

INTERIM REPORT JANUARY-SEPTEMBER 2021



Hansa on track to achieve key 2021 objectives:

- Agreements on funding obtained in three countries; HTA submissions in ten countries; and Marketing Authorization Applications filed in Switzerland and Israel
- Growing number of patient candidates identified as leading transplantation centers get clinically ready to transplant this underserved population
- Enrollment in AMR and GBS programs accelerated by initiation of additional centers; On track for completion according to previous guidance
- Dialogue with FDA on regulatory path in anti-GBM expected to be concluded later this year as previously guided
- U.S. RCT study – site initiation progressing with first site open for recruitment in San Antonio, TX

Highlights for the third quarter 2021

- Launch and Market Access efforts for Idefix® in Europe are progressing as planned in early launch countries. Reimbursement has been secured in Sweden, the Netherlands, Finland.
- Health Technology Assessment (HTA) dossiers have been submitted in ten countries, including UK, Germany, Norway and Israel and most recently in Italy and Scotland during the third quarter. Hansa expects to complete HTA filings in all EU5 by year-end, with France and Spain expected to be submitted in Q4 2021.
- Growing number of patient candidates identified as select leading transplantation centers get clinically ready to transplant this underserved population and prioritization programs and policies are adjusted to HLA-incompatible kidney patients, who cannot access an organ through existing allocation systems.
- Marketing Authorization Application for Idefix® submitted in Switzerland and Israel.
- European Society for Organ Transplantation (ESOT) Congress in Milan – Hansa-sponsored symposium and KOL meetings with very strong interest across entire European transplant community. An ESOT workstream with leading transplantation KOLs has been formed to advance European clinical guidelines for desensitization practices in incompatible kidney transplant patients. Workstream expected to be concluded by year-end.
- Patient recruitment in the Phase 2 clinical studies in active antibody mediated rejection (AMR) and Guillain-Barré Syndrome (GBS) has been accelerated by initiation of new centers. In the AMR and GBS trials, 19 and 14 patients, respectively, out of a target of 30 patients in each of the studies have now been enrolled. Completion of enrollment continues to be expected by H2'21/H1'22, with a first data read-out in both studies expected in the second half of 2022, as previously guided.
- Anti-Glomerular Basement Membrane (Anti-GBM): In the U.S., dialogue with FDA initiated regarding regulatory path forward, which is expected to conclude later this year as previously guided. In Europe, constructive regulatory advice meeting held with German health authorities BfArM; Hansa is now preparing for dialogue with the European Medicines Agency (EMA).
- Partnership with Sarepta and preclinical collaboration with argenx moving forward according to plan.
- Hansa Biopharma awarded “Great Place to Work” certification for second consecutive year.

Events after the end of the reporting period

- US Randomized Controlled Trial in kidney transplant: First site open for recruitment in San Antonio, Tx. Additional centers are expected to be initiated in the coming months and patient enrollment to start in Q4-2021. The U.S. trial targets 64 patients with the highest unmet medical need and is expected to support a BLA submission under the accelerated approval pathway in H1 2024.

Financial Summary

- Solid cash position of SEK 1,007m at the end of September 2021. With its existing cash position Hansa expects its operations to be financed into 2023.
- Investments in R&D in the third quarter amounted to SEK 61m (Q3'20: SEK 71m) and to SEK 163m for the first nine months of 2021 (first nine months'20: SEK 177m). SG&A expenses amounted to SEK 83m in Q3 2021 (Q3'20: SEK 52m) and to SEK 224m for the first nine months of the year 2021 (first nine months'20: SEK 140m), in line with plans.
- Cash flow from operating activities for the third quarter ended at SEK -132m (Q3'20: SEK 5m) and SEK -365m for the first nine months of 2021 (first nine months'20: -194m).

<i>SEKm, unless otherwise stated - unaudited</i>	Q3 2021	Q3 2020	9M 2021	9M 2020
Revenue	4.9	0.8	18.5	2.3
SG&A expenses	-82.8	-51.7	-224.1	-139.8
R&D expenses	-60.6	-71.3	-162.5	-176.8
Operating profit/loss	-148.2	-123.4	-384.2	-316.6
Net profit/loss	-148.4	-122.4	-384.9	-315.0
Cash flow from operating activities	-131.5	4.8	-364.9	-193.8
Cash and short-term investments	1,006.7	1,476.2	1,006.7	1,476.2
Shareholders' equity	899.6	1,338.2	899.6	1,338.2
EPS before and after dilution (SEK)	-3.34	-2.77	-8.65	-7.61
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	44,135,067	44,473,452	41,405,758
Number of employees at the end of the period	127	80	127	80

Søren Tulstrup, President and CEO, comments

"We continue to make good progress in advancing our clinical, commercial and corporate strategy with solid progress in our efforts to build and advance a pipeline of valuable drug candidates for rare immunologic diseases and launch Idefix® in Europe. We see Idefix® as a potential new transformative therapy that can bring hope to the thousands of highly sensitized patients across the continent who are currently waiting for a compatible kidney transplant. With this novel therapy, we are paving a new path and changing the transplantation ecosystem to accommodate transplants for incompatible kidney patients.

Our goal is to have a positive impact on patients as we work closely with the transplant community to reshape the area of desensitization and integrate Idefix® into clinical practice as a new standard-of-care. We do this in a very focused way – center by center, one patient at a time. We are taking this strategic approach as Idefix® is the first and only approved drug to enable kidney transplants in highly sensitized patients in the EU, who are incompatible with a deceased donor, and the long-term market uptake of this innovative product is highly dependent on successful early experiences in key early adopter centers. Operationally, our Market Access activities in Europe continue according to plan in the early launch countries as evidenced by the recent positive Pricing and Reimbursement decisions by the authorities in the Netherlands and Finland. In addition, we are pleased to have executed agreements with the relevant regions in Sweden on the basis of the June 2021 decision by the national New Therapies Council to recommend Idefix® in highly sensitized patients.

In the U.S., the first site is now open for recruitment in our randomized controlled clinical trial in kidney transplants and we expect the first patient to be enrolled in the fourth quarter. The study initiation marks an important milestone for Hansa Biopharma's efforts to access the U.S. market. The new trial will target 64 highly sensitized patients with a cPRA score of ≥99.9%, representing the group of patients with the highest unmet medical need. We expect to enroll patients at 12-15 leading transplantation centers across the U.S. and that the U.S. trial will generate valuable experience at these key centers.

In our ongoing Phase 2 programs for GBS and AMR, we have initiated additional centers in Q3 to accelerate patient enrollment. We now have 12 centers open for recruitment in AMR and 8 in GBS and expect to open additional centers in the fourth quarter to meet our target of completing enrollment H2 '21/H1 '22, as previously guided, assuming no further escalation of the COVID-19 pandemic. As of October 21, 2021, 19 out of a target of 30 patients have now been enrolled in the AMR study and 14 out of a target of 30 patients have been enrolled in the GBS study.

Further, we have now initiated dialogue with the FDA on our anti-GBM program. As previously guided, we aim to achieve alignment on the regulatory path forward later this year. I am also pleased to announce a new study in 12 patients in the U.S. to assess whether imlifidase in combination with bortezomib, belatacept, rituximab and IVIg can optimize patient outcomes in highly sensitized patients with donor specific antibodies (DSA) rebound and antibody mediated kidney transplant rejection (AMR). The study will be run at the NYU Langone Transplant Institute and is expected to commence next year.

Regarding our strategic partnerships, our preclinical collaboration with argenx is moving forward according to plan. The preclinical focus of the collaboration aims at understanding potential benefits of combining imlifidase with efgartigimod, argenx' FcRn inhibitor.

Within gene therapy, our partnership with Sarepta to assess imlifidase as a pretreatment to Sarepta's gene therapy programs in Duchenne and Limb-Girdle Muscular Dystrophy is also progressing according to plan. If positive preclinical data is generated we expect imlifidase to move into the clinic as a next step.

Lastly, I also want to highlight that Hansa Biopharma AB was recently awarded certification as a Great Place to Work® for the second consecutive year. The certification as a Great Place to Work® reflects our successful efforts over the past years to not only build and maintain a high performance team, but also to create a rewarding and stimulating workplace for our employees.

I look forward to keeping you updated on progress in our mission to leverage our unique IgG-cleaving enzyme technology platform to develop innovative, lifesaving and life-altering immunomodulating therapies, bring these to the patients with rare diseases who need them and generate value to society at large."



Søren Tulstrup
President and CEO, Hansa Biopharma

Continuous progress with our pipeline activities

Candidate/ Project	Indications	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients ^{1,2}				→		*)	EU: Additional agreements around reimbursement from H2 2021. Post Approval Study to be initiated H2 2021
	US: Kidney transplantation in highly sensitized patients ^{1,2}							First patient recruited H2 2021 Completion of enrollment H2 2022
	Anti-GBM antibody disease ³							Agreement with regulators in H2 2021 on a path forward toward BLA/MAA
	Antibody mediated kidney transplant rejection (AMR)							Complete enrollment of 30 patients in H2 2021/H1 2022
	Guillain-Barré syndrome (GBS)							Complete enrollment of 30 patients in H2 2021/H1 2022
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Pre-Clinical phase
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Pre-Clinical phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Initiation of toxicology studies in H1 2021
EnzE	Cancer immunotherapy							Research phase

1 Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)

2 Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)

3 Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

*) 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.

■ Complete ■ Ongoing

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.

Market Access efforts for Idefix® in Europe are progressing as planned in early launch countries. Pricing and reimbursement have been secured in the Netherlands and Finland. In addition Hansa has executed agreements with the relevant regions in Sweden on the back of the decision from the New Therapies Council to recommend imlifidase in highly sensitized patients.

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.

Health Technology Assessment (HTA) dossiers have been submitted in ten countries, most recently in Italy and Scotland during the third quarter. Additional market access agreements with early launch countries are expected to be reached on an ongoing basis from mid-2021 onward.

Commercial supply chain for supporting the launch is established. A post approval study is expected to be initiated during the second half of 2021.

US: Kidney transplantation for highly sensitized patients – New RCT (ClinicalTrials.gov ID: NCT04935177)

The U.S. trial design for a randomized, controlled trial of imlifidase in highly sensitized kidney transplant patients was announced in late June 2021 with the first center initiated for recruitment in October 2021. The study will enroll 64 highly sensitized kidney patients with a cPRA score of $\geq 99.9\%$ or above, who will be randomized to either imlifidase desensitization treatment or to a control arm 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. Results from the trial are expected to support a 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 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 demonstrate graft survival of 84% after imlifidase treatment and transplantation and a mean eGFR of 55 mL/min/1.73 m² (61 mL/min/m² for those without AMR). Data is in line with expectations in imlifidase treated transplant patients compared to outcomes in patients undergoing HLA-incompatible transplantation. For a subgroup of 13 patients with cPRA of $\geq 99.9\%$ graft survival was 92% and improved kidney function for patients with a mean eGFR at 60 mL/min/1.73 m² after year three. The data from the three-year follow study was published in American Journal of Transplantation in July 2021.

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 function¹, 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 ended up on dialysis after six months. These positive data mark an important milestone for the expansion of imlifidase outside transplantation.

In the U.S., a dialogue with the FDA has been initiated regarding the regulatory path forward, which is expected to conclude later this year, as previously guided. In EU, a constructive regulatory advice meeting was recently held with BfArM and we are now preparing for dialogue with EMA.

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 transplants² 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 by the end of 2020. As of October 21, 2021, 19 out of a target of 30 patients with active AMR episodes have been enrolled at 12 centers across the U.S., Europe and Australia.

Hansa plans to open one additional center for the recruitment of AMR patients during the fourth quarter of 2021. Completion of enrollment is expected toward the end of 2021 or first half of 2022 with a first data read-out in the second half of 2022, as previously guided. The guidance assumes no further escalation of the COVID-19 pandemic potentially forcing trial centers to re-prioritize 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 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 by the end of 2020. As of October 21, 2021, 14 out of a target of 30 patients with GBS, have been enrolled at 8 centers across France, the United Kingdom (UK) and the Netherlands.

Hansa plans to expand to 10 centers in total engaged in the recruitment of GBS patients during the fourth quarter of 2021. Completion of enrollment is expected toward the end of 2021 or first half of 2022, with a first data read-out in the second half of 2022, as previously guided. The guidance assumes no further escalation of the COVID-19 pandemic potentially forcing trial centers to re-prioritize patient recruitment or even shut down again.

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

A new study in 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.

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

² 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 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 findings³ demonstrate how pre-treatment with imlifidase in tumor animal models can increase the efficacy of currently available antibody-based cancer therapies. This treatment concept is currently being investigated under the project name, EnzE, Enzyme-based antibody Enhancement.

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

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

On July 2, 2020, Hansa Biopharma 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 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.

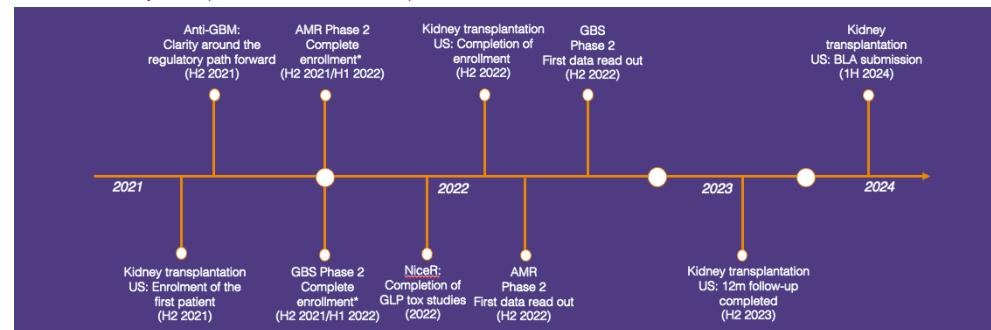
The partnership has been progressing as planned and is ongoing with pre-clinical investigations with imlifidase as a potential pre-treatment in the gene therapy setting. For further information regarding Sarepta's gene therapy programs in DMD and LGMD, please refer to www.sarepta.com.

Pre-clinical research collaboration with argenx BV

On March 29, 2021 Hansa Biopharma 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



* 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 reinitiated enrollment in Q4 2020 under a risk-based, site-by-site approach.



³ 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 – September 2021

Revenue

Revenue for the third quarter 2021 amounted to SEK 4.9m (Q3'20: SEK 0.8m) and SEK 18.5 for the first nine months of 2021 (first 9 months '20 SEK 2.3m) 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).

Cost of revenue

The cost of revenue for the third quarter of 2021 amounted to SEK -7.7m (Q3'20: SEK -0.3m) and to SEK -11.8m (first nine months '20: SEK -0.8m) for the first nine months of 2021. Cost of revenue includes mainly cost related to product sales and provision for excess and obsolete inventories.

SG&A expenses

Sales, general and administration expenses for the third quarter of 2021 amounted to SEK 82.8m (Q3 '20: SEK 51.7m) and to SEK 224.1m (first nine months '20: SEK 139.8m) for the first nine months 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, included in the above SG&A expenses, amounted to SEK 24.0m for the first nine months of the year (first nine months '20: SEK 19.7m).

R&D expenses

Research and development expenses for the third quarter of 2021 amounted to SEK 60.6m (Q3'20: SEK 71.3m) and to SEK 162.5m for the first nine months of the year 2021 (first nine months '20: SEK 176.8m). Recorded non-cash cost for the Company's employee long-term incentive programs, included in the above R&D expenses, amounted to SEK 12.0m for the first nine months of the year 2021 (first nine months '20: SEK 10.2m).

Financial result

The operating result for the third quarter of 2021 amounted to SEK -148.2m (Q3'20: SEK -123.4m) and to SEK -384.2m for the first nine months of 2021 (first nine months '20 SEK -316.6m). 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 third quarter of 2021 amounted to SEK -148.4m (Q3'20: SEK -122.4m) and to SEK -384.9m for the first nine months of the year 2021 (first nine months '20: -315.0).

Cash flow, cash and investments

Cash flow from operating activities for the third quarter of 2021 amounted to SEK -131.5m (Q3'20: SEK 4.8m) and to SEK -364.9m for the first nine months of 2021 (first nine months '20: -193.8m). 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. Hansa receipt 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 1,006.7 on September 30, 2021 as compared to SEK 1,377.5m at year-end 2020 and SEK 1,139.4m as of June 30, 2021.

Shareholders' equity

On September 30, 2021, equity amounted to SEK 899.6m as compared to SEK 1,242.1m at the end of the year 2020.

Parent Company

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.

The parent company's revenue for the third quarter of 2021 amounted to SEK 4.9m (Q3'20: SEK 0.8m) and to SEK 18.5m for the first nine months of the year 2021 (first nine months '20 2.3m).

Loss for the parent company for the third quarter 2021 amounted to SEK -148.6m (Q3'20: SEK -122.5m) and to SEK -385.5m for the first nine months of the year 2021 (first nine months '20 -315.7m).

The parent company's equity amounted to SEK 898.3m as per September 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, Hansa Biopharma Inc. and Hansa Biopharma Australia PTY LTD. Hansa Biopharma Inc had four employees at the end of September 2021. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of September 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 September 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

Ongoing programs	LTIP 2018	LTIP 2019	LTIP 2020	LTIP 2021
Maximum number of issuable shares*	163 781	582 014	1 173 999	1 400 000
Number of allocated and outstanding share rights and options	119 284	436 703	903 076	987 000
Number of acquired and outstanding warrants	6 701	11 000	-	-
Estimated total cost including social contributions, KSEK	10 437	30 915	95 932	88 836
Total cost per program, including social contributions, as of September 30, 2021 YTD, KSEK	1 496	2 338	22 278	9 871
<i>*As of 30 September 2021, including issuable shares to cover social contributions under the LTIP.</i>				
Total costs, including social contributions, as of September 30, 2021 YTD, KSEK				<u>35 983</u>

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.

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

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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.

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

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 September 30, 2021	SEK ~5.5bn (USD ~630m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of September 30, 2021

Name	Number of shares	Ownership in pct
Redmile Group, LLC	5 768 619	13.0
Handelsbanken Asset Management	2 729 853	6.1
Fjärde AP-Fonden (AP 4)	2 207 397	4.9
Nexttobe AB	2 155 400	4.8
Invesco Advisers, Inc.	1 973 200	4.4
Olausson, Thomas	1 820 500	4.1
Tredje AP-Fonden (AP 3)	1 488 473	3.4
Schroder Investment Management, LTD	1 160 900	2.6
The Vanguard Group, Inc.	1 158 200	2.6
Försäkrings AB Avanza Pension	1 156 542	2.6
Other	22 854 368	51.5
Outstanding shares in total	44 473 452	100.0

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

Hansa Biopharma had approximately 18,500 shareholders as of September 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 been reviewed by the company's auditors.

Lund October 20, 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

Condensed unaudited financial statements

Consolidated income statement

KSEK	Q3		January-September	
	2021	2020	2021	2020
Revenue	4 947	762	18 480	2 270
Cost of revenue	-7 735	-285	-11 802	-824
Sales, general and administration expenses	-82 768	-51 726	-224 102	-139 753
Research and development expenses	-60 619	-71 250	-162 523	-176 758
Other operating expenses	-2 004	-946	-4 274	-1 556
Operating profit/loss	-148 179	-123 445	-384 221	-316 621
Financial income/expenses	-201	1 027	-700	1 568
Profit/loss for the period before tax	-148 380	-122 418	-384 921	-315 053
Tax	10	10	29	31
Net profit/loss for the period	-148 370	-122 408	-384 892	-315 022
Attributable to:				
Parent company shareholders	-148 370	-122 408	-384 892	-315 022
Earnings per share (EPS)				
Before dilution (SEK)	-3,34	-2,77	-8,65	-7,61
After dilution (SEK)	-3,34	-2,77	-8,65	-7,61
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	37	164	144	13
Other comprehensive income for the period	37	164	144	13
Total net comprehensive income	-148 333	-122 244	-384 748	-315 009

Consolidated statement of financial position

KSEK	September 30		December 31
	2021	2020	2020
ASSETS			
Non-current assets			
Intangible assets	29 443	33 104	31 410
Property and equipment	6 624	5 486	5 206
Leased assets	20 164	5 713	4 493
Total non-current assets	56 231	44 303	41 109
Current assets			
Inventories	123	-	98
Current receivables, non-interest bearing	29 247	5 979	15 783
Short-term investments	238 051	237 978	238 144
Cash and cash equivalents	768 614	1 238 188	1 139 362
Total current assets	1 036 035	1 482 145	1 393 387
TOTAL ASSETS	1 092 266	1 526 448	1 434 496
EQUITY AND LIABILITIES			
Shareholders' equity			
Deferred tax liabilities	426	450	424
Provisions	7 994	11 199	14 426
Lease liabilities	16 392	1 445	630
Deferred revenue	50 066	59 933	62 026
Contingent consideration	700	672	663
Total non-current liabilities	75 578	73 699	78 169
Current liabilities			
Lease liabilities	3 777	4 782	4 415
Current liabilities, non-interest bearing	31 079	34 033	36 257
Deferred revenue	24 518	29 967	17 406
Accrued expenses and deferred income	57 749	45 787	56 125
Total current liabilities	117 123	114 569	114 203
TOTAL EQUITY AND LIABILITIES	1 092 266	1 526 448	1 434 496

Consolidated statements of changes in shareholder's equity

KSEK	September 30		Year 2020
	2021	2020	
Opening balance of shareholders' equity as reported	1 242 124	562 815	562 815
Adjustment of the opening balance	0	-304	0
Adjusted opening balance of shareholders' equity reported	1 242 124	562 511	562 815
Result for the period	-384 892	-315 022	-420 853
Other comprehensive income for the period	144	-173	-297
Net comprehensive income	-384 748	-315 195	-421 150
Transactions with the group's owner			
Proceeds from new share issuance, net	-	1 071 331	1 070 581
Long term incentive programs	42 189	19 533	29 878
Total transactions with the group's owner	42 189	1 090 864	1 100 459
Closing balance of shareholders' equity	899 565	1 338 180	1 242 124

Consolidated statement of cash flow

KSEK	Q3		January-September	
	2021	2020	2021	2020
Operating activities				
Operating profit/loss	-148 179	-123 445	-384 221	-316 621
Adjustment for items not included in cash flow ^[1]	18 728	19 703	41 913	34 690
Interest received and paid, net	-158	-87	-414	-235
Income taxes paid	-51	-	-73	-
Cash flow from operations before change in working capital	-129 660	-103 829	-342 795	-282 166
Changes in working capital	-1 841	108 661	-22 115	88 414
Cash flow from operating activities	-131 501	4 834	-364 910	-193 753
Investing activities				
Acquisition of property and equipment	-	-	-2 399	-294
Sale of short term investments	-	14 913	-	182 828
Cash flow from investing activities	-	14 913	-2 399	182 534
Financing activities				
Proceeds from share issuance ^[2]	-	1 071 330	-	1 071 330
Repayment of lease liabilities	-1 346	-1 173	-3 641	-3 491
Cash flow from financing activities	-1 346	1 070 157	-3 641	1 067 839
Net change in cash	-132 847	1 089 902	-370 950	1 056 620
Cash and cash equivalents, beginning of period	901 391	148 377	1 139 362	181 697
Currency exchange variance, cash and cash equivalents	71	-92	203	-129
Cash and cash equivalents, end of period	768 614	1 238 188	768 614	1 238 188

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	Q3		January-September	
	2021	2020	2021	2020
Revenue	4 947	762	18 480	2 270
Cost of revenue	-7 735	-285	-11 802	-824
Sales, general and administration expenses	-84 993	-51 810	-224 516	-140 025
Research and development expenses	-58 633	-71 330	-162 864	-177 033
Other operating expenses	-2 003	-948	-4 272	-1 535
Operating profit/loss	-148 417	-123 611	-384 974	-317 148
Result from financial items:				
Finance income	-	2 137	-	1 615
Finance costs	-150	-1 066	-543	-138
Loss for the period before tax	-148 567	-122 540	-385 517	-315 671
Income tax benefit/expense	-	-	-	-
Loss for the period after tax	-148 567	-122 540	-385 517	-315 671
Other comprehensive income for the period	-	-	-	-
Total comprehensive income for the period	-148 567	-122 540	-385 517	-315 671

Parent company – Statement of changes in shareholders' equity

KSEK	September 30		December 31
	2021	2020	2020
Opening shareholders' equity as reported	1 241 578	562 763	562 763
Result for the period	-385 517	-315 671	-421 644
Other comprehensive income for the period	-	-	-
Net comprehensive income	-385 517	-315 671	-421 644
Proceeds from new share issuance, net	-	1 071 331	1 070 581
Long term incentive programs	42 189	19 533	29 878
Total transactions with the group's owner	42 189	1 090 864	1 100 459
Closing shareholders' equity	898 250	1 337 956	1 241 578

Parent company – Statement of financial position

KSEK	September 30		December 31
	2021	2020	2020
ASSETS			
Non-current assets			
Intangible assets	27 181	29 651	29 171
Property, plant and equipment	6 624	5 486	5 206
Leased assets	20 164	5 713	4 493
Investment in subsidiaries	5 095	5 095	5 095
Receivables, group companies	2 100	2 165	1 972
Total non-current assets	61 164	48 110	45 937
Current assets			
Inventories	123	-	98
Current receivables, non-interest bearing	28 843	5 461	15 268
Receivables, group companies	-	4 496	-
Short-term investments	238 051	237 978	238 144
Cash and cash equivalents	762 005	1 232 489	1 133 647
Total current assets	1 029 022	1 480 424	1 387 157
TOTAL ASSETS	1 090 186	1 528 534	1 433 094
EQUITY AND LIABILITIES			
Shareholders' equity			
	898 250	1 337 956	1 241 578
Non-current liabilities			
Provisions	7 994	11 396	14 426
Lease liabilities	16 392	1 445	630
Deferred revenue	50 066	59 933	62 026
Contingent consideration	700	672	663
Total non-current liabilities	75 152	73 446	77 745
Current liabilities			
Lease liabilities	3 777	4 782	4 415
Liabilities, group companies	2 261	4 453	1 613
Current liabilities, non-interest bearing	30 857	34 545	34 950
Deferred revenue	24 518	29 967	17 406
Accrued expenses and deferred income	55 371	43 385	55 387
Total current liabilities	116 784	117 132	113 771
TOTAL EQUITY AND LIABILITIES	1 090 186	1 528 534	1 433 094

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. 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

Revenue

Product sales

Contract revenue, Axis-Shield agreement

Cost reimbursement, Axis-Shield agreement

Contract revenue, Sarepta agreement

Parent company

Revenue:

Product sales

Contract revenue, Axis-Shield agreement

Cost reimbursement, Axis-Shield agreement

Contract revenue, Sarepta agreement

	Q3		January-September	
	2021	2020	2021	2020
Product sales	-	-	6 026	-
Contract revenue, Axis-Shield agreement	522	582	1 567	1 747
Cost reimbursement, Axis-Shield agreement	46	180	466	523
Contract revenue, Sarepta agreement	4 378	-	10 420	-
	4 946	762	18 480	2 270

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 2021.

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 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 September 30, 2021 amounted to SEK 238.1 million (Year end'20: SEK 238.1 million) and belonged to level 2 in the fair value hierarchy. The fair value of the financial liability for contingent consideration at September 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.

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.

Enzyme

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

Guillain-Barré syndrome (GBS)

Guillain-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 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.