

INTERIM REPORT JANUARY-MARCH 2022



Solid sales growth in Q1'22; Market access secured in Germany and in France; Marketing authorization granted in Israel; Results from Phase 2 program in anti-GBM published in Journal of American Society of Nephrology (JASN)

Highlights for the first quarter 2022

- Solid sales growth in the first quarter with SEK 24.2m in product sales; total revenue amounted to SEK 30.3m.
- Commercial launch activities and market access efforts for Idefix® in Europe continued to progress as planned during Q1 2022 with market access secured in France through a reimbursed Early Access Program and in Germany through commercial access on negotiated terms. Additional market access procedures are ongoing in 11 countries, including Spain, Italy and the U.K.
- Hansa and Medison Pharma announced that a marketing authorization in Israel for Idefix® has been granted for desensitization treatment of highly sensitized kidney transplant patients.
- Key data from a Phase 2 program of imlifidase in anti-Glomerular Basement Membrane (anti-GBM) disease patients were published in the Journal of American Society of Nephrology (JASN). The publication recognizes the study's significance in autoimmune diseases as it suggests that deactivation of autoantibodies could alter the course of an autoimmune disease.
- In January, Hansa and AskBio entered into an agreement 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 preclinical and clinical feasibility program for patients with pre-existing neutralizing antibodies (NAbs). As part of the agreement, Hansa received a USD 5 million upfront payment, while AskBio has received an exclusive option to negotiate a full development and commercialization agreement.
- The partnership with Sarepta investigating imlifidase in gene therapy and the preclinical collaboration with argenx exploring the potential for combination therapy with imlifidase moved forward according to plan.

Clinical pipeline update

- U.S. ConfIdaS: 16 patients have been enrolled for randomization in our pivotal U.S. open-label, randomized, controlled trial "ConfIdaS" with the aim of completing enrollment by the end of this year, as previously guided.
- AMR: In the Antibody Mediated Rejection (AMR) Phase 2 trial, 28 out of a target of 30 patients have been enrolled, and completion of enrollment is expected in the first half of 2022, as previously guided.
- GBS: In the Guillain Barré Syndrome (GBS) Phase 2 trial, 16 patients out of a target of 30 patients have been enrolled. The COVID-19 pandemic has significantly impacted the enrollment rate in our GBS trial at the participating hospitals. To accelerate enrollment rate, we have implemented a number of initiatives to address the current situation and we expect these initiatives to support the completion of enrollment of GBS patients in H2 2022.

Events after the reporting period

- Anti-GBM: On April 19, 2022, Hansa announced that the US FDA has accepted Hansa's Investigational New Drug (IND) application to proceed with a Phase 3 study of imlifidase in 50 patients across EU and the U.S. The first patient is expected to be enrolled in 2022, as previously guided.

Financial Summary

<i>SEKm, unless otherwise stated – unaudited</i>	Q1 2022	Q1 2021	12M 2021
Revenue	30.3	9.0	33.9
SG&A expenses	(80.4)	(60.1)	(327.3)
R&D expenses	(70.9)	(47.4)	(230.8)
Loss from operation	(135.0)	(103.7)	(547.0)
Loss for the period	(138.4)	(103.9)	(548.3)
Net cash used in operation	(130.4)	(120.9)	(481.2)
Cash and short-term investments	753.7	1,254.7	889.0
Shareholders' equity	636.0	1,149.8	757.6
EPS before and after dilution (SEK)	(3.11)	(2.34)	(12.33)
Number of outstanding shares	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
Number of employees at the end of the period	141	101	133

Søren Tulstrup, President and CEO, comments

"Hansa's commercial launch activities and market access efforts for Idefirix® in Europe continue to progress as planned. During the first quarter of 2022, we have seen additional key transplant centers becoming both clinically and commercially ready to use Idefirix® and solid sales growth. Market access were secured in two of the five major European markets, namely in France on an early access basis and in Germany - two countries with more than 5,600 kidney transplants annually, of which approximately 75% are transplanted from a deceased donor.

We are very pleased to have reached these important agreements with both the German payer association, National Association of Statutory Health Insurance Funds (GKV-SV), and the early access granted by the French Haute Autorité de Santé (HAS). We expect to complete additional agreements in the course of the year as we have market access procedures ongoing in 11 countries, including Spain, Italy and the U.K. During 2021, market access was secured in Sweden and the Netherlands, as well as on an individual hospital basis in Finland and Greece.

Looking beyond our core markets, I am also pleased to see that our new collaboration with Medison Pharma is off to a good start with the recent marketing authorization obtained in Israel for Idefirix® for the treatment of highly sensitized kidney transplant patients. Beyond Israel, our collaboration with Medison also covers Poland, Hungary, Croatia and Slovenia.

In the beginning of March, key data from the investigator-initiated open-label Phase 2 study of imlifidase in patients with anti-glomerular basement membrane (anti-GBM) disease were published in the leading nephrology publication Journal of the American Society of Nephrology (JASN). The publication recognizes the study's significance in autoimmune diseases as it suggests that deactivation of autoantibodies could alter the course of an autoimmune disease, allowing restoration of kidney function. These results highlight the potential of imlifidase as we expand beyond kidney transplantation.

Speaking about anti-GBM, we are also pleased to share the positive news that the U.S. FDA recently accepted Hansa's Investigational New Drug (IND) application to proceed with a pivotal Phase 3 study of imlifidase in approximately 50 patients across EU and the U.S. The first patient is expected to be enrolled later this year, as previously guided.

In the U.S., our pivotal ConfIdeS trial in kidney transplantation is progressing with 16 out of a target of 64 patients enrolled for randomization. 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 have now initiated enrollment at nine sites and expect participation by up to 15 leading transplantation centers across the U.S., with the aim of completing enrollment by the end of this year.

Turning to our ongoing Phase 2 programs for GBS and AMR, we have enrolled 28 out of a target of 30 patients in the AMR study, while 16 out of a target of 30 patients have been enrolled in the GBS study.

With respect to our GBS program, we have seen how the impact of the COVID-19 pandemic and the emergence of the new variants have negatively affected the enrollment rate across a number of trial centers. To mitigate this situation we have recently implemented several significant initiatives to increase the enrollment rate and we expect these initiatives will support the completion of enrollment of GBS patients in the second half of 2022.

Last, we were pleased to announce at the beginning of January that Hansa and AskBio, a subsidiary of Bayer AG, have entered into a collaboration to evaluate imlifidase in a preclinical and clinical feasibility program as pre-treatment ahead of gene therapy in Pompe disease in patients with pre-existing neutralizing antibodies (NAbs). We see significant potential for our antibody-cleaving enzyme technology to help overcome this barrier in gene therapy as NAbs against adeno-associated virus remain a major challenge.

We have commenced another exciting year with several important milestones to be achieved across our platform and franchises, and I look forward to making further progress in the remainder of the year towards the vision that we are pursuing with single-minded focus: A world where patients with rare immunologic diseases can lead long and healthy lives."



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 ^{1,2}	Completed	Completed	Completed	Planned	Completed	*)	EU: Additional agreements around reimbursement from H2'21
	US: Kidney transplantation in highly sensitized patients ^{1,2}	Completed	Completed	Ongoing				Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease ³	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				Completion of enrollment (30 patients) H2 2022
	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)	Ongoing						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

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

■ 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 activities and market access efforts for Idefix® in Europe continued to progress as planned during Q1 with market access secured in France through a reimbursed Early Access Program and in Germany with commercial access on negotiated terms. Additional market access procedures are ongoing in a total of 11 countries including Spain, Italy and the U.K. During 2021 market access was secured in Sweden and the Netherlands as well as on an individual hospital basis in Finland and Greece.

On March 28, 2022, Hansa and Medison Pharma announced that a marketing authorization in Israel was granted for Idefix® for desensitization treatment of highly sensitized kidney transplant patients. In addition Hansa has a marketing authorization application (MAA) under review in Switzerland.

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. 64 highly sensitized (cPRA ≥99.9%) patients on the waitlist for kidney transplantation in the US will be 1:1 randomized to either desensitization with imlifidase or standard of care and patients are randomized at time of organ offer.

As of April 20, 2022, 16 patients have been enrolled for randomization. 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 nine are activated for recruitment as of April 20, 2022. Results from the trial are expected to support a Biologics License Application (BLA) under the accelerated approval pathway in the first half of 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 m² (61 mL/min/m² for those without AMR). Data are 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 m² after year three. The data from the three-year follow-up study were 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 five-year data will be published.

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

Anti-GBM is an acute autoimmune disease where antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM), causing acute injury of kidney and/or lung function. Anti-GBM is an ultrarare and very severe disease that affects approximately 1.6 people per million, annually. A majority of patients lose their kidney function¹, requiring chronic dialysis and/or kidney transplantation.

On March 8, 2022, Hansa announced that key data from an investigator-initiated Phase 2 trial (GoodIdeS) of imlifidase to treat anti-GBM disease were published in JASN. The study, led by Principal Investigator Mårten Segelmark, Professor of Nephrology at Lund University, previously Linköping University, showed that two-thirds of patients achieved dialysis independence six months after treatment as compared to typically two-thirds of patients losing their kidney function and ending up on dialysis after six months. These positive results mark an important milestone for the expansion of imlifidase outside transplantation and into autoimmune diseases.

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

On April 19, 2022 Hansa announced that the U.S. FDA has accepted Hansa’s IND application to proceed with a Phase 3 study of imlifidase in 50 patients across EU and the US. The first patient is expected to be enrolled in 2022, as previously guided.

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 DSA in the treatment of active episodes of acute AMR in kidney transplant patients, in comparison to plasma exchange.

As of April 20, 2022, 28 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).

As of April 20, 2022, 16 out of a target of 30 patients with GBS have been enrolled at ten centers across France, the U.K. and the Netherlands.

The widespread impact of the COVID-19 pandemic and the emergence of new variants have impacted the availability of staff across a number of our GBS trial centers. Additionally, a shortage of IVIg has affected the enrollment rate at a subset of participating hospitals. To mitigate these hurdles, Hansa has implemented a number of significant initiatives during the last couple of months to increase the enrollment rate including simplifying the study protocol, actively supported the hiring of additional staff at the clinics and added two additional recruitment sites for the recruitment of GBS patients in the U.K. and the Netherlands. Hansa expects these initiatives to support the completion of enrollment of GBS patients in the second half of 2022.

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

Non-clinical data suggest that a combination of bortezomib and belatacept can reduce the levels of DSA and the risk for AMR after incompatible kidney transplantation³. Based on these findings a new single center study will be initiated to evaluate if a combination of bortezomib and belatacept can reduce the risk for AMR following desensitization with imlifidase. The study 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 three months from transplantation. The study will be run by Associate Professor Vasishtha 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.

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.

³ Kwun, J., Burghuber, C., Manook, M., Ezekian, B., Park, J., Yoon, J., Yi, J. S., Iwakoshi, N., Gibby, A., Hong, J. J., Farris, A. B., Kirk, A. D., & Knechtle, S. J. (2017). Successful desensitization with proteasome inhibition and costimulation blockade in sensitized nonhuman primates. *Blood advances*, 1(24), 2115–2119. <https://doi.org/10.1182/bloodadvances.2017010991>

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 findings⁴ 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 pre-treatment for cancer therapy. High levels of plasma IgG have been shown to limit the efficacy of therapeutic antibodies, as plasma IgG can saturate the receptors of the patient's immune cells, preventing them from efficiently killing the tumor cells. Removing the inhibiting IgG antibodies with imlifidase or a novel IgG-clearing enzyme prior to dosing the patient with a therapeutic antibody can potentially increase the efficacy of the given cancer therapy.

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

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

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

The partnership has been progressing as planned and is ongoing with preclinical investigations with imlifidase as a potential pre-treatment to Sarepta's gene therapies. For further information regarding Sarepta's gene therapy programs in DMD and LGMD, please refer to 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 was initiated during the first quarter 2022 and is set out to evaluate the potential use of imlifidase as a pre-treatment prior to the administration of AskBio's gene therapy in Pompe disease in a

preclinical and clinical feasibility program for patients with pre-existing NABs to the adeno-associated viral vector used in AskBio's gene therapy.

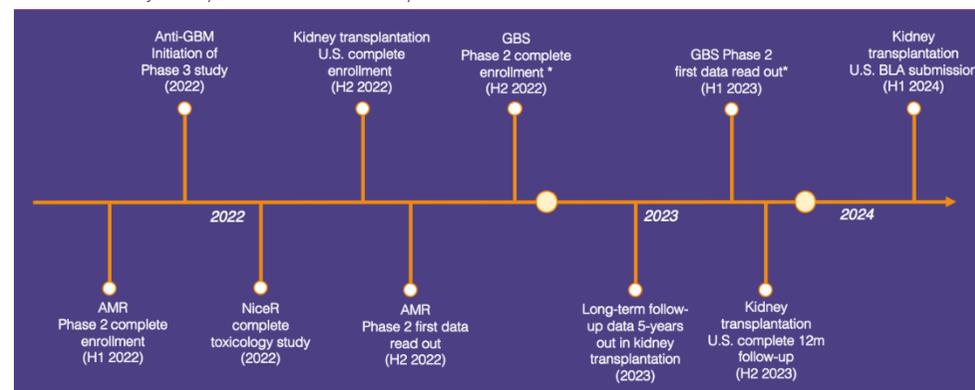
Under the terms of the agreement, Hansa received a USD 5 million payment upon execution of the agreement and AskBio has the exclusive option to negotiate a full development and commercialization agreement following evaluation of the results from an initial Phase 1/2 study. For further information regarding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

Preclinical research collaboration with argenx BV

In March 2021, Hansa announced a preclinical research collaboration agreement with argenx BV to explore the potential of combining imlifidase, 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



⁴ Järnum et al., "Enzymatic inactivation of endogenous IgG by IdeS enhances therapeutic antibody efficacy", Molecular Cancer Therapeutics, 2017, Sep; 16(9):1887-1897

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Financial review January – March 2022

Revenue

Revenue for the first quarter of 2022 amounted to SEK 30.3m (Q1 '21: SEK 9.0m) and comprises of SEK 24.2m Idefirix® product sales, SEK 5.2m revenue recognition from the upfront payment the Company received under the Sarepta Agreement and SEK 0.8m contract revenue under the Axis-Shield Diagnostics (Abbott group) agreement.

SG&A expenses

Sales, general and administrative expenses for the first quarter of 2022 amounted to SEK 80.4m (Q1 '21: SEK 60.1m) 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 10.2m for the first quarter of the year 2022 (Q1 '21: SEK 1.4m).

R&D expenses

Research and development expenses for the first quarter of 2022 amounted to SEK 70.9m (Q1 '21: SEK 47.4m). Recorded non-cash costs for the Company's employee long-term incentive programs, included in the above R&D expenses, amounted to SEK 5.0m for the first quarter of the year 2022 (Q1 '21: SEK 0.9m).

Financial results

The loss from operation for the first quarter of 2022 amounted to SEK 135.0m (Q1 '21: SEK 103.7m). 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.

Loss for the first quarter of 2022 amounted to SEK 138.4m (Q1 '21: SEK 103.9m).

Cash flow, cash and investments

Net cash used in operating activities for the first quarter of 2022 amounted to SEK 130.4m (Q1 '21: SEK 120.9m). The change as compared to the previous year period 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, in Q1-2022, Hansa received a USD 5 million (SEK 45.8 million) upfront payment related to its agreement with AskBio. Cash and cash equivalents, including short-term investments, amounted to SEK 753.7m on March 31, 2022, as compared to SEK 889.0m at year-end 2021.

Shareholders' equity

On March 31, 2022, shareholders' equity amounted to SEK 636.0m as compared to SEK 757.6m at the end of the year 2021.

Parent Company

The parent company's revenue for the first quarter of 2022 amounted to SEK 30.3m (Q1 '21: SEK 9.0m).

Loss for the parent company for the first quarter 2022 amounted to SEK 138.8m (Q1 '21: SEK 104.1m).

The parent company's equity amounted to SEK 633.8m as of March 31, 2022, as compared to SEK 755.9m at the end of the year 2021.

The Group consists of the parent company, Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc. and Hansa Biopharma Australia PTY LTD. Hansa Biopharma Inc had four employees at the end of March 2022. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of March 2022.



Long-term incentive programs

Hansa Biopharma's past Annual General Meetings have resolved to adopt share-based long-term incentive programs (LTIPs). As of March 31, 2022, 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 2021 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*	82 377	569 828	1 167 499	1 400 000
Number of allocated and outstanding share rights and options	56 666	427 329	898 076	987 000
Number of acquired and outstanding warrants	6 701	11 000	-	-
Estimated total cost including social contributions, KSEK	4 210	39 538	90 748	75 738
Total cost per program, including social contributions, as of March 31, 2022 YTD, KSEK	104	2 478	7 074	5 578

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

Total costs, including social contributions, as of March 31, 2022 YTD, KSEK 15 234

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

Other information

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Legal disclaimer

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

Financial calendar 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 March 31, 2022	SEK ~3bn (USD ~320m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of March 31, 2022

Name	Number of shares	Ownership in pct
Redmile Group, LLC	5 415 663	12.2
Fjärde AP-Fonden (AP 4)	2 207 397	4.9
Nexttobe AB	2 155 379	4.8
Invesco Advisers, Inc.	1 973 931	4.4
Olausson, Thomas	1 820 500	4.1
Tredje AP-Fonden (AP 3)	1 389 650	3.1
Handelsbanken Asset Management (Sweden)	1 369 877	3.1
Försäkrings AB Avanza Pension	1 314 165	3.0
The Vanguard Group, Inc.	1 223 839	2.8
Schroder Investment Management, LTD	888 132	2.0
Others	24 714 919	55.6
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 18,000 shareholders as of March 31, 2022.

Assurance

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

Lund April 20, 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.

Condensed unaudited financial statements Consolidated statement of financial position

KSEK	March 31		December 31
	2022	2021	2021
ASSETS			
Non-current assets			
Intangible assets	28 111	30 882	28 761
Property and equipment	6 186	5 618	6 432
Leased assets	33 380	3 273	35 273
Total non-current assets	67 677	39 773	70 466
Current assets			
Inventories	184	83	242
Trade receivables & contract assets	28 825	119	9 712
Current receivables, non-interest bearing	39 065	16 007	43 427
Short-term investments	234 612	238 060	237 619
Cash and cash equivalents	519 136	1 016 686	651 342
Total current assets	821 822	1 270 955	942 342
TOTAL ASSETS	889 499	1 310 728	1 012 808
EQUITY AND LIABILITIES			
Shareholders' equity	635 986	1 149 820	757 573
Non-current liabilities			
Deferred tax liabilities	427	448	426
Provisions	5 866	5 156	7 357
Lease liabilities	26 723	582	28 491
Deferred revenue	66 937	61 268	47 020
Contingent consideration	761	735	722
Total non-current liabilities	100 714	68 189	84 016
Current liabilities			
Lease liabilities	6 953	3 270	6 888
Current liabilities, non-interest bearing	32 813	27 043	66 908
Deferred revenue	49 610	20 745	24 961
Contract liabilities	4 047	-	-
Accrued expenses and deferred income	59 376	41 661	72 462
Total current liabilities	152 799	92 719	171 219
TOTAL EQUITY AND LIABILITIES	889 499	1 310 728	1 012 808

Consolidated income statement

KSEK	Q1		Year
	2022	2021	2021
Revenue	30 280	8 998	33 878
Cost of revenue	(11 234)	(1 734)	(15 425)
Sales, general and administration expenses	(80 384)	(60 086)	(327 269)
Research and development expenses	(70 907)	(47 403)	(230 764)
Other operating expenses	(2 778)	(3 461)	(7 398)
Loss from operations	(135 023)	(103 686)	(546 978)
Financial income (expenses), net	(3 357)	(251)	(1 152)
Loss for the period before tax	(138 380)	(103 937)	(548 130)
Tax	(57)	10	(152)
Loss for the period	(138 437)	(103 927)	(548 282)
Attributable to:			
Parent company shareholders	(138 437)	(103 927)	(548 282)
Earnings per share (EPS)			
Before dilution (SEK)	(3,11)	(2,34)	(12,33)
After dilution (SEK)	(3,11)	(2,34)	(12,33)
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the period			
Translation differences	123	149	264
Other comprehensive income for the period	123	149	264
Total net comprehensive income	(138 314)	(103 778)	(548 018)

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Consolidated statements of changes in shareholder's equity

KSEK	Q1		Year
	2022	2021	2021
Opening balance of shareholders' equity as reported	757 573	1 242 124	1 242 124
Result for the period	(138 437)	(103 927)	(548 282)
Other comprehensive income for the period	123	149	264
Net comprehensive income	(138 314)	(103 778)	(548 018)
Transactions with the group's owner			
Proceeds from new share issuance, net	-	-	0
Long term incentive programs	16 726	11 475	63 467
Total transactions with the group's owner	16 726	11 475	63 467
Closing balance of shareholders' equity	635 986	1 149 820	757 573

Consolidated statement of cash flow

KSEK	Q1		Year
	2022	2021	2021
Cash Flows from Operating Activities			
Loss for the period	(138 437)	(103 927)	(548 282)
Adjustment for items not included in cash flow ¹⁾	18 287	4 630	64 998
Interest received and paid, net	(339)	(98)	(627)
Income taxes paid	-	-	(143)
Cash flow from operations before change in working capital	(120 489)	(99 395)	(484 053)
Changes in working capital	(10 025)	(21 515)	2 886
Net cash used in operating activities	(130 514)	(120 910)	(481 167)
Investing activities			
Acquisition of property and equipment	(140)	(683)	(2 399)
Cash flow from investing activities	(140)	(683)	(2 399)
Financing activities			
Repayment of lease liabilities	(1 703)	(1 193)	(4 857)
Cash flow from financing activities	(1 703)	(1 193)	(4 857)
Net change in cash	(132 357)	(122 786)	(488 423)
Cash and cash equivalents, beginning of period	651 342	1 139 362	1 139 362
Currency exchange variance, cash and cash equivalents	151	110	403
Cash and cash equivalents, end of period	519 136	1 016 686	651 342

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

Parent company – Statement of financial position

KSEK	March 31		December 31
	2022	2021	2021
ASSETS			
Non-current assets			
Intangible assets	25 855	28 508	26 518
Property, plant and equipment	6 186	5 618	6 432
Leased assets	33 980	3 273	35 273
Investment in subsidiaries	5 095	5 095	5 095
Receivables, group companies	2 271	2 100	2 203
Total non-current assets	72 787	44 594	75 521
Current assets			
Inventories	184	83	242
Trade receivables & contract assets	28 825	119	9 712
Current receivables, non-interest bearing	38 864	15 513	43 201
Short-term investments	234 612	238 060	237 619
Cash and cash equivalents	510 861	1 013 298	644 975
Total current assets	813 346	1 267 073	935 749
TOTAL ASSETS	886 133	1 311 667	1 011 270
EQUITY AND LIABILITIES			
Shareholders' equity	633 843	1 148 974	755 948
Non-current liabilities			
Provisions	5 866	5 156	7 357
Lease liabilities	26 723	582	28 491
Deferred revenue	66 937	61 268	47 020
Contingent consideration	761	735	722
Total non-current liabilities	100 288	67 741	83 590
Current liabilities			
Lease liabilities	6 953	3 270	6 888
Liabilities, group companies	2 655	3 901	3 901
Current liabilities, non-interest bearing	32 482	26 257	66 598
Deferred revenue	49 610	20 745	24 961
Contract liabilities	4 047	-	-
Accrued expenses and deferred income	56 255	40 779	69 384
Total current liabilities	152 002	94 952	171 732
TOTAL EQUITY AND LIABILITIES	886 133	1 311 667	1 011 270

Parent company – Income statement

KSEK	Q1		Year
	2022	2021	2021
Revenue	30 280	8 998	33 878
Cost of revenue	(11 234)	(1 734)	(15 425)
Sales, general and administration expenses	(80 453)	(60 188)	(327 031)
Research and development expenses	(71 290)	(47 477)	(231 974)
Other operating expenses	(2 777)	(3 462)	(7 395)
Loss from operations	(135 474)	(103 863)	(547 947)
Result from financial items:			
Finance income	-	(83)	67
Finance costs	(3 357)	(133)	(1 218)
Loss for the period before tax	(138 831)	(104 079)	(549 098)
Income tax benefit/expense	-	-	-
Loss for the period	(138 831)	(104 079)	(549 098)
Other comprehensive income for the period	-	-	-
Total comprehensive income for the period	(138 831)	(104 079)	(549 098)

Parent company – Statement of changes in shareholders' equity

KSEK	Q1		December 31
	2 022	2 021	2 021
Opening shareholders' equity as reported	755 948	1 241 578	1 241 578
Result for the period	(138 831)	(104 079)	(549 098)
Other comprehensive income for the period	-	-	-
Net comprehensive income	(138 831)	(104 079)	(549 098)
Proceeds from new share issuance, net	-	-	-
Long term incentive programs	16 726	11 474	63 467
Total transactions with the group's owner	16 726	11 474	63 467
Closing shareholders' equity	633 843	1 148 974	755 948

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

Financial notes

Note 1 Basis of preparation and accounting policies

This consolidated interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting and recommendation RFR2 of the Swedish Reporting Board, Accounting for Legal entities. The same accounting principles have been used as in the latest annual report except for what is stated below. Hansa's Annual Report 2021 was published on April 6, 2022 and is available at www.hansabiopharma.com. Disclosures in accordance with IAS 34.16A are as applicable in the notes or on the pages before the consolidated income statement.

Note 2 Revenue

Income per significant category of income	Q1		Year
	2022	2021	2021
KSEK			
Group			
Revenue			
Product sales	24 237	6 026	15 017
Contract revenue, Axis-Shield agreement	381	523	2 624
Cost reimbursement, Axis-Shield agreement	450	-	527
Contract revenue, Sarepta agreement	5 212	2 449	15 710
	30 280	8 998	33 878
Parent company			
Revenue:			
Product sales	24 237	6 026	15 017
Contract revenue, Axis-Shield agreement	381	523	2 624
Cost reimbursement, Axis-Shield agreement	450	-	527
Contract revenue, Sarepta agreement	5 212	2 449	15 710
	30 280	8 998	33 878

The Company is a 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 March 31, 2022 amounted to SEK 234.6 million (Year end '21: SEK 237.6 million) and belonged to level 2 in the fair value hierarchy. The fair value of the financial liability for contingent consideration at March 31, 2021 amounted to SEK 0.8 million (Year end'21: SEK 0.7 million) and belongs to level 3 in the fair value hierarchy. All other financial instruments are measured at amortized cost. The carrying values of those instruments are considered reasonable approximations of their fair values.



Glossary

Adeno-associated virus (AAV)

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

Allogeneic hematopoietic stem cell transplantation (HSCT)

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

AMR

Antibody mediated transplant rejection.

Antibody

One type of protein produced by the body's immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM.

Anti-GBM disease (Goodpasture syndrome)

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

Autoimmune disease

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

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.

CD20

B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

Clinical studies

Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical Phase 1

The first time a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical Phase 2

Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical Phase 3

Trials that involve many patients and often continue for a longer time; they are intended to identify the drug's effects and side effects during ordinary but still carefully controlled conditions.

DSA

Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

EMA

The European Medicines Agency (EMA) is an EU agency for the evaluation of medicinal products.

Enzyme

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

ESOT

The European Society for Organ Transplantation (ESOT) is an umbrella organization which overlooks how transplantations are structured and streamlined.

FDA

U.S. Food and Drug Administration.

Guillain-Barré syndrome

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

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HBP

Heparin Binding Protein is a naturally occurring protein that is produced by certain immune cells, i.e. neutrophilic granulocytes, to direct immune cells from the bloodstream into the tissues.

HLA

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

IgG

IgG, Immunoglobulin G, is the predominant type of antibody in serum.

Imlifidase

Imlifidase, is the immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

IND

Investigational New Drug (IND) application is required to get approval from the FDA to administer an investigational drug or biological product to humans.

INN

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

In vitro

Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

In vivo

Term within biomedical science to indicate that experiments or observations are made in living organisms.

IVD

IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Marketing Authorization Application (MAA)

A Marketing Authorization Application (MAA) is an application submitted to the European Medicines Agency (EMA) to market a medicinal product in the EU member states.

Neutralizing Antibodies (NABs)

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

Pivotal trial

A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat life-threatening or severely debilitating conditions.

Panel Reactive Antibody (PRA)

PRA is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

Preclinical development

Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

Randomized Control Trial (RCT)

RCT is a study design where the trial subject is randomly allocated to one of two or more study cohorts to test a specific intervention against other alternatives, such as placebo or standard of care.

Streptococcus pyogenes

A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.