	<b>44,473,452</b>	<b>100.0</b>

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

\*As of April 6 2021, Handelsbanken Fonder flagged ownership above 5%.

Hansa Biopharma had approximately 17,000 shareholders as of March 31, 2021.

# 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 22, 2021

**Ulf Wiinberg**  
Chairman of the Board

**Birgit Stattin Norinder**  
Board member

**Eva Nilsagård**  
Board member

**Mats Blom**  
Board member

**Andreas Eggert**  
Board member

**Anders Gersel Pedersen**  
Board member

**Søren Tulstrup**  
President & CEO

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## Condensed unaudited financial statements

### Consolidated income statement

KSEK	Q1		Year
	2021	2020	2020
Revenue	8 998	885	6 098
Cost of revenue	-1 734	-423	-997
<b>Gross profit</b>	<b>7 264</b>	<b>462</b>	<b>5 101</b>
Other operating income	-	-	2 270
Sales, general and administration expenses	-60 086	-38 670	-202 987
Research and development expenses	-47 403	-52 545	-227 191
Other operating expenses	-3 461	-598	-
<b>Operating profit/loss</b>	<b>-103 686</b>	<b>-91 351</b>	<b>-422 807</b>
Financial income/expenses	-251	-2 029	1 914
<b>Profit/loss for the period before tax</b>	<b>-103 937</b>	<b>-93 380</b>	<b>-420 893</b>
Tax	10	11	40
<b>Net profit/loss for the period</b>	<b>-103 927</b>	<b>-93 369</b>	<b>-420 853</b>
Attributable to:			
Parent company shareholders	-103 927	-93 369	-420 853
Earnings per share (EPS)			
Before dilution (SEK)	-2,34	-2,33	-9,98
After dilution (SEK)	-2,34	-2,33	-9,98
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the period			
Translation differences	149	90	-297
<b>Other comprehensive income for the period</b>	<b>149</b>	<b>90</b>	<b>-297</b>
<b>Total net comprehensive income</b>	<b>-103 778</b>	<b>-93 279</b>	<b>-421 150</b>

## Consolidated statement of financial position

KSEK	March 31		December 31
	2021	2020	2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	30 882	33 210	31 410
Property and equipment	5 618	5 884	5 206
Leased assets	3 273	8 153	4 493
<b>Total non-current assets</b>	<b>39 773</b>	<b>47 247</b>	<b>41 109</b>
<b>Current assets</b>			
Inventories	83	-	98
Current receivables, non-interest bearing	16 126	15 334	15 783
Short-term investments	238 060	327 747	238 144
Cash and cash equivalents	1 016 686	149 159	1 139 362
<b>Total current assets</b>	<b>1 270 955</b>	<b>492 240</b>	<b>1 393 387</b>
<b>TOTAL ASSETS</b>	<b>1 310 728</b>	<b>539 486</b>	<b>1 434 496</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>1 149 820</b>	<b>473 946</b>	<b>1 242 124</b>
<b>Non-current liabilities</b>			
Deferred tax liabilities	448	505	424
Provisions	5 156	958	14 426
Lease liabilities	582	4 711	630
Deferred revenue	61 268	-	62 026
Contingent consideration	735	760	663
<b>Total non-current liabilities</b>	<b>68 189</b>	<b>6 934</b>	<b>78 169</b>
<b>Current liabilities</b>			
Lease liabilities	3 270	3 852	4 415
Current liabilities, non-interest bearing	27 043	25 295	36 274
Deferred revenue	20 745	-	17 406
Accrued expenses and deferred income	41 661	29 459	56 108
<b>Total current liabilities</b>	<b>92 719</b>	<b>58 606</b>	<b>114 203</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1 310 728</b>	<b>539 486</b>	<b>1 434 496</b>

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](http://www.hansabiopharma.com).

## Consolidated statements of changes in shareholder's equity

KSEK	Q1		Year
	2021	2020	2020
Opening balance of shareholders' equity as reported	1 242 124	562 815	562 815
Result for the period	-103 927	-93 369	-420 853
Other comprehensive income for the period	149	90	-297
<b>Net comprehensive income</b>	<b>-103 778</b>	<b>-93 279</b>	<b>-421 150</b>
Transactions with the group's owner			
Proceeds from new share issuance, net	-	-	1 070 581
Long term incentive programs	11 475	4 410	29 878
<b>Total transactions with the group's owner</b>	<b>11 475</b>	<b>4 410</b>	<b>1 100 459</b>
<b>Closing balance of shareholders' equity</b>	<b>1 149 820</b>	<b>473 946</b>	<b>1 242 124</b>

## Consolidated statement of cash flow

KSEK	Q1		Year
	2021	2020	2020
<b>Operating activities</b>			
Operating profit/loss	-103 686	-91 351	-422 807
Adjustment for items not included in cash flow <sup>1)</sup>	4 389	5 528	51 430
Interest received and paid, net	-98	-122	-68
Income taxes paid	-	-	-105
<b>Cash flow from operations before change in working capital</b>	<b>-99 395</b>	<b>-85 944</b>	<b>-371 550</b>
Changes in working capital	-21 514	-35 235	81 276
<b>Cash flow from operating activities</b>	<b>-120 910</b>	<b>-121 180</b>	<b>-290 274</b>
<b>Investing activities</b>			
Acquisition of property and equipment	-683	-138	-294
Sale of short term investments	-	89 741	182 828
<b>Cash flow from investing activities</b>	<b>-683</b>	<b>89 602</b>	<b>182 534</b>
<b>Financing activities</b>			
Proceeds from new share issuance, net	-	-	1 070 581
Repayment of lease liabilities	-1 193	-1 155	-4 674
<b>Cash flow from financing activities</b>	<b>-1 193</b>	<b>-1 155</b>	<b>1 065 906</b>
Net change in cash	-122 786	-32 733	958 166
Cash and cash equivalents, beginning of period	1 139 362	181 697	181 697
Currency exchange variance, cash and cash equivalents	110	195	-501
<b>Cash and cash equivalents, end of period</b>	<b>1 016 686</b>	<b>149 159</b>	<b>1 139 362</b>

1) Values are mainly costs of share based incentive programs including social contributions and depreciation.

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## Parent company – Income statement

KSEK	Q1		Year
	2021	2020	2020
Revenue	8 998	885	6 098
Cost of revenue	-1 734	-423	-997
<b>Gross profit</b>	<b>7 264</b>	<b>462</b>	<b>5 101</b>
Other operating income	-	-	-
Sales, general and administration expenses	-60 188	-38 972	-203 346
Research and development expenses	-47 477	-52 445	-227 531
Other operating expenses	-3 462	-597	2 270
<b>Operating profit/loss</b>	<b>-103 863</b>	<b>-91 553</b>	<b>-423 507</b>
Result from financial items:			
Finance income	-83	-1 910	1 782
Finance costs	-133	-119	81
<b>Loss for the period before tax</b>	<b>-104 079</b>	<b>-93 582</b>	<b>-421 644</b>
Income tax benefit/expense	-	-	-
<b>Loss for the period after tax</b>	<b>-104 079</b>	<b>-93 582</b>	<b>-421 644</b>
<b>Other comprehensive income for the period</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Total comprehensive income for the period</b>	<b>-104 079</b>	<b>-93 582</b>	<b>-421 644</b>

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

KSEK	March 31		Year
	2021	2020	2020
Opening shareholders' equity as reported	1 241 578	562 763	562 763
Result for the period	-104 079	-93 582	-421 644
Other comprehensive income for the period	-	-	-
<b>Net comprehensive income</b>	<b>-104 079</b>	<b>-93 582</b>	<b>-421 644</b>
Proceeds from new share issuance, net	-	-	1 070 581
Long term incentive programs	11 474	4 410	29 878
<b>Total transactions with the group's owner</b>	<b>11 474</b>	<b>4 410</b>	<b>1 100 459</b>
<b>Closing shareholders' equity</b>	<b>1 148 974</b>	<b>473 592</b>	<b>1 241 578</b>

## Parent company – Statement of financial position

KSEK	March 31		December 31
	2021	2020	2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	28 508	29 398	29 171
Property, plant and equipment	5 618	5 884	5 206
Leased assets	3 273	8 153	4 493
Investment in subsidiaries	5 095	5 095	5 095
Receivables, group companies	2 100	2 359	1 972
<b>Total non-current assets</b>	<b>44 594</b>	<b>50 889</b>	<b>45 937</b>
<b>Current assets</b>			
Inventories	83	-	98
Current receivables, non-interest bearing	15 632	14 836	15 268
Receivables, group companies	-	926	-
Short-term investments	238 060	327 747	238 144
Cash and cash equivalents	1 013 298	144 079	1 133 647
<b>Total current assets</b>	<b>1 267 073</b>	<b>487 588</b>	<b>1 387 157</b>
<b>TOTAL ASSETS</b>	<b>1 311 667</b>	<b>538 477</b>	<b>1 433 094</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>1 148 974</b>	<b>473 592</b>	<b>1 241 578</b>
<b>Non-current liabilities</b>			
Provisions	5 156	958	14 426
Lease liabilities	582	4 711	630
Deferred revenue	61 268	-	62 026
Contingent consideration	735	759	663
<b>Total non-current liabilities</b>	<b>67 741</b>	<b>6 428</b>	<b>77 745</b>
<b>Current liabilities</b>			
Lease liabilities	3 270	3 852	4 415
Liabilities, group companies	3 901	1 700	1 613
Current liabilities, non-interest bearing	26 257	24 968	34 950
Deferred revenue	20 745	-	17 406
Accrued expenses and deferred income	40 779	27 937	55 387
<b>Total current liabilities</b>	<b>94 952</b>	<b>58 457</b>	<b>113 771</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1 311 667</b>	<b>538 477</b>	<b>1 433 094</b>

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](http://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. The Annual report 2020 was published on April 8, 2021 and is available at [www.hansabiopharma.com](http://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
	2021	2020	2020
KSEK			
Group			
Revenue			
Product sales	6 026	-	-
Contract revenue, Axis-Shield agreement	523	582	2 864
Cost reimbursement, Axis-Shield agreement	-	302	636
Contract revenue, Sarepta agreement	2 449	-	2 599
	8 998	885	6 098
Parent company			
Revenue:			
Product sales	6 026	-	-
Contract revenue, Axis-Shield agreement	523	582	2 864
Cost reimbursement, Axis-Shield agreement	-	302	636
Contract revenue, Sarepta agreement	2 449	-	2 599
	8 998	885	6 098

In the past, the Company has entered into several royalty agreements (the "Royalty Agreements") with researchers and institutions (the "Counterparties") related to IdeS or imlifidase pursuant to which the Counterparties assign certain IP, patent and other rights (the "Rights") to the Company. As a compensation for the assignment of the Rights to the Company, the Counterparties are granted rights to receive royalties on net income and/or other compensation related to other payments the Company may receive related to IdeS or imlifidase in accordance with the terms of the Royalty Agreements. 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 plans to commercially launch Idefirix® in the EU during 2021, above mentioned compensation obligations under the Royalty Agreements may become effective during 2021.

On April 20, 2021 Hansa received a request for arbitration from the Counterparties claiming a 10% financial participation in the upfront payment Hansa received under the Sarepta agreement in 2020 as well as entitlement to participate in royalty payments Hansa may receive under the Sarepta agreement. Hansa has assessed the claims provided to the Company and considers them unsubstantiated.

## 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 interest funds at March 31, 2021 amounted to SEK 238.1 million (Year end'20: SEK 238.1 million) and belonged to level 2 in the fair value hierarchy. The fair value of the financial liability for contingent consideration at March 31, 2021 amounted to SEK 0.7 million (Year end'20: 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.



# Glossary

## AMR

Antibody mediated rejection of a transplanted organ.

## Antibody

A 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 disease is a disorder in which circulating anti- bodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

## Autoimmune disease

A diseases that occur when the body's immune system reacts against the body's own structures.

## B-cells

B-cells, also known as B-lymphocytes, are a type of white blood cell of the lymphocyte subtype. They are an important part of the adaptive immune system and secrete antibodies.

## 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.

## Biopharmaceutical

A pharmaceutical drug that is manufactured using biotechnology.

## Biotechnology

The use of live cells or components of cells, to produce or modify products used in health care, food, and agriculture.

## Clinical Phase 1

The first time a drug under development is administered to humans. Phase 1 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.

## Donor specific antibodies (DSA)

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.

## Enzyme

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

## Guillian-Barré syndrome (GBS)

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

## Heparin Binding Protein (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.

## Human Leukocyte Antigen (HLA)

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

## Immunoglobulin G (IgG)

Immunoglobulin G is the predominant type of antibody in serum.

## Imlifidase

imlifidase (INN), previously known as Immunoglobulin G-degrading enzyme of Streptococcus pyogenes (IdeS), is 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.

## International Non-proprietary Name (INN)

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

## 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.