Solid advancements in our pipeline. Agreement on a clear regulatory path with the FDA; EMA process on track

Highlights for the fourth quarter 2019

- The ongoing review of an MAA for imlifidase in Europe by EMA is on track. Responses to the Day 120 questions were submitted on December 20, 2019. An opinion from the CHMP is expected in the second quarter of 2020.
- Reached agreement with the FDA on a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients in the U.S. Hansa will conduct a randomized, controlled clinical study in a well-defined population with the highest unmet medical need in context of the Kidney Allocation System.
- Our pipeline advanced with completion of enrollment in the investigator initiated Anti-GBM study and two patients treated in each of the new Phase 2 programs in Guillain Barré Syndrome (GBS) and Antibody Mediated Rejection (AMR).
- The Company continued to build a medical and commercial organization to support a potential commercial launch of imlifidase in 2020. Accordingly, investments in R&D and SG&A increased in the fourth quarter to SEK 58m (Q4'18: SEK 43m) and SEK 53m (SEK 36m), respectively.
- Cash position was SEK 601m at the end of December 2019, positively impacted by the divestment of the equity holding in Genovis in April 2019 generating gross proceeds of SEK 89m.
- Cash flow from operating activities for the fourth quarter ended at SEK -75m (SEK -57m) and at SEK - 335m (SEK -205m) for the financial year 2019.

Events after the end of the reporting period

- CSO, Christian Kjellman, will assume an expanded responsibility as CSO and COO effective immediately as we prepare to implement a focused launch strategy through leading transplantation clinics and experts upon a conditional approval of imlifidase in the EU.

Financial Summary

SEKm, unless otherwise stated - unaudited	Q4 2019	Q4 2018	FY 2019	FY 2018
Net Revenue	1.2	1.4	3.4	3.4
SG&A expenses	-53.4	-36.3	-167.3	-90.4
R&D expenses	-57.7	-42.6	-192.9	-154.6
Other operating income/expenses	-0.1	-2.3	-1.9	-4.0
Operating profit/loss	**-110.1**	**-80.6**	**-359.7**	**-246.5**
Net profit/loss	-110.9	-81.2	-360.0	-248.0
Cash flow from operating activities	-75.0	-57.5	-334.8	-204.6
Cash and short-term investments Dec 31, 2019	**601.1**	**858.2**	**601.1**	**858.2**
Shareholders' equity, Dec 31, 2019	562.8	859.9	562.8	859.9
EPS before and after dilution (SEK)	-2.77	-2.07	-9.00	-6.47
Number of outstanding shares	40,026,107	39,959,890	40,026,107	38,959,890
Weighted average number of shares before and after dilution	40,026,107	39,153,175	40,020,429	38,326,098
Number of employees	74	52	74	52

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Søren Tulstrup, President and CEO, comments

"2019 was an important and overall successful year for Hansa Biopharma – a year with significant progress across our pipeline and platform development activities and a year where we achieved the landmark milestone of getting our first Marketing Authorization Application accepted for review by a regulatory agency, namely the MAA for imlifidase in kidney transplantation in Europe, which was accepted for review by EMA on Feb 28, 2019. If approved, we would be able to launch the first in a series of drug candidates in our internal pipeline addressing conditions with high unmet medical need and through this transform Hansa into a commercial-stage biopharmaceutical company. The review is progressing according to plan, and we submitted the Day 120 responses to EMA in December.

In the US, following a meeting with the FDA on November 20, 2019 we now have a clear path forward towards a BLA submission for imlifidase in kidney transplantation that could support accelerated approval. Given the requirement by the FDA to conduct a randomized, controlled trial prior to submitting a BLA, I am pleased that we were able to agree with the FDA on a trial design that is limited in scope, includes patients with a high degree of unmet medical need, and is strongly powered to show a significant benefit for the imlifidase arm compared to the control arm.

Among our pipeline activities we have also seen significant progress in other areas during 2019. The completion of enrollment of patients in the investigator initiated anti-GBM antibody disease study marks an important milestone for Hansa Biopharma's expansion outside transplantation. We look forward to the next milestone in the third quarter this year when the first data read-out from the anti-GBM study is expected to be presented.

In addition to the anti-GBM study, we have also initiated two new programs in Phase 2 during 2019, one in Antibody Mediated Rejection episodes (AMR) and one in the acute autoimmune disease Guillain Barré Syndrome (GBS). Both studies are now actively recruiting patients and we expect to complete enrollment in AMR towards the end of 2020 and in GBS during the first half of 2021.

Hansa Biopharma is continuously making progress in transitioning the organization into a fully integrated global biopharmaceutical company that brings lifesaving and life altering therapies to patients with rare diseases who need them and generates value to society at large.

An exciting year lies ahead of us and I look forward to updating you on our journey and progress during 2020."

Søren Tulstrup
President and CEO, Hansa Biopharma

Continuous development in our pipeline activities

Candidate/ Project	Indications	Research/ Preclinical	Phase 1	Potentially Pivotal/ Phase 2	Marketing Authorization	Marketed	Next Anticipated Milestone
THERAPEUTICS							
Imlifidase	Kidney transplantation in highly sensitized patients	■	■	■	*)		EU: CHMP Opinion US: Initiation of clinical study to support BLA submission in 2023
	Anti-GBM antibody disease	■	■	□			Data read-out Q3 2020
	Antibody mediated kidney transplant rejection (AMR)	■	■	□			Complete enrollment of 30 patients
	Guillain-Barré syndrome (GBS)	■	■	□			Complete enrollment 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: Agreement with the FDA on a regulatory path forward in the US. New clinical study to support BLA submission by 2023

Clinical studies with imlifidase

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 Europe.

The Marketing Authorization Application (MAA) for imlifidase is currently under review for conditional approval by the European Medicines Agency (EMA). Hansa Biopharma submitted responses to the Day 120 questions on December 20, 2019 and the review process is on track. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected in the second quarter of 2020, followed by a potential decision by the European Commission during the summer 2020.

In the U.S., Hansa Biopharma recently agreed with the FDA on a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients. Upon agreement with the FDA and following submission of a final study protocol, the Company will conduct a randomized, controlled clinical study in a limited group of highly sensitized kidney patients using a surrogate endpoint.

The new study will target a limited and well-defined population with the highest unmet medical need, consisting of very highly sensitized kidney patients with a cPRA level of ≥99.9% who are waiting for a deceased donor transplantation. These patients have very limited access to transplantation and the only available therapy today is waiting on dialysis for a compatible transplant. In 2019, around 3,000 patients were registered on the waiting list in the US with a cPRA level of 99.9% or above.

The study discussed with the FDA includes approximately 50 patients to be randomized when a donor kidney becomes available to either imlifidase or to a control arm that will continue on the waitlist. A surrogate endpoint measured in the form of eGFR (kidney function) will be used to demonstrate the clinical benefit of imlifidase over the control group after 12 months.

Results from this clinical study could support a future submission of a Biologics License Application (BLA) in the U.S. under the accelerated approval pathway by 2023.

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.

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An abstract was accepted ahead of the Cutting Edge of Transplantation, CEOT, an annual congress arranged by the American Society of Transplantation on March 5-7, 2020. The long-term data indicate that the graft survival for this study population of highly sensitized and cross match positive population was overall comparable to data reported in the literature with other desensitization methods and the general transplantation population.

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

Anti-GBM is an indication, 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 lose their kidneys[1], requiring chronic dialysis and kidney transplantation.

The ongoing anti-GBM study is an open label investigator-initiated Phase 2 trial with Mårten Segelmark, Professor at the universities in Linköping and Lund, as Principal Investigator. The study is designed to evaluate the safety and tolerability of imlifidase in patients with severe anti-GBM disease on top of standard care consisting of plasmapheresis, steroids and cyclophosphamide.

The enrollment of the anti-GBM study was completed by the end of January 2020 and the first data read-out is expected in the third quarter of 2020. The study is done in partnership with Hansa Biopharma across five European countries.

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

Acute antibody mediated rejection is a serious condition after transplantation that occurs in 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 donor specific antibodies (DSAs) in the treatment of active episodes of acute AMR in kidney transplant patients in comparison to plasma exchange.

Two of the targeted 30 patients have been treated with imlifidase in AMR so far while 6 of 8 sites have been initiated to recruit patients across US, Europe and Australia. Enrollment is expected to be complete towards the end of 2020.

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

GBS is an acute autoimmune attack on the peripheral nervous system, which affects 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 first two out of the targeted 30 patients were treated with imlifidase end of 2019, while 6 of 10 clinical sites have been initiated to recruit patients across France and the UK. Enrollment is expected to be completed in the first 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 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.

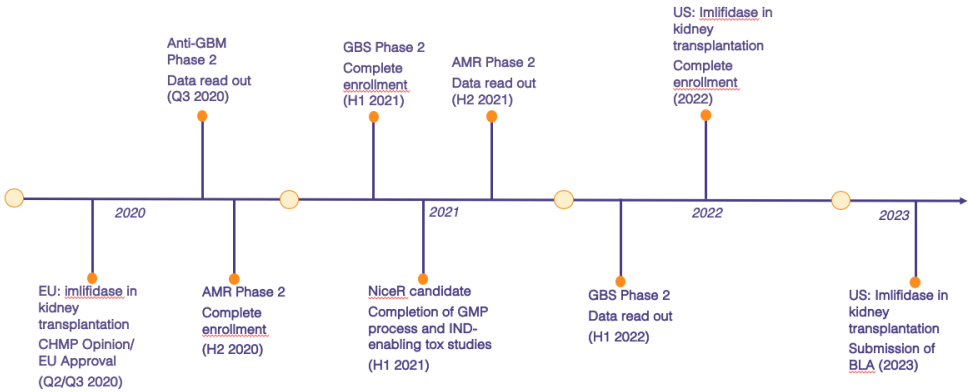
In March 2019, Hansa announced that a lead candidate for clinical development had been selected. This is the first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development. Development of a GMP-manufacturing process for the lead NiceR candidate has since been initiated and preparations for toxicology studies and a clinical Phase 1 study are now ongoing.

EnzE – Enzyme-based antibody Enhancement

Published findings[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.

Upcoming milestones and news flow



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 2019

Net revenue

Net revenue for the fourth quarter 2019 amounted to SEK 1.2m (Q4'18: SEK 1.4m) and to SEK 3.4m for the full year 2019 (2018: SEK 3.4m) and comprises of royalty income from Axis-Shield Diagnostics (Abbott group) and patent cost reimbursements.

Other operating income and expenses

No other operating income for the fourth quarter 2019 (SEK 0.1m). For the full year 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 0.1m (SEK 2.4m) for the fourth quarter 2019 and to SEK 2.1m (SEK 4.7m) for the full year 2019.

SG&A expenses

Sales, general and administration expenses for the fourth quarter 2019 amounted to SEK 53.4m (SEK 36.3m) and to SEK 167.3m (SEK 90.4m) for the full year 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 3.0m (SEK 0.6m) for the fourth quarter and to SEK 5.9m (SEK 10.9m) for the full year 2019 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 57.7m (SEK 42.6m) for the fourth quarter 2019 and to SEK 192.9m (SEK 154.6m) for the full year 2019. Recorded non-cash cost for the company's employee long-term incentive programs (LTIP 2016, LTIP 2018 and LTIP 2019) amounting to SEK 1.7m (SEK 0.5) for the fourth quarter and to SEK 1.1m (SEK 4.9m) for the full year 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, initiation of studies in Guillain Barré Syndrome (GBS) and Antibody Mediated Rejection (AMR) 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

The operating result for the fourth quarter 2019 amounted to SEK -110.1m (SEK -80.6m) and SEK -359.7m (SEK -246.5m) for the full year 2019.

Net profit/loss for the fourth quarter 2019 amounted to SEK -110.9m (SEK-81.2m) and to SEK -360.0m (SEK -248.0m) for the full year 2019.

Cash flow, cash and investments

Cash flow from operating activities amounted to SEK -75.0m (SEK -57.5m) for the fourth quarter 2019 and to SEK -334.8m (SEK -204.6m) for the full year 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 4.3m due to the fact that the leasing fees' amortization part is reported as payment in the financing activities.

Annual 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 601.1m on December 31, 2019 as compared to SEK 680.2m at the end of the third quarter 2019.

Shareholders' equity

On December 31, 2019, equity amounted to SEK 562.8m compared to SEK 859.9m at the end of the 2018.

Parent Company

The parent company's net revenue for the fourth quarter 2019 amounted to SEK 1.2m (SEK 1.4m) and to SEK 3.4m (SEK 3.6m) for the full year 2019. Profit/loss for the parent company amounted to SEK -110.9m (SEK -81.3m) for the fourth quarter and to SEK -283.4m (SEK -248.3m) for the full year 2019. The gain from the divestment of the equity holding in Genovis was realized in the second quarter.

On December 31, 2019, cash and cash equivalents including short term investments amounted to SEK 595.9m compared to SEK 673.2m at the end of the third quarter 2019.

The parent company's equity amounted to SEK 562.9m as per December 31, 2019, as compared to SEK 833.3m at the end of 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 December 2019. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had two employees at the end of 2019.

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Long-term incentive programs

Ongoing programs	LTIP 2016	LTIP 2018	LTIP 2019
Maximum number of issuable shares incl social contributions	35 000	789 321	1 154 463
Number of allocated and outstanding share rights and options	35 000	238 638	455 456
Number of acquired and outstanding warrants	-	6 701	11 000
Estimated total cost including social contributions, KSEK	2 848	20 574	42 396
Cost including social contributions Q4-2019 ytd, KSEK	-6 326	4 877	8 361

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

April 2, 2020 - Annual Report 2019
April 28, 2020 - Interim report for Jan - Mar. 2020
May 5, 2020 – Annual General Meeting
July 16, 2020 - Interim report for Jan - Jun. 2020
October 22, 2020 – Interim report for Jan - Sep 2020

Contacts

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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. Dec. 31, 2019	SEK 3.5bn
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of December 31, 2019

Name	Number of shares	Ownership in pct
NXT2B	5 755 379	14.4
Invesco	2 116 818	5.3
Thomas Olausson	1 667 654	4.2
Avanza Pension	1 554 486	3.9
Third Swedish National Pension Fund	1 316 470	3.3
Gladiator	1 150 000	2.9
Fourth Swedish National Pension Fund	1 112 044	2.8
Vanguard	930 991	2.3
Swedbank Robur Funds	892 944	2.2
ClearBridge, LLC	691 486	1.7
Other	22 837 835	57.0
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 December 31, 2019, Hansa Biopharma had 14,125 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 February 6, 2020

Ulf Wiinberg
Chairman of the Board

Eva Nilsagård
Chairman of the Audit Committee

Søren Tulstrup
President & CEO

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Condensed unaudited financial statements
Consolidated statement of comprehensive income

	Q4		Year	
KSEK	2019	2018	2019	2018
Net revenue	1 203	1 386	3 364	3 358
Direct cost of net revenue	-160	-765	-866	-916
Gross profit	**1 043**	**621**	**2 498**	**2 442**
Other operating income	-	54	166	725
Sales, general and administration expenses	-53 421	-36 285	-167 310	-90 387
Research and development expenses	-57 659	-42 635	-192 949	-154 558
Other operating expenses	-74	-2 360	-2 073	-4 720
Operating profit/loss	**-110 111**	**-80 605**	**-359 668**	**-246 498**
Financial income/expenses	-572	-634	76	-1 516
Profit/loss for the period before tax	**-110 683**	**-81 239**	**-359 592**	**-248 014**
Tax	-171	10	-417	40
Net profit/loss for the period	**-110 855**	**-81 229**	**-360 009**	**-247 974**
Attributable to:				
Parent company shareholders	-110 855	-81 229	-360 009	-247 974
Earnings per share (EPS)				
Before dilution (SEK)	-2.77	-2.07	-9.00	-6.47
After dilution (SEK)	-2.77	-2.07	-9.00	-6.47
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	-11	-27	143	65
Changes in fair value on available-for-sale financial assets	-760	-	207	-
Items that cannot be reclassified to profit or loss for the year				
Shares valued to fair value as comprehensive income	-	-799	49 597	21 029
Other comprehensive income for the year	**-772**	**-826**	**49 947**	**21 094**
Total net comprehensive income	**-111 627**	**-82 055**	**-310 062**	**-226 880**

Consolidated balance sheet

	December 31	
KSEK	2019	2018
ASSETS		
Non-current assets		
Intangible fixed assets	33 348	33 197
Tangible fixed assets	6 035	5 876
Leased fixed assets	9 109	-
Financial fixed assets	-	39 528
Total non-current assets	**48 493**	**78 601**
Current assets		
Current receivables, non-interest bearing	14 650	8 033
Short-term investments	419 397	418 746
Cash and cash equivalents	181 697	439 441
Total current assets	**615 743**	**866 220**
TOTAL ASSETS	**664 236**	**944 821**
EQUITY AND LIABILITIES		
Shareholders' equity	**562 815**	**859 876**
Long term liabilities		
Deferred tax liabilities	507	511
Other provisions	1 490	10 948
Long term leasing liabilities, interest bearing	4 827	-
Other long term liabilities, interest bearing	730	1 155
Total long term liabilities	**7 553**	**12 614**
Current liabilities		
Current liabilities, non-interest bearing	50 573	46 089
Current leasing liabilities, interest bearing	4 632	-
Accrued expenses and deferred income	38 663	26 242
Total current liabilities	93 868	72 331
TOTAL EQUITY AND LIABILITIES	**664 236**	**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	Year 2019	Year 2018
Opening shareholders' equity	**859 876**	**630 661**
Result for the period	-360 009	-247 974
Other comprehensive income for the period	49 947	21 094
Net comprehensive income	**-310 062**	**-226 880**
Transactions with the group's owner		
New share issue [1]	0	453 075
Expenses attributable to new share issue [2]	-7 646	-20 712
Sales own shares [1]	877	4 474
Issued warrants	193	354
Long term incentive programs	17 268	5 390
By employees redeemed stock options	2 309	13 514
Total transactions with the group's owner	**13 001**	**456 095**
Closing shareholders' equity	**562 815**	**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	Q4 2019	Q4 2018	Year 2019	Year 2018
Operating activities				
Operating profit/loss	-110 112	-80 605	-359 668	-246 498
Adjustment for items not included in cash flow [1]	6 467	1 239	15 292	13 444
Interest received and paid, net	33	372	-337	-210
Income taxes paid	216	-	-123	-
Cash flow from operations before change in working capital	**-103 396**	**-78 994**	**-344 835**	**-233 264**
Change in working capital	28 410	21 528	10 061	28 704
Cash flow from operating activities	**-74 986**	**-57 466**	**-334 775**	**-204 560**
Investing activities				
Investments in intangible fixed assets	-6	-103	-729	-127
Investments in tangible fixed assets	-1 368	-613	-2 699	-2 366
Divestment of tangible fixed assets	-	-	87	-
Divestment of financial assets	-	-	89 125	-
Short term investments	-	-	-	-493 984
Divestment short term investments	-	10 000	-	109 000
Cash flow from investing activities	**-1 374**	**9 284**	**85 784**	**-387 477**
Financing activities				
New share issue [2]	-	453 075	-	453 075
Issue expenses	-	-19 561	-7 646	-20 712
Sales of own shares [2]	-	-	877	4 473
By employees redeemed stock options	-	-	2 309	13 514
Loans raised	-24	-	-	-
Repayment of leasing liabilities	-1 121	-44	-4 424	-44
Cash flow from financing activities	**-1 144**	**433 470**	**-8 884**	**450 307**
Net change in cash	**-77 505**	**385 288**	**-257 875**	**-141 730**
Cash and cash equivalents, beginning of period	**259 359**	**54 060**	**439 441**	**581 078**
Currency exchange variance, cash and cash equivalents	-157	93	131	93
Cash and cash equivalents, end of period	**181 697**	**439 441**	**181 697**	**439 441**

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

	Q4		Year	
KSEK	2019	2018	2019	2018
Net revenue	1 203	1 424	3 364	3 603
Direct cost of net revenue	-160	-765	-866	-916
Gross profit	**1 043**	**659**	**2 498**	**2 687**
Other operating income	-	54	166	725
Sales, general and administration expenses	-54 416	-33 359	-168 520	-85 938
Research and development expenses	-56 902	-45 628	-192 570	-159 137
Other operating expenses	-99	-2 360	-2 074	-4 720
Operating profit/loss	**-110 375**	**-80 634**	**-360 501**	**-246 383**
Result from sales of financial fixed assets	-	28	76 626	52
Result from short term financial receivables	-560	-	511	-
Other financial expenses	44	-654	-59	-1 966
Loss for the period before tax	-110 891	-81 260	-283 423	-248 297
Income tax benefit/expense	-	-	-	-
Loss for the period after tax	**-110 891**	**-81 260**	**-283 423**	**-248 297**
Other comprehensive income for the period	-	-	-	-
Total net comprehensive income	**-110 891**	**-81 260**	**-283 423**	**-248 297**

Parent company - Changes in equity

	Year	
KSEK	2019	2018
Opening shareholders' equity	**833 270**	**625 528**
Result for the period	-283 423	-248 297
Other comprehensive income for the period	-	-
Net comprehensive income	-283 423	-248 297
New share issue [1]	-	453 467
Expenses attributable to new share issue [2]	-7 646	-20 712
Sales and purchase own shares [1]	877	4 082
Issued warrants	193	354
Long term incentive programs	17 324	5 334
By employees redeemed stock options	2 309	13 514
New share issue under registration	-	-
Total transactions with the group's owner	**13 057**	**456 039**
Closing shareholders' equity	**562 905**	**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

	31-Dec	
KSEK	2019	2018
ASSETS		
Non-current assets		
Intangible fixed assets	29 522	30 163
Tangible fixed assets	6 035	5 290
Financial fixed assets	5 095	17 594
Receivables, group companies	2 244	-
Total non-current assets	**42 896**	**53 047**
Current assets		
Receivables, group companies	1 061	2 834
Current receivables non-interest bearing	14 368	8 035
Short-term investments	419 190	418 746
Cash and cash equivalents	176 715	433 875
Total current assets	**611 334**	**863 490**
TOTAL ASSETS	**654 230**	**916 537**
EQUITY AND LIABILITIES		
Shareholders' equity	**562 905**	**833 270**
Long term liabilities		
Other provisions	818	10 948
Long term liabilities, non-interest bearing	730	679
Total long term liabilities	**1 548**	**11 627**
Current liabilities		
Liabilities, group companies	2 793	-
Current liabilities, non-interest bearing	56 883	45 428
Accrued expenses and deferred income	30 100	26 212
Total current liabilities	**89 776**	**71 640**
TOTAL EQUITY AND LIABILITIES	**654 230**	**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 34.16A 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 full year 2019 has increased and cash flow from financing activities decreased by SEK 4.3 million since the leasing fees’ amortization part is reported as payment in the financing activities. The discount rate used is 3.4%.

Note 2 Net revenue

Income per significant category of income	Q4		Year	
KSEK	2019	2018	2019	2018
Group				
Net revenue:				
Royalty and license revenue	566	562	2 265	2 071
Milestone revenue	573	621	573	621
Patent reimbursement	64	203	526	666
	1 203	1 386	3 364	3 358
Parent company				
Net revenue:				
Royalty and license revenue	566	562	2 265	2 071
Milestone revenue	573	621	573	621
Patent reimbursement	64	241	526	911
	1 203	1 424	3 364	3 603

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 amounted to SEK 419.4 million (SEK 418.7 million) per year end and belonged to level 2 in the fair value hierarchy. The fair value of the financial liability for contingent consideration amounted to SEK 0.7 million (SEK 0.7 million) per year end 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.

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.