

# YEAR-END REPORT 2021



## Hansa Biopharma year-end report 2021:

- Commercial launch and market access efforts in Europe progressing as planned; new multiregional commercialization partnership with Medison Pharma
- First patients enrolled into the pivotal U.S. ConfIdeS study
- Agreement established with AskBio to evaluate feasibility of imlifidase as pre-treatment ahead of gene therapy in Pompe disease
- Platform strategy: Hansa to explore desensitization treatment in allogeneic hematopoietic stem cell transplantation
- Year-end cash position of SEK 889 million; Hansa financed into 2023, as previously guided

## Highlights for the fourth quarter 2021

- Commercial launch and market access efforts for Idefix® in Europe are progressing as planned. Reimbursement has been secured in Sweden and the Netherlands, as well as on an individual hospital basis in Finland and Greece.
- Market access procedures are ongoing in 14 countries including Germany, France, Italy and the United Kingdom (U.K.). A Health Technology Assessment (HTA) dossier for Spain was submitted in January 2022, which completes HTA filings in all of the five largest markets in Europe.
- In December 2021, Hansa and Medison Pharma announced a multiregional commercialization partnership for Idefix® for kidney transplantation covering Israel and major countries in the Central Eastern European region.
- The first patients in the pivotal U.S. open-label, randomized, controlled trial "ConfIdeS," were enrolled at the Columbia University Medical Center, New York during December 2021.
- Clinical pipeline update: In the Antibody Mediated Rejection (AMR) trial, 23 patients out of a target of 30 patients have been enrolled, and in the Guillain Barré Syndrome (GBS) trial 15 patients out of a target of 30 patients have been enrolled as of February 2 2022. The widespread impact of the COVID-19 pandemic and the emergence of the Omicron variant have impacted the availability of staff across a number of trial centers. Additionally, a shortage of IVIg has affected the enrollment rate at a subset of participating hospitals in our GBS program. Given the current difficulty of predicting enrollment due to the direct and indirect effects of the continued pandemic and increased infection rates due to omicron, Hansa expects to update its guidance related to the GBS timelines in April, in connection with the publication of its Q1 report. In the meantime, in order to support mitigating these hurdles, Hansa has simplified the study protocol, is actively supporting the hiring of additional staff at the clinics and is adding two sites for the recruitment of patients in the U.K. and the Netherlands.
- Plans to initiate a Phase 3 study of imlifidase to treat anti-Glomerular Basement Membrane (anti-GBM) disease were announced in November 2021, after a successful pre-IND meeting with the U.S. FDA. The planned pivotal Phase 3 clinical study will enroll approximately 50 patients with anti-GBM disease across the U.S. and Europe. The first patient is expected to be enrolled in 2022.
- Partnership with Sarepta and preclinical collaboration with argenx moving forward according to plan.

## Events after the reporting period

- On January 3, 2022, Hansa entered into an agreement with AskBio to evaluate the potential use of imlifidase as a pre-treatment prior to the administration of AskBio's investigational gene therapy in Pompe disease in a pre-clinical and clinical feasibility program for patients with pre-existing neutralizing antibodies (Nabs). Upon execution, Hansa receives a USD 5 million payment, while AskBio has an exclusive option to negotiate a full development and commercialization agreement.

## Financial Summary

- On January 9, 2022, Hansa announced that it intends to explore the potential development of imlifidase in allogeneic hematopoietic stem cell transplantation (HSCT), also known as "bone-marrow transplantation".
- Cash position of SEK 889m at the end of December 2021, expected to fund Hansa's operations into 2023.
- Investments in R&D in the fourth quarter amounted to SEK 68m (Q4'20: SEK 50m) and to SEK 231m for the full year of 2021 (full year '20: SEK 227m). SG&A expenses amounted to SEK 103m in Q4 2021 (Q4'20: SEK 63m) and to SEK 327m for the full year 2021 (full year '20: SEK 203m), in line with plans.
- Cash flow from operating activities for the fourth quarter of 2021 was SEK -116m (Q4 '20: SEK -97m) and SEK -481m for the full year 2021 (full year '20: -290m).

<i>SEKm, unless otherwise stated – unaudited</i>	Q4 2021	Q4 2020	12M 2021	12M 2020
Revenue	15.4	3.8	33.9	6.1
SG&A expenses	-103.2	-63.2	-327.3	-203.0
R&D expenses	-68.2	-50.4	-230.8	-227.2
Operating profit/loss	-162.8	-106.2	-547.0	-422.8
Net profit/loss	-163.4	-105.8	-548.3	-420.9
Cash flow from operating activities	-116.3	-96.5	-481.2	-290.3
Cash and short-term investments	889.0	1,377.5	889.0	1,377.5
Shareholders' equity	757.6	1,242.1	757.6	1,242.1
EPS before and after dilution (SEK)	-3.67	-2.38	-12.33	-9.98
Number of outstanding shares	44,473,452	44,473,452	44,473,452	44,473,452
Weighted avg. number of shares before and after dilution	44,473,452	44,473,452	44,473,452	42,176,872
Number of employees at the end of the period	133	87	133	87

## Søren Tulstrup, President and CEO, comments

*"2021 was, overall, a transformative and successful year for Hansa Biopharma as the Company advanced into a fully integrated, commercial-stage biopharmaceutical company following the commercial launch in Europe of Idefix® (imlifidase), labeled for desensitization of highly sensitive kidney transplant patients incompatible to a deceased donor.*

*From a strategic point of view, we have executed throughout the year on our key priorities, including meeting our R&D, commercial and organizational objectives. In addition, I am very encouraged to see the high level of interest from other healthcare companies to partner with Hansa. During the last 12 months, the Company has entered into three new collaborations, which serves as further validation of the potential of our unique IgG-cleaving enzyme technology platform.*

*Hansa's mission is to leverage this technology to develop innovative, lifesaving and life-altering immunomodulating therapies, bring these to the patients with rare diseases and conditions who need them and generate value to society at large. To achieve this mission, we are building a high-performance team by attracting and integrating the most talented and experienced candidates, while creating a rewarding, productive and stimulating workplace for our employees. The progress we are making was again evidenced in 2021 as we received certification as a "Great Place to Work" for the second consecutive year by the GPTW Institute.*

*On the operational side, we have seen solid execution in expanding our market access and geographical footprint in Europe. Pricing and reimbursement have been secured in Sweden and the Netherlands, as well as on a hospital basis in Finland and Greece. Market access procedures are now ongoing in 14 countries including Spain, which was submitted in January this year. Hansa has now submitted in all the five largest markets in Europe, which is an important milestone as we build the foundation for Idefix®, our potentially transformative therapy that is bringing hope to the thousands of highly sensitized patients across the continent, currently waiting for a compatible kidney transplant.*

*Looking beyond the early launch countries, I was also pleased that we could announce a multiregional commercialization partnership with Medison Pharma for Hansa's desensitization treatment for kidney transplant in Central Eastern Europe and Israel. Medison is a recognized international pharma company focused on providing access to highly innovative therapies to patients in international markets, and this commercial partnership represents an important milestone for Hansa as we expand access to Idefix® beyond initial markets for highly sensitized patients awaiting kidney transplants.*

*In the U.S., we announced that the first patients in our pivotal ConfIdeS trial in kidney transplantation were enrolled at the Columbia University Medical Center, New York. The ConfIdeS study is evaluating imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a deceased donor kidney through the U.S. kidney allocation system. We expect to enroll patients at 12-15 leading transplantation centers across the U.S., with the aim of completing enrollment by the end of this year. We believe that the U.S. trial will generate valuable experience at these key centers while also generating important data.*

*In gene therapy, we were excited to announce an agreement with AskBio, a subsidiary of Bayer AG, to evaluate imlifidase in a pre-clinical and clinical feasibility program as pre-treatment ahead of gene therapy in Pompe disease in patients with pre-existing neutralizing antibodies (Nabs). Nabs against adeno-associated virus used in gene therapies remain a major challenge and we see significant potential for our antibody-cleaving enzyme technology to help overcome this barrier. The new collaboration with AskBio marks another key step in the implementation of our partnership strategy in the gene therapy space.*

*Turning to our ongoing Phase 2 programs for GBS and AMR, we have enrolled 23 out of a target of 30 patients in the AMR study while 15 out of a target of 30 patients have been enrolled in the GBS study as of February 2, 2022.*

*In regards to our GBS program we see how the impact of the COVID-19 pandemic and the emergence of the Omicron variant have affected the availability of staff across a number of trial centers. Additionally, a shortage of IVIg has affected the enrollment rate in the GBS program at a subset of participating hospitals. Given the current difficulty of predicting enrollment due to the direct and indirect effects of the continued pandemic and increased infection rates due to omicron, Hansa expects to update its guidance related to the GBS timelines*

*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).*

*in April, in connection with the publication of its Q1 report. In the meantime, in order to support mitigating these hurdles, Hansa has simplified the study protocol, is actively supporting the hiring of additional staff at the clinics and is adding two sites for the recruitment of patients in the U.K. and the Netherlands.*

*In anti-GBM disease, Hansa recently announced plans to initiate a Phase 3 study of imlifidase, following a successful pre-IND meeting with the U.S. FDA. The planned pivotal study will enroll approximately 50 patients with anti-GBM disease across the U.S. and Europe, with the first patient expected to be enrolled in 2022.*

*As part of Hansa Biopharma's platform strategy and objective to broaden the application of imlifidase as a potential therapy to change the course of IgG-mediated immunological diseases and conditions, the Company is exploring new indications with a high unmet need. One of the indications Hansa intends to explore further is allogeneic hematopoietic stem cell transplantation (HSCT), also known as "bone-marrow" transplantation. Desensitization treatment of patients with elevated levels of donor specific antibodies (DSA) prior to allogeneic HSCT transplant is a challenge, and currently there are no approved drugs for managing these patients. Imlifidase may have the potential to transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation so as to create the basis for successful transplantation.*

*An exciting year lies ahead of us with many potential milestones to be achieved across our platform and many indication areas. I look forward to updating you on our progress.*



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

## Continuous progress with our pipeline activities

Candidate/ Program	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Conditional approval	Completed	Marketed *	EU: Additional agreements around reimbursement from H2'21
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Ongoing			Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease <sup>3</sup>	Completed	Completed	Completed	Planned			Pivotal Phase 3 study expected to commence in 2022 (50 patients)
	Antibody mediated kidney transplant rejection (AMR)	Completed	Completed	Ongoing				Completion of enrollment (30 patients) H1 2022
	Guillain-Barré syndrome (GBS)	Completed	Completed	Ongoing				Timeline guidance under review
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Ongoing						Preclinical phase
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)	Ongoing						Preclinical phase
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)	Planned						Preclinical phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	Ongoing						Completion of GLP toxicology studies in 2022
EnzE	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

■ Completed      ■ Ongoing  
■ Planned      ■ Conditional approval based on Phase 2 data

## Imlifidase – Commercial, Clinical and Regulatory Interactions

### EU: 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 and Market Access efforts for Idefix® in Europe are progressing as planned. Reimbursement has been secured in Sweden and the Netherlands, as well as on a hospital basis in Finland and Greece. Market access procedures are ongoing in thirteen countries, including Germany, France, Italy and

the U.K. and a number of smaller EU countries. In addition, the HTA dossier for Spain was submitted during January 2022, which completes HTA filings in all of the five largest markets in Europe.

In December 2021, Hansa and Medison Pharma announced a multiregional commercialization partnership for Hansa's desensitization treatment for kidney transplantation covering Israel and key countries in the Central Eastern European region, i.e. Croatia, Hungary, Poland and Slovenia. An application for marketing authorization for desensitization treatment in kidney transplant was filed in Israel in June 2021.

#### U.S. Randomized Controlled Trial “ConfldeS” (ClinicalTrials.gov ID: NCT04935177)

On December 29, 2021, Hansa announced that the first patient in its pivotal U.S. open-label, randomized, controlled trial “ConfldeS,” was enrolled at the Columbia University Medical Center, New York. The ConfldeS study is evaluating imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a deceased donor kidney through the U.S. kidney allocation system.

As of February 2, 2022, two out of a target of 64 patients have been enrolled. Completion of enrollment in the study is expected in the second half of 2022, with a 12-month follow-up study expected to be completed in the second half of 2023, as previously guided. Hansa is preparing to engage with 12-15 leading transplantation centers in the U.S. to conduct the study, of which five are activated as of February 2, 2022. Results from the trial are expected to support a Biologics License Application (BLA) under the accelerated approval pathway in H1 2024.

#### Long-term follow-up trial of kidney transplant patients (ClinicalTrials.gov ID: NCT04711850)

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

The three-year follow-up data in highly sensitized kidney transplant patients demonstrate graft survival of 84% after imlifidase treatment and transplantation and a mean eGFR of 55 mL/min/1.73 m<sup>2</sup> (61 ml/min/m<sup>2</sup> for those without AMR). Data is in line with expectations in imlifidase treated transplant patients compared to outcomes in patients undergoing HLA-incompatible transplantation. For a subgroup of 13 patients with cPRA of ≥ 99.9%, graft survival was 92% and improved kidney function for patients with a mean eGFR at 60ml/min/1.73 m<sup>2</sup> after year three. The data from the three-year follow up study was published in the American Journal of Transplantation in July 2021. The next read out on the long-term follow-up trial is expected in 2023, when the 5-year data will be published.

#### 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 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.

In September 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 that two-thirds of patients achieved dialysis independence six months after treatment as compared to typically two-thirds of patients losing their kidney function and ending up on dialysis after six months. These positive results mark an important milestone for the expansion of imlifidase outside transplantation and into auto-immune diseases.

Hansa plans to initiate a Phase 3 study of imlifidase to treat anti-GBM disease following a successful pre-IND meeting with the U.S. FDA. The planned pivotal Phase 3 clinical study will enroll approximately 50 patients with anti-GBM disease across the U.S. and Europe with the first patient expected to be enrolled in 2022.

#### 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 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 and reinitiated at the end of 2020. As of February 2, 2022, 23 out of a target of 30 patients with active AMR episodes have been enrolled at 14 centers across the U.S., Europe and Australia.

A first data read-out is expected in the second half of 2022, as previously guided. The guidance assumes no further escalation or sustained negative impact of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.

#### Guillain-Barré Syndrome (GBS) (ClinicalTrials.gov ID: NCT03943589)

GBS is an acute autoimmune attack on the peripheral nervous system, which affects approximately 1 in 100,000 people. In 2019, Hansa initiated an open-label, single arm, multi-center study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients in combination with standard of care intravenous immunoglobulin (IVIg).

The recruitment process for this Phase 2 study was temporarily halted during a large part of 2020 due to the COVID-19 pandemic, and reinitiated at the end of 2020. As of February 2, 2022, 15 out of a target of 30 patients with GBS have been enrolled at eight centers across France, the U.K. and the Netherlands.

The widespread impact of the COVID-19 pandemic and the emergence of the Omicron variant have impacted the availability of staff across a number of trial centers. Additionally, a shortage of IVIg has affected the enrollment rate at a subset of participating hospitals in our GBS program. Given the current difficulty of predicting enrollment due to the direct and indirect effects of the continued pandemic and increased infection rates due to omicron, Hansa expects to update its guidance related to the GBS timelines in April, in connection with the publication of its Q1 report. In the meantime, in order to support mitigating these hurdles, Hansa has simplified the study protocol, is actively supporting the hiring of additional staff at the clinics and is adding two sites for the recruitment of patients in the U.K. and the Netherlands.

#### DSA rebound in patients treated with imlifidase prior to transplantation (ClinicalTrials.gov ID: NCT05049850)

A new combination study will be initiated to evaluate if a combination of bortezomib and belatacept can reduce the risk for AMR following desensitization with imlifidase, which has been indicated by preclinical data. The study will include 12 patients to assess whether imlifidase, in combination with bortezomib, belatacept, rituximab and IVIg, can suppress DSA and the occurrence of AMR in highly sensitized patients with chronic kidney disease with a positive crossmatch towards their living donor during a period of 3 months from transplantation. The study will be run by Associate Professor Vasishta Tatapudi, MD and Program Director at the NYU Langone Transplant Institute.

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

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)

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

## 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 of 2021 in preparation for a 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-clearing enzyme prior to dosing the patient with a therapeutic antibody can potentially increase the efficacy of the given cancer therapy.

### Pre-treatment ahead of gene therapy in Limb-Girdle (LGMD) & Duchenne (DMD) (partnered with Sarepta)

In July 2020, Hansa entered into an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy in DMD and LGMD in patients with pre-existing NABs to adeno-associated virus (AAV).

Under the terms of the agreement, Hansa received USD 10 million as an upfront payment and will book all future sales of imlifidase. In addition, Hansa will be eligible for up to USD 397.5 million in development, regulatory and sales milestones, as well as royalties on any Sarepta gene therapy sales enabled through pre-treatment with imlifidase in NABs-positive patients.

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

### Pre-treatment ahead of gene therapy in Pompe disease (partnered with AskBio)

On January 3, 2022, Hansa announced a collaboration agreement with AskBio (subsidiary of Bayer AG), a fully integrated AAV gene therapy company dedicated to developing medicines that improve the quality of life for patients with genetic diseases.

The collaboration will evaluate the potential use of imlifidase as a pre-treatment prior to the administration of AskBio's gene therapy in Pompe disease in a pre-clinical and clinical feasibility program for patients with pre-existing NABs to the adeno-associated viral vector used in AskBio's gene therapy.

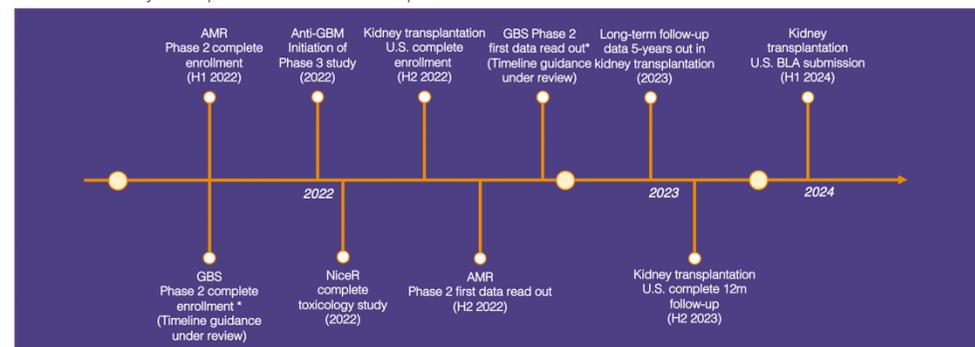
Under the terms of the agreement, Hansa receives a USD 5 million payment upon execution of the agreement and AskBio has the exclusive option negotiate a full development and commercialization agreement following evaluation of the results from an initial Phase 1/2 study. For further information regarding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

### Pre-clinical research collaboration with argenx BV

In March 2021, Hansa announced a pre-clinical 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. The preclinical collaboration is progressing according to plan.

## Upcoming milestones

*Milestones subject to potential COVID-19 impact*



<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

## Financial review January – December 2021

### Revenue

Revenue for the fourth quarter 2021 amounted to SEK 15.4m (Q4 '20: SEK 3.8m) and SEK 33.9m for the full year of 2021 (full year '20 SEK 6.1m) 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).

### Cost of revenue

The cost of revenue for the fourth quarter of 2021 amounted to SEK -3.6m (Q4 '20: SEK -0.2m) and to SEK -15.4m for the full year of 2021 (full year '20: SEK -1.0m). Cost of revenue chiefly includes costs related to product sales and a provision for excess and obsolete inventories.

### SG&A expenses

Sales, general and administration expenses for the fourth quarter of 2021 amounted to SEK 103.2m (Q4 '20: SEK 63.2m) and to SEK 327.3m for the full year of 2021 (full year '20: SEK 203.0m). 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, included in the above SG&A expenses, amounted to SEK 37.5m (for the full year '20: SEK 29.2m).

### R&D expenses

Research and development expenses for the fourth quarter of 2021 amounted to SEK 68.2m (Q4 '20: SEK 50.4m) and to SEK 230.8m for the full year of the year 2021 (for the full year '20: SEK 227.2m). Recorded non-cash cost for the Company's employee long-term incentive programs, included in the above R&D expenses, amounted to SEK 19.2m for the full year of the year 2021 (full year '20: SEK 14.1m).

### Financial results

The operating result for the fourth quarter of 2021 amounted to SEK -162.8m (Q4 '20: SEK -106.2m) and to SEK -547.0m for the full year of 2021 (full year '20 SEK -422.8m). 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 fourth quarter of 2021 amounted to SEK -163.4m (Q4 '20: SEK -105.8m) and to SEK -548.3m for the full year of the year 2021 (full year '20: -420.9m).

### Cash flow, cash and investments

Cash flow from operating activities for the fourth quarter of 2021 amounted to SEK -116.3m (Q4 '20: SEK -96.5m) and to SEK -481.2m for the full year of 2021 (full year '20: -290.3m). The 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. Additionally, Hansa received a SEK 89.9m one time cash payment related to the Sarepta agreement in Q3 -2020.

Cash and cash equivalents, including short term investments, amounted to SEK 889.0m on December 31, 2021 as compared to SEK 1,377.5m at year-end 2020.

### Shareholders' equity

On December 31, 2021, shareholders' equity amounted to SEK 757.6m as compared to SEK 1,242.1m at the end of the year 2020.

### Parent Company

The parent company's revenue for the fourth quarter of 2021 amounted to SEK 15.4m (Q4 '20: SEK 3.8m) and to SEK 33.9m for the full year of the year 2021 (for the full year '20, SEK 6.1m).

Loss for the parent company for the fourth quarter 2021 amounted to SEK -163.6m (Q4 '20: SEK -106.0m) and to SEK -549.1m for the full year of the year 2021 (full year '20, SEK -421.6m).

The parent company's equity amounted to SEK 755.9m as of December 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, Hansa Biopharma Inc. and Hansa Biopharma Australia PTY LTD. Hansa Biopharma Inc had four employees at the end of December 2021. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of December 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, 2021, the following LTIPs were ongoing: LTIP 2018, LTIP 2019, LTIP 2020 and LTIP 2021.

The respective costs related to such ongoing programs are indicated in the table below. For further information on the different LTIP programs, please refer to Hansa Biopharma's 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*	86 823	569 828	1 141 499	1 400 000
Number of allocated and outstanding share rights and options	60 086	427 329	898 076	987 000
Number of acquired and outstanding warrants	6 701	11 000	-	-
Estimated total cost including social contributions, KSEK	4 458	40 538	92 435	79 510
Total cost per program, including social contributions, as of December 31, 2021 YTD, KSEK	917	11 383	28 863	15 460

\*As of 31 December 2021, including issuable shares to cover social contributions under the LTIP.

Total costs, including social contributions, as of December 31, 2021 YTD, KSEK 56 624

## Risks and uncertainties

Hansa's business is influenced by a number of factors, the effects of which on the Company's earnings and financial position in certain respects cannot be controlled by the Company, at all, or in part. In an assessment of the Company's future development, it is important, alongside the possibilities for growth in earnings, to also consider these risks.

Risk factors include, among others, uncertainties with regards to clinical trials and regulatory approvals, collaboration and partnerships, intellectual property issues, dependence on key products, market and competition, manufacturing, purchasing and pricing, as well as dependence on key persons and financial risks.

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

Hansa Biopharma's Board of Directors and senior management reviews, on a regular basis, the development of these risks and uncertainties. No material changes from the presentation in the 2020 Annual Report have been identified as of the date of this quarterly report.

## Other information

### Contacts

Klaus Sindahl, Head of Investor Relations

Hansa Biopharma

Mobile: +46 (0) 709-298 269

E-mail: [klaus.sindahl@hansabiopharma.com](mailto:klaus.sindahl@hansabiopharma.com)

Katja Margell, Head of Corporate Communications

Hansa Biopharma

Mobile: +46 (0) 768-198 326

E-mail: [katja.margell@hansabiopharma.com](mailto:katja.margell@hansabiopharma.com)

### Legal disclaimer

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

### Financial calendar 2022

April 7, 2022 - Annual Report 2021

April 21, 2022 - Interim report for January - March 2022

June 16, 2022 - Annual General Meeting 2022

July 21, 2022 - Half year 2022 report

October 20, 2022 - Interim Report for January-September 2022

## Shareholder information

### Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	46,335,361 (44,473,452 A-shares and 1,861,909 C-shares)
Market Cap December 31, 2021	SEK ~4bn (USD ~440m)
Ticker	HNSA
ISIN	SE0002148817

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

Name	Number of shares	Ownership in pct
Redmile Group, LLC	5 768 619	13.0
Handelsbanken Asset Management (Sweden)	2 266 350	5.1
Fjärde AP-Fonden (AP 4)	2 207 397	4.9
Nexttobe AB	2 155 379	4.8
Invesco Advisers, Inc.	1 973 200	4.4
Olausson, Thomas	1 820 500	4.1
Tredje AP-Fonden (AP 3)	1 389 650	3.1
Försäkrings AB Avanza Pension	1 232 081	2.8
Schroder Investment Management, LTD	1 160 900	2.6
The Vanguard Group, Inc.	1 158 200	2.6
Other	23 341 176	52.6
<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).

Hansa Biopharma had approximately 18,000 shareholders as of December 31, 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).

## Assurance

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

Lund February 2, 2022

**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	Q4		January-December	
	2021	2020	2021	2020
Revenue	15 398	3 828	33 878	6 098
Cost of revenue	-3 623	-173	-15 425	-997
Sales, general and administration expenses	-103 160	-63 234	-327 262	-202 987
Research and development expenses	-68 241	-50 433	-230 764	-227 191
Other operating expenses	-3 124	3 826	-7 398	2 270
<b>Operating profit/loss</b>	<b>-162 750</b>	<b>-106 186</b>	<b>-546 971</b>	<b>-422 807</b>
Financial income/expenses	-451	346	-1 151	1 914
<b>Profit/loss for the period before tax</b>	<b>-163 201</b>	<b>-105 840</b>	<b>-548 122</b>	<b>-420 893</b>
Tax	-187	9	-158	40
<b>Net profit/loss for the period</b>	<b>-163 388</b>	<b>-105 831</b>	<b>-548 280</b>	<b>-420 853</b>
Attributable to:				
Parent company shareholders	-163 388	-105 831	-548 280	-420 853
Earnings per share (EPS)				
Before dilution (SEK)	-3,67	-2,38	-12,33	-9,98
After dilution (SEK)	-3,67	-2,38	-12,33	-9,98
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	120	-310	264	-297
<b>Other comprehensive income for the period</b>	<b>120</b>	<b>-310</b>	<b>264</b>	<b>-297</b>
<b>Total net comprehensive income</b>	<b>-163 268</b>	<b>-106 141</b>	<b>-548 016</b>	<b>-421 150</b>

## Consolidated statement of financial position

KSEK	December 31	
	2021	2020
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets	28 761	31 410
Property and equipment	6 432	5 206
Leased assets	35 273	4 493
<b>Total non-current assets</b>	<b>70 466</b>	<b>41 109</b>
<b>Current assets</b>		
Inventories	242	98
Accounts receivables	9 712	110
Current receivables, non-interest bearing	43 427	15 673
Short-term investments	237 619	238 144
Cash and cash equivalents	651 342	1 139 362
<b>Total current assets</b>	<b>942 342</b>	<b>1 393 387</b>
<b>TOTAL ASSETS</b>	<b>1 012 808</b>	<b>1 434 496</b>
<b>EQUITY AND LIABILITIES</b>		
Shareholders' equity	757 575	1 242 124
<b>Non-current liabilities</b>		
Deferred tax liabilities	426	424
Provisions	7 357	14 426
Lease liabilities	28 491	630
Deferred revenue	47 020	62 026
Contingent consideration	722	663
<b>Total non-current liabilities</b>	<b>84 016</b>	<b>78 169</b>
<b>Current liabilities</b>		
Lease liabilities	6 888	4 415
Current liabilities, non-interest bearing	66 906	36 257
Deferred revenue	24 961	17 406
Accrued expenses and deferred income	72 462	56 125
<b>Total current liabilities</b>	<b>171 217</b>	<b>114 203</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1 012 808</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	December 31	
	2021	2020
<b>Opening balance of shareholders' equity as reported</b>	<b>1 242 124</b>	<b>562 815</b>
Result for the period	-548 280	-420 853
Other comprehensive income for the period	264	-297
<b>Net comprehensive income</b>	<b>-548 016</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	63 467	29 878
<b>Total transactions with the group's owner</b>	<b>63 467</b>	<b>1 100 459</b>
<b>Closing balance of shareholders' equity</b>	<b>757 575</b>	<b>1 242 124</b>

## Consolidated statement of cash flow

KSEK	Q4		January-December	
	2021	2020	2021	2020
<b>Operating activities</b>				
Operating profit/loss	-162 750	-106 186	-546 971	-422 807
Adjustment for items not included in cash flow <sup>1)</sup>	22 970	16 740	64 883	51 430
Interest received and paid, net	-213	167	-627	-68
Income taxes paid	-76	-	-149	-
<b>Cash flow from operations before change in working capital</b>	<b>-140 068</b>	<b>-89 279</b>	<b>-482 863</b>	<b>-371 445</b>
Changes in working capital	23 740	-7 243	1 625	81 171
<b>Cash flow from operating activities</b>	<b>-116 328</b>	<b>-96 522</b>	<b>-481 238</b>	<b>-290 274</b>
<b>Investing activities</b>				
Acquisition of property and equipment	-	-	-2 399	-294
Sale of short term investments	-	-	-	182 828
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-</b>	<b>-2 399</b>	<b>182 534</b>
<b>Financing activities</b>				
Proceeds from share issuance, net <sup>2)</sup>	-	-750	-	1 070 580
Repayment of lease liabilities	-1 145	-1 183	-4 786	-4 674
<b>Cash flow from financing activities</b>	<b>-1 145</b>	<b>-1 933</b>	<b>-4 786</b>	<b>1 065 906</b>
Net change in cash	-117 474	-98 456	-488 423	958 166
Cash and cash equivalents, beginning of period	768 614	1 238 187	1 139 362	181 697
Currency exchange variance, cash and cash equivalents	200	-372	403	-501
<b>Cash and cash equivalents, end of period</b>	<b>651 342</b>	<b>1 139 362</b>	<b>651 342</b>	<b>1 139 362</b>

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

2) Total share issue cost amounted to SEK 41,255 k

## Parent company – Income statement

KSEK	Q4		January-December	
	2021	2020	2021	2020
Revenue	15 398	3 828	33 878	6 098
Cost of revenue	-3 623	-173	-15 425	-997
<b>Gross profit</b>	<b>11 775</b>	<b>3 655</b>	<b>18 453</b>	<b>5 101</b>
Other operating income	-	-	-	-
Sales, general and administration expenses	-102 515	-63 321	-327 031	-203 346
Research and development expenses	-69 110	-50 498	-231 974	-227 531
Other operating expenses	-3 123	3 806	-7 395	2 270
<b>Operating profit/loss</b>	<b>-162 973</b>	<b>-106 358</b>	<b>-547 947</b>	<b>-423 507</b>
Result from financial items:				
Finance income	67	555	67	2 170
Finance costs	-675	-169	-1 218	-307
<b>Loss for the period before tax</b>	<b>-163 581</b>	<b>-105 972</b>	<b>-549 098</b>	<b>-421 644</b>
Income tax benefit/expense	-	-	-	-
<b>Loss for the period after tax</b>	<b>-163 581</b>	<b>-105 972</b>	<b>-549 098</b>	<b>-421 644</b>
Other comprehensive income for the period	-	-	-	-
<b>Total comprehensive income for the period</b>	<b>-163 581</b>	<b>-105 972</b>	<b>-549 098</b>	<b>-421 644</b>

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

KSEK	December 31	
	2021	2020
Opening shareholders' equity as reported	1 241 578	562 763
Result for the period	-549 098	-421 644
Other comprehensive income for the period	-	-
<b>Net comprehensive income</b>	<b>-549 098</b>	<b>-421 644</b>
Proceeds from new share issuance, net	-	1 070 581
Long term incentive programs	63 467	29 878
<b>Total transactions with the group's owner</b>	<b>63 467</b>	<b>1 100 459</b>
<b>Closing shareholders' equity</b>	<b>755 948</b>	<b>1 241 578</b>

## Parent company – Statement of financial position

KSEK	December 31	
	2021	2020
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets	26 518	29 171
Property, plant and equipment	6 432	5 206
Leased assets	35 273	4 493
Investment in subsidiaries	5 095	5 095
Receivables, group companies	2 203	1 972
<b>Total non-current assets</b>	<b>75 521</b>	<b>45 937</b>
<b>Current assets</b>		
Inventories	242	98
Accounts receivables	9 712	110
Current receivables, non-interest bearing	43 201	15 158
Short-term investments	237 619	238 144
Cash and cash equivalents	644 975	1 133 647
<b>Total current assets</b>	<b>935 749</b>	<b>1 387 157</b>
<b>TOTAL ASSETS</b>	<b>1 011 270</b>	<b>1 433 094</b>
<b>EQUITY AND LIABILITIES</b>		
Shareholders' equity	755 948	1 241 578
<b>Non-current liabilities</b>		
Provisions	7 357	14 426
Lease liabilities	28 491	630
Deferred revenue	47 020	62 026
Contingent consideration	722	663
<b>Total non-current liabilities</b>	<b>83 590</b>	<b>77 745</b>
<b>Current liabilities</b>		
Lease liabilities	6 888	4 415
Liabilities, group companies	3 901	1 613
Current liabilities, non-interest bearing	66 598	34 950
Deferred revenue	24 961	17 406
Accrued expenses and deferred income	69 384	55 387
<b>Total current liabilities</b>	<b>171 732</b>	<b>113 771</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1 011 270</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	Q4		January-December	
	2021	2020	2021	2020
Revenue				
Product sales	8 991	-	15 017	-
Contract revenue, Axis-Shield agreement	1 056	1 117	2 624	2 864
Cost reimbursement, Axis-Shield agreement	61	113	527	636
Contract revenue, Sarepta agreement	5 290	2 599	15 710	2 599
	<b>15 398</b>	<b>3 828</b>	<b>33 878</b>	<b>6 098</b>
Parent company				
Revenue:				
Product sales	8 991	-	15 017	-
Contract revenue, Axis-Shield agreement	1 056	1 117	2 624	2 864
Cost reimbursement, Axis-Shield agreement	61	113	527	636
Contract revenue, Sarepta agreement	5 290	2 599	15 710	2 599
	<b>15 398</b>	<b>3 828</b>	<b>33 878</b>	<b>6 098</b>

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

On April 20, 2021, the Company received a request for arbitration from the Counterparties claiming they were entitled to 10% of the upfront payment the Company received under its 2020 collaboration agreement with Sarepta as well as entitlement to participate in payments the Company may receive under the Sarepta agreement in the future. The Company believes these claims are without merit. The arbitration proceedings are ongoing at an initial stage.

## 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 December 31, 2021 amounted to SEK 237.6 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 December 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

## Adeno-associated virus (AAV)

AAV is a versatile viral vector technology that can be engineered for very specific functionality in gene therapy applications.

## Allogeneic hematopoietic stem cell transplantation (HSCT)

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

## AMR

Antibody mediated 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 antibodies are 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 disease that occurs 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 surface 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 substance 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.

## Neutralizing antibodies (Nabs)

Nab is an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically.