Interim report January-September 2022

HANSA BIOPHARMA

Total Revenue of SEK 67m in Q3; Positive reimbursement decisions received in Poland and Scotland; $70 million raised in non-dilutive financing; Imlifidase included in ESOT guidelines published in *Transplant International*

Highlights for the third quarter of 2022

- Total Q3 revenue of SEK 67m including SEK 23m in product sales and SEK 44m under our agreements with Sarepta and AskBio
- Positive reimbursement decisions received in Poland and Scotland for Idefirix® in highly sensitized kidney transplant patients. Market access has now been secured in nine European countries and procedures are ongoing in eight countries, including Spain, Italy and Belgium.
- First patient treated in the post-authorization efficacy study (PAES) of imlifidase in highly sensitized kidney transplant patients, at the Vall d'Hebron University Hospital in Barcelona.
- $70 million non-dilutive financing executed with NovaQuest to support continued development of the company's antibody-cleaving enzyme technology platform. The transaction extends Hansa's cash runway through 2024.
- The European Society for Organ Transplantation's (ESOT) guidelines for desensitization treatment of highly sensitized kidney transplant patients published in *Transplant International* in August 2022. Guidelines include imlifidase and provide a new clinical practice tool for healthcare professionals and represents the first international consensus on a management pathway for highly sensitized patients.
- Hansa received Great Place to Work® certification for the third consecutive year. The 2022 certification is based on a company-wide survey completed by 99% of Hansa employees.

Clinical pipeline update

- U.S. ConfIdeS: 39 out of the targeted 64 patients have been enrolled for randomization in the 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. The aim is to complete randomization in the first half 2023, while a BLA submission is expected in 2024 under the accelerated approval path.
- AMR: After completing enrollment in Q2-22, the first data read out is expected toward end of 2022 as previously guided. The AMR study is a randomized, open-label, multicenter, active control study designed to evaluate efficacy of imlifidase in eliminating donor specific antibodies (DSA) in the treatment of active episodes of acute and chronic acute AMR in kidney transplant patients, in comparison to plasma exchange.

Clinical pipeline update, continued

- GBS: In the Guillain Barré Syndrome (GBS) phase2 trial, 20 out of a target of 30 patients have been enrolled. Several initiatives have been implemented to support enrollment including simplifying the protocol and increasing capacity at the center level. New centers were also added before and over the summer with further measures being taken to accelerate recruitment in the coming months. The aim is to complete enrollment of GBS patients H2 2022/H1 2023.
- Anti-GBM: Preparations to commence a phase 3 study later this year, as previously guided, are on track with a protocol in place and approved by FDA. Selection of investigators and site set up activities are now ongoing.

Financial Summary

SEKm, unless otherwise stated – unaudited	Q3 2022	Q3 2021	9M 2022	9M 2021
Revenue	67.1	4.9	123.8	18.5
SG&A expenses	(83.5)	(82.8)	(254.2)	(224.1)
R&D expenses	(90.4)	(60.6)	(254.0)	(162.5)
Loss from operation	(139.5)	(148.2)	(442.3)	(384.2)
Loss for the period	(154.0)	(148.4)	(462.5)	(384.9)
Net cash used in operations	(128.7)	(131.5)	(392.6)	(364.9)
Cash and short-term investments	1,215.3	1,006.7	1,215.3	1,006.7
Shareholders' equity	344.8	899.6	344.8	899.6
EPS before and after dilution (SEK)	(3.45)	(3.34)	(10.39)	(8.65)
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	44,588,118	44,473,452	44,517,974	44,473,452
Number of employees at the end of the period	145	127	145	127

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

"I am pleased to see continued good execution of our market access and commercial launch activities across Europe.

We also welcome the first international guidelines for desensitization treatment of highly sensitized kidney transplant patients, issued by the European Society for Organ Transplantation."

Søren Tulstrup
President and CEO, Hansa Biopharma

In July, we executed a $70 million non-dilutive financing transaction, strengthening our existing cash position to support the continued development of transformative drug candidates based on our unique antibody-cleaving enzyme technology platform and the commercial launch of Idefirix® in Europe.

So, I am pleased to see continued good execution of our market access and commercial launch activities across Europe. During the third quarter, we secured reimbursement in Scotland and Poland, and market access has now been secured in nine European countries, including Germany, France, and the UK, while market access procedures continue to progress in eight additional countries, including Spain, Italy and Belgium.

We also welcome the publication in *Transplant International* of the first international guidelines for desensitization treatment of highly sensitized kidney transplant patients by the European Society for Organ Transplantation (ESOT). These guidelines, which are the first to include imlifidase, represent the first supranational consensus on a management pathway for highly sensitized patients and articulate the variability in definitions, approaches, outcomes as well as the perceived success of HLA-related transplantations. It is our expectation that these guidelines can help improve access to lifesaving kidney transplants for highly sensitized patients across Europe.

In the U.S., our pivotal ConfIdeS trial in kidney transplantation 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. Enrollment is progressing according to plan, with 39 out of a target of 64 patients now enrolled across the U.S. Randomization of all patients is aimed for completion in the first half of 2023 with BLA submission under the accelerated approval pathway in 2024.

As for our AMR clinical development program, we look forward to the first data read-out from our phase 2 study later this year, following the completion of enrolment in May 2022. Acute AMR episodes post kidney transplantation occur in 5-7% of patients, with significant risk of patients losing graft function. There is currently no approved treatment for AMR.

With respect to our GBS phase 2 program, we have implemented several significant initiatives and are taking further measures to increase the enrolment rate as the trial has been impacted by the pandemic in various ways, including shortage of IVIg as well as reduced availability of staff across a number of trial centers. We believe we will see an acceleration in recruitment due to these initiatives as well as higher infection rates[1] as we approach the winter season. Completion of enrollment in the GBS trial is anticipated H2 2022/H1 2023.

In anti-GBM, we plan 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 will enroll 50 patients across the EU and U.S. and will be initiated later this year, as previously guided.

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

I look forward to keeping you updated on our continued progress, with several upcoming 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.

[1] Journal of Neurology, Neurosurgery, and Psychiatry 86(11) DOI:10.1136/jnnp-2014-309056

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Continued pipeline progress

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) H2'22/H1'23
	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

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Imlifidase – Commercial, Clinical and Regulatory Interactions

EU: Kidney transplantation for highly sensitized patients

In August 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 continued to progress as planned during the first nine months of 2022, with commercial access now in nine European countries including the United Kingdom incl. Scotland, Poland as well as Germany and in France through a reimbursed Early Access Program. Additional market access procedures are ongoing in a total of eight countries including Spain, Italy, and Belgium.

In spring 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 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®.

On August 11, 2022, the European Society for Organ Transplantation's (ESOT) guidelines for desensitization treatment of highly sensitized kidney transplant patients was published in *Transplant International*. The guidelines, which are the first to include imlifidase, provide a new clinical practice tool for healthcare professionals and represent the first international consensus on a management pathway for highly sensitized patients.

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. A total of 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 also randomized at time of organ offer.

As of October 19, 2022, 39 patients have been enrolled for randomization to imlifidase treatment or standard of care (i.e. wait for a matched donor or subject for experimental treatment).

Completion of enrollment in the study is expected toward the end of 2022, as previously guided, while randomization is aimed for completion by the first half of 2023. Following a 12-month follow-up study, results are expected to support a Biologics License Application (BLA) under the accelerated approval pathway in 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-initiatedphase 2 trial (GoodIdeS) of imlifidase to treat anti-GBM disease were published in Journal of American Society of Nephrology (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. The study is expected to be initiated toward the end of 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[2] and is a significant challenge to long-term graft survival. There is no approved drug in AMR.

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 and chronic 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 AMR phase 2 trial in 30 patients with active or chronic active AMR episodes, which included 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 October 19, 2022, 20 out of a target of 30 patients with GBS have been enrolled at 10 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 and a shortage of IVIg has affected the enrollment rate at a subset of participating hospitals. During the second quarter and over summer, Hansa worked on mitigating these hurdles through implementation a number of significant initiatives including adding additional sites in the U.K. and the Netherlands. We continue to implement additional measures to increase capacity and accelerate recruitment. Completion of enrollment in the GBS trail is anticipated H2 2022/H1 2023.

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 aims at including 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 crossmatch positive patients undergoing living donor transplantation. The study will be run by Associate Professor Vasishta Tatapudi, MD and Program Director at the NYU Langone Transplant Institute.

[2] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.

Preclinical programs

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

Hansa 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, after which 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 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.

On September 29, 2022, Sarepta announced that it had submitted a Biologics License Application (BLA) to the U.S. FDA for the accelerated approval of SRP-9001 to treat ambulant patients with DMD. For further information regarding Sarepta's gene therapy programs in DMD and LGMD, please refer to www.sarepta.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

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 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.

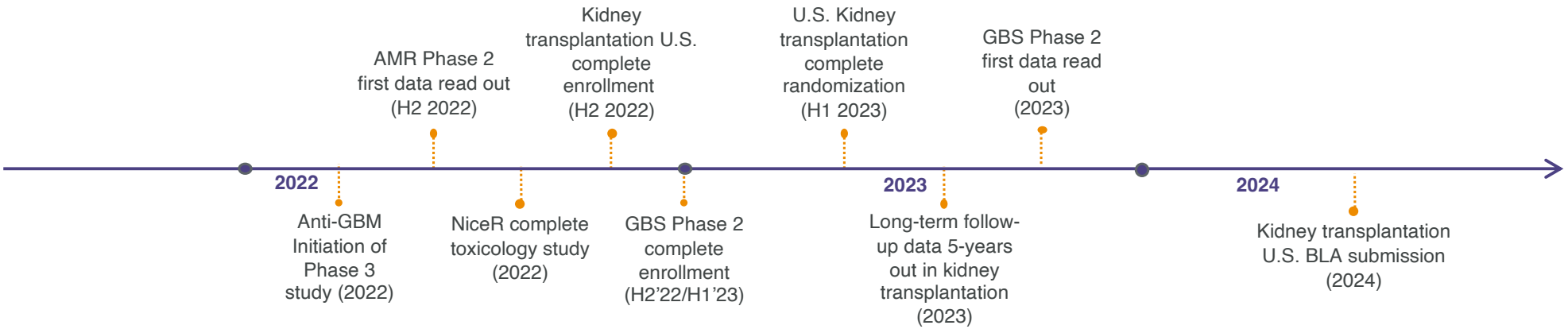
The collaboration is progressing as planned, currently at a preclinical stage.

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



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Financial review January – September 2022

Revenue

Revenue for the third quarter of 2022 amounted to SEK 67.1m (Q3 ’21: SEK 4.9m) including Idefirix® product sales of SEK 22.7m (Q3 ’21: SEK NIL) and contract revenue of SEK 44.3m (Q3 ’21: SEK 4.9m), mainly from the upfront payments the Company received under the Sarepta and AskBio Agreements.

Revenue for the first nine months of 2022 amounted to SEK 123.8m (Nine months ’21: SEK 18.5m) and mainly comprises of Idefirix® product sales of SEK 66.4m (Nine months ’21: SEK 6.0m), and contract revenue of SEK 56.8m (Nine months ’21: SEK 12.0m), mainly related to revenue recognition of SEK 55.1m (Nine months ’21: SEK 10.4m) from the upfront payments the Company received under the Sarepta and AskBio Agreements.

SG&A expenses

Sales, general and administrative expenses for the third quarter of 2022 amounted to SEK 83.5m (Q3 ’21: SEK 82.8m) and to SEK 254.2m for the first nine months of 2022 (Nine months ’21: SEK 224.1m). 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 costs for the Company’s employee long-term incentive programs, included in the above SG&A expenses amounted to SEK 33.5m for the first nine months of the year 2022 (Nine months ’21: SEK 24.0m).

R&D expenses

Research and development expenses for the third quarter of the year 2022 amounted to SEK 90.4m (Q3 ’21: SEK 60.6m) and to SEK 254.0m for the first nine months of 2022 (Nine months ’21: SEK 162.5m). The increase over the respective 2021 periods is mainly driven by the ongoing U.S. ConfIdeS study, as well as the preparation and initiation of the EU post-approval study and the anti-GBM phase 3 program. Recorded non-cash costs for the Company’s employee long-term incentive programs, included in the above R&D expenses, amounted to SEK 16.2m for the first nine months of the year 2022 (Nine months ’21: SEK 12.0m).

Other operating expenses and financial expenses

Other operating expenses for the third quarter of 2022 amounted to 15.1m (Q3 ’21: SEK 2.0m) and to SEK 24.0m for the first nine months of 2022 (Nine months ’21: SEK 4.3m). The increase over the respective 2021 periods is mainly driven by a one-off settlement payment the Company made related to arbitration proceedings as further described in Note 2 below, as well as the impact of the US dollar exchange rate appreciation against the Swedish Krona on the deferred revenue positions as well as the accounts payable/accounts receivables positions in the balance sheet.

Financial expenses, net, for the third quarter of 2022 amounted to 14.0m (Q3 ’21: SEK 0.2m) and to SEK 19.5m for the first nine months of 2022 (Nine months ’21: SEK 0.7m). The increase over the respective 2021 periods is mainly driven by accrued interest related to the long-term loan (see Note 4 below).

Financial results

The loss from operations for the third quarter of 2022 amounted to SEK 139.5m (Q3 ’21: SEK 148.2m) and to SEK 442.3m for the first nine months of 2022 (Nine months ’21: SEK 384.2m). The increase as compared to previous year periods is mainly driven by Hansa’s broadened commercial activities and organizational expansion related to the launch of Idefirix® in Europe and its broadened R&D pipeline activities.

Loss for the third quarter of 2022 amounted to SEK 154.0m (Q3 ’21: SEK 148.4m) and to SEK 462.5m for the first nine months of 2022 (Nine months ’21: SEK 384.9m).

Cash flow, cash and investments

Net cash used in operating activities for the third quarter of 2022 amounted to SEK 128.7m (Q3 ’21: SEK 131.5m) and to SEK 392.6m for the first nine months of 2022 (first nine months ’21 SEK 364.9m). The change as compared to the previous year periods 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, partly compensated by higher revenue in 2022. 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 1,215.3m on September 30, 2022, as compared to SEK 889.0m at year-end 2021.

Long term incentive programs

Ongoing programs	LTIP 2018	LTIP 2019	LTIP 2020	LTIP 2021	LTIP 2022
Maximum number of issuable shares*	**-**	**216 741**	**1 151 580**	**1 275 642**	**1 400 000**
Number of allocated and outstanding share rights and options	**-**	**166 724**	**885 831**	**981 263**	**927 000**
Number of acquired and outstanding warrants	**-**	**-**	**-**	**-**	**-**
Estimated total cost including social contributions, KSEK	**-**	**2 144**	**89 440**	**74 596**	**67 607**
Total cost per program, including social contributions, as of September 30, 2022 YTD, KSEK	**294**	**5 332**	**21 679**	**17 694**	**4 695**

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

Total costs, including social contributions, as of September 30, 2022 YTD, KSEK	49 693

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Shareholders' equity

On September 30, 2022, shareholders' equity amounted to SEK 344.8m as compared to SEK 757.6m at the end of the year 2021.

Parent Company

The parent company's revenue for the third quarter of 2022 amounted to SEK 67.1m (Q3 '21: SEK 4.9m) and to SEK 123.8m for the first nine months of 2022 (Nine months '21: SEK 18.5m).

Loss for the parent company for the third quarter of 2022 amounted to SEK 153.9m (Q3 '21: SEK 148.6m) and to SEK 463.3m for the first nine months of 2022 (Nine months '21: SEK 385.5m).

The parent company's equity amounted to SEK 342.1m as of September 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 September 2022. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of September 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 September 30, 2022, the following LTIPs were ongoing: LTIP 2019, LTIP 2020, LTIP 2021 and LTIP 2022.

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.

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 regard 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 February 24, 2022, Russia invaded Ukraine. Hansa does not have any operations in nor collaborations 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 have and is expected to continue to have general negative impacts on the global economy, stock markets, exchange rates, energy prices, global supply, and free trade, and, as such, does indirectly negatively impact Hansa's business.

In the 2021 Annual Report (pages 102-105 ENG), the risks and uncertainties which are considered to have greatest significance for Hansa Biopharma 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

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Hansa Biopharma
Mobile: +46 (0) 709–298 269
E-mail: klaus.sindahl@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 2022/2023

February 2, 2023	Year-end Report for January-December 2022
March 30, 2023	2022 Annual Report
April 20, 2023	Interim Report for January-March 2023
June 14, 2023	2023 Annual General Meeting
July 20, 2023	Half-year Report for January-June 2023
October 18, 2023	Interim Report for January-September 2023

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	47,186,130 (44,588,118 A-shares and 2,598,012 C-shares)
Market Cap September 30, 2022	SEK ~2.6bn (USD ~240m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of September 30, 2022

Name	Number of shares	Ownership in pct
Redmile Group, LLC	5 252 057	11,8%
Fjärde AP-Fonden (AP 4)	2 207 397	5,0%
Nexttobe AB	2 155 379	4,8%
Invesco Advisers, Inc.	1 973 931	4,4%
Försäkrings AB Avanza Pension	1 894 818	4,2%
Olausson, Thomas	1 820 500	4,1%
Tredje AP-Fonden (AP 3)	1 389 650	3,1%
The Vanguard Group, Inc.	1 223 839	2,7%
Schroder Investment Management, LTD	888 132	2,0%
C WorldWide Asset Management	799 749	1,8%
Other	24 982 666	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 September 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 been reviewed by the company's auditors.

Lund October 20, 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

KPMG

Translation from the Swedish original

Review report

To the Board of Directors of Hansa Biopharma AB

Corp. id. 556734-5359

Introduction

We have reviewed the condensed interim financial information (interim report) of Hansa Biopharma AB as of 30 September 2022 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Stockholm October 20, 2022

KPMG AB

Stefan Lundberg

Authorized Public Accountant

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

	September 30		December 31
KSEK	2022	2021	2021
ASSETS			
Non-current assets			
Intangible assets	26,665	29,443	28,761
Property and equipment	5,408	6,624	6,432
Leased assets	29,602	20,164	35,273
Total non-current assets	**61,675**	**56,231**	**70,466**
Current assets			
Inventories	957	123	242
Trade receivables & contract assets	52,481	463	9,712
Current receivables, non-interest bearing	50,614	28,784	43,427
Short-term investments	-	238,051	237,619
Cash and cash equivalents	1,215,282	768,614	651,342
Total current assets	**1,319,334**	**1,036,035**	**942,342**
TOTAL ASSETS	**1,381,009**	**1,092,266**	**1,012,808**
EQUITY AND LIABILITIES			
Shareholders' equity	344,823	899,565	757,573
Non-current liabilities			
Long-term loan	760,792	-	-
Deferred tax liabilities	403	426	426
Provisions	6,560	7,994	7,357
Lease liabilities	23,141	16,392	28,491
Deferred revenue	39,130	50,066	47,020
Contingent consideration	717	700	722
Total non-current liabilities	**830,743**	**75,578**	**84,016**
Current liabilities			
Lease liabilities	7,083	3,777	6,888
Current liabilities, non-interest bearing	49,103	31,079	66,908
Deferred revenue	42,713	24,518	24,961
Contract liabiities	17,459	-	-
Accrued expenses and deferred income	89,085	57,749	72,462
Total current liabilities	**205,443**	**117,123**	**171,219**
TOTAL EQUITY AND LIABILITIES	**1,381,009**	**1,092,266**	**1,012,808**

Consolidated statement of financial position

	Q3		January-September	
KSEK	2022	2021	2022	2021
Revenue	67,083	4,947	123,759	18,480
Cost of revenue	(17,633)	(7,735)	(33,942)	(11,802)
Sales, general and administration expenses	(83,479)	(82,768)	(254,169)	(224,102)
Research and development expenses	(90,378)	(60,619)	(253,969)	(162,523)
Other operating expenses	(15,083)	(2,004)	(24,023)	(4,274)
Loss from operations	**(139,490)**	**(148,179)**	**(442,344)**	**(384,221)**
Financial income (expenses), net	(13,966)	(201)	(19,477)	(700)
Loss for the period before tax	**(153,456)**	**(148,380)**	**(461,821)**	**(384,921)**
Tax	(495)	10	(639)	29
Loss for the period	**(153,951)**	**(148,370)**	**(462,460)**	**(384,892)**
Attributable to:				
Parent company shareholders	(153,951)	(148,370)	(462,460)	(384,892)
Earnings per share (EPS)				
Before dilution (SEK)	(3.45)	(3.34)	(10.39)	(8.65)
After dilution (SEK)	(3.45)	(3.34)	(10.39)	(8.65)
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	45	37	264	144
Other comprehensive income for the period	**45**	**37**	**264**	**144**
Total net comprehensive income	**(153,906)**	**(148,333)**	**(462,196)**	**(384,748)**

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

	September 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	(462,460)	(384,892)	(548,282)
Other comprehensive income for the period	264	144	264
Net comprehensive income	**(462,196)**	**(384,748)**	**(548,018)**
Transactions with the group's owner			
Long term incentive programs	49,444	42,189	63,467
Total transactions with the group's owner	**49,444**	**42,189**	**63,467**
Closing balance of shareholders' equity	**344,823**	**899,565**	**757,573**

Consolidated statement of cash flow

	Q3		January-September	
KSEK	**2022**	**2021**	**2022**	**2021**
Cash Flows from Operating Activities				
Loss for the period	(153,951)	(148,370)	(462,460)	(384,892)
Adjustment for items not included in cash flow [1]	52,652	18,728	90,261	41,913
Interest received and paid, net	(222)	(158)	(217)	(414)
Income taxes paid	(699)	(51)	(699)	(73)
Cash flow from operations before change in working capital	**(102,220)**	**(129,851)**	**(373,115)**	**(343,466)**
Changes in working capital	(26,521)	(1,650)	(19,521)	(21,444)
Net cash used in operating activities	**(128,741)**	**(131,501)**	**(392,636)**	**(364,910)**
Investing activities				
Proceeds from sale of short-term investments	99,791	-	232,644	-
Acquisition of property and equipment	-	-	(140)	(2,399)
Cash flow from investing activities	**99,791**	**-**	**232,504**	**(2,399)**
Financing activities				
Proceeds from long-term loan financing	736,400	-	736,400	-
Loan issue cost	(8,027)		(8,027)	-
Repayment of lease liabilities	(1,718)	(1,346)	(5,154)	(3,641)
Cash flow from financing activities	**726,655**	**(1,346)**	**723,219**	**(3,641)**
Net change in cash	697,705	(132,847)	563,087	(370,950)
Cash and cash equivalents, beginning of period	517,203	901,391	651,342	1,139,362
Currency exchange variance, cash and cash equivalents	375	71	853	203
Cash and cash equivalents, end of period	**1,215,282**	**768,614**	**1,215,282**	**768,614**

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

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Parent company – Statement of financial position

	September 30		December 31
KSEK	2022	2021	2021
ASSETS			
Non-current assets			
Intangible assets	24,528	27,181	26,518
Property, plant and equipment	5,408	6,624	6,432
Leased assets	29,602	20,164	35,273
Investment in subsidiaries	5,095	5,095	5,095
Receivables, group companies	2,588	2,100	2,203
Total non-current assets	**67,221**	**61,164**	**75,521**
Current assets			
Inventories	957	123	242
Trade receivables & contract assets	52,481	463	9,712
Current receivables, non-interest bearing	50,327	28,380	43,201
Short-term investments	-	238,051	237,619
Cash and cash equivalents	1,206,273	762,005	644,975
Total current assets	**1,310,039**	**1,029,022**	**935,749**
TOTAL ASSETS	**1,377,260**	**1,090,186**	**1,011,270**
EQUITY AND LIABILITIES			
Shareholders' equity	**342,132**	**898,250**	**755,948**
Non-current liabilities			
Long-term loan	760,792	-	-
Provisions	6,560	7,994	7,357
Lease liabilities	23,141	16,392	28,491
Deferred revenue	39,130	50,066	47,020
Contingent consideration	717	700	722
Total non-current liabilities	**830,341**	**75,152**	**83,590**
Current liabilities			
Lease liabilities	7,083	3,777	6,888
Liabilities, group companies	3,620	2,261	3,901
Current liabilities, non-interest bearing	48,433	30,857	66,598
Deferred revenue	42,713	24,518	24,961
Contract liabilities	17,459	-	-
Accrued expenses and deferred income	85,479	55,371	69,384
Total current liabilities	**204,787**	**116,784**	**171,732**
TOTAL EQUITY AND LIABILITIES	**1,377,260**	**1,090,186**	**1,011,270**

Parent company – Income statement

	Q3		January-September	
KSEK	2022	2021	2022	2021
Revenue	67,083	4,947	123,759	18,480
Cost of revenue	(17,633)	(7,735)	(33,942)	(11,802)
Sales, general and administration expenses	(83,338)	(84,993)	(254,138)	(224,516)
Research and development expenses	(90,930)	(58,633)	(255,447)	(162,864)
Other operating expenses	(15,081)	(2,003)	(24,020)	(4,272)
Loss from operations	**(139,899)**	**(148,417)**	**(443,788)**	**(384,974)**
Result from financial items:				
Finance income	2,738	106	2,738	-
Finance costs	(16,707)	(256)	(22,210)	(543)
Loss for the period before tax	**(153,868)**	**(148,567)**	**(463,260)**	**(385,517)**
Income tax benefit/expense	-	-	-	-
Loss for the period	(153,868)	(148,567)	(463,260)	(385,517)
Other comprehensive income for the period	-	-	-	-
Total comprehensive income for the period	**(153,868)**	**(148,567)**	**(463,260)**	**(385,517)**

Parent company – Statement of changes in shareholders' equity

	September 30		December 31
KSEK	2022	2021	2021
Opening shareholders' equity as reported	**755,948**	**1,241,578**	**1,241,578**
Result for the period	**(463,260)**	**(385,517)**	**(549,098)**
Other comprehensive income for the period	-	-	-
Net comprehensive income	**(463,260)**	**(385,517)**	**(549,098)**
Long term incentive programs	49,444	42,189	63,467
Total transactions with the group's owner	**49,444**	**42,189**	**63,467**
Closing shareholders' equity	**342,132**	**898,250**	**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	Q3		January-September	
KSEK	2022	2021	2022	2021
Group				
Revenue				
Product sales	22,703	-	66,398	6,026
Contract revenue, Axis-Shield agreement	572	522	1,716	1,567
Cost reimbursement, Axis-Shield agreement	88	46	538	466
Contract revenue, Sarepta, AskBio agreement	43,720	4,378	55,107	10,420
	67,083	**4,947**	**123,759**	**18,480**
Parent company				
Revenue:				
Product sales	22,703	-	66,398	6,026
Contract revenue, Axis-Shield agreement	572	522	1,716	1,567
Cost reimbursement, Axis-Shield agreement	88	46	538	466
Contract revenue, Sarepta, AskBio agreement	43,720	4,378	55,107	10,420
	67,083	**4,947**	**123,759**	**18,480**

The Company is a party to two separate royalty agreements (the "Royalty Agreements") with certain 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 utilization 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 have 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 has recently settled these arbitration proceedings with the Counterparties. The settlement includes a one-off settlement payment and the entitlement of the Counterparties to low single-digit royalties on net sales as well as mid single-digit participation in any once-only consideration received by Hansa. This settlement includes all compensation obligations under the Royalty Agreements.

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 the financial liability for contingent consideration on September 30, 2022 amounted to SEK 0.7 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. The Group sold all its investments in interest funds during the period – see further information in the Cash Flow Statement.

Note 4 Long-term loan

On July 18, 2022, the Company entered into a $70.0 million funding agreement with NovaQuest. The funding was accounted for as liability classified debt as the Company has an unavoidable obligation to settle the funding in cash. The debt will be accounted for at amortized cost.

The net proceeds from the funding were $69.2 million after the deduction of transaction costs. The transaction costs were capitalized and offset against the carrying value of the debt and will be amortized over the term of the debt.

The debt is secured by certain of the Company's intellectual property and assets.

Under the terms of the debt, the Company will make quarterly mid-single-digit royalty payments to NovaQuest on future worldwide annual net sales of imlifidase, commencing upon approval in the U.S. of imlifidase in kidney transplantation or anti-GBM. In addition, Hansa will make certain milestone payments to NovaQuest upon U.S. approval of imlifidase in kidney transplantation or anti-GBM. Total payments by Hansa to NovaQuest are capped at $140 million. The agreement also provides for time-based catch-up payments within the payment cap if specified payment amounts have not been received by NovaQuest by specified dates, with the last potential catch-up payment due on December 31, 2028.

The Company will record the difference between the principal and the total payments as interest expense over the forecasted term of the debt by applying the effective-interest-rate method. Based on the progress of the payments, the Company will recalculate the effective interest each reporting period until the debt is satisfied.

On 30 September 2022, the loan amounted to SEK 760.8 million, thereof SEK 16.5 million in accrued interest.

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.

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 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.

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.