Interim report
January-June 2022

HANSA BIOPHARMA

Continued solid sales in Q2; Positive NICE recommendation obtained; Completed enrollment in imlifidase Phase 2 program in AMR; Peter Nicklin elected as new Chairman of the Board of Directors

Highlights for the second quarter 2022

- Continued solid sales in the second quarter with SEK 19.5m in product sales; total revenue amounted to SEK 26.4m.
- On June 16, 2022, the National Institute for Health, and Care Excellence (NICE) recommended Idefirix® for desensitization of highly sensitized adult patients prior to kidney transplant from a deceased donor. NICE considers Idefirix® to be a clinically and cost-effective treatment. Market access has now been secured in 7 European countries and procedures are ongoing in 11 countries, including Spain and Italy.
- On May 13, 2022, Hansa announced that the Swiss Agency for Therapeutic Products (Swissmedic) granted temporary marketing authorization for Idefirix® in adult patients with a positive crossmatch against an available organ from a diseased donor.
- On April 20, 2022, Idefirix® was granted ASMR 3 rating by the Transparency Commission (TC) of the French National Authority for Health (HAS) following the reimbursed AP2 early access program in France, which potentially can enable a faster commercial access process. In addition to ASMR 3 status, Idefirix® also received designation as SMR Important (Service Médical Rendu), reflecting the actual medical benefit.
- Annual General Meeting held on June 30, 2022, where all resolutions proposed by the board of directors were approved by shareholders, including the appointment of Peter Nicklin as the new Chairman of the Board of Directors. Peter Nicklin is currently chairman of the boards of Versantis AG (CH), Sciensus Ltd (U.K.), and Tunstall Group Ltd (U.K.). Peter Nicklin was recently the CEO at Amann Girrbach. He has also held senior executive positions at Baxter, Bayer Healthcare, Novartis and Bristol Myers Squibb, amongst others.

Clinical pipeline update

- U.S. ConfIdeS: 22 patients have been enrolled for randomization in our pivotal U.S. open label, randomized, controlled trial of imlifidase in kidney transplant with the aim of completing enrollment by the end of this year, as previously guided.
- AMR: On-time completion of enrollment in the Antibody Mediated Rejection (AMR) Phase 2 trial; A first data read out is expected in the second half of 2022, as previously guided.
- GBS: In the Guillain Barré Syndrome (GBS) Phase 2 trial, 18 out of a target of 30 patients have been enrolled. Hansa expects to complete enrollment of GBS patients in the second half of 2022 based on several initiatives taken to support enrollment including measures such as simplifying the protocol and increasing capacity.
- Anti-GBM: Preparations to commence Phase 3 study later this year as previously guided are on track.

Events after the closing period

- On July 11, 2022, the first patient was treated in Hansa's post approval efficacy study (PAES). The PAES is an obligation under the European conditional marketing authorization and will be used to further investigate the long-term graft survival in 50 highly sensitized kidney transplant patients treated with Idefirix®
- On July 18, 2022 Hansa concluded a USD 70 million non-dilutive financing transaction with NovaQuest Capital Management to support the continued development of the Company's antibody-cleaving enzyme technology platform across multiple therapeutic areas while extending the expected cash runway through 2024.

Financial Summary

SEKm, unless otherwise stated – unaudited	Q2 2022	Q2 2021	H2 2022	H1 2021
Revenue	26.4	4.5	56.7	13.5
SG&A expenses	(90.3)	(81.2)	(170.7)	(141.3)
R&D expenses	(92.7)	(54.5)	(163.6)	(101.9)
Loss from operation	(167.8)	(132.4)	(302.9)	(236.0)
Loss for the period	(170.1)	(132.6)	(308.5)	(236.5)
Net cash used in operation	(135.6)	(112.5)	(266.1)	(233.4)
Cash and short-term investments	616.5	1,139.4	616.5	1.139.4
Shareholders' equity	482.0	1,031.2	482.0	1.031.2
EPS before and after dilution (SEK)	(3.82)	(2.98)	(6.94)	(5.32)
Number of outstanding shares	44,588,118	44,473,452	44,588,118	44,473,452
Weighted avg. number of shares before and after dilution	44,491,093	44,473,452	44,482,321	44,473,452
Number of employees at the end of the period	145	113	145	113

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.

CEO comments

"Hansa's commercial launch activities and market access efforts for Idefirix® in Europe continue to progress as planned. During the second quarter of 2022, we have seen continued to solid sales and achievement of the important milestone of becoming the first and only product recommended by NICE for the desensitization of highly sensitized patients waiting for a kidney transplant from a deceased donor in England, Wales and Northern Ireland"

Søren Tulstrup
President and CEO, Hansa Biopharma

"Hansa's commercial launch activities and market access efforts for Idefirix® in Europe continue to progress as planned. During the second quarter of 2022, we have seen continued solid sales and achievement of the important milestone of becoming the first and only product recommended by NICE for the desensitization of highly sensitized patients waiting for a kidney transplant from a deceased donor in England, Wales and Northern Ireland. Additionally, NICE also highlighted Idefirix® as a clinically and cost-effective treatment, which is rare for orphan drugs. This recommendation is an important step forward for Hansa's commercialization efforts and for patients in England, Wales and Northern Ireland, who have been struggling to find a donor match and in most cases had no other alternative but to remain on long-term dialysis.

Beyond the U.K., we are also pleased that Idefirix® was granted ASMR 3 rating by the Transparency Commission (TC) of the French National Authority for Health (HAS). Less than 6% of all new medicines are granted ASMR 3, and so the achievement of this status is a testament to the importance and medical benefit of Idefirix® as a new transformative therapy. Moreover, we are also pleased that the Swiss Agency for Therapeutic Products (Swissmedic) granted temporary marketing authorization in Switzerland for Idefirix® in kidney transplantation in addition to the already received marketing authorizations in the EU, the U.K. and Israel.

Turning to our clinical development programs, at the end of May we announced the completion of enrollment in our imlifidase Phase 2 study in antibody mediated rejection (AMR) episodes post kidney transplantation. 30 patients with active or chronic active AMR episodes post kidney transplantation have been enrolled across 14 centers in France, Germany, Austria, Australia, and the U.S. Acute AMR episodes post kidney transplantation occur in 5-7% of patients, with significant risk of patients losing graft function. There is no approved treatment for AMR. The on-time completion of enrollment marks an important milestone for Hansa as we explore the potential of imlifidase in the post transplantation setting. First data read out is expected in the second half of 2022, as previously guided.

In the U.S., our pivotal ConfIdeS trial in kidney transplantation is progressing with 22 out of a target of 64 patients now 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 ten 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.

In anti-GBM, we expect to commence a pivotal Phase 3 study of imlifidase following FDA's acceptance of Hansa's Investigational New Drug (IND) application earlier this year. The new study is expected to enroll approximately 50 patients across the EU and U.S, with the first patient expected to be enrolled later this year, as previously guided.

With respect to our GBS Phase 2 program, which has been impacted by the pandemic, we have recently implemented several significant initiatives to increase the enrollment rate. As of July 19, 2022 18 out of a target of 30 patients were enrolled and we expect to see a further acceleration in recruitment of patients during the second half of the year, which will help to complete enrollment towards the end of 2022, as previously guided.

Lastly, I am also pleased to see the appointment of Peter Nicklin as new Chairman of the Board of Directors. Peter Nicklin brings significant global experience from both non-executive and senior executive roles within the life-science industry at companies such as Baxter, Bayer Healthcare, Novartis and Bristol-Myers Squibb. Peter Nicklin is currently chairman of the boards of Versantis AG (CH), Sciensus Ltd (U.K.), and Tunstall Group Ltd (U.K.). Whilst having spent significant time living and working across the globe, Peter now lives in Europe.

I look forward to keeping you updated on our continued progress with several upcoming and important milestones to be achieved across our platform and franchises as we continue the development of new, transformative medicines for patients suffering from serious, rare immunologic diseases."

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.

Continuous progress with our pipeline activities

Candidate/ Project	Indication	Research/ Preclinical	Phase 1	Potentially Pivotal/ 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 H2'21
	US: Kidney transplantation in highly sensitized patients[1,2]							Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease[3]							Pivotal Phase 3 study expected to commence in 2022 (50 patients)
	Antibody mediated kidney transplant rejection (AMR)							First data read-out H2 2022
	Guillain-Barré syndrome (GBS)							Completion of enrollment (30 patients) H2 2022
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Preclinical research
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)							Preclinical research
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Completion of GLP toxicology studies in 2022
EnzE	Cancer immunotherapy							Research

[1] Results from the Phase 1 study have been published, Winstedt el 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

Completed
Ongoing
Planned
Post approval study running in parallel with commercial launch

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.

Imlifidase – Commercial, Clinical and Regulatory Interactions

EU: Kidney transplantation for highly sensitized patients

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

Commercial launch activities and market access efforts for Idefirix® in Europe continue to progress as planned during the first half of 2022 with commercial access secured on negotiated terms in England, Wales and Northern Ireland as well as Germany and in France through a reimbursed Early Access Program. Additional market access procedures are ongoing in a total of 11 countries including Spain and Italy. During 2021, market access was secured in Sweden and the Netherlands as well as on an individual hospital basis in Finland and Greece.

On May 13, 2022, Hansa announced that the Swiss Agency for Therapeutic Products (Swissmedic) granted temporary marketing authorization for Idefirix® in adult kidney transplant patients with a positive crossmatch against an available organ from a diseased donor. In addition, Hansa and Medison Pharma have obtained marketing authorization in Israel for Idefirix® earlier this year.

On July 11, 2022, Hansa announced that the first patient was treated in the post approval efficacy study (PAES). The PAES is an obligation under the European conditional marketing authorization and will be used to further investigate the long-term graft survival in 50 highly sensitized kidney transplant patients treated with Idefirix®

U.S. Randomized Controlled Trial "ConfIdeS" (ClinicalTrials.gov ID: NCT04935177)

On December 29, 2021, Hansa announced that the first patient in its pivotal U.S. open label, randomized, controlled trial "ConfIdeS," was enrolled at the Columbia University Medical Center, New York. The ConfIdeS study is evaluating imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a deceased donor kidney through the U.S. kidney allocation system. 64 highly sensitized (cPRA ≥99.9%) patients on the waiting list for kidney transplantation in the U.S. 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 July 19, 2022, 22 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 up to 15 leading transplantation centers in the U.S. to conduct the study, of which ten are activated for recruitment as of July 19, 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 patents 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 was published in the American Journal of Transplantation in July 2021. The next read-out on the long-term follow-up trial is expected in 2023, when the 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 function, 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 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.

On April 19, 2022, Hansa announced that the U.S. FDA accepted Hansa's IND application to proceed with a global Phase 3 study of imlifidase in 50 patients across EU and the U.S. In Europe, the study protocol is under final EMA review. The first patient in this Phase 3 study is expected to be enrolled in 2022, as previously guided.

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

Acute AMR episodes post kidney transplantation occur in 5-7% of patients, with significant risk of patients losing graft function. 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.

On May 23, 2022, Hansa announced the on-time completion of enrollment in the Antibody Mediated Rejection (AMR) Phase 2 trial in 30 patients with active or chronic active AMR episodes 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.

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 July 19, 2022, 18 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 first half 2022 to increase the enrollment rate including simplifying the study protocol, actively supporting the hiring of additional staff at the clinics and adding two additional 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 transplantation1. 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 Vasishta Tatapudi, MD and Program Director at the NYU Langone Transplant Institute.

Preclinical programs

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

Hansa Biopharma is developing novel IgG-degrading enzymes with the objective of enabling repeat dosing in autoimmune conditions, oncology and transplantation, where patients may benefit from more than one dose of an IgG-modulating enzyme. The Company has developed and patented several novel immunoglobulin cysteine endopeptidases.

The first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development has been selected. Development of a GMP-manufacturing process is ongoing and IND-enabling toxicology studies for the lead NiceR candidate were initiated during the second quarter of 2021 in preparation for a clinical Phase 1 study. The toxicology studies are expected to be completed in 2022. Upon completion of these studies, Hansa expects to advance the NiceR program into the clinic.

EnzE – Enzyme-based antibody Enhancement

Published findings 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 NAb-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.

[1] 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

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.

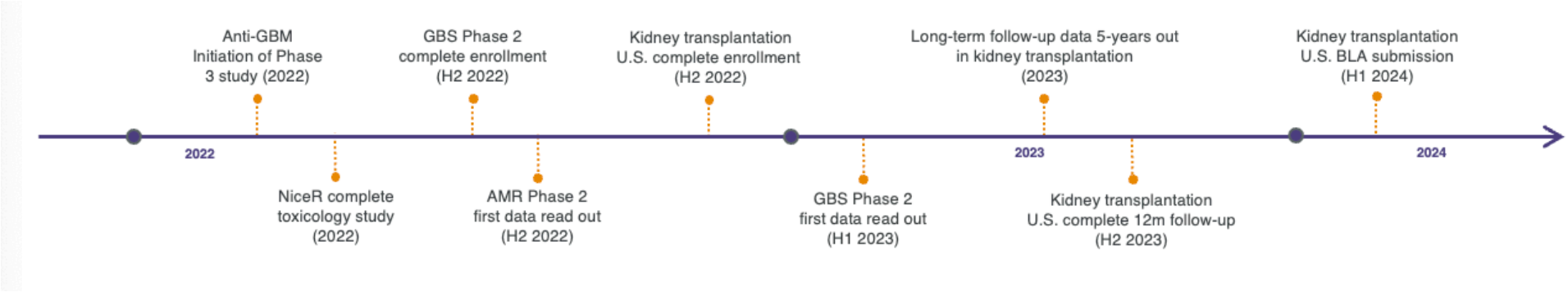
The collaboration is progressing as planned, currently at a preclinical stage.

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.

Upcoming milestones

Milestones subject to potential COVID-19 impact



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 review January – June 2022

Revenue

Revenue for the second quarter of 2022 amounted to SEK 26.4m (Q2 ’21: SEK 4.5m) and to SEK 56.7m for the first half of 2022 (H1’21 SEK 13.5m) and mainly comprises of Idefirix® product sales of SEK 19.5m (H1’22: SEK 43.7m; H1’21: SEK 6.0m), revenue recognition from the upfront payment the Company received under the Sarepta Agreement and contract revenue under the Axis-Shield Diagnostics (Abbott group) agreement.

SG&A expenses

Sales, general and administrative expenses for the second quarter of 2022 amounted to SEK 90.3m (Q2: ’21: SEK 81.2m) and to SEK 170.7m for the first half of 2022 (H1’21 SEK 141.3m). 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 21.2m for the first half of the year 2022 (H1’21: SEK 10.2m).

R&D expenses

Research and development expenses for the first half of the year 2022 amounted to SEK 92.7m (Q2 ’21: SEK 54.5m) and to SEK 163.6m for the first half of 2022 (H1’21 SEK 101.9m). The increase over respective 2021 periods is mainly driven by the preparation and initiation of the U.S. ConfIdeS study, the EU post approval study, and the anti-GBM Phase 3 study. Recorded non-cash costs for the Company’s employee long-term incentive programs, included in the above R&D expenses, amounted to SEK 10.3m for the first half of the year 2022 (H1 ’21: SEK 9.6m).

Financial results

The loss from operations for the second quarter of 2022 amounted to SEK 167.8m (Q2 ’21: SEK 132.4m) and to SEK 302.9m for the first half of 2022 (H1’21 SEK 236.0m). 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 and its broadened R&D pipeline activities.

Loss for the second quarter of 2022 amounted to SEK 170.1m (Q2 ’21: SEK 132.6m) and to SEK 308.5m for the first half of 2022 (H1’21 SEK 236.5m).

Cash flow, cash and investments

Net cash used in operating activities for the second quarter of 2022 amounted to SEK 135.6m (Q2 ’21: SEK 112.5m) and to SEK 266.1m for the first half of 2022 (H1’21 SEK 233.4m). The change as compared to the previous year period is driven by increased operating expense levels due to Hansa’s broadened R&D and commercial activities as well as organizational expansion related to the launch of Idefirix® in Europe. Additionally, in Q1-2022, Hansa received a USD 5m (SEK 45.8m) upfront payment related to its agreement with AskBio. Cash and cash equivalents, including short-term investments, amounted to SEK 616.5m on June 30, 2022, as compared to SEK 889.0m at year-end 2021.

Shareholders’ equity

On June 30, 2022, shareholders’ equity amounted to SEK 482.0m as compared to SEK 757.6m at the end of the year 2021.

Parent Company

The parent company’s revenue for the second quarter of 2022 amounted to SEK 26.4m (Q2 ’21: SEK 4.5m) and to SEK 56.7m for the first half of 2022 (H1’21 SEK 13.5m).

Loss for the parent company for the second quarter of 2022 amounted to SEK 170.6m (Q2 ’21: SEK 132.9m) and to SEK 309.4m for the first half of 2022 (H1’21 SEK 237.0m).

The parent company’s equity amounted to SEK 479.3m as of June 30, 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 five employees at the end of June 2022. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of June 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 June 30, 2022, the following LTIPs were ongoing: 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*	**0**	**231,041**	**1,167,499**	**1,283,100**
Number of allocated and outstanding share rights and options	**0**	**166,724**	**898,076**	**987,000**
Number of acquired and outstanding warrants	**0**	**11,000**	**-**	**-**
Estimated total cost including social contributions, KSEK	**0**	**2,144**	**90,655**	**75,738**
Total cost per program, including social contributions, as of June 30, 2022 YTD, KSEK	**294**	**4,908**	**14,894**	**11,358**

*As of 30 June 2022, including issuable shares to cover social contributions under the LTIP.

Total costs, including social contributions, as of June 30, 2022 YTD, KSEK	31,455

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.

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.

On 24 February 2022 Russa invaded Ukraine. Hansa does not have any own operations in nor collaborates with any third-party service providers from either Ukraine or Russia. Therefore, Hansa's operational activities are not directly affected by the conflict. However, the conflict does already have or is expected to have general negative impacts on global economy, stock markets, energy prices, global supply and free trade, and as such may indirectly negatively impact Hansa's business.

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

Contacts

Klaus Sindahl, Head of Investor Relations
Hansa Biopharma
Mobile: +46 (0) 709–298 269
E-mail: klaus.sindahl@hansabiopharma.com

Katja Margell, Head of Corporate Communications
Hansa Biopharma
Mobile: +46 (0) 768-198 326
E-mail: katja.margelll@hansabiopharma.com

Legal disclaimer

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

Financial calendar 2022

October 20, 2022 Interim Report for January-September 2022

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	46,335,361 (44,588,118 A-shares and 1,747,243 C-shares)
Market Cap March 31, 2022	SEK ~2.3bn (USD ~220m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of June 30, 2022

Name	Number of shares	Ownership in pct
Redmile Group, LLC	5,380,863	12,1%
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%
Försäkrings AB Avanza Pension	1,743,201	4,0%
Tredje AP-Fonden (AP 3)	1,389,650	3,1%
The Vanguard Group, Inc.	1,223,839	2,7%
Schroder Investment Management	888,132	2,0%
C WorldWide Asset Management	799,749	1,8%
Other	25,005,477	56,1%
Total	44,588,118	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 June 30, 2022.

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.

Assurance

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

Lund July 18, 2022

Peter Nicklin
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	June 30 2022	June 30 2021	December 31 2021
ASSETS			
Non-current assets			
Intangible assets	27,400	30,144	28,761
Property and equipment	5,797	6,997	6,432
Leased assets	31,476	21,538	35,273
Total non-current assets	**64,673**	**58,679**	**70,466**
Current assets			
Inventories	377	123	242
Trade receivables & contract assets	55,590	420	9,712
Current receivables, non-interest bearing	47,817	19,641	43,427
Short-term investments	99,269	238,038	237,619
Cash and cash equivalents	517,203	901,391	651,342
Total current assets	**720,256**	**1,159,613**	**942,342**
TOTAL ASSETS	**784,929**	**1,218,292**	**1,012,808**
EQUITY AND LIABILITIES			
Shareholders' equity	481,999	1,031,240	757,573
Non-current liabilities			
Deferred tax liabilities	418	434	426
Provisions	5,053	8,357	7,357
Lease liabilities	24,940	17,645	28,491
Deferred revenue	40,124	55,121	47,020
Contingent consideration	781	746	722
Total non-current liabilities	**71,316**	**82,303**	**84,016**
Current liabilities			
Lease liabilities	7,003	3,870	6,888
Current liabilities, non-interest bearing	54,960	24,330	66,908
Deferred revenue	79,000	21,724	24,961
Contract liabiities	12,124	-	-
Accrued expenses and deferred income	78,527	54,825	72,462
Total current liabilities	**231,614**	**104,749**	**171,219**
TOTAL EQUITY AND LIABILITIES	**784,929**	**1,218,292**	**1,012,808**

Consolidated statement of financial position

KSEK	Q2 2022	Q2 2021	H1 2022	H1 2021
Revenue	26,396	4,535	56,676	13,533
Cost of revenue	(5,075)	(2,333)	(16,309)	(4,067)
Sales, general and administration expenses	(90,306)	(81,248)	(170,690)	(141,334)
Research and development expenses	(92,684)	(54,501)	(163,591)	(101,904)
Other operating expenses	(6,162)	1,191	(8,940)	(2,270)
Loss from operations	**(167,831)**	**(132,356)**	**(302,854)**	**(236,042)**
Financial income (expenses), net	(2,154)	(248)	(5,511)	(499)
Loss for the period before tax	**(169,985)**	**(132,604)**	**(308,365)**	**(236,541)**
Tax	(87)	9	(144)	19
Loss for the period	**(170,072)**	**(132,595)**	**(308,509)**	**(236,522)**
Attributable to:				
Parent company shareholders	(170,072)	(132,595)	(308,509)	(236,522)
Earnings per share (EPS)				
Before dilution (SEK)	(3.82)	(2.98)	(6.94)	(5.32)
After dilution (SEK)	(3.82)	(2.98)	(6.94)	(5.32)
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	96	(42)	219	107
Other comprehensive income for the period	**96**	**(42)**	**219**	**107**
Total net comprehensive income	**(169,976)**	**(132,637)**	**(308,290)**	**(236,415)**

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.

Consolidated statements of changes in shareholder's equity

	June 30		Year
KSEK	**2022**	**2021**	**2021**
Opening balance of shareholders' equity as reported	**757,573**	**1,242,124**	**1,242,124**
Result for the period	(308,509)	(236,522)	(548,282)
Other comprehensive income for the period	219	107	264
Net comprehensive income	**(308,290)**	**(236,415)**	**(548,018)**
Transactions with the group's owner			
Long term incentive programs	32,714	25,531	63,467
Total transactions with the group's owner	**32,714**	**25,531**	**63,467**
Closing balance of shareholders' equity	**481,999**	**1,031,240**	**757,573**

Consolidated statement of cash flow

	Q2		H1	
KSEK	**2022**	**2021**	**2022**	**2021**
Cash Flows from Operating Activities				
Loss for the period	(170,072)	(132,595)	(308,509)	(236,522)
Adjustment for items not included in cash flow [1]	19,322	18,555	37,609	23,185
Interest received and paid, net	344	(158)	5	(256)
Income taxes paid	-	(22)	-	(22)
Cash flow from operations before change in working capital	**(150,406)**	**(114,220)**	**(270,895)**	**(213,615)**
Changes in working capital	14,784	1,721	4,759	(19,794)
Net cash used in operating activities	**(135,622)**	**(112,499)**	**(266,136)**	**(233,409)**
Investing activities				
Proceeds from sale of short-term investments	132,853	-	132,853	-
Acquisition of property and equipment	-	(1,716)	(140)	(2,399)
Cash flow from investing activities	**132,853**	**(1,716)**	**132,713**	**(2,399)**
Financing activities				
Proceeds from the sale of treasury shares [2]	2,243	-	2,243	-
Repayment of lease liabilities	(1,733)	(1,102)	(3,436)	(2,295)
Cash flow from financing activities	**510**	**(1,102)**	**(1,193)**	**(2,295)**
Net change in cash	(2,259)	(115,317)	(134,617)	(238,103)
Cash and cash equivalents, beginning of period	519,136	1,016,686	651,342	1,139,362
Currency exchange variance, cash and cash equivalents	327	22	478	132
Cash and cash equivalents, end of period	**517,203**	**901,391**	**517,203**	**901,391**

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

2) The sale is to cover witholding tax of participants under the LTIP 2019 program

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.

Parent company – Statement of financial position

	June 30		December 31
KSEK	2022	2021	2021
ASSETS			
Non-current assets			
Intangible assets	25,191	27,845	26,518
Property, plant and equipment	5,797	6,997	6,432
Leased assets	31,476	21,538	35,273
Investment in subsidiaries	5,095	5,095	5,095
Receivables, group companies	2,446	2,061	2,203
Total non-current assets	**70,005**	**63,536**	**75,521**
Current assets			
Inventories	377	123	242
Trade receivables & contract assets	58,280	420	9,712
Current receivables, non-interest bearing	47,491	19,219	43,201
Short-term investments	99,269	238,038	237,619
Cash and cash equivalents	508,978	896,114	644,975
Total current assets	**714,396**	**1,153,914**	**935,749**
TOTAL ASSETS	**784,401**	**1,217,450**	**1,011,270**
EQUITY AND LIABILITIES			
Shareholders' equity	**479,269**	**1,030,159**	**755,948**
Non-current liabilities			
Provisions	5,053	8,357	7,357
Lease liabilities	24,940	17,645	28,491
Deferred revenue	40,124	55,121	47,020
Contingent consideration	781	746	722
Total non-current liabilities	**70,899**	**81,869**	**83,590**
Current liabilities			
Lease liabilities	7,003	3,870	6,888
Liabilities, group companies	3,275	4,325	3,901
Current liabilities, non-interest bearing	54,184	24,172	66,598
Deferred revenue	79,000	21,724	24,961
Contract liabilities	14,814	-	-
Accrued expenses and deferred income	75,957	51,331	69,384
Total current liabilities	**234,233**	**105,422**	**171,732**
TOTAL EQUITY AND LIABILITIES	**784,401**	**1,217,450**	**1,011,270**

Parent company – Income statement

	Q2		H2	
KSEK	2022	2021	2022	2021
Revenue	26,396	4,535	56,676	13,533
Cost of revenue	(5,075)	(2,333)	(16,309)	(4,067)
Sales, general and administration expenses	(90,347)	(79,335)	(170,800)	(139,523)
Research and development expenses	(93,227)	(56,754)	(164,517)	(104,231)
Other operating expenses	(6,162)	1,193	(8,939)	(2,269)
Loss from operations	**(168,415)**	**(132,694)**	**(303,889)**	**(236,557)**
Result from financial items:				
Finance income	-	(23)	-	(106)
Finance costs	(2,146)	(154)	(5,503)	(287)
Loss for the period before tax	**(170,561)**	**(132,871)**	**(309,392)**	**(236,950)**
Income tax benefit/expense	-	-	-	-
Loss for the period	(170,561)	(132,871)	(309,392)	(236,950)
Other comprehensive income for the period	-	-	-	-
Total comprehensive income for the period	**(170,561)**	**(132,871)**	**(309,392)**	**(236,950)**

Parent company – Statement of changes in shareholders' equity

	June 30		December 31
KSEK	2022	2021	2021
Opening shareholders' equity as reported	**755,948**	**1,241,578**	**1,241,578**
Result for the period	**(309,392)**	**(236,950)**	**(549,098)**
Other comprehensive income for the period	-	-	-
Net comprehensive income	**(309,392)**	**(236,950)**	**(549,098)**
Long term incentive programs	32,714	25,531	63,467
Total transactions with the group's owner	**32,714**	**25,531**	**63,467**
Closing shareholders' equity	**479,269**	**1,030,159**	**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	Q2		January-June	
KSEK	2022	2021	2022	2021
Group				
Revenue				
Product sales	19,458	-	43,695	6,026
Contract revenue, Axis-Shield agreement	763	522	1,144	1,045
Cost reimbursement, Axis-Shield agreement	-	420	450	420
Contract revenue, Sarepta agreement	6,175	3,593	11,387	6,042
	26,396	**4,535**	**56,676**	**13,533**
Parent company				
Revenue:				
Product sales	19,458	-	43,695	6,026
Contract revenue, Axis-Shield agreement	763	522	1,144	1,045
Cost reimbursement, Axis-Shield agreement	-	420	450	420
Contract revenue, Sarepta agreement	6,175	3,593	11,387	6,042
	26,396	**4,535**	**56,676**	**13,533**

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.

Note 3 Fair value of financial instruments

The Group measures its investments in interest funds and its financial liability for contingent consideration at fair value. The fair value of interest funds at June 30, 2022 amounted to SEK 99.3 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 June 30, 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.

logics 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.

linical 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 organsation which overlooks how transplantations are structured and streamlined.

FDA
U.S. Food and Drug Administration.

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

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.