INTERIM REPORT JANUARY – SEPTEMBER 2019

Positive results from a pooled analysis in highly sensitized patients

Highlights for the third quarter 2019

- Positive results from a pooled analysis of Phase 2 trials with imlifidase for desensitization in highly sensitized kidney transplant patients were presented for the first time at the European Society of Organ Transplantation's (ESOT) Congress on September 17. Imlifidase enabled kidney transplantation in 46 sensitized patients. The data presented was fully in line with previously reported data on transplantation of highly sensitized patients with imlifidase.
- Hansa Biopharma continued to advance imlifidase towards a potential marketing approval in the EU. A Marketing Authorization Application (MAA) for imlifidase for enabling kidney transplantation in highly sensitized patients is currently under review by the European Medicines Agency, EMA. An opinion from the Committee for Medicinal Products for Human Use is expected during the first half of 2020.
- In the United States, a follow-up meeting with the U.S. Food and Drug Administration (FDA) has been scheduled. At the meeting, the Company intends to continue the discussion from the December 2018 meeting regarding the path forward for a regulatory filing for imlifidase in kidney transplantation of highly sensitized patients in the U.S. The meeting will take place on November 20th, 2019. Minutes from the FDA meeting expected by end-of-December 2019.
- Our pipeline has advanced with the first patient treated within our Phase 2 study in acute Antibody Mediated Rejection (AMR). In the Anti-GBM study we enrolled 11 patients at the end of the third quarter.
- Hansa Biopharma continued building its' medical and commercial organization to support a potential commercial launch of imlifidase in 2020: Investments in R&D and SG&A increased in the third quarter to SEK 47m (Q3'18: SEK 36m) and SEK 46m (SEK 24m) respectively.
- Cash flow from operating activities for the third quarter ended at SEK -80m (SEK -54m); the Company's cash position was SEK 680m at the end of September 2019.

Financial Summary

SEKm, unless otherwise stated	Q3 2019	Q3 2018	9M 2019	9M 2018
Net Revenue	0.7	0.5	2.2	2.0
SG&A expenses	-45.9	-23.8	-113.9	-54.1
R&D expenses	-47.2	-36.4	-135.3	-111.9
Other operating income/expenses	-0.5	-0.7	-1.8	-1.7
Operating profit/loss	**-93.2**	**-60.5**	**-249.6**	**-165.9**
Net profit/loss	-94.3	-61.5	-249.2	-166.7
Cash flow from operating activities	-80.2	-54.0	-259.8	-147.1
Cash and short-term investments Sep 30, 2019	**680.2**	**483.4**	**680.2**	**483.4**
Shareholders' equity, Sep 30, 2019	668.1	506.3	668.1	506.3
EPS before and after dilution Sep 30, 2019 (SEK)	-2.36	-1.61	-6.23	-4.38
Number of outstanding shares, Sep 30, 2019	40,026,107	38,133,125	40,026,107	38,133,125
Weighted average number of shares before and after dilution, Sep 30, 2019	40,026,107	38,214,480	40,018,515	38,047,377
Number of employees, Sep 30, 2019	64	49	64	49

Hansa Biopharma is leveraging its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product candidate, imlifidase, is a unique antibody-cleaving enzyme that potentially may enable kidney transplantation in highly sensitized patients with potential for further development in other solid organ transplantation and acute autoimmune indications. Imlifidase is currently under review for marketing authorization by EMA. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in Europe and US.

Søren Tulstrup, President and CEO, comments

"Hansa Biopharma's evolution into a fully integrated, commercial biopharmaceutical company continues according to plan. During the first nine months of 2019 we made solid progress across the organization with the expansion of our global footprint, advancements in our pipeline and continued engagements with the healthcare community in transplantation, autoimmune diseases and beyond.

Our top priority is advancing our lead candidate, imlifidase, through market authorization to enable kidney transplants for highly sensitized patients. At the same time, we continue to develop our proprietary enzyme technology platform in rare autoimmune diseases, where there is a significant unmet medical need.

In September, Hansa Biopharma presented positive imlifidase data at the ESOT Congress in Copenhagen, Denmark. The data was based on a pooled analysis of highly sensitized kidney transplant patients from four single arm, 6-month, open label, Phase 2 trials of imlifidase treatment prior to deceased and living donor transplantation in sensitized patients. The analysis included 46 patients, of which 50% had a cPRA of 100%, 85% were crossmatch positive and 70% were re-transplanted. Following the treatment of imlifidase, the donor specific antibodies (DSA) levels rapidly decreased and all positive crossmatches were converted to negative, thus enabling transplantation of all patients. The data was fully in line with previously reported data on transplantation of highly sensitized patients with imlifidase.

In Europe, the regulatory review process for imlifidase is progressing as planned, following the acceptance of our Marketing Authorization Application end of February. We expect to receive an opinion from the committee for medical products of European Medicines Agency in the first half of 2020.

In the U.S., we recently confirmed a follow-up meeting with the FDA. The purpose of the meeting will be to continue the discussion from our December 2018 meeting regarding the path forward for a regulatory filing of imlifidase in kidney transplantation of highly sensitized patients in the U.S.

Talking about the U.S., we welcome the initiative by the current administration in the United States, who recently issued an executive order to improve the care of people with end stage renal disease (ESRD). Following the executive order, the U.S. Department of Health and Human Services (HHS) set out three specific goals for ESRD:

1) *Reducing the number of Americans developing ESRD by 25 percent by 2030*
2) *Having 80 percent of new ESRD patients in 2025 either receiving a transplant or homecare dialysis*
3) *Doubling the number of kidneys available for transplant by 2030*

In the U.S., approximately 37 million people have chronic kidney disease and more than 700,000 have ESRD. There are nearly 100,000 Americans waiting to receive a kidney transplant, and approximately 20% of the money spent on traditional Medicare in the U.S. are related to kidney disease. If approved, imlifidase may have the potential to help highly sensitized patients getting off dialysis by enabling transplantation.

We have also continued advancing our pipeline during the first 9 months of 2019, with the initiation of two Phase 2 studies in Guillain-Barré Syndrome (GBS) and acute Antibody Mediated Rejection (AMR) in kidney transplantation. In AMR, the first patient has now been treated with imlifidase. Our Anti-Glomerular Basement Membrane (Anti-GBM) program is also progressing as expected, with 11 patients enrolled so far and it's our aim to complete enrollment in this study by year-end.

With the continued progress across the organization and significant progress for our lead candidate and pipeline activities, we are well-positioned to become a global biopharmaceutical company that brings lifesaving and life altering therapies to patients with rare diseases who need them and generate value to society at large. I look forward to updating you on our continued progress."

Søren Tulstrup
President and CEO, Hansa Biopharma

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Continuous development in our pipeline activities

Candidate/ Project	Indications	Research/ Preclinical	Phase 1	Phase 2/ Pivotal program	Marketing Authorization	Marketed	Next Anticipated Milestone
THERAPEUTICS							
Imlifidase	Kidney transplantation in highly sensitized patients				*)		MAA review by EMA / Follow-up meeting with FDA Nov 20, 2019
	Anti-GBM antibody disease						Complete enrolment of 15 patients
	Antibody mediated kidney transplant rejection (AMR)						Complete enrolment of 30 patients
	Guillain-Barré syndrome (GBS)						Complete enrolment of 30 patients
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology						Development of CMC process / Tox studies
EnzE	Cancer immunotherapy						Research phase

Completed Ongoing

*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2. A confirmatory study would need to be executed in case of approval.

FDA: Discussion on path forward in the US is still ongoing.

Ongoing clinical studies with imlifidase

Imlifidase in kidney transplantation

Completed a Phase 2 program, which created the basis for an MAA filing in EU and interactions with FDA in relation to a potential Biologic License Application (BLA) filing.

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

An open-label, investigator-initiated, Phase 2 study in severe anti-GBM antibody disease with imlifidase. 11 of the targeted 15 patients with this ultra-rare disease have been enrolled in the study, which aims to evaluate the safety and tolerability of imlifidase and to assess efficacy based on renal function at six months after treatment.

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

The first patient in our AMR Phase 2 study was recently treated with imlifidase following CTA approval back in the spring 2019. The study aims to enroll approximately 30 patients at eight clinical trial centers in France, Sweden, Austria, Australia and the U.S. It is a randomized, open-label, multi-center, controlled study against plasma exchange, designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in the treatment of active episodes of acute AMR in kidney transplant patients.

Guillain-Barré Syndrome (GBS) (ClinicalTrials.gov ID: NCT03943589)

Imlifidase in GBS entered early stage clinical development following CTA approval in Europe in the spring 2019. The study aims to enroll up to 30 patients at approximately ten clinical trial centers in France, U.K. and the Netherlands. It is 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).

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Latest developments in our clinical program

Enabling kidney transplantation for highly sensitized patients

Hansa Biopharma continues to advance imlifidase towards marketing authorization for enabling kidney transplantation in highly sensitized patients in the EU and the U.S.

The Marketing Authorization Application (MAA) for imlifidase is currently under review by the European Medicines Agency (EMA). The submission of the MAA was accepted by EMA at the end of February 2019 and an opinion from the CHMP is expected in the first half of 2020. After adoption of a CHMP opinion, a final decision will be made by the European Commission within approximately two to three months.

In the U.S. Hansa Biopharma has recently scheduled a follow-up meeting with the FDA on November 20, 2019 to continue the discussion on the regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients in the U.S. Since the last meeting in December 2018, Hansa Biopharma has conducted complementary analyses to illustrate the potential value that imlifidase brings to highly sensitized patients in the U.S.

At the 19th European Society of Organ Transplantation (ESOT) Congress in September, Lena Winstedt, PhD, Head of Science at Hansa Biopharma, presented positive results from a pooled analysis of Phase 2 trials with imlifidase for desensitization in sensitized kidney transplant patients.

The data was based on a pooled analysis of sensitized kidney transplant patients from four single arm, 6-month, open label, Phase 2 trials of imlifidase treatment, prior to deceased and living donor transplantation in sensitized patients. The analysis included 46 patients, of which 50% had a cPRA of 100%, 85% were crossmatch positive and 70% were re-transplanted. Following imlifidase treatment, patients' DSA levels rapidly decreased and all crossmatches were converted to negative, thus enabling transplantation of all patients. The results were fully in line with previously reported data on transplantation of highly sensitized patients with imlifidase.

While the majority of patients had DSA rebound post transplantation, there was no strong correlation between DSA levels and antibody mediated rejection (AMR) episodes. AMR episodes occurred in 33% of patients and were all treated with standard of care therapy. This is within the range of what has previously been reported after transplantation of highly sensitized patients.

Treatment in anti-GBM antibody disease

To date, eleven patients have been treated with imlifidase in the anti-GBM Phase 2 study. Additional sites have been added to this study, which will continue to actively recruit patients with this ultra-rare disease. Completion of patient enrollment is anticipated by the end of 2019.

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Treatment of acute AMR in kidney transplantation

Acute AMR is one of the most challenging adverse events after kidney transplantation and is the main cause for graft dysfunction.[1]

Hansa initiated a Phase 2 study in AMR in the spring 2019 and the first patient was recently treated with imlifidase. The AMR study aims to recruit approximately 30 patients from eight sites in the U.S., France, Sweden, Austria and Australia. It is a randomized, open-label, multi-center, controlled study against plasma exchange, 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.

Treatment of Guillian-Barré syndrome

Hansa received Clinical Trial Application and Ethics Committee approvals for the Company's Phase 2 study of imlifidase in GBS in the spring 2019. GBS is a rare, acute inflammatory disease of the peripheral nervous system that affects 1-2 in 100,000 people annually.[2]

The Phase 2 study aims to recruit up to 30 patients at approximately ten European sites. It is 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 IVIg. Patients will be compared to matched controls from the International GBS Outcome Study (IGOS).

Preclinical development projects

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.

In March 2019 Hansa announced that a lead candidate for clinical development has been selected. This is the first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development. 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.

EnzE – Enzyme-based antibody Enhancement

Published findings[3] 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.

1 Puttarajappa et al., "Antibody-Mediated Rejection in Kidney Transplantation: A Review", J. Transplant.Volume 2012 (2012), Article ID 193724
2 McGrogan et al., "The Epidemiology of Guillain-Barré Syndrome Worldwide ", Neuroepidemiology;2009, 32(2):150-63
3 Järnum et al., "Enzymatic inactivation of endogenous IgG by IdeS enhances therapeutic antibody efficacy", Molecular Cancer Therapeutics, 2017, Sep; 16(9):1887-1897

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Financial review January – September 2019

Net revenue

Net revenue for the third quarter 2019 amounted to SEK 0.7m (SEK 0.5m) and to SEK 2.2m for the first 9 months of 2019 (SEK 2.0m) and comprises of royalty income from Axis-Shield Diagnostics and patent reimbursements.

Other operating income and expenses

No other operating income for the third quarter 2019 (SEK 0.4m). For the first nine months of 2019 other operating income amounted to SEK 0.2m (SEK 0.7m) and is comprised of a research grant from Vinnova. Other operating expense, comprised of net currency differences, amounted to SEK 0.5m (SEK 1.1m) for the third quarter 2019 and to SEK 2.0m (SEK 2.4m) for the first nine months of 2019.

SG&A expenses

Sales, general and administration expenses for the third quarter 2019 amounted to SEK 45.9m (SEK 23.8m) and to SEK 113.9m (SEK 54.1m) for the first nine months of 2019. The increase in expenses reflects the continuing activities related to the ramp-up of the organization in preparation of a potential commercial launch of imlifidase. Recorded non-cash cost for the company's employee long-term incentive programs (LTIP 2016, LTIP 2018 and LTIP 2019) amounting to SEK 2.5m (SEK 4.8m) for the third quarter and to SEK 2.9m (SEK 10.3m) for the first nine months is included in above SG&A expenses.

As new IFRS 16 Lease agreement replaces the previous standard IAS 17 from January 1, 2019, the effect of the new principle is marginal for the year to date 2019 compared with the previous year.

R&D expenses

Research and development expenses amounted to SEK 47.2m (SEK 36.4m) for the third quarter 2019 and to SEK 135.3m (SEK 111.9m) for the first nine months of 2019. Recorded non-cash cost for the company's employee long-term incentive programs (LTIP 2016, LTIP 2018 and LTIP 2019) amounting to SEK 0.9m (SEK 0) for the third quarter and to SEK -0.6m (SEK 4.4m) for the first nine months of 2019 is included in above R&D expenses. Compared to the previous year, the higher expenses are due to ramp-up of activities within medical affairs and the development of the organization related to the potential commercial launch of imlifidase.

As new IFRS 16 Lease agreement replaces the previous standard IAS 17 from January 1, 2019, the effect of the new principle is marginal for the year to date 2019 compared to the previous year.

Financial result

Operating result for the third quarter 2019 amounted to SEK -93.2m (SEK -60.5m) and SEK -249.6m (SEK -165.9m) for the first nine months of 2019.

Net profit/loss for the third quarter 2019 amounted to SEK -94.3m (SEK-61.5m) and to SEK -249.2m (SEK -166.7m) for the first nine months of 2019.

Cash flow, cash and investments

Cash flow from operating activities amounted to SEK -80.2m (SEK -54.0m) for the third quarter 2019 and to SEK -259.8m (SEK -147.1m) for the first nine months of 2019. Compared to the previous year, the higher cash consumption is due to ramp-up of activities throughout the organization related to a potential commercial launch of imlifidase. As new IFRS 16 Lease agreement replaces the previous standard IAS 17 from January 1, 2019, the effect of the new principle on the cash flow statement is that cash flow from operating activities is higher and cash flow from financing activities is lower by SEK 3.3m due to the fact that the leasing fees' amortization part is reported as payment in the financing activities.

Cash flow was positively impacted by the divestment of the equity holding in Genovis, which generated gross proceeds of SEK 89.1m in April 2019.

Cash and cash equivalents including short term investments amounted to SEK 680.2m on September 30, 2019, as compared to SEK 762.7m at the end of the second quarter 2019.

Shareholders' equity

On September 30, 2019 equity amounted to SEK 668.1m compared to SEK 506.3m at the end of the corresponding period 2018.

Parent Company

The parent company's net revenue for the third quarter 2019 amounted to SEK 0.7m (SEK 0.5m) and to SEK 2.2m (SEK 2.2m) for the first nine months of 2019. Profit/loss for the parent company amounted to SEK -94.1m (SEK -61.5m) for the third quarter and to SEK -172.5m (SEK -167.0m) for the first nine months 2019. The gain from the divestment of the equity holding in Genovis was realized in the second quarter.

On September 30, 2019, cash and cash equivalents including short term investments amounted to SEK 673.2m compared to SEK 757.5m at the end of the second quarter 2019.

The parent company's equity amounted to SEK 667.5m as per September 30, 2019, as compared to SEK 479.0m at the end of the corresponding period 2018.

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 four employees at the end of September 2019. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had at the end of September 2019 two employees.

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Long-term incentive programs

Ongoing programs	LTIP 2016	LTIP 2018	LTIP 2019
Maximum number of issuable shares incl social contributions	305 000	789 321	1 154 463
Number of allocated and outstanding share rights and options	198 250	238 638	437 875
Number of acquired and outstanding warrants	-	6 701	11 000
Estimated total cost including social contributions, KSEK	13 137	23 003	46 130
Cost including social contributions Q3-2019 ytd, KSEK	-6 983	4 188	5 128

LTIP 2019

The Hansa Biopharma Annual General Meeting (the "AGM") on May 22, 2019 resolved to adopt a long-term incentive program, LTIP 2019.

Under the terms of LTIP 2019 key employees may participate in the program and may receive so-called performance-based share awards free-of charge (a "Share Right) which, provided certain pre-defined Performance Conditions (as briefly summarized below) and other criteria are met, give the participants the right to acquire ordinary shares in Hansa Biopharma (a "Performance Share") at no cost. Each Share Right represents the right to acquire one Performance Share and shall carry a vesting period of three years commencing on the day of its allotment to a participant (the "Vesting Period").

The final number of Performance Shares a participant is entitled to receive is, amongst other terms, conditional upon meeting the following performance conditions during the Vesting Period (the "Performance Conditions"):

- Condition 1: Obtain market approval in the EU by EMA
- Condition 2: Obtain market approval in the United States by the FDA
- Condition 3: Total shareholder return of at least 25%

A maximum of 550,699 Share Rights may be allotted to participants under the LTIP 2019 from the day following the 2019 AGM up and until the day prior to the AGM in 2020.

In order to fund LTIP 2019 (including social security charges), the 2019 AGM further resolved to authorize the Hansa Biopharma Board of Directors to issue a maximum of 715,910 Class C shares which may be converted to ordinary shares whereby the Company's share capital may not be increased by more than SEK 715,910. The Class C shares were issued on September 2, 2019.

The maximum dilution under the LTIP 2019 is expected to amount to approximately 1.79%on a fully diluted basis.

Expenses related to LTIP 2019 will be reported in accordance with IFRS 2. Please refer to the table above for further information.

Share option program 2019 (the "SOP 2019")

The 2019 AGM resolved to adopt a share option program, SOP 2019.

The SOP 2019 consists of two option series: Series 1 - Warrants, and Series 2 - Employee Stock Options.

Series 1 consists of not more than 169,848 Warrants that can be transferred to senior executives who are taxable in Sweden. The Warrants can be exercised after approximately three years, after which the holder is entitled to exercise the Warrants to subscribe for ordinary shares during a period of one month. Each Warrant entitles the holder to subscribe for one new ordinary share in Hansa Biopharma. The transfer to participants is made at a price corresponding to the market value of the warrants at the time of transfer. The Company will, pre taxation, subsidy up to 100 per cent of the price for the transfer of the warrants through a one-time cash bonus offered to participants.

Series 2 consists of not more than 268,705 Employee Stock Options that can be allotted to senior executives. The Employee Stock Options have a vesting period of three years, after which the holder is entitled to exercise the options during a period of one month. Each Employee Stock Option entitles the holder to subscribe for one new ordinary share in Hansa Biopharma. The options are allotted free of charge.

Each Warrant or Employee Stock Option entitles the holder to receive one new ordinary share in Hansa Biopharma at a subscription price corresponding to 110 per cent of the volume weighted average share price during the 10 trading days immediately prior to the offer to subscribe for the warrants.

In order to fund SOP 2019 (including resulting social security charges), the 2019 AGM further resolved to authorize the Board to issue a maximum of 438,553 ordinary shares, whereby the Company's share capital may not be increased by more than SEK 438,553.

The maximum dilution under the SOP 2019 is expected to amount to approximately 1.52% on a fully diluted basis. Expenses related to SOP 2019 will be reported in accordance with IFRS 2. Please refer to the table above for further information.

Please refer to the Company's 2019 AGM Notice on www.hansabiopharma.com for further information regarding the LTIP 2019 and SOP 2019.

Previous years' long-term incentive programs

The Company has adopted long-term incentive programs LTIP 2015 (ended June 15, 2019), LTIP 2016 and LTIP 2018.

For further information on such programs please refer to the Annual Report 2018, page 62-66 and 94-95 (ENG version).

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 2018 (page 35-36 ENG) the risks which are considered to have greatest significance for Hansa Biopharma' future development are described in more detail.

Other information

Financial calendar 2020

February 6, 2020 - Interim report for Jan – Dec. 2019
April 2, 2020 - Annual Report 2019
April 28, 2020 - Interim report for Jan – Mar. 2020

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Legal disclaimer

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

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	41,447,564 (40,026,107 A-shares and 1,421,457 C-shares)
Market Cap. September 30, 2019	SEK 5,388m
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of September 30, 2019

Name	Number of shares	Ownership in pct
NXT2B	5 757 659	14.4
Invesco	2 659 217	6.6
Thomas Olausson	1 617 654	4.0
Handelsbanken Funds	1 511 766	3.8
Avanza Pension	1 309 565	3.3
Fourth Swedish National Pension Fund	1 067 044	2.7
Norron Funds	959 557	2.4
AFA Insurance	953 734	2.4
Vanguard	909 375	2.3
Gladiator	900 000	2.2
Other	22 380 536	55.9
Outstanding shares in total	40 026 107	100.0

Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

As of September 30, 2019, Hansa Biopharma had 12,582 shareholders.

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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.

Lund October 31, 2019

Ulf Wiinberg
Chairman of the Board

Eva Nilsagård
Chairman of the Audit Committee

Søren Tulstrup
President & CEO

Hansa Biopharma is leveraging its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product candidate, imlifidase, is a unique antibody-cleaving enzyme that potentially may enable kidney transplantation in highly sensitized patients with potential for further development in other solid organ transplantation and acute autoimmune indications. Imlifidase is currently under review for marketing authorization by EMA. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in Europe and US.

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 2019 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.

Malmö 31 October 2019

KPMG AB

Jonas Nihlberg

Authorized Public Accountant

Condensed financial statements
Consolidated statement of comprehensive income

	Q3		January-September	
KSEK	2019	2018	2019	2018
Net revenue	652	484	2 161	1 972
Direct cost of net revenue	-208	-50	-706	-151
Gross profit	**444**	**434**	**1 455**	**1 821**
Other operating income	-	370	166	671
Sales, general and administration expenses	-45 936	-23 797	-113 888	-54 102
Research and development expenses	-47 155	-36 424	-135 290	-111 923
Other operating expenses	-545	-1 086	-1 999	-2 360
Operating profit/loss	**-93 192**	**-60 503**	**-249 556**	**-165 893**
Financial income/expenses	-947	-958	648	-882
Profit/loss for the period before tax	**-94 139**	**-61 461**	**-248 908**	**-166 775**
Tax	-125	10	-246	30
Net profit/loss for the period	**-94 264**	**-61 451**	**-249 154**	**-166 745**
Attributable to:				
Parent company shareholders	-94 264	-61 451	-249 154	-166 745
Earnings per share (EPS)				
Before dilution (SEK)	-2.36	-1.61	-6.23	-4.38
After dilution (SEK)	-2.36	-1.61	-6.23	-4.38
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	76	-23	154	92
Changes in fair value on available-for-sale financial assets	967	-	967	-
Items that cannot be reclassified to profit or loss for the year				
Shares valued to fair value as comprehensive income	-	18 621	49 598	21 828
Other comprehensive income for the year	**1 043**	**18 598**	**50 719**	**21 920**
Total net comprehensive income	**-93 221**	**-42 853**	**-198 435**	**-144 825**

Consolidated balance sheet

	September 30		December 31
KSEK	2019	2018	2018
ASSETS			
Non-current assets			
Intangible fixed assets	33 497	33 395	33 197
Tangible fixed assets	4 962	5 605	5 876
Leased fixed assets	11 124	-	-
Financial fixed assets	-	40 328	39 528
Total non-current assets	**49 583**	**79 328**	**78 601**
Current assets			
Current receivables, non-interest bearing	5 607	7 257	8 033
Short-term investments	420 805	429 343	418 746
Cash and cash equivalents	259 359	54 060	439 441
Total current assets	**685 771**	**490 660**	**866 220**
TOTAL ASSETS	**735 355**	**569 988**	**944 821**
EQUITY AND LIABILITIES			
Shareholders' equity	**668 115**	**506 302**	**859 876**
Long term liabilities			
Deferred tax liabilities	451	531	511
Other provisions	3 096	11 969	10 948
Long term leasing liabilities, interest bearing	5 310	-	-
Other long term liabilities, interest bearing	778	1 177	1 155
Total long term liabilities	**9 635**	**13 677**	**12 614**
Current liabilities			
Current liabilities, non-interest bearing	28 508	15 453	46 089
Current leasing liabilities, interest bearing	5 098	-	-
Accrued expenses and deferred income	23 999	34 556	26 242
Total current liabilities	57 605	50 009	72 331
TOTAL EQUITY AND LIABILITIES	**735 355**	**569 988**	**944 821**

Hansa Biopharma is leveraging its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product candidate, imlifidase, is a unique antibody-cleaving enzyme that potentially may enable kidney transplantation in highly sensitized patients with potential for further development in other solid organ transplantation and acute autoimmune indications. Imlifidase is currently under review for marketing authorization by EMA. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in Europe and US.

Consolidated changes in equity

KSEK	January-September 2019	January-September 2018	Year 2018
Shareholders' equity	**859 876**	**630 661**	**630 661**
Result for the period	-249 154	-166 745	-247 974
Other comprehensive income for the period	50 719	21 920	21 094
Net comprehensive income	**-198 435**	**-144 825**	**-226 880**
Transactions with the group's owner			
New share issue [1]	2 309	-	453 075
Expenses attributable to new share issue [2]	-7 646	-1 150	-20 712
Sales own shares [1]	877	4 473	4 474
Issued warrants	111	340	354
Long term incentive programs	11 023	3 288	5 390
By employees redeemed stock options	-	11 271	13 514
New share issue during registration	-	2 243	-
Total transactions with the group's owner	**6 674**	**20 466**	**456 095**
Closing shareholders' equity	**668 115**	**506 302**	**859 876**

1) Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares. 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.
2) 2019 expenses relate to the directed share issue in 2018 (KSEK -7,586) and the LTIPs (KSEK -60)

Consolidated cash flow statement

KSEK	Q3 2019	Q3 2018	January-September 2019	January-September 2018
Operating activities				
Operating profit/loss	-93 192	-60 503	-249 556	-165 893
Adjustment for items not included in cash flow [1]	6 149	9 922	8 825	12 205
Interest received and paid, net	-122	-225	-370	-582
Income taxes paid	-156	-	-339	-
Cash flow from operations before change in working capital	**-87 321**	**-50 806**	**-241 440**	**-154 270**
Change in working capital	7 113	-3 205	-18 349	7 176
Cash flow from operating activities	**-80 208**	**-54 011**	**-259 789**	**-147 094**
Investing activities				
Investments in intangible fixed assets	-723	-	-723	-24
Investments in tangible fixed assets	-407	-149	-1 331	-1 753
Divestment of tangible fixed assets	-	-	87	-
Divestment of financial assets	-	-	89 125	-
Short term investments	-	-	-	-493 984
Divestment short term investments	-	44 000	-	99 000
Cash flow from investing activities	**-1 130**	**43 851**	**87 158**	**-396 761**
Financing activities				
Issue expenses	-60	-80	-7 646	-1 150
Sales of own shares [2]	-	-	877	4 473
By employees redeemed stock options	10	4 195	2 309	13 246
Issued warrants	-	-	-	268
Loans raised	24	-	24	-
Repayment of leasing liabilities	-1 515	-	-3 303	-
Cash flow from financing activities	**-1 541**	**4 115**	**-7 739**	**16 837**
Net change in cash	**-82 879**	**-6 045**	**-180 370**	**-527 018**
Cash and cash equivalents, beginning of period	**342 076**	**60 105**	**439 441**	**581 078**
Currency exchange variance, cash and cash equivalents	162	-	288	-
Cash and cash equivalents, end of period	**259 359**	**54 060**	**259 359**	**54 060**

1) Values are mainly costs of share based incentive programs including social contributions.
2) Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares. 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.

Hansa Biopharma is leveraging its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product candidate, imlifidase, is a unique antibody-cleaving enzyme that potentially may enable kidney transplantation in highly sensitized patients with potential for further development in other solid organ transplantation and acute autoimmune indications. Imlifidase is currently under review for marketing authorization by EMA. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in Europe and US.

Parent company
Statement of comprehensive income

	Q3		January-September	
KSEK	2019	2018	2019	2018
Net revenue	652	541	2 161	2 179
Direct cost of net revenue	-208	-50	-706	-151
Gross profit	**444**	**491**	**1 455**	**2 028**
Other operating income	-	370	166	671
Sales, general and administration expenses	-45 983	-22 370	-114 104	-52 579
Research and development expenses	-47 159	-38 015	-135 668	-113 509
Other operating expenses	-521	-1 087	-1 975	-2 360
Operating profit/loss	**-93 219**	**-60 611**	**-250 126**	**-165 749**
Result from sales of financial fixed assets	-	-	76 626	-
Result from short term financial receivables	-819	5	1 071	24
Other financial expenses	-22	-887	-103	-1 312
Profit/loss for the period (before and after taxes)	**-94 060**	**-61 493**	**-172 532**	**-167 037**
Other comprehensive income for the period	**0**	**0**	**0**	**0**
Total net comprehensive income	**-94 060**	**-61 493**	**-172 532**	**-167 037**

Parent company – Changes in equity

	January-September		Dec 31
KSEK	2019	2018	2018
Opening shareholders' equity	**833 270**	**625 528**	**625 528**
Result for the period	-172 532	-167 037	-248 297
New share issue [1]	2 309	-	453 467
Expenses attributable to new share issue [2]	-7 646	-1 150	-20 712
Sales and purchase own shares [1]	877	4 473	4 082
Issued warrants	111	340	354
Long term incentive programs	11 082	3 288	5 334
By employees redeemed stock options	-	11 271	13 514
New share issue under registration	-	2 243	-
Total transactions with the group's owner	**6 733**	**20 466**	**456 039**
Closing shareholders' equity	**667 471**	**478 957**	**833 270**

1) Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares. In H1, 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.

2) 2019 expenses relate to the directed share issue in 2018 (KSEK -7,586) and the LTIPs (KSEK -60)

Parent company
Balance sheet

	September 30		Dec 31
KSEK	2019	2018	2018
ASSETS			
Non-current assets			
Intangible fixed assets	29 651	30 291	30 163
Tangible fixed assets	4 962	4 992	5 290
Financial fixed assets	5 095	17 594	17 594
Total non-current assets	**39 708**	**52 877**	**53 047**
Current assets			
Receivables group companies	5 748	3 486	2 834
Current receivables non-interest bearing	6 445	7 254	8 035
Short-term investments	419 838	429 343	418 746
Cash and cash equivalents	253 312	48 320	433 875
Total current assets	**685 343**	**488 403**	**863 490**
TOTAL ASSETS	**725 051**	**541 280**	**916 537**
EQUITY AND LIABILITIES			
Shareholders' equity	**667 471**	**478 957**	**833 270**
Long term liabilities			
Other provisions	2 157	11 969	10 948
Long term liabilities, non-interest bearing	778	675	679
Total long term liabilities	**2 935**	**12 644**	**11 627**
Current liabilities			
Liabilities to group companies	3 604	-	-
Current liabilities, non-interest bearing	27 173	15 148	45 428
Accrued expenses and deferred income	23 867	34 531	26 212
Total current liabilities	**54 644**	**49 679**	**71 640**
TOTAL EQUITY AND LIABILITIES	**725 051**	**541 280**	**916 537**

Hansa Biopharma is leveraging its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product candidate, imlifidase, is a unique antibody-cleaving enzyme that potentially may enable kidney transplantation in highly sensitized patients with potential for further development in other solid organ transplantation and acute autoimmune indications. Imlifidase is currently under review for marketing authorization by EMA. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in Europe and US.

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 2018 was published on April 15, 2019 and is available on www.hansabiopharma.com. Disclosures in accordance with IAS 32.16A are as applicable in the notes or on the pages before the consolidated income statement

IFRS 16 Lease

IFRS 16 Lease Agreement replaces, as of January 1, 2019, existing IFRS related to the recognition of leasing agreements, such as IAS 17 Leasing and IFRIC 4 Determining whether an agreement contains a lease. The introduction of IFRS 16 has affected how the Group reports agreements on renting premises. Under previous accounting principles, these are reported as operating leases, which means that the rental cost is recognized in the income statement on a straight-line basis during the lease term. Under IFRS 16, for these agreements, a liability in the balance sheet corresponding to the obligation to pay leasing fees is reported at the same time as a corresponding asset that reflects the right to use the premises is reported. In the income statement, the depreciation of the asset is reported as well as interest on the lease liability. However, in accordance with IFRS 16, the Group has decided to exclude leases where the lease term (calculated in accordance with IFRS 16) is less than 12 months.

	KSEK
Operational leasing commitments as of December 31, 2018 according to note 26 in the annual report for 2018	**14 453**
Discounted with marginal loan rate as of January 1, 2019	12 814
Additional - financial leasing liabilities as of December 31, 2018	578
Departs - short-term lease	-38
Leasing debt as of January 1, 2019	**13 354**

Hansa Biopharma has chosen to apply the "modified retrospective approach" at the transition to IFRS 16, which means that comparative figures for 2018 will not be recalculated. Furthermore, as of January 1, 2019, the Group has chosen to report access rights as- set to the same amount as the lease liability, but with the addition of prepaid rents that are reported in the consolidated balance sheet. Thus, no effect on equity is realized on the transition to IFRS 16.

The transition to IFRS 16 has not affected the accounting of existing leases that are reported as financial leases under the current accounting principles.

IFRS 16 has not be applied in the Parent Company in accordance with the relief rules in RFR 2.

As of January 1, 2019, the transition to IFRS 16 has resulted in an increase of the Group's liabilities by SEK 14.0 million (of which SEK 6.0 million is short-term liabilities), while at the same time a utilization rights asset of SEK 14.0 million has been reported. The effect on operating result after tax is expected to be insignificant. Cash flow from operating activities for the first nine months of 2019 has increased and cash flow from financing activities decreased by SEK 3.3m since the leasing fees' amortization part is reported as payment in the financing activities. The discount rate used is 3.4%.

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.

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.

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