YEAR-END REPORT JANUARY-DECEMBER 2020

Commercial launch activities for Idefirix® progressing as planned; Patient recruitment in clinical studies reinitiated in December 2020; Company financed into 2023

Highlights for the fourth quarter 2020

- Commercial launch activities in early launch countries within the European Union are underway as planned. During Q4'20, initial pharmacy level pricing for Idefirix® was published in the first markets. National level reimbursement application processes have been initiated, and decisions by authorities in the first of the early launch countries are expected from mid-year onwards. Depending on the impact of the COVID-19 pandemic, access to special and local budgets for individual patients could be achieved by certain centers prior to the granting of national level reimbursement.
- US trial: Discussions with the FDA about the study protocol are ongoing. Assuming agreement is reached in the coming months, Hansa will proceed to set up centers in the US. Depending on the impact of the COVID-19 pandemic in the US, enrollment is expected to complete in 2022, as previously guided, with a potential Biologics License Application (BLA) submission by 2023 under the accelerated approval pathway.
- Patient recruitment in the phase 2 studies in AMR and GBS was reinitiated in December 2020, as previously guided. The recruitment process in both studies had been temporarily paused due to the COVID-19 pandemic. In the AMR trial, 5 patients out of a target of 30 patients have been enrolled, and in the GBS trial 5 patients out of a similar target of 30 patients have been enrolled.
- Following the publication of positive high-level data in the anti-GBM phase 2 trial at the end of September 2020, discussions with EMA/FDA will now be initiated to determine the regulatory path forward for this indication.
- On October 29, 2020 Hansa Biopharma hosted its third Capital Markets Day. The three-hour virtual CMD event was attended by more than 500 live viewers. A recorded version is available on the Company's web.
- Investments in SG&A and R&D increased in the fourth quarter to SEK 63.2m (Q4'19: SEK 53.4m) and SEK 50.4m (Q4'19: SEK 57.7m), respectively. Cash position was SEK 1,378m at the end of December 2020. Cash flow from operating activities for the fourth quarter ended at SEK -96.5m (Q4'19: SEK -75.0m).
- COVID-19 Pandemic: The global COVID-19 pandemic may still adversely impact Hansa Biopharma's operational business and trial activities.

Financial Summary

SEKm, unless otherwise stated - unaudited	Q4 2020	Q4 2019	FY 2020	FY 2019
Revenue	3.8	1.2	6.1	3.4
SG&A expenses	-63.2	-53.4	-203.0	-167.3
R&D expenses	-50.4	-57.7	-227.2	-192.9
Operating profit/loss	**-106.2**	**-110.1**	**-422.8**	**-359.7**
Net profit/loss	-105.8	-110.9	-420.9	-360.0
Cash flow from operating activities	-96.5	-75.0	-290.3	-334.8
Cash and short-term investments	1,377.5	601.1	1,377.5	601.1
Shareholders' equity	1,241.8	562.8	1,241.8	562.8
EPS before and after dilution (SEK)	-2.38	-2.77	-9.98	-9.00
Number of outstanding shares	44,473,452	40,026,107	44,473,452	40,026,107
Weighted average number of shares before and after dilution	44,473,452	40,026,107	42,176,872	40,020,429
Number of employees	87	74	87	74

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

Søren Tulstrup, President and CEO, comments

"Hansa Biopharma enters the new year well positioned to execute successfully on our key priorities and objectives for 2021, which are to ensure the successful launch of Idefirix® (imlifidase) in leading transplantation centers in select European markets, initiate a randomized, controlled clinical study in the US to support a future filing of a BLA for imlifidase in highly sensitized patients waiting for a kidney transplant, and continue the strong current momentum behind our efforts to advance our pipeline of drug candidates within auto-immune diseases and gene therapy.

2020 was overall a very successful and transformative year for Hansa Biopharma – a year which saw significant milestones achieved, including the conditional approval of Idefirix® by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

We are also very excited about the progress of our efforts to advance a valuable pipeline of drug candidates in therapeutic areas beyond transplantation. In July, we announced the achievement of a landmark milestone with the agreement with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy for Duchenne muscular dystrophy and Limb-girdle muscular dystrophy in patients with neutralizing antibodies (NAbs) to adeno-associated virus (AAV). The partnership is progressing as planned, and during the second half of 2020 Sarepta initiated ongoing pre-clinical investigations with imlifidase in the gene therapy setting.

We also announced positive high-level data from an investigator-initiated phase 2 trial with imlifidase in anti-GBM antibody disease, evaluating safety, tolerability and efficacy of imlifidase in 15 severe anti-GBM patients. We are very encouraged by the positive outcome, demonstrating that two-thirds of the anti-GBM patients achieved dialysis independence six months after treatment. The positive data marks another important milestone for the advancement of a valuable pipeline of drug candidates targeting indications beyond transplantation.

While 2020 has been a transformative year for Hansa Biopharma with a lot of progress, we have also seen the negative effects from the escalating COVID-19 pandemic impacting our operational business and trial activities during the year. The global COVID-19 pandemic may still adversely impact Hansa Biopharma's operational business and trial activities in 2021, and the Company will continue to take appropriate measures to protect employees and take social responsibility during this global healthcare crisis while working to limit the potential negative effects on our business.

In relation to COVID-19, we have seen our pipeline activities materially impacted during 2020 by the pandemic. Recruitment of patients in the GBS and AMR studies was temporarily halted during a large part of the year. In December 2020, patient enrollment was reinitiated in both studies under a risk-based, site-by-site approach. Depending on the development of the COVID-19 pandemic and its impact, we expect to finalize recruitment in both studies towards the end of this year.

In the US, we are currently in ongoing discussions with the U.S. Food and Drug Administration (FDA) about a proposed study protocol for a new, randomized controlled study of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients. Assuming a near term approval of the final study protocol, and depending on the development of the COVID-19 pandemic in the United States and its impact on patient enrollment, the Company expects to complete enrollment of this study in 2022, enabling a potential Biologics License Application (BLA) submission by 2023 under the accelerated approval pathway.

Hansa Biopharma's evolution into a fully integrated, commercial stage biopharmaceutical company is becoming a reality now. An exciting year lies ahead of us with the commercial roll-out of the Company's first approved drug, Idefirix, developed to help highly sensitized patients get off dialysis by enabling a lifesaving transplantation.

I look forward to updating you on progress in our efforts to deliver on our mission to bring lifesaving and life altering therapies to the patients with rare diseases who need them and generate value to society at large."

Søren Tulstrup
President and CEO, Hansa Biopharma

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Continuous development in our pipeline activities

Candidate/ Project	Indications	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: Commercial launch Q1 2021
	US: Kidney transplantation in highly sensitized patients[1,2]	■	■	■	**)			US: First patient dosed 1H 2021
	Anti-GBM antibody disease[3]	■	■					Agreement with regulators on a path forward toward BLA/MAA
	Antibody mediated kidney transplant rejection (AMR)	■	■					Complete enrollment of 30 patients in H2 2021
	Guillain-Barré syndrome (GBS)	■	■					Complete enrollment of 30 patients in H2 2021
	Pre-treatment ahead of gene therapy in Limb-Girdle (LGMD) & Duchenne (DMD) (Partnered with Sarepta)							Pre-Clinical phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Initiation of toxicology studies in H1 2021
EnzE	Cancer immunotherapy							Research phase

■ Completed ■ Ongoing

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

*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch

**) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients. Given the continued impact of the COVID-19 pandemic and the timeline for the finalization of the study protocol Hansa expect recruitment of the first patient to be in H1 2021

Imlifidase - Clinical programs and regulatory interactions

Enabling kidney transplantation for highly sensitized patients

On August 26, 2020 Idefirix® (imlifidase) 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 approval served as a landmark milestone for Hansa Biopharma, as Idefirix® is the Company's first approved drug and will transform Hansa Biopharma into a commercial stage biopharmaceutical company.

Commercial launch activities are underway as planned. During the fourth quarter of 2020, initial pharmacy level pricing for Idefirix® was published in the first markets, and agreements around reimbursement with national healthcare providers and payers are expected to be completed in the early launch countries beginning in the middle of the year. Depending on the impact of the COVID-19 pandemic, access to special and local budgets for individual patients could be achieved by certain centers prior to the granting of national level reimbursement. Further, manufacturing of the first commercial packaged product has been completed.

In the US, Hansa is in ongoing discussions with the U.S. Food and Drug Administration (FDA) about a proposed study protocol for a new, randomized controlled study of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients.

Assuming agreement on the final study protocol is reached in the coming months, and depending on the development of the severe COVID-19 pandemic in the United States and the resulting impact on patient

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enrollment, the Company expects to complete enrollment of this study in 2022, enabling a potential Biologics License Application (BLA) submission by 2023 under the accelerated approval pathway.

Beyond the four completed phase 2 studies in kidney transplantation, Hansa Biopharma is also 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 2-year follow-up data demonstrates graft survival of 90% for 31 patients post imlifidase treatment with a median eGFR of 61.5 ml/min and an AMR frequency that was comparable with less sensitized patients.

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

Anti-GBM is an acute auto-immune disease where antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM) causing acute injury of kidney and/or lung. Anti-GBM is an ultra-rare and very severe disease that annually is affecting approximately 1.6 in a million globally. A majority of patients lose their kidney function[1], requiring chronic dialysis and kidney transplantation.

On September 24, 2020 positive high-level data was presented from an investigator-initiated phase 2 trial led by Principal Investigator Mårten Segelmark, Professor at the universities in Linköping and Lund with imlifidase to treat anti-GBM disease, with two-thirds of patients achieving dialysis independence six months after treatment. Normally, two-thirds of patients will lose kidney function and end up in dialysis after six months.

The positive data marks an important milestone for the expansion of imlifidase outside transplantation. Regulatory discussions with the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) will be initiated to determine the regulatory path forward for imlifidase in anti-GBM.

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

Active antibody mediated rejection is a serious condition after transplantation that occurs in roughly 10-15% of kidney transplants[2] or approximately 3,200[3] new patients annually[4] and is a significant challenge to long term graft survival.

In 2019, Hansa Biopharma 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 DSAs in the treatment of active episodes of acute AMR in kidney transplant patients in comparison to plasma exchange.

The recruitment process for this phase 2 study was temporarily halted during a large part of 2020 due to the COVID-19 pandemic, but reinitiated in the fourth quarter of 2020, as previously guided. As of Feb 4, 2021, 5 of a target of 30 patients with active AMR episodes have been enrolled. Depending on the impact of the COVID-19 pandemic, enrollment is expected to be completed in the second half of 2021.

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. In 2019, Hansa Biopharma initiated an open-label, single arm, multi-center study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients in combination with standard of care intravenous immunoglobulin (IVIg).

The recruitment process for this phase 2 study was temporarily halted during a large part of 2020 due to the COVID-19 pandemic, but reinitiated in the fourth quarter of 2020, as previously guided. As of Feb 4, 2021 5 of a target of 30 patients with GBS, have been enrolled in this phase 2 study . Depending on the impact of the COVID-19 pandemic, enrollment is expected to be completed in the second half of 2021.

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

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

3 Jordan et al., British Medical Bulletin, 2015, 114:113-125.

4 http://www.irodat.org.

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Preclinical programs

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

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

The first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development has been selected. Development of a GMP-manufacturing process for the lead NiceR candidate has since been initiated and preparations for toxicology studies and a clinical Phase 1 study are now ongoing. IND-enabling tox studies are expected to commence in the first half of 2021.

EnzE – Enzyme-based antibody Enhancement

Published findings[5] demonstrate how pre-treatment with imlifidase in tumor animal models can increase the efficacy of currently available antibody-based cancer therapies. This treatment concept is currently being investigated under the project name EnzE, Enzyme-based antibody Enhancement.

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

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

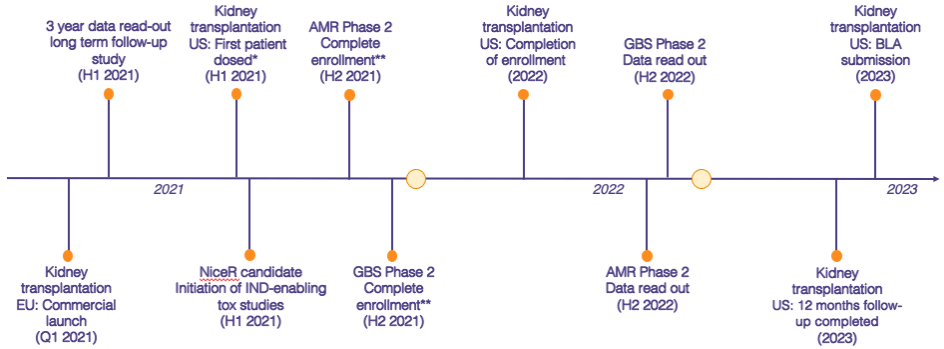
On July 2, 2020, Hansa Biopharma announced an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy in Duchenne muscular dystrophy and Limb-girdle muscular dystrophy in patients with neutralizing antibodies (NAbs) to adeno-associated virus (AAV).

Under the terms of the agreement, Hansa received USD 10m as an upfront payment and will book all sales of imlifidase. In addition, Hansa will be eligible for up to USD 397.5m 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 during the second half of 2020 Sarepta initiated ongoing pre-clinical investigations with imlifidase as a potential pre-treatment in the gene therapy setting. For further information regarding Sarepta's gene therapy programs in DMD and LGMD please refer to www.sarepta.com.

Upcoming milestones and news flow

Milestones subject to potential COVID-19 impact



*) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients.

**) AMR/GBS Due to the impact from the COVID-19 pandemic, the enrollment in GBS and AMR were temporarily halted during large parts of 2020. Hansa Biopharma reinitiated enrollment in Q4 2020 under a risk-based, site-by-site approach.

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

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Financial review January – December 2020

Revenue

Revenue for the fourth quarter 2020 amounted to SEK 3.8m (Q4'19: SEK 1.2m) and to SEK 6.1m for the full year of 2020 (full year'19 SEK 3.4m) and comprises of revenue recognition from the upfront payment the company received under the Sarepta Agreement, royalty income from Axis-Shield Diagnostics (Abbott group) and patent cost reimbursements. The company received a USD 10M (SEK 81.9M) upfront payment in July 2020 related to the Agreement with Sarepta. The upfront payment is recognized over time as Hansa fulfils its performance obligations under the contract. The company recognized SEK 2.6M in revenue in Q4-2020 under the contract.

Other operating income and expenses

No other operating income was recorded for the fourth quarter 2020 (Q4'19: SEK 0.0m) and no other operating income was recorded for the full the year 2020 (full year '19: SEK 0.2). The other operating income 2019 comprise of a research grant from Vinnova. Other operating income and expense was SEK 3.8M for the fourth quarter 2020 (Q4'19: SEK -0.1m) and to SEK 2.3m for the full year of 2020 (full year '19: SEK -2.1m) and mainly represent foreign currency gain on net exposure in USD.

SG&A expenses

Sales, general and administration expenses for the fourth quarter 2020 amounted to SEK 63.2m (Q4'19: SEK 53.4m) and to SEK 203.0m for the full year of 2020 (full year '19: SEK 167.3m). The increase in expenses reflects the continuing activities related to preparing for a commercial launch of imlifidase. Recorded non-cash cost for the company's employee long-term incentive programs for the fourth quarter amounted to SEK 9.4m (Q4'19: SEK 2.9m) and SEK 29.2m for the full year of 2020 (full year '19: SEK 5.9m) is included in above SG&A expenses.

R&D expenses

Research and development expenses for the fourth quarter 2020 amounted to SEK 50.4m (Q4'19: SEK 57.7m) and to SEK 227.2m for the full year of 2020 (full year '19: SEK 192.9m) . Compared to the previous year, the higher expenses are due to ramp-up of activities within medical affairs, performing of studies in Guillain Barré Syndrome (GBS) and Antibody Mediated Rejection (AMR) and the development of the organization related to the commercial launch of imlifidase. Recorded non-cash cost for the company's employee long-term incentive programs amounting to SEK 3.9m for the fourth quarter (Q4'19: SEK 1.7m) and to SEK 14.1m for the full year of 2020 (full year '19: SEK 1.1m) is included in above R&D expenses.

Financial result

The operating result for the fourth quarter 2020 amounted to SEK -106.2m (Q4'19: SEK -110.1m) and to SEK -422.8m for the full year of 2020 (full year '19: SEK -359.7m).

Net loss for the fourth quarter 2020 amounted to SEK -105.8m (Q4'19: SEK -110.9m) and to SEK -420.9m for the full year of 2020 (full year '19: -360.0m).

Cash flow, cash and investments

Cash flow from operating activities for the fourth quarter 2020 amounted to SEK -96.5m (Q4'19: SEK -75.0m) and to SEK -290.3m for the full year of 2020 (full year '19: -334.8m).

Compared to the previous year, the lower cash consumption for the full year 2020 compared to the full year 2019 is mainly driven by the upfront payment of SEK 81.9m related to the Sarepta agreement. Eliminating this one time effect the operating cash consumption increased primarily due to preparatory activities throughout the organization related to the commercial launch of imlifidase and increased investments in ongoing R&D activities.

On 8 July 2020 the company announced the successful completion of its 4.4M share issuance resulting in net cash proceeds of SEK 1.1bn.

Cash and cash equivalents including short term investments amounted to SEK 1,377.5m on December 31, 2020 as compared to SEK 601.1m at the end of the year 2019.

Shareholders' equity

On December 31, 2020, equity amounted to SEK 1,241.8m as compared to SEK 562.8m at the end of the year 2019.

Parent Company

The parent company's net revenue for the fourth quarter of 2020 amounted to SEK 3.8m (Q4'19: SEK 1.2m) and to SEK 6.1m for the full year of 2020 (for full year '19: SEK 3.4m).

Loss for the parent company for the fourth quarter 2020 amounted to SEK -106.0m (Q4'19: SEK -111.0) and to SEK -421.6m for the full year of 2020 (full year '19: SEK -360.4m).

On December 31, 2020, cash and cash equivalents including short term investments amounted to SEK 1,371.8m compared to SEK 596.1m at the end of the year 2019.

The parent Company's equity amounted to SEK 1,241.8m as per December 31, 2020, as compared to SEK 562.8m at the end of year 2019.

The Group consists of the parent company Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd and Hansa Biopharma Inc. Hansa Biopharma Inc had three employees at the end of December 2020. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had two employees at the end of December 2020.

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Long-term incentive programs

Hansa Biopharma's past Annual General Meetings have resolved to adopt share-based long-term incentive programs (LTIPs). As of December 31, 2020, the following LTIPs were ongoing: LTIP 2018, LTIP 2019 and LTIP 2020.

The respective cost related to such ongoing programs are indicated in below table. For further information to the different LTIP programs please refer to Hansa Biopharma's 2019 Annual Report which can be found at www.hansabiopharma.com.

Ongoing programs	LTIP 2016	LTIP 2018	LTIP 2019	LTIP 2020
Maximum number of issuable shares*	-	789 321	1 154 463	1 011 376
Number of allocated and outstanding share rights and options	-	223 778	436 703	867 076
Number of acquired and outstanding warrants	-	6 701	11 000	-
Estimated total cost including social contributions, KSEK	-	25 481	42 141	120 739
Total cost per program, including social contributions, as of December 31 2020 YTD, KSEK	395	9 231	16 457	17 265

**Includes issuable shares to cover social contributions under the LTIP*

Total costs, including social contributions, as of 31 December 2020 YTD, KSEK	43 348

Risks and uncertainties

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

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

In the Annual Report 2019 (pages 35-37 ENG) the risks which are considered to have greatest significance for Hansa Biopharma's future development is described in more detail.

Other information

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Financial calendar 2021

April 8, 2021 - Annual Report 2020
April 22, 2021 - Interim report for Jan - Mar 2021
May 12, 2021 - Annual General Meeting 2021
July 15, 2021 - Interim report for Jan - Jun 2021
Oct. 21, 2021 - Interim report for Jan – Sep 2021

Legal disclaimer

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

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	45,894,909 (44,473,452 A-shares and 1,421,457 C-shares)
Market Cap Dec 31, 2020	SEK 11bn (USD ~1.25bn)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of December 31, 2020

Name	Number of shares	Ownership in pct
Redmile Group	4 625 590	10.4
Consonance Capital Management LP	2 212 527	5.0
NXT2B	2 155 379	4.8
Invesco	1 999 188	4.5
Handelsbanken Fonder AB	1 936 783	4.4
Thomas Olausson	1 770 474	4.0
Fourth Swedish National Pension Fund	1 564 846	3.5
Avanza Pension	1 257 577	2.8
Gladiator	1 025 000	2.3
ClearBridge, LLC	1 012 786	2.3
Other	24 913 302	56.0
Outstanding shares in total	44,473,452	100.0

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

As of December 31, 2020, Hansa Biopharma had approximately 17,000 shareholders.

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

Assurance

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

Lund February 4, 2021

Ulf Wiinberg
Chairman of the Board

Birgit Stattin Norinder
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 leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

Condensed unaudited financial statements

Consolidated income statement

	Q4		January-December	
KSEK	2020	2019	2020	2019
Revenue	3 828	1 203	6 098	3 364
Cost of revenue	-173	-160	-997	-866
Gross profit	**3 655**	**1 043**	**5 101**	**2 498**
Other operating income	-	-	-	166
Sales, general and administration expenses	-63 234	-53 421	-202 987	-167 310
Research and development expenses	-50 433	-57 659	-227 191	-192 949
Other operating expenses	3 826	-74	2 270	-2 073
Operating profit/loss	**-106 186**	**-110 111**	**-422 807**	**-359 668**
Financial income/expenses	346	-572	1 914	76
Profit/loss for the period before tax	**-105 840**	**-110 683**	**-420 893**	**-359 592**
Tax	9	-171	40	-417
Net profit/loss for the period	**-105 831**	**-110 855**	**-420 853**	**-360 009**
Attributable to:				
Parent company shareholders	-105 831	-110 855	-420 853	-360 009
Earnings per share (EPS)				
Before dilution (SEK)	-2,38	-2,77	-9,98	-9,00
After dilution (SEK)	-2,38	-2,77	-9,98	-9,00
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	-310	-11	-297	143
Changes in fair value on available-for-sale financial assets		-760	-	207
	-310	**-772**	**-297**	**350**
Items that cannot be reclassified to profit or loss for the period				
Shares valued to fair value as comprehensive income		-		49 597
Other comprehensive income for the period	**-310**	**-772**	**-297**	**49 947**
Total net comprehensive income	**-106 141**	**-111 627**	**-421 150**	**-310 062**

Consolidated statement of financial position

	December 31	
KSEK	2020	2019
ASSETS		
Non-current assets		
Intangible assets	31 410	33 348
Property and equipment	5 206	6 035
Leased assets	4 493	9 109
Total non-current assets	**41 109**	**48 493**
Current assets		
Inventories	98	-
Current receivables, non-interest bearing	15 783	14 650
Short-term investments	238 144	419 397
Cash and cash equivalents	1 139 362	181 697
Total current assets	**1 393 387**	**615 743**
TOTAL ASSETS	**1 434 496**	**664 236**
EQUITY AND LIABILITIES		
Shareholders' equity	**1 241 827**	**562 815**
Non-current liabilities		
Deferred tax liabilities	424	507
Provisions	14 426	818
Lease liabilities	630	4 827
Deferred revenue	62 026	-
Contingent consideration	663	730
Total non-current liabilities	**78 169**	**6 881**
Current liabilities		
Lease liabilities	4 415	4 632
Current liabilities, non-interest bearing	36 274	57 513
Deferred revenue	17 406	-
Accrued expenses and deferred income	56 405	32 395
Total current liabilities	**114 500**	**94 540**
TOTAL EQUITY AND LIABILITIES	**1 434 496**	**664 236**

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

Consolidated statements of changes in shareholder's equity

	Year	
KSEK	2020	2019
Opening balance of shareholders' equity as reported	**562 815**	**859 876**
Adjustment of the opening balance	-297	-
Adjusted opening balance of shareholders's equity	**562 518**	**859 876**
Result for the period	-420 853	-360 009
Other comprehensive income for the period	-297	49 947
Net comprehensive income	**-421 150**	**-310 062**
Transactions with the group's owner		
Proceeds from new share issuance, net	1 070 581	-6 930
Issued warrants	-	193
Long term incentive programs	29 878	17 268
Treasury shares acquired		-716
Treasury shares sold	-	877
Issuance of ordinary shares upon exercise of stock options	-	2 309
Total transactions with the group's owner	**1 100 459**	**13 001**
Closing balance of shareholders' equity	**1 241 827**	**562 815**

Consolidated statement of cash flow

	Q4		January-December	
KSEK	2020	2019	2020	2019
Operating activities				
Operating profit/loss	-106 186	-110 112	-422 807	-359 668
Adjustment for items not included in cash flow [1]	16 740	6 467	51 430	15 292
Interest received and paid, net	167	33	-68	-337
Income taxes paid	-	216	-	-123
Cash flow from operations before change in working capital	**-89 279**	**-103 396**	**-371 445**	**-344 835**
Changes in working capital	-7 243	28 410	81 171	10 061
Cash flow from operating activities	**-96 522**	**-74 986**	**-290 274**	**-334 775**
Investing activities				
Acquisition of intangible assets	-	-6	-	-729
Acquisition of property, plant and equipment	-	-1 368	-294	-2 699
Proceeds from sale of equipment	-	-	-	87
Sale of short term investments	-	-	182 828	-
Proceeds from sale of shares in Genovis	-	-	-	89 125
Cash flow from investing activities	**-**	**-1 374**	**182 534**	**85 784**
Financing activities				
Proceeds from new share issuance, net	-750	-	1 070 580	-7 646
Sale of treasury shares [2]	-	-	-	877
Exercise of Stock options	-	-	-	2 309
Loans raised	-	-24	-	-
Repayment of lease liabilities	-1 183	-1 121	-4 674	-4 424
Cash flow from financing activities	**-1 933**	**-1 144**	**1 065 906**	**-8 884**
Net change in cash	-98 456	-77 505	958 166	-257 875
Cash and cash equivalents, beginning of period	1 238 187	259 359	181 697	439 441
Currency exchange variance, cash and cash equivalents	-372	-157	-501	131
Cash and cash equivalents, end of period	**1 139 362**	**181 697**	**1 139 362**	**181 697**

1) Values are mainly costs of share based incentive programs including social contributions and depreciation.
2) In Q1 2019 50,000 shares where issued due to the TO 2015 program and 16,217 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program.

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Parent company – Income statement

	Q4		January-December	
KSEK	2020	2019	2020	2019
Revenue	3 828	1 203	6 098	3 364
Cost of revenue	-173	-160	-997	-866
Gross profit	**3 655**	**1 043**	**5 101**	**2 498**
Other operating income	-	-	-	166
Sales, general and administration expenses	-63 321	-54 478	-203 346	-168 520
Research and development expenses	-50 498	-56 905	-227 531	-192 565
Other operating expenses	3 806	-110	2 270	-2 052
Operating profit/loss	**-106 358**	**-110 451**	**-423 507**	**-360 474**
Result from sales of financial fixed assets				
Result from short term financial receivables	167	-560	1 782	511
Other financial expenses	219	-11	81	-435
Loss for the period before tax	-105 972	-111 022	-421 644	-360 398
Income tax benefit/expense	-	-	-	-
Loss for the period after tax	**-105 972**	**-111 022**	**-421 644**	**-360 398**
Other comprehensive income				
Change in fair value of financial assets	-	-760	-	49 804
Other comprehensive income for the period	**-**	**-760**	**-**	**49 804**
Total comprehensive income for the period	**-105 972**	**-111 782**	**-421 644**	**-310 594**

Parent company – Statement of changes in shareholders' equity

	December 31	
KSEK	2020	2019
Opening shareholders' equity as reported	562 763	**833 270**
Adjustment of the opening balance due to change in accounting policy	-207	**27 030**
Adjusted opening balance of shareholders's equity	**562 556**	**860 300**
Result for the period	-421 644	-360 398
Other comprehensive income for the period	-	**49 804**
Net comprehensive income	-421 644	-310 594
New share issue	1 070 581	-6 930
Issued warrants	-	193
Long term incentive programs	29 878	17 324
Treasury shares acquired		-716
Treasury shares sold	-	877
Issuance of ordinary shares upon exercise of stock options	-	2 309
Total transactions with the group's owner	**1 100 459**	**13 057**
Closing shareholders' equity	**1 241 371**	**562 763**

Parent company – Statement of financial position

	31-Dec	
KSEK	2020	2019
ASSETS		
Non-current assets		
Intangible assets	29 171	29 522
Property, plant and equipment	5 206	6 035
Leased assets	4 493	9 109
Investment in subsidiaries	5 095	5 095
Receivables, group companies	1 972	2 244
Total non-current assets	**45 937**	**52 005**
Current assets		
Receivables, group companies	-	1 061
Inventories	98	-
Current receivables, non-interest bearing	15 268	14 369
Short-term investments	238 144	419 397
Cash and cash equivalents	1 133 647	176 715
Total current assets	**1 387 157**	**611 542**
TOTAL ASSETS	**1 433 094**	**663 547**
EQUITY AND LIABILITIES		
Shareholders' equity	**1 241 371**	562 763
Non-current liabilities		
Provisions	14 426	818
Lease liabilities	630	4 827
Deferred revenue	62 026	-
Contingent consideration	663	730
Total non-current liabilities	**77 745**	**6 375**
Current liabilities		
Lease liabilities	4 415	4 632
Liabilities, group companies	1 613	2 793
Current liabilities, non-interest bearing	34 950	56 883
Deferred revenue	17 406	-
Accrued expenses and deferred income	55 594	30 102
Total current liabilities	**113 978**	**94 410**
TOTAL EQUITY AND LIABILITIES	**1 433 094**	**663 547**

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

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. The Annual report 2019 was published on April 2, 2020 and is available on 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.

Change in accounting principles for the Parent Company

During previous periods, Hansa Biopharma has used the exemptions provided in RFR 2 Accounting for legal entities that allow a parent company not to apply IFRS 9 Financial instruments and IFRS 16 Leases in its financial statements. In order to provide more relevant information about financial instruments and leases in the parent company, Hansa Biopharma has chosen to apply IFRS 9 and IFRS 16 in the parent company. The accounting principles for financial instruments and for leases are therefore the same in the parent company as in the Group.

The change in accounting principle has been applied retrospectively and comparative periods for 2019 have been restated for the parent company

Effects of the change to IFRS 9

The change to IFRS 9 led to an increase in the opening balance of equity as per 1 January 2019 amounting to SEK 27,030k. The change to IFRS 9 led to an increase in other comprehensive income of SEK 967k for Q4-2019 and 49,804k for the full year 2019, while profit and loss changed by -76,626k for the full year 2019.

The change led to an increase in the balance sheet of investment in Genovis AB at 1 January 2019 of SEK 27,030k and the contra entry was recorded in equity. The investment in Genovis was sold in April 2019.

The change led to an increase in the balance sheet of short-term investment at 31 December 2019 amounting to SEK 207k.

There was no change in the statement of cash flows.

Effects of the change to IFRS 16

The change to IFRS 16 led to the parent company recognizing leasing liabilities of SEK 13,354k and right-of-use assets of SEK 13,354k as per 1 January 2019. Per 31 December 2019, the leasing liabilities amounted to SEK 9,459k and right-of-use assets to SEK 9,109k.

The change to IFRS 16 led to the parent company recognizing leasing liabilities of SEK 9,459k and right-of-use assets of SEK 9,109k as per 31 December 2019.

The change to IFRS 16 led to an impact on the statement of profit or loss for the parent company for the full year 2019 of depreciation amounting to SEK -4,680k and interest expenses amounting to SEK -376k and partly offset by lease expenses amounting SEK 4,708k for the full year 2019. The net impact on the profit and loss before tax was SEK 348k.

The change to IFRS 16 led to an impact on the statement of profit or loss for the parent company for Q4 2019 of depreciation amounting to SEK -879k and interest expenses amounting to SEK -55k and partly offset by lease expenses amounting SEK 865k in the fourth quarter of 2019. The net impact on the profit and loss before tax was SEK 69k

For further information for the Groups transition to IFRS 16, see note 1 in the 2019 Annual Report.

Note 2 Revenue

Income per significant category of income		Q4		12M	
KSEK		2020	2019	2020	2019
Group					
Revenue					
	Contract revenue, Axis-Shield agreement	1 117	1139	2 864	2 838
	Cost reimbursement, Axis-Shield agreement	113	64	636	526
	Contract revenue, Sarepta agreement	2 599	-	2 599	-
		3 828	1 203	6 098	3 364
Parent company					
Revenue:					
	Contract revenue, Axis-Shield agreement	1 117	1139	2 864	2 838
	Cost reimbursement, Axis-Shield agreement	113	64	636	526
	Contract revenue, Sarepta agreement	2 599	-	2 599	-
		3 828	1 203	6 098	3 364

The company received USD 10M (SEK 81.9M) upfront payment in July 2020 related to the License agreement with Sarepta Therapeutics. The upfront payment is recognized over time as Hansa fulfils its performance obligations under the contract. The company recognized SEK 2.6M in revenue in Q4-2020 under the contract.

Note 3 Fair value of financial instruments

The Group measures its investments in interest funds and its financial liability for contingent consideration at fair value. The fair value of interest funds at December 31, 2020 amounted to SEK 238.1 million (Q4'19: SEK 419.4 million) and belonged to level 2 in the fair value hierarchy. The fair value of the financial liability for contingent consideration at December 31, 2020 amounted to SEK 0.7 million (Q4'19: SEK 0.7 million) and belongs to level 3 in the fair value hierarchy. All other financial instruments are measured at amortized cost. The carrying values of those instruments are considered reasonable approximations of their fair values.

Glossary

AMR
Antibody mediated rejection of a transplanted organ.

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

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

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

B-cells
B-cells, also known as B-lymphocytes, are a type of white blood cell of the lymphocyte subtype. They are an important part of the adaptive immune system and secrete antibodies.

Biologics License Application (BLA)
A Biologics License Application (BLA) is submitted to the Food and Drug Administration (FDA) to obtain permission for distribution of a biologic product across the United States.

Biopharmaceutical
A pharmaceutical drug that is manufactured using biotechnology.

Biotechnology
The use of live cells or components of cells, to produce or modify products used in health care, food, and agriculture.

Clinical Phase 1
The first time a drug under development is administered to humans. Phase 1 studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical Phase 2
Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical Phase 3
Trials that involve many patients and often continue for a longer time; they are intended to identify the drug's effects and side effects during ordinary but still carefully controlled conditions.

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

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

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

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

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

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

Imlifidase
imlifidase (INN), previously known as Immunoglobulin G-degrading enzyme of Streptococcus pyogenes (IdeS), is a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

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

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

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