

INTERIM REPORT JANUARY – JUNE 2019



Imlifidase benefits highlighted in recent ATC presentations. Expansion outside transplantation with initiation of study in Guillain-Barré Syndrome (GBS) continues.

Highlights for the second quarter 2019

- At the 2019 American Transplant Congress (ATC), Dr. Edmund Huang of Cedars-Sinai Medical Center presented data demonstrating a significant reduction in time to transplant for highly sensitized patients treated with imlifidase over matched controls waiting under Kidney Allocations System (KAS). Dr. Huang's session won ATC's People's Choice Award for the most impactful presentation.
- Hansa Biopharma continued to advance imlifidase toward potential marketing authorization for enabling kidney transplantation in highly sensitized patients in the EU and the U.S. MAA is currently under review by EMA while complementary analyses are conducted in the U.S. to further illustrate the value of imlifidase over matched controls. Subsequent meeting with the FDA expected to take place in the second half of 2019.
- CTA approvals received in Europe for a Phase 2 study with imlifidase in Guillain-Barré Syndrome (GBS). The initiation of the GBS study represents a continuation of the Company's expansion outside the transplantation area into autoimmune diseases.
- Divested the equity holding in Genovis, which generated gross proceeds of SEK 89m (USD 9.6m).
- All resolutions passed at Hansa Biopharma's 2019 Annual General Meeting. Two new board members, Eva Nilsagård and Mats Blom, appointed.
- Spending in R&D and SG&A increased in the second quarter to SEK 46m (Q2'18 SEK 44m) and SEK 39m (Q2'18 SEK 15m) respectively as the Company continues to ramp-up in R&D and prepare for a potential launch of imlifidase in kidney transplantation.
- Cash flow from operating activities for the second quarter ended at SEK -78m (SEK -49m); the Company's cash position ended at SEK 763m end of June 2019. Cash flow was mainly driven by investments in activities related to the potential launch of imlifidase and the divestment of the Genovis equity holding.

Financial Summary

<i>SEKm, unless otherwise stated</i>	Q2 2019	Q2 2018	H1 2019	H1 2018
Net Revenue	0.6	0.9	1.5	1.5
SG&A expenses	-38.5	-14.8	-67.9	-30.0
R&D expenses	-45.6	-44.0	-88.1	-75.5
Other operating income/expenses	-0.1	-0.8	-1.2	-1.0
Operating profit/loss	-83.7	-58.8	-156.4	-105.4
Net profit/loss	-82.4	-58.8	-154.9	-105.3
Cash flow from operating activities	-78.0	-49.0	-179.6	-93.1
Cash and short term investments June 30, 2019	762.7	534.2	762.7	534.2
Shareholders' equity, June 30, 2019	755.4	543.0	755.4	543.0
EPS before and after dilution June 30, 2019 (SEK)	-2.06	-1.55	-3.87	-2.77
Number of outstanding shares, June 30, 2019	40,026,107	38,083,125	40,026,107	38,083,125
Weighted average number of shares before and after dilution	40,026,107	37,976,440	40,014,056	37,962,440
Number of employees, June 30, 2019	60	40	60	40

Søren Tulstrup, President and CEO, comments

"Hansa Biopharma's evolution into a commercial stage biopharmaceutical company continues according to plan. During the second quarter, our organization grew its footprint in both Europe and the U.S., and we continued to increase our engagement with the broader healthcare community within transplantation, autoimmune diseases and beyond.

I recently returned from the 2019 American Transplant Congress (ATC) in Boston where I noted a high level of excitement around Hansa Biopharma, our technology platform and our pipeline. Imlifidase was highlighted in three presentations during the conference including a plenary presentation by Dr. Edmund Huang from Cedars-Sinai Medical Center in Los Angeles. Dr. Huang presented data demonstrating that imlifidase significantly reduces the time to transplant for patients treated with imlifidase compared to matched controls on the kidney transplantation waitlist. This session won the ATC's People's Choice Award as the most impactful to the transplant community, further validating the transformative potential of imlifidase and our technology.

In the U.S., we are seeing signs from the current administration that increasing the kidney transplant rate and improving equity of access to this lifesaving therapy is high on the political agenda as part of a goal to significantly increase survival rate and quality of life for dialysis patients and at the same time reduce the > \$100 billion spent annually by the U.S. government to treat chronic kidney disease and end-stage renal disease. If approved, imlifidase could be a key driver in helping thousands of highly sensitized patients get off of dialysis by enabling transplantation.

The regulatory review process for imlifidase in Europe is progressing following the acceptance of our Marketing Authorization Application (MAA) in February. The timeline for the process is 210 working days plus clock stops, as we have communicated earlier. Meanwhile, in the U.S. we are conducting complementary analyses with respect to transplantability for the highly sensitized patients participating in the Phase 2 studies with imlifidase compared to matched controls from the U.S. transplant registry in order to further illustrate the value of imlifidase in the U.S. healthcare system. Once completed, we will schedule a subsequent meeting with the U.S. Food and Drug Administration, which is expected to take place in the second half of 2019.

Overall, we continue to execute on our strategic agenda, with solid progress across our pipeline, including the recent initiation of two Phase 2 studies in Guillain-Barré Syndrome (GBS) and acute Antibody Mediated Rejection in kidney transplantation. In April, we decided to divest our equity holding in Genovis. The transaction provided a profitable exit from a non-core investment and generated funds that will help accelerate the development of our pipeline of clinical stage drug candidates as well as our next generation NiceR program for repeat dosing.

We envision a world where all patients with rare immunologic diseases can lead long and healthy lives. To help achieve this vision we are building a high-performance organization to exploit our unique immunomodulating technology platform to develop innovative lifesaving and life altering therapies, bring these to the patients with rare diseases who need them, and generate value to society at large."



Søren Tulstrup

President and CEO, Hansa Biopharma

Solid development in our pipeline activities with advances across multiple indications

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	Completed	Completed	Completed	Ongoing *)		MAA review by EMA / Follow-up meeting FDA
	Anti-GBM antibody disease	Completed	Completed	Ongoing			Complete enrolment of 15 patients
	Antibody mediated kidney transplant rejection (AMR)	Completed	Completed	Ongoing			Complete enrolment of 30 patients
	Guillain-Barré syndrome (GBS)	Completed	Completed	Ongoing			Complete enrolment of 30 patients
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	Ongoing					Development of CMC process / Tox studies
EnzE	Cancer immunotherapy	Ongoing					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 BLA filing.

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

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

AMR (ClinicalTrials.gov ID: NCT03897205)

Imlifidase in AMR entered early stage clinical development following CTA approval in March 2019. The study aims to enroll approximately 30 patients at eight clinical trial centers in France, Sweden, Austria, Australia and the United States. 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.

GBS (ClinicalTrials.gov ID: NCT03943589)

Imlifidase in GBS entered early stage clinical development following CTA approval in Europe in April 2019. The study aims to enroll approximately 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).

Latest developments in our clinical program

Enabling kidney transplantation for highly sensitized patients

Hansa Biopharma continues to advance imlifidase toward commercialization for enabling kidney transplantation in highly sensitized patients in the European Union and the United States.

The Company's MAA for imlifidase is currently under review by the European Medicines Agency (EMA). The submission of the MAA was accepted by EMA on February 28, 2019 and an opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected within 210 working days from submission (plus any clock-stops for the applicant to provide answers to questions during the review). After adoption of a CHMP opinion, a final decision regarding the MAA for imlifidase is made by the European Commission.

Hansa Biopharma is also pursuing a path for regulatory approval with the FDA. To further illustrate the value of imlifidase in the U.S. healthcare system, the Company is conducting complementary analyses in transplantability based on data from the completed Phase 2 studies of imlifidase and matched controls from the U.S. transplant registry. Following completion of these analyses, Hansa will schedule a meeting with the FDA, which is expected to take place in the second half of 2019. Hansa's dialogue with the FDA will determine the path forward for the U.S regulatory approval process and the Company will provide updated guidance regarding the timeline for a potential Biologics License Application submission following its next meeting with the agency.

At the 2019 American Transplant Congress (ATC), which took place in Boston, MA in the first week of June, imlifidase was highlighted in three presentations.

In a plenary presentation, which won the ATC's People's Choice Award, Edmund Huang, MD, Associate Professor and Transplant Nephrologist at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center in Los Angeles, reported a statistically significant reduction in time to transplantation among imlifidase treated patients, compared to similarly sensitized matched controls.

Robert A. Montgomery, M.D., Director, NYU Langone Transplant Institute, NYC, presented the complete results and conclusions from the HighdeS study during the oral presentation "Safety and Efficacy of Imlifidase in Highly-Sensitized Kidney Transplant Patients: Results from a Phase 2 Study." The six months follow up results show that imlifidase has enabled all patients to undergo transplantation resulting in good kidney function and graft survival.

Lastly, Dr. Matthew J. Everly, Director of the Terasaki Research Institute in Los Angeles, reported on the results of modeled simulations for the group of highly sensitized patients, which demonstrated that transplant rates could be increased by 25% if there were a therapy to address the HLA antibody barrier.

Treatment in anti-GBM antibody disease

To date, nine 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 to this study is anticipated by the end of 2019.



Treatment of acute antibody-mediated rejection (AMR) in kidney transplantation

Acute AMR is one of the most challenging adverse events after kidney transplantation, occurring in 10-15% of patients, and is the main cause for graft dysfunction.¹

Hansa initiated a Phase 2 study in AMR in March 2019. 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 only, 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.

Treatment of Guillain-Barré syndrome (GBS)

Hansa received Clinical Trial Application and Ethics Committee approvals for the Company's Phase 2 study of imlifidase in GBS in April. 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. 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 findings³ 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 inhibiting IgG antibodies with imlifidase or novel IgG-clearing enzymes 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

Financial review January – June 2019

Net revenue

Net revenue for the second quarter 2019 amounted to SEK 0.6m (Q2'18: SEK 0.9m) and to SEK 1.5m for the first half 2019 (H1'18 SEK 1.5m) and comprises of royalty income from Axis-Shield Diagnostics and patent reimbursements.

Other operating income and expenses

Other operating income amounted to SEK 0.1m (0.1) for the second quarter 2019 and to SEK 0.2m (0.3) for the first half 2019 and is comprised of a research grant from Vinnova. Other operating expense, comprised of net currency differences, amounted to SEK 0.2m (0.9) for the second quarter 2019 and to SEK 1.5m (1.3) for the first half 2019.

SG&A expenses

Sales, general and administration expenses for the second quarter 2019 amounted to SEK 38.5m (14.8) and to SEK 68.0m (30.3) for the first half 2019. The increase in expenses reflects the continuing activities related to the ramp-up of the organization in preparation for the potential 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 0.4m (5.5) is included. 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 first half 2019 compared with the previous year.

R&D expenses

Research and development expenses amounted to SEK 45.6m (44.0) for the second quarter 2019 and to SEK 88.1m (75.5) for the first half 2019 and include a positive non-cash cost impact from the company's long-term incentive programs amounting to SEK 1.5m. Compared with 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 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 first half 2019 compared to the previous year.

Financial result

Operating result for the second quarter 2019 amounted to SEK -83.7m (-58.8) and SEK -156.4m (-105.4) for the first half 2019.

Profit/loss for the second quarter 2019 amounted to SEK -82.4m (-58.8) and to SEK -154.9m (-105.3) for the first half 2019.

Cash flow and investments

Cash flow from operating activities amounted to SEK -78.0m (-49.0) for the second quarter 2019 and to SEK -179.6m (-93.1) for the first half 2019. Compared to the previous year, 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 1.8m due to the fact that the leasing fees' amortization part is reported as payment in the financing activities. Cash and cash equivalents including short term investments amounted to SEK 762.7m on June 30, 2019, as compared to SEK 759.2m at the end of the first quarter.

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

Investments for the second quarter 2019 amounted to SEK 0.9m (1.3) and to SEK 0.9m (1.6) for the first half 2019. Cash flow from financing activities amounted to SEK 8.1m (9.3) for the second quarter 2019 and to SEK 6.2m (12.7) for the first half 2019.

Shareholders' equity

On June 30, 2019 equity amounted to SEK 755.4m compared to SEK 543.0m at the end of the corresponding period 2018.

Parent Company

The parent company's net revenue for the second quarter 2019 amounted to SEK 0.6m (1.0) and to SEK 1.5m (1.6) for the first half 2019. Profit/loss for the parent company amounted to SEK -5.9m (-58.7) for the second quarter and to SEK -78.5m (-105.5) for the first half 2019. The gain from the divestment of the equity holding in Genovis is realized in the second quarter. On June 30, 2019, cash and cash equivalents including short term investments amounted to SEK 757.5m compared to SEK 531.4m at the end of 2018.

The parent company's equity amounted to SEK 755.1m as per June 30, 2019, as compared to SEK 534.3m 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 June 2019. Hansa Biopharma Ltd is owner of patent rights to the EnzE concept and had at the end of June 2019 one employee.



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	254 135	437 875
Number of acquired and outstanding warrants	-	6 701	11 000
Estimated total cost including social contributions, KSEK	18 733	25 745	50 949
Cost including social contributions ytd, KSEK	-4 712	2 230	1 396

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 maximum dilution under the LTIP 2019 is expected to amount to approximately 1.71% 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, subsidize 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 1.04% 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 at www.hansabiopharma.com for further information on 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 is described in more detail.

Other information

Financial calendar 2019

October 31, 2019 - Interim report for Jan – Sep. 2019

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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	40,731,654 (40,026,107 A-shares and 705,547 C-shares)
Market Cap. June 30, 2019	SEK 7,006m
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of June 30, 2019

Name	Number of shares	Ownership in pct
NXT2B	5 755 379	14.4
Invesco	2 648 180	6.6
Handelsbanken Funds	1 626 766	4.1
Thomas Olausson	1 613 474	4.0
Avanza Pension	1 313 540	3.2
Norron Funds	1 172 642	2.9
Third Swedish National Pension Fund	1 149 017	2.9
Fourth Swedish National Pension Fund	1 030 321	2.6
AFA Insurance	953 734	2.4
Gladiator	900 000	2.2
Other	21 840 331	54.6
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 June 30 2019, Hansa Biopharma had 12,682 shareholders.

Condensed financial statements

Consolidated statement of comprehensive income

KSEK	Q2		H1	
	2019	2018	2019	2018
Net revenue	592	900	1 509	1 488
Direct cost of net revenue	-97	-51	-498	-101
Gross profit	495	849	1 011	1 387
Other operating income	106	87	166	301
Sales, general and administration expenses	-38 505	-14 835	-67 952	-30 305
Research and development expenses	-45 554	-43 962	-88 135	-75 499
Other operating expenses	-225	-907	-1 454	-1 274
Operating profit/loss	-83 683	-58 768	-156 364	-105 390
Financial income/expenses	1 245	-38	1 595	76
Profit/loss for the period before tax	-82 438	-58 806	-154 769	-105 314
Tax	26	10	-121	20
Net profit/loss for the period	-82 412	-58 796	-154 890	-105 294
Attributable to:				
Parent company shareholders	-82 412	-58 796	-154 890	-105 294
Earnings per share (EPS)				
Before dilution (SEK)	-2,06	-1,55	-3,87	-2,77
After dilution (SEK)	-2,06	-1,55	-3,87	-2,77
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	-51	-8	78	115
Changes in fair value on available-for-sale financial assets	-	-341	-	3 208
Items that cannot be reclassified to profit or loss for the year				
Shares valued to fair value as comprehensive income	7 157	-	49 598	-
Other comprehensive income for the year	7 106	-349	49 676	3 323
Total net comprehensive income	-75 306	-59 145	-105 214	-101 971

Consolidated balance sheet

KSEK	June 30		December 31
	2019	2018	2018
ASSETS			
Non-current assets			
Intangible fixed assets	32 930	33 571	33 197
Tangible fixed assets	5 041	5 123	5 876
Leased fixed assets	12 319	-	-
Financial fixed assets	-	21 705	39 528
Total non-current assets	50 290	60 399	78 601
Current assets			
Current receivables, non-interest bearing	4 789	9 315	8 033
Short-term investments	420 651	474 073	418 746
Cash and cash equivalents	342 076	60 105	439 441
Total current assets	767 516	543 493	866 220
TOTAL ASSETS	817 806	603 892	944 821
EQUITY AND LIABILITIES			
Shareholders' equity	755 395	542 966	859 876
Long term liabilities			
Deferred tax liabilities	461	549	511
Other provisions	5 152	4 538	10 948
Long term leasing liabilities, interest bearing	6 389	-	-
Other long term liabilities, interest bearing	741	668	1 155
Total long term liabilities	12 743	5 755	12 614
Current liabilities			
Current liabilities, non-interest bearing	21 510	10 455	46 089
Current leasing liabilities, interest bearing	5 136	-	-
Accrued expenses and deferred income	23 022	44 716	26 242
Total current liabilities	49 668	55 171	72 331
TOTAL EQUITY AND LIABILITIES	817 806	603 892	944 821

Consolidated changes in equity

KSEK	H1		Year
	2019	2018	2018
Shareholders' equity	859 876	630 661	630 661
Result for the period	-154 890	-105 294	-247 974
Other comprehensive income for the period	49 676	3 323	21 094
Net comprehensive income	-105 214	-101 971	-226 880
Transactions with the group's owner			
New share issue ^[1]	2 309	-	453 075
Expenses attributable to new share issue	-7 596	-1 070	-20 711
Sales own shares ^[1]	877	4 473	4 473
Issued warrants	27	327	354
Long term incentive programs	5 116	1 495	5 390
By employees redeemed stock options	-	9 051	13 514
Total transactions with the group's owner	734	14 276	456 095
Closing shareholders' equity	755 395	542 966	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 were issued due to the TO 2015 program and 16,217 of the C-shares were converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program.

Consolidated cash flow statement

KSEK	Q2		H1	
	2019	2018	2019	2018
Operating activities				
Operating profit/loss	-83 683	-58 768	-156 364	-105 390
Adjustment for items not included in cash flow ^[1]	-697	570	2 676	2 283
Interest received and paid, net	76	-150	-248	-357
Income taxes paid	-183	-	-183	-
Cash flow from operations before change in working capital	-84 487	-58 348	-154 119	-103 464
Change in working capital	6 507	9 359	-25 462	10 381
Cash flow from operating activities	-77 980	-48 989	-179 581	-93 083
Investing activities				
Investments in intangible fixed assets	-	1	-	-24
Investments in tangible fixed assets	-901	-1 329	-924	-1 604
Divestment of tangible fixed assets	-	-	87	-
Divestment of financial assets	89 125	-	89 125	-
Short term investments	-	-43 989	-	-493 984
Divestment short term investments	-	45 000	-	55 000
Cash flow from investing activities	88 224	-317	88 288	-440 612
Financing activities				
Issue expenses	-7 576	-	-7 586	-1 070
Sales of own shares ^[2]	-	-	877	4 473
By employees redeemed stock options	-10	9 051	2 299	9 051
Issued warrants	-	268	-	268
Repayment of leasing liabilities	-531	-	-1 788	-
Cash flow from financing activities	-8 117	9 319	-6 198	12 722
Net change in cash	2 127	-39 987	-97 491	-520 973
Cash and cash equivalents, beginning of period	339 927	100 092	439 441	581 078
Currency exchange variance, cash and cash equivalents	22	-	126	-
Cash and cash equivalents, end of period	342 076	60 105	342 076	60 105

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 were issued due to the TO 2015 program and 16,217 of the C-shares were converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program.

Parent company Statement of comprehensive income

KSEK	Q2		H1	
	2019	2018	2019	2018
Net revenue	592	953	1 509	1 638
Direct cost of net revenue	-97	-51	-498	-101
Gross profit	495	902	1 011	1 537
Other operating income	106	87	166	301
Sales, general and administration expenses	-38 583	-14 746	-68 121	-30 209
Research and development expenses	-45 673	-43 919	-88 509	-75 494
Other operating expenses	-225	-906	-1 454	-1 273
Operating profit/loss	-83 880	-58 582	-156 907	-105 138
Result from sales of financial fixed assets	76 626	-	76 626	-
Result from short term financial receivables	1 342	16	1 890	19
Other financial expenses	-5	-173	-81	-425
Profit/loss for the period (before and after taxes)	-5 917	-58 739	-78 472	-105 544
Other comprehensive income for the period	0	0	0	0
Total net comprehensive income	-5 917	-58 739	-78 472	-105 544

Parent company – Changes in equity

KSEK	H1		Dec 31
	2019	2018	2018
Opening shareholders' equity	833 270	625 528	625 528
Result for the period	-78 472	-105 544	-248 297
New share issue ^[1]	2 309	-	453 467
Expenses attributable to new share issue	-7 596	-1 070	-20 712
Sales and purchase own shares ^[1]	877	4 473	4 082
Issued warrants	27	327	354
Long term incentive programs	4 670	1 495	5 334
By employees redeemed stock options	-	9 051	13 514
Total transactions with the group's owner	287	14 276	456 039
Closing shareholders' equity	755 085	534 260	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 were issued due to the TO 2015 program and 16,217 of the C-shares were converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program.

Parent company Balance sheet

KSEK	June 30		Dec 31
	2019	2018	2018
ASSETS			
Non-current assets			
Intangible fixed assets	29 884	30 430	30 163
Tangible fixed assets	5 042	5 123	5 290
Financial fixed assets	5 095	17 594	17 594
Total non-current assets	40 021	53 147	53 047
Current assets			
Receivables group companies	4 108	743	2 834
Current receivables non-interest bearing	5 570	9 315	8 035
Short-term investments	420 651	473 994	418 746
Cash and cash equivalents	336 895	57 421	433 875
Total current assets	767 224	541 473	863 490
TOTAL ASSETS	807 245	594 620	916 537
EQUITY AND LIABILITIES			
Shareholders' equity	755 085	534 260	833 270
Long term liabilities			
Other provisions	5 152	4 538	10 948
Long term liabilities, non-interest bearing	741	668	679
Total long term liabilities	5 893	5 206	11 627
Current liabilities			
Liabilities to group companies	2 683	1	-
Current liabilities, non-interest bearing	20 596	10 456	45 428
Accrued expenses and deferred income	22 987	44 697	26 212
Total current liabilities	46 266	55 154	71 640
TOTAL EQUITY AND LIABILITIES	807 245	594 620	916 537

Hansa Biopharma AB is harnessing 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, imlifidase, is a unique antibody-degrading enzyme in late-stage clinical development to enable kidney transplantation in highly sensitized patients, with additional clinical studies in acute autoimmune conditions. Hansa's research and development program is advancing the Company's technology to develop next generation IgG-cleaving enzymes with lower immunogenicity, potentially enabling repeat dosing in relapsing autoimmune diseases, chronic transplant rejection, oncology and gene therapy. Hansa Biopharma is based in Lund, Sweden with operations in both Europe and the U.S. - Hansa Biopharma AB Scheelevägen 22, SE 223 63 Lund, Sweden - Corporation ID 556734-5359

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.

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 has increased and cash flow from financing activities decreased by SEK 1.8m 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

One type of proteins produced by the body's immune system with the ability to recognize foreign substances, bacteria or viruses. Anti- bodies 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.