

# INTERIM REPORT JANUARY-JUNE 2021



## Idefix® recommended by Swedish New Therapies Council for use in highly sensitized kidney patients in Sweden. U.S. trial design announced; first patient expected to be dosed H2 2021

### Highlights for the second quarter 2021

- Commercial launch activities for Idefix® in Europe are progressing as planned in early launch countries, such as the Nordics, Benelux, U.K. and Germany. Hansa continues to prioritize its Market Access efforts through close interactions with national reimbursement authorities and leading transplant clinics.
- In late June 2021, the Swedish New Therapies Council recommended the use of Idefix® as desensitization treatment for highly sensitized kidney transplant patients. The recommendation provided by the New Therapies Council in Sweden represents the first national level decision by an EU member state.
- Hansa hosted an Idefix® launch symposium on June 30, 2021 with attendance from more than 120 transplant physicians representing around 80 transplant centers from 13 European countries.
- Following US FDA interactions, the U.S. trial design for a randomized, controlled trial of imlifidase in highly sensitized kidney transplant patients was announced in late June 2021. The new study will target 64 patients with the highest unmet medical need in the U.S., with the first patient expected to be included in H2 2021 as previously guided.
- Patient recruitment in the phase 2 clinical studies in active antibody mediated rejection (AMR) and Guillain-Barré Syndrome (GBS) continues under a risk-based, site-by-site approach due to the COVID-19 pandemic. In the AMR and GBS trials, 12 and 10 patients, respectively, out of a target of 30 patients in each of the studies have now been enrolled. The persistent presence of the COVID-19 pandemic in Europe, most recently the emergence of the Delta variant causing new waves in several European countries where important trial centers are located, negatively impacts enrollment rates. As remedial action, efforts are underway to initiate recruitment in new centers. While the increase in number of active trial centers is expected to also increase the enrollment rate in H2 2021 despite the continued impact of COVID-19, the volatility of the situation leads Hansa to expand its guidance for completion of enrollment to also include the first half of 2022. First data read-out in both studies is expected in the second half of 2022, as previously guided.
- IND-enabling toxicology studies for the NiceR program were initiated in the second quarter as planned. GLP toxicology studies are expected to be completed in 2022. Upon successful completion of these studies, Hansa expects to advance the NiceR program into clinical studies.
- Annual General Meeting held on May 12, 2021, all resolutions were approved by shareholders, including the appointment of Hilary Malone, Ph.D. to the Board of Directors. Dr. Malone is currently COO and EVP at Valo Health, Inc. (U.S.) and has previously held global executive positions at Sanofi, Reata Pharmaceuticals, Pfizer, Wyeth and AstraZeneca, among others.
- Handelsbanken Fonder reported ownership above 5% on April 6 2021.

### Financial Summary

- Solid cash position of SEK 1,139m at the end of June 2021. Hansa expects its operations to be financed into 2023.
- Investments in R&D in the second quarter amounted to SEK 55m (Q2'20: SEK 53m) and to SEK 102m for the first half-year (H1'20: SEK 106m). SG&A expenses amounted to SEK81m in Q2 2021 (Q2'20: SEK 49m) and to SEK 141m for the first half-year (H1'20: SEK 88m), in line with plans.
- Cash flow from operating activities for the second quarter ended at SEK -113m (Q2'20: SEK -77m) and SEK -233m for the first half of 2021 (H1'20: -199m).

<i>SEKm, unless otherwise stated - unaudited</i>	Q2 2021	Q2 2020	H1 2021	H1 2020
Revenue	4.5	0.6	13.5	1.5
Gross profit	2.2	0.5	9.5	1.0
SG&A expenses	-81.2	-49.4	-141.3	-88.0
R&D expenses	-54.5	-53.0	-101.9	-105.5
<b>Operating profit/loss</b>	<b>-132.4</b>	<b>-101.8</b>	<b>-236.0</b>	<b>-193.2</b>
Net profit/loss	-132.6	-99.2	-236.5	-192.6
Cash flow from operating activities	-112.5	-77.4	-233.4	-198.6
Cash and short-term investments	1,139.4	400.2	1,139.4	400.2
Shareholders' equity	1,031.2	378.1	1,031.2	378.1
EPS before and after dilution (SEK)	-2.98	-2.48	-5.32	-4.81
Number of outstanding shares	44,473,452	40,026,107	44,473,452	40,026,107
Weighted avg. number of shares before and after dilution	44,473,452	40,026,107	44,473,452	40,026,107
Number of employees	113	78	113	78

## Søren Tulstrup, President and CEO, comments

*"Hansa Biopharma's transformation into a fully integrated, commercial-stage biopharmaceutical company has become a reality in 2021, and we continue to deliver on our strategic priorities to build tomorrow's Hansa Biopharma by ensuring the successful commercialization of Idefirix® in the first markets, advancing our platform in new indications and therapeutic areas, building our organizational capabilities and expanding our technology platform.*

*In Europe, we continue to roll out our commercial launch activities in the early launch countries as planned and are pleased with the progress we have made so far. As part of this effort, Hansa hosted a very productive Idefirix® launch symposium on June 30, 2021 with attendance from more than 120 transplant physicians representing 80 transplant centers from 13 European countries. The symposium focused on Idefirix® as the potential new standard of care for highly sensitized kidney transplant patients needing desensitization treatment and included multiple sessions where expert speakers discussed specific patient cases to address topics around patient selection, AMR management and patient care.*

*Hansa also continues to maintain close interactions with national reimbursement authorities and leading transplant clinics. A first national level market access decision was announced on June 28, 2021 by Sweden's New Therapies Council, who recommends use of Idefirix® as a desensitization treatment for highly sensitized kidney transplant patients in Sweden.*

*We are very pleased with this decision, which is an important step for transplant clinics across Sweden who would like to introduce Idefirix® as a desensitization treatment to enable highly sensitized patients to qualify for potentially lifesaving and life-altering kidney transplant from a deceased donor. The recommendation follows an earlier health-economic assessment by the Swedish Dental and Pharmaceutical Benefits Agency (TLV), which concluded that Idefirix® treatment would be cost effective or even cost saving for the society. Moving forward, we expect additional decisions and agreements around reimbursement, funding and market access to be reached in other early launch countries beginning in the second half of 2021 and onwards.*

*In the U.S., Hansa announced the study design for a randomized, controlled trial of imlifidase in highly sensitized kidney transplant patients. In the study, 64 highly sensitized kidney patients with a cPRA score of ≥99.9% will be enrolled, representing a subset of very highly sensitized patients that continue to be disadvantaged despite prioritization under the U.S. Kidney Allocation System.*

*We are pleased to move forward with this study that we believe could support a BLA in the U.S. under the accelerated approval pathway in the first half of 2024. Preparatory work has been initiated and we expect to engage with 12-15 leading U.S. transplantation centers to conduct the study. Among the new centers are Northwestern Memorial Hospital in Chicago and University of Alabama (UAB) Hospital in Birmingham. Robert A. Montgomery, M.D. Professor of Surgery and Director, NYU Langone Transplant Institute, New York City has been appointed t Principal Investigator and we expect study initiation over the summer with the first patient enrolled in the second half of 2021.*

*In our ongoing phase 2 programs for 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. At the end of 2020, patient enrollment was reinitiated in both studies under a risk-based, site-by-site approach.*

*As of July 15, 2021, 12 out of a target of 30 patients have now been enrolled in the AMR study, while 10 out of a target of 30 patients have been enrolled in the GBS study. To increase the rate of enrollment of patients in both studies, we plan to open additional centers this summer, reaching a total of 14 centers in the AMR*

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*study and 10 centers in the GBS trial compared to the 7 centers currently enrolling in each of the two studies. The persistent presence of the COVID-19 pandemic in Europe, most recently the emergence of the Delta variant, which has caused new waves in several European countries where important trial centers are located, continues to negatively impact enrollment rates. Given the volatility of the situation, we expand our guidance for completion of enrollment to also include the first half of 2022.*

*We are also pleased to have now initiated IND enabling toxicology studies with the lead candidate from our next generation of antibody cleaving enzymes, also known as "NiceR". NiceR is a new set of enzymes developed for repeat dosing scenarios that may potentially open up a broad array of new indications to pursue, including reoccurring AMR, relapsing autoimmune diseases and oncology.*

*Lastly, I also want to highlight how we continue to build a high-performance organization while adding new competences. At the end of June, Hansa had 113 employees, which represents close to a threefold increase in less than 3 years. Our international team is a diverse, talented and highly experienced group of professionals driven by a passion to make a difference for patients with rare immunologic diseases.*

*I look forward to keeping you updated on the progress of Hansa Biopharma's journey as we take the next steps towards building a global leader in rare diseases across multiple broad therapeutic areas through the development of new, transformative medicines for patients suffering from rare immunologic diseases."*



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

## Continuous progress with 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>	Complete	Complete	Complete	→	Complete	*)	EU: Additional agreements around reimbursement from H2 2021
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Complete	Complete	Complete	**)			US: First patient dosed H2 2021
	Anti-GBM antibody disease <sup>3</sup>	Complete	Complete	Ongoing				Agreement with regulators in H2 2021 on a path forward toward BLA/MAA
	Antibody mediated kidney transplant rejection (AMR)	Complete	Complete	Ongoing				Complete enrollment of 30 patients in H2 2021/H1 2022
	Guillain-Barré syndrome (GBS)	Complete	Complete	Ongoing				Complete enrollment of 30 patients in H2 2021/H1 2022
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)	Ongoing						Pre-Clinical phase
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Ongoing						Pre-Clinical phase
<b>NiceR</b>	Recurring treatment in autoimmune disease, transplantation and oncology	Ongoing						Initiation of toxicology studies in H1 2021
<b>EnzE</b>	Cancer immunotherapy	Ongoing						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> Lorant 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  
 \*\*) 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

Complete   
  Ongoing

## Imlifidase – Commercial, Clinical and Regulatory Interactions

### Enabling kidney transplantation for highly sensitized patients

On August 26, 2020 Idefix® 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 Idefix® is the Company's first approved drug.

Commercial launch activities in early launch countries are being carried out with ongoing national level reimbursement application processes underway as planned. In late June 2021, the Swedish New Therapies Council announced their recommendation to use of Idefix® as desensitization treatment for highly sensitized

kidney transplant patients. The recommendation provided by the New Therapies Council represents the first national level decision by a European Union Member State. Market access agreements with additional early launch countries are expected to be reached on an ongoing basis from mid-2021 and onward. Commercial supply chain for supporting the launch is established

The U.S. trial design for a randomized, controlled trial of imlifidase in highly sensitized kidney transplant patients was announced in late June 2021. The study will enroll 64 highly sensitized kidney patients with a cPRA score of ≥99.9% or above, who will be randomized to either imlifidase desensitization treatment or to a control arm

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that will receive standard of care (i.e. waiting for a compatible kidney offer or receiving an experimental desensitization treatment). A surrogate endpoint measured in the form of eGFR (kidney function) at 12-months after randomization will be used to demonstrate the clinical benefit of imlifidase compared to the control group.

Hansa Biopharma is preparing to engage with 12-15 leading transplantation centers in the U.S. to conduct the study, with the first patient expected to be included in the second half of 2021. Results from the trial are expected to support a BLA under the accelerated approval pathway in H1 2024.

Beyond the four completed phase 2 studies in kidney transplantation, Hansa Biopharma is conducting a prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration.

The three-year follow-up data in highly sensitized kidney transplant patients demonstrates outcome and safety data in line with expectations in imlifidase treated transplant patients compared to outcomes in patients undergoing HLA-incompatible transplantation. Later this year, a manuscript is expected to be published in 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 function. Anti-GBM is an ultrarare and very severe disease that annually affects approximately 1.6 people per million annually. A majority of patients lose their kidney function<sup>1</sup>, requiring chronic dialysis and/or kidney transplantation.

On September 24, 2020 positive high-level data were presented from an investigator-initiated phase 2 trial of imlifidase to treat anti-GBM disease. The study, led by Principal Investigator Mårten Segelmark, Professor at the Universities in Linköping and Lund, showed two-thirds of patients achieved dialysis independence six months after treatment. Normally, two-thirds of patients would have lost kidney function and end up on dialysis after six months.

These positive data mark an important milestone for the expansion of imlifidase outside transplantation. Clarity around the regulatory path forward for imlifidase in anti-GBM with the EMA and FDA is expected to be announced in the second half of 2021.

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

Active antibody mediated rejection is a serious condition after transplantation that occurs in roughly 10% of kidney transplants<sup>2</sup> and is a significant challenge to long term graft survival.

In 2019, Hansa 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 was temporarily halted during a large part of 2020 due to the COVID-19 pandemic, but was reinitiated end of 2020. As of July 15, 2021, 12 of a target of 30 patients with active AMR episodes have been enrolled at 7 centers across the U.S., Europe and Australia.

In order to accelerate the recruitment of patients to the AMR study Hansa plans to expand to 14 centers during the second half of 2021. However due to the persistent presence of the COVID-19 pandemic in Europe, most recently the emergence of the Delta variant causing new waves in several European countries where important trial centers are located, the volatility of the situation leads Hansa to expand its guidance for completion of

enrollment to also include the first half of 2022. Hansa continues to expect a first data read-out in AMR in the second half of 2022.

#### 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 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 was reinitiated end of 2020. As of July 15, 2021 10 of a target of 30 patients with GBS, have been enrolled at 7 centers across France, the United Kingdom (UK) and the Netherlands.

Hansa plans to expand to 10 centers engaged in the recruitment of GBS patients during the second half of 2021. However due to the persistent presence of the COVID-19 pandemic in Europe, most recently the emergence of the Delta variant causing new waves in several European countries where important trial centers are located, the volatility of the situation leads Hansa to expand its guidance for completion of enrollment to also include the first half of 2022. Hansa continues to expect a first data read-out in GBS in the second half of 2022.



<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.

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## 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 is ongoing and IND-enabling toxicology studies for the lead NiceR candidate were initiated during the second quarter 2021 in preparation for clinical phase 1 study. The toxicology studies are expected to be completed in 2022. Upon completion of these studies, Hansa expects to advance the NiceR program into the clinic.

### EnzE – Enzyme-based antibody Enhancement

Published findings<sup>3</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-cleaving 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 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 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 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.

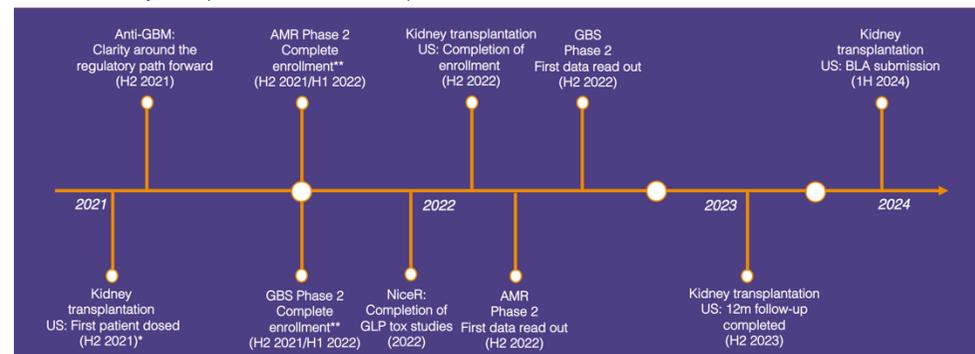
The partnership has been progressing as planned, and during the second half of 2020 Sarepta initiated ongoing pre-clinical investigations with imlifidase as a potential pre-treatment in the gene therapy setting. For further information regarding Sarepta's gene therapy programs in DMD and LGMD please 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



\*] FDA: 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.  
\*\*] AMR/GBS Due to the impact from the COVID-19 pandemic, the enrollment in GBS and AMR were temporarily halted during large parts of 2020. Hansa Biopharma reinstated enrollment in Q4 2020 under a risk-based, site-by-site approach.



<sup>3</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 – June 2021

## Revenue

Revenue for the second quarter 2021 amounted to SEK 4.5m (Q2'20: SEK 0.6m) and SEK 13.5 for the first half of 2021 (H1'20 SEK 1.5m) 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 second quarter 2021 amounted to SEK 81.2m (Q2'20: SEK 49.4m) and to SEK 141.3m (H1'20: SEK 88.0m) for the first half of 2021. 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 amounted to SEK 10.2m for the first half of the year (H1'20: SEK 7.5m) and is included in the above SG&A expenses.

## R&D expenses

Research and development expenses for the second quarter 2021 amounted to SEK 54.5m (Q2'20: SEK 53.0m) and to SEK 101.9m for the first half of the year 2021 (H1'20: SEK 105.5m). Recorded non-cash cost for the Company's employee long-term incentive programs for the first half of the year 2021 amounted to SEK 9.6m (H1'20: SEK 4.1m) and is included in the above R&D expenses.

## Financial result

The operating result for the second quarter 2021 amounted to SEK -132.4m (Q2'20: SEK -101.8m) and to SEK -236.0m for the first half 2021 (H1'20 SEK 193.2m). The increase as compared to previous year periods is mainly driven by Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix® in Europe.

Net loss for the second quarter 2021 amounted to SEK -132.6m (Q2'20: SEK -99.2m) and to SEK -236.5m for the first half of the year 2021 (H1'20: 192.6).

## Cash flow, cash and investments

Cash flow from operating activities for the second quarter 2021 amounted to SEK -112.5m (Q2'20: SEK -77.4m) and to SEK -233.4m for the first half 2021 (H1'20: 198.6m). Change as compared to previous year periods is driven by increased operating expense levels due to Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix® in Europe.

Cash and cash equivalents including short term investments amounted to SEK 1,139.4m on June 30, 2021 as compared to SEK 1,377.5m at year-end 2020 and SEK 1,254.7m as of March 31, 2021.

## Shareholders' equity

On June 30, 2021, equity amounted to SEK 1,031.2m as compared to SEK 1,242.1m at the end of the year 2020.

## Parent Company

The parent company's revenue for the second quarter of 2021 amounted to SEK 4.5m (Q2'20: SEK 0.6m) and to SEK 13.5m for the first half of the year 2021 (H1'20 1.5m).

Loss for the parent company for the second quarter 2021 amounted to SEK -132.8m (Q2'20: SEK -99.7) ) and to SEK -237.0m for the first half of the year 2021 (H1'20 -193.3m).

The parent company's equity amounted to SEK 1,030.2m as per June 30, 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 four employees at the end of June 2021. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of June 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 June 30, 2021, the following LTIPs were ongoing: LTIP 2018, LTIP 2019, LTIP 2020 and LTIP 2021.

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	LTIP 2021
Maximum number of issuable shares*	166 659	582 014	1 173 999	1 400 000
Number of allocated and outstanding share rights and options	121 498	436 703	903 076	987 000
Number of acquired and outstanding warrants	6 701	11 000	-	-
Estimated total cost including social contributions, KSEK	20 746	32 799	99 296	91 880
Total cost per program, including social contributions, as of June 30, 2021 YTD, KSEK	1 161	1 150	14 825	2 552

\*As of 30 June 2021, including issuable shares to cover social contributions under the LTIP.

Total costs, including social contributions, as of June 30, 2021 YTD, KSEK 19 688

## 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

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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 development within research programs.

### Financial calendar 2021-2022

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

Feb. 3, 2022 - Year-End report for Jan - Dec 2021

April 7, 2022 - Annual Report 2021

April 21, 2022 - Interim report for Jan - Mar 2022

## 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 June 30, 2021	SEK ~7bn (USD ~800m)
Ticker	HNSA
ISIN	SE0002148817

### Top 10 shareholders as of June 30, 2021

Name	Number of shares	Ownership in pct
Redmile Group, LLC	5 532 800	12.4
Handelsbanken Asset Management*	2 751 946	6.2
Nexttobe AB	2 155 400	4.9
Fjärde AP-Fonden (AP 4)	2 122 796	4.8
Invesco Advisers, Inc.	1 973 200	4.4
Olausson, Thomas	1 820 474	4.1
Försäkrings AB Avanza Pension	1 378 800	3.1
Schroder Investment Management, LTD	1 160 900	2.6
The Vanguard Group, Inc.	1 158 200	2.6
Norges Bank Investment Management	1 080 100	2.4
Other	23 338 836	52.5
<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 June 30, 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 July 14, 2021

**Ulf Wiinberg**  
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](http://www.hansabiopharma.com).*

## Condensed unaudited financial statements

### Consolidated income statement

KSEK	Q2		H1	
	2021	2020	2021	2020
Revenue	4 535	623	13 533	1 508
Cost of revenue	-2 333	-116	-4 067	-539
<b>Gross profit</b>	<b>2 202</b>	<b>507</b>	<b>9 466</b>	<b>969</b>
Other operating income	-	-	-	-
Sales, general and administration expenses	-81 248	-49 357	-141 334	-88 027
Research and development expenses	-54 501	-52 963	-101 904	-105 508
Other operating expenses	1 191	-12	-2 270	-610
<b>Operating profit/loss</b>	<b>-132 356</b>	<b>-101 825</b>	<b>-236 042</b>	<b>-193 176</b>
Financial income/expenses	-248	2 570	-499	541
<b>Profit/loss for the period before tax</b>	<b>-132 604</b>	<b>-99 255</b>	<b>-236 541</b>	<b>-192 635</b>
Tax	9	10	19	21
<b>Net profit/loss for the period</b>	<b>-132 595</b>	<b>-99 245</b>	<b>-236 522</b>	<b>-192 614</b>
Attributable to:				
Parent company shareholders	-132 595	-99 245	-236 522	-192 614
Earnings per share (EPS)				
Before dilution (SEK)	-2,98	-2,48	-5,32	-4,81
After dilution (SEK)	-2,98	-2,48	-5,32	-4,81
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	-42	-241	107	-151
<b>Other comprehensive income for the period</b>	<b>-42</b>	<b>-241</b>	<b>107</b>	<b>-151</b>
<b>Total net comprehensive income</b>	<b>-132 637</b>	<b>-99 486</b>	<b>-236 415</b>	<b>-192 765</b>

## Consolidated statement of financial position

KSEK	June 30		December 31
	2021	2020	2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	30 144	32 757	31 410
Property and equipment	6 997	5 760	5 206
Leased assets	21 538	6 933	4 493
<b>Total non-current assets</b>	<b>58 679</b>	<b>45 450</b>	<b>41 109</b>
<b>Current assets</b>			
Inventories	123	-	98
Current receivables, non-interest bearing	20 061	14 149	15 783
Short-term investments	238 038	251 797	238 144
Cash and cash equivalents	901 391	148 378	1 139 362
<b>Total current assets</b>	<b>1 159 613</b>	<b>414 324</b>	<b>1 393 387</b>
<b>TOTAL ASSETS</b>	<b>1 218 292</b>	<b>459 773</b>	<b>1 434 496</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>1 031 240</b>	<b>378 082</b>	<b>1 242 124</b>
<b>Non-current liabilities</b>			
Deferred tax liabilities	434	458	424
Provisions	8 357	4 249	14 426
Lease liabilities	17 645	2 649	630
Deferred revenue	55 121	-	62 026
Contingent consideration	746	721	663
<b>Total non-current liabilities</b>	<b>82 303</b>	<b>8 077</b>	<b>78 169</b>
<b>Current liabilities</b>			
Lease liabilities	3 870	4 751	4 415
Current liabilities, non-interest bearing	24 330	30 505	36 257
Deferred revenue	21 724	-	17 406
Accrued expenses and deferred income	54 825	38 358	56 125
<b>Total current liabilities</b>	<b>104 749</b>	<b>73 614</b>	<b>114 203</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1 218 292</b>	<b>459 773</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	June 30		Year
	2021	2020	2020
Opening balance of shareholders' equity as reported	1 242 124	562 815	562 815
Adjustment of the opening balance	0	-302	0
<b>Adjusted opening balance of shareholders' equity reported</b>	<b>1 242 124</b>	<b>562 513</b>	<b>562 815</b>
Result for the period	-236 522	-192 614	-420 853
Other comprehensive income for the period	107	-151	-297
<b>Net comprehensive income</b>	<b>-236 415</b>	<b>-192 765</b>	<b>-421 150</b>
<b>Transactions with the group's owner</b>			
Proceeds from new share issuance, net	-	-	1 070 581
Long term incentive programs	25 531	8 334	29 878
<b>Total transactions with the group's owner</b>	<b>25 531</b>	<b>8 334</b>	<b>1 100 459</b>
<b>Closing balance of shareholders' equity</b>	<b>1 031 240</b>	<b>378 082</b>	<b>1 242 124</b>

## Consolidated statement of cash flow

KSEK	Q2		H1	
	2021	2020	2021	2020
<b>Operating activities</b>				
Operating profit/loss	-132 356	-101 825	-236 042	-193 176
Adjustment for items not included in cash flow <sup>(1)</sup>	18 796	9 459	23 185	14 987
Interest received and paid, net	-158	-26	-256	-148
Income taxes paid	-22	-	-22	-
<b>Cash flow from operations before change in working capital</b>	<b>-113 740</b>	<b>-92 392</b>	<b>-213 135</b>	<b>-178 337</b>
Changes in working capital	1 240	14 988	-20 274	-20 247
<b>Cash flow from operating activities</b>	<b>-112 501</b>	<b>-77 402</b>	<b>-233 409</b>	<b>-198 585</b>
<b>Investing activities</b>				
Acquisition of property and equipment	-1 716	-156	-2 399	-294
Sale of short term investments	-	78 174	-	167 915
<b>Cash flow from investing activities</b>	<b>-1 716</b>	<b>78 018</b>	<b>-2 399</b>	<b>167 621</b>
<b>Financing activities</b>				
Repayment of lease liabilities	-1 102	-1 163	-2 295	-2 318
<b>Cash flow from financing activities</b>	<b>-1 102</b>	<b>-1 163</b>	<b>-2 295</b>	<b>-2 318</b>
Net change in cash	-115 317	-549	-238 103	-33 282
Cash and cash equivalents, beginning of period	1 016 686	149 159	1 139 362	181 697
Currency exchange variance, cash and cash equivalents	22	-232	132	-37
<b>Cash and cash equivalents, end of period</b>	<b>901 391</b>	<b>148 378</b>	<b>901 391</b>	<b>148 378</b>

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

## Parent company – Income statement

KSEK	Q2		H1	
	2021	2020	2021	2020
Revenue	4 535	623	13 533	1 508
Cost of revenue	-2 333	-116	-4 067	-539
<b>Gross profit</b>	<b>2 202</b>	<b>507</b>	<b>9 466</b>	<b>969</b>
Other operating income	-	-	-	-
Sales, general and administration expenses	-87 988	-49 243	-139 523	-88 215
Research and development expenses	-48 101	-53 258	-104 231	-105 703
Other operating expenses	1 193	9	-2 269	-588
<b>Operating profit/loss</b>	<b>-132 694</b>	<b>-101 985</b>	<b>-236 557</b>	<b>-193 538</b>
Result from financial items:				
Finance income	-23	1 181	-106	-729
Finance costs	-154	1 047	-287	928
<b>Loss for the period before tax</b>	<b>-132 871</b>	<b>-99 757</b>	<b>-236 950</b>	<b>-193 339</b>
Income tax benefit/expense	-	-	-	-
<b>Loss for the period after tax</b>	<b>-132 871</b>	<b>-99 757</b>	<b>-236 950</b>	<b>-193 339</b>
Other comprehensive income for the period	-	-	-	-
<b>Total comprehensive income for the period</b>	<b>-132 871</b>	<b>-99 757</b>	<b>-236 950</b>	<b>-193 339</b>

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

KSEK	June 30		31 December
	2021	2020	2020
Opening shareholders' equity as reported	1 241 578	562 763	562 763
Result for the period	-236 950	-193 339	-421 644
Other comprehensive income for the period	-	-	-
<b>Net comprehensive income</b>	<b>-236 950</b>	<b>-193 339</b>	<b>-421 644</b>
Proceeds from new share issuance, net	-	-	1 070 581
Long term incentive programs	25 531	8 335	29 878
<b>Total transactions with the group's owner</b>	<b>25 531</b>	<b>8 335</b>	<b>1 100 459</b>
<b>Closing shareholders' equity</b>	<b>1 030 159</b>	<b>377 759</b>	<b>1 241 578</b>

## Parent company – Statement of financial position

KSEK	June 30		December 31
	2021	2020	2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	27 845	29 273	29 171
Property, plant and equipment	6 997	5 760	5 206
Leased assets	21 538	6 933	4 493
Investment in subsidiaries	5 095	5 095	5 095
Receivables, group companies	2 061	2 280	1 972
<b>Total non-current assets</b>	<b>63 536</b>	<b>49 341</b>	<b>45 937</b>
<b>Current assets</b>			
Inventories	123	-	98
Current receivables, non-interest bearing	19 639	13 711	15 268
Receivables, group companies	-	3 731	-
Short-term investments	238 038	251 797	238 144
Cash and cash equivalents	896 114	142 846	1 133 647
<b>Total current assets</b>	<b>1 153 914</b>	<b>412 085</b>	<b>1 387 157</b>
<b>TOTAL ASSETS</b>	<b>1 217 450</b>	<b>461 426</b>	<b>1 433 094</b>
<b>EQUITY AND LIABILITIES</b>			
Shareholders' equity	1 030 159	377 759	1 241 578
<b>Non-current liabilities</b>			
Provisions	8 357	4 249	14 426
Lease liabilities	17 645	2 649	630
Deferred revenue	55 121	-	62 026
Contingent consideration	746	721	663
<b>Total non-current liabilities</b>	<b>81 869</b>	<b>7 619</b>	<b>77 745</b>
<b>Current liabilities</b>			
Lease liabilities	3 870	4 751	4 415
Liabilities, group companies	4 325	3 555	1 613
Current liabilities, non-interest bearing	24 172	30 353	34 950
Deferred revenue	21 724	-	17 406
Accrued expenses and deferred income	51 331	37 389	55 387
<b>Total current liabilities</b>	<b>105 422</b>	<b>76 048</b>	<b>113 771</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1 217 450</b>	<b>461 426</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. Hansa's 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 KSEK Group	Q2		H1	
	2021	2020	2021	2020
Revenue				
Product sales	-	-	6 026	-
Contract revenue, Axis-Shield agreement	522	582	1 045	1 164
Cost reimbursement, Axis-Shield agreement	420	41	420	344
Contract revenue, Sarepta agreement	3 593	-	6 042	-
	<b>4 535</b>	<b>623</b>	<b>13 533</b>	<b>1 508</b>
Parent company				
Revenue:				
Product sales	-	-	6 026	-
Contract revenue, Axis-Shield agreement	522	582	1 045	1 164
Cost reimbursement, Axis-Shield agreement	420	41	420	344
Contract revenue, Sarepta agreement	3 593	-	6 042	-
	<b>4 535</b>	<b>623</b>	<b>13 533</b>	<b>1 508</b>

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 has initiated the commercial launch of Idefirix® in the EU, 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. The arbitration proceedings are in an initial phase.

## 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 June 30, 2021 amounted to SEK 238.0 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 June 30, 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.