

# INTERIM REPORT JANUARY-MARCH 2020



EMA process on track: Responses to the Day 180 questions submitted end of Q1.  
An opinion from the CHMP is expected in the second quarter.

## Highlights for the first quarter 2020

- The ongoing review of the MAA for imlifidase in Europe by EMA is on track. Responses to the Day 180 questions were submitted at the end of March 2020. An opinion from the CHMP is expected in Q2 2020.
- Discussions with the FDA on the design of a randomized, controlled trial in kidney transplantation in the US is progressing according to plan. Submission of the study protocol is expected in Q2, and recruitment of the first patient is targeted for the fourth quarter of this year.
- Long-term follow-up data from patients in the Phase 2 trials was presented at the Cutting Edge of Transplantation Summit on March 6, 2020 demonstrating two-year graft survival of 89% after imlifidase treatment and transplantation.
- Enrollment in the investigator initiated Anti-GBM study was completed end of January 2020. The completion marks an important milestone for Hansa Biopharma's expansion beyond transplantation. In the phase 2 studies in Guillain Barré Syndrome (GBS) and Antibody Mediated Rejection (AMR) four patients had been treated in each of the studies by end of March 2020.
- The COVID-19 virus pandemic may impact parts of Hansa Biopharma's business, namely: recruitment timelines of ongoing clinical studies, start of recruitment into the US Randomized Control Trial, the potential European launch of imlifidase in kidney transplantation and the financing strategy.
- CSO Christian Kjellman has assumed an expanded responsibility as CSO and COO effective February 2020 as the Company prepares to implement a focused launch strategy through leading transplantation clinics across Europe.
- Consonance Capital Management LP, reported being a new major shareholder in Hansa Biopharma as per March 9, 2020 with shareholdings greater than 5% of total shares outstanding.
- Investments in R&D and SG&A increased in the first quarter to SEK 53m (Q1'19: SEK 43m) and SEK 39m (SEK 29m), respectively. Cash position was SEK 477m at the end of March 2020. Cash flow from operating activities for the first quarter ended at SEK -121m (SEK -102m).

## Financial Summary

<i>SEK m, unless otherwise stated - unaudited</i>	Q1 2020	Q1 2019	FY 2019
Revenue	0.9	0.9	3.4
SG&A expenses	-38.7	-29.4	-167.3
R&D expenses	-52.5	-42.6	-192.9
Other operating income/expenses	-0.6	-1.2	-1.9
<b>Operating profit/loss</b>	<b>-91.4</b>	<b>-72.7</b>	<b>-359.7</b>
Net profit/loss	-93.4	-72.5	-360.0
Cash flow from operating activities	-121.2	-101.6	-334.8
<b>Cash and short-term investments</b>	<b>476.9</b>	<b>759.2</b>	<b>601.1</b>
Shareholders' equity	473.9	835.1	562.8
EPS before and after dilution (SEK)	-2.33	-1.81	-9.00
Number of outstanding shares	40,026,107	40,026,107	40,026,107
Weighted average number of shares before and after dilution	40,026,107	40,003,078	40,020,429
Number of employees	78	57	74

## Søren Tulstrup, President and CEO, comments

*"Hansa Biopharma's strategy to transform the organization into a fully integrated, commercial stage global biopharmaceutical company continues according to plan. Our top priority is to get our lead compound imlifidase to market to enable lifesaving kidney transplants for highly sensitized patients, who currently cannot receive this standard of care treatment.*

*While an exciting and potentially transformative year lies ahead of us, the COVID-19 virus pandemic imposes additional changes and challenges to us as a company. We have taken measures to protect our employees and take social responsibility while attempting to limit negative effects on Hansa's business. It is still too early to fully assess the potential negative impacts that the pandemic will have on our business but there are some key areas, where we do expect to see an impact, including clinical and commercial operations*

*In Europe our lead candidate imlifidase for kidney transplantation in highly sensitized patients is currently under review by EMA. The review process is progressing according to plan with the submission of the Day 180 responses to EMA at the end of March. An opinion from the CHMP is expected in the second quarter. Assuming the opinion from CHMP is positive, we can expect a formal decision to be adopted by the European Commission in the third quarter of 2020.*

*If approved, imlifidase for kidney transplantation will be the first in a series of drug candidates in our internal pipeline addressing conditions with high unmet medical need, transforming the Company into a commercial-stage biopharmaceutical company.*

*While we are very excited about a potential near-term approval and commercialization in Europe, we also acknowledge that the potential launch may be negatively affected by the COVID-19 virus pandemic, including lack of access to and reduced decision-making ability of market access authorities, potentially delaying pricing and reimbursement approval in early launch countries.*

*In addition, our pre-launch communication activities may also be impacted negatively by reduced ability to engage with key opinion leaders and clinicians at targeted centers. It remains, however, our aim to launch imlifidase in the first clinics this year, also leveraging digital communication technologies*

*In the US we are currently in close interaction with the FDA about the final study protocol. Once the protocol is formally approved, we will set up the specific trial centers in the US and apply for the necessary ethical approvals.*

*The planned new trial in the US will include approximately 50 highly sensitized kidney patients with a cPRA score of 99.9% or above. After twelve months the patients' eGFR (estimated Glomerular Filtration Rate) will be measured as a surrogate marker to demonstrate a clinical benefit of imlifidase therapy versus patients in the control arm.*

*While we aim to commence recruitment for the trial in the 4th quarter of 2020 we also acknowledge the risk of potential timeline impact due to the COVID-19 virus pandemic as a consequence of potential reprioritization of activities by the FDA.*

*Looking beyond transplantation indications, we see significant potential for imlifidase in the area of acute autoimmune diseases. In January, we completed the enrollment of patients in the investigator initiated anti-GBM antibody disease study. The completion marks an important milestone for Hansa Biopharma's expansion*

*outside transplantation. We look forward to the next milestone in the third quarter of 2020 when the first data read-out from the anti-GBM study is expected.*

*In addition to the ongoing anti-GBM study, we are also enrolling patients in two other Phase 2 programs, namely Guillain Barré Syndrome and Antibody Mediated Rejection in kidney transplant patients. While both studies have been actively recruiting, we do expect the recruitment process to be slower due to the impact of COVID-19. We now expect a delay of 3-6 months in both studies.*









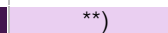











*A key priority of ours in 2020 will be to continue to build a high-performance medical affairs and commercial organization to ensure a successful potential launch of imlifidase in kidney transplantation. Launching a highly innovative drug requires a high-quality internal, functional infrastructure with a clear focus on building the necessary external disease awareness and medical intervention preference and associated infrastructure.*



*I look forward to keeping you updated on the progress of Hansa Biopharma's journey as we transform the company into a fully integrated, commercial-stage biopharmaceutical company that brings lifesaving and life-altering therapies to patients with rare diseases and generates long-term value to our shareholders and society at large.*



**Søren Tulstrup**  
President and CEO, Hansa Biopharma

## Continuous development in our pipeline activities

Candidate/ Project	Indications	Research/ Preclinical	Phase 1	Potentially Pivotal/ Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
<b>Imlifidase</b>	EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>					 *)		CHMP Opinion Q2 2020
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>				 **)			Finalization of study design Q2 2020 / First patient dosed Q4 2020
	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
<b>NiceR</b>	Recurring treatment in autoimmune disease, transplantation and oncology							Development of CMC process / Tox studies
<b>EnzE</b>	Cancer immunotherapy							Research phase

 Completed
  Ongoing

1) Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7).  
 2) Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine).  
 \*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2. A post-approval study would need to be executed in case of approval.  
 \*\*) FDA: Agreement with the FDA on a regulatory path forward in the US. New randomized control trial could 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 180 questions end of March 2020 and the review process is on track.

An opinion from the CHMP is expected in the second quarter of 2020. Assuming the opinion is positive a potential decision by the European Commission is expected in Q3 2020.

In the U.S., the discussions with the FDA on the design of a randomized, controlled trial is progressing according to plan. 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% or above, 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.

The study discussed with the FDA will 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.

Submission of the study protocol to the FDA is expected in the second quarter, while it is our aim to dose the first patient in the fourth quarter. 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.

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.

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.

At the Cutting Edge of Transplantation (CEOT) Summit held in March this year, the long-term data was presented demonstrating two-year graft survival of 89% after imlifidase treatment and transplantation. The long-term follow-up data is in line with best expectations in this group of highly sensitized patients.

#### **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 of patients lose their kidney function<sup>1</sup>, requiring chronic dialysis and kidney transplantation.

The 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 of 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.

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

Active antibody mediated rejection is a serious condition after transplantation that occurs in roughly 10-15% of kidney transplants<sup>2</sup> or approximately 3,200<sup>3</sup> new patients annually<sup>4</sup> 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.

End of the first quarter 4 of the targeted 30 patients have been treated with imlifidase in AMR across centers in the US, Europe and Australia. The continued recruitment is however expected to be impacted following the COVID-19 virus pandemic. We now expect to complete enrollment in AMR in H1 2021 (3-6 months delay).

#### **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).

By the end of the first quarter 4 of the targeted 30 patients were treated with imlifidase in GBS across centers in France, UK and the Netherlands. The continued recruitment is however expected to be impacted following the COVID-19 virus pandemic. We now expect to complete enrollment in GBS in H2 2021 (3-6 months delay).



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

<sup>2</sup> Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.

<sup>3</sup> Jordan et al., British Medical Bulletin, 2015, 114:113-125.

<sup>4</sup> <http://www.irodat.org>.



## Preclinical development projects

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

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

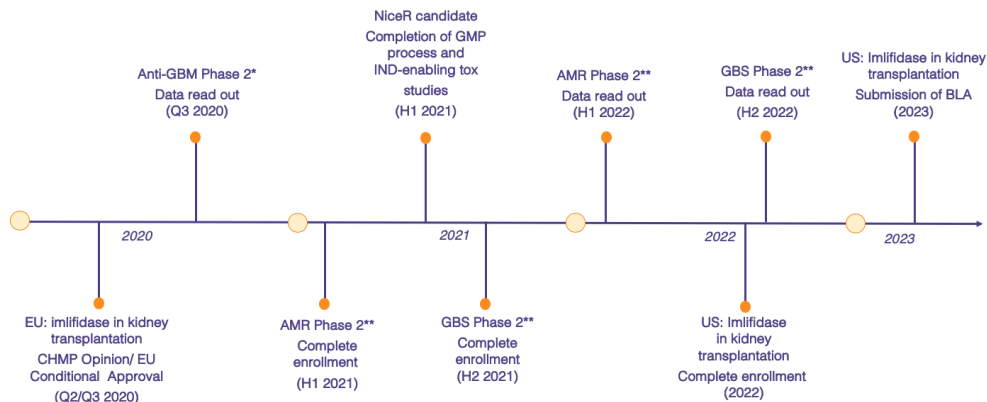
The first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development has been selected. Development of a GMP-manufacturing process for the lead NiceR candidate has since been initiated and preparations for toxicology studies and a clinical Phase 1 study are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

### EnzE – Enzyme-based antibody Enhancement

Published findings<sup>5</sup> 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



\* Investigator-initiated study by [Mårten Segelmark](#), Professor at the universities in Linköping and Lund

\*\* An expected delay in the recruitment of patients of 3-6 months in the AMR and GBS studies have been incorporated following the COVID-19 virus (Corona).



**HANSA**  
BIOPHARMA

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

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 review January – March 2020

## Net revenue

Net revenue for the first quarter 2020 amounted to SEK 0.9m (Q1'19: SEK 0.9m) and comprises of royalty income from Axis-Shield Diagnostics (Abbott group) and patent cost reimbursements.

## Other operating income and expenses

No other operating income was recorded for the first quarter 2020 (SEK 0.1m). Other operating expense for the first quarter 2020, comprised of net currency differences, amounted to SEK 0.6m (SEK 1.2m).

## SG&A expenses

Sales, general and administration expenses for the first quarter 2020 amounted to SEK 38.7m (SEK 29.4m). The increase in expenses reflects the continuing activities related to a potential commercial launch of imlifidase. Recorded non-cash cost for the company's employee long-term incentive programs for the first quarter (LTIP 2016, LTIP 2018 and LTIP 2019) amounting to SEK 2.9m (SEK 0.4m) is included in above SG&A expenses.

## R&D expenses

Research and development expenses for the first quarter 2020 amounted to SEK 52.5m (SEK 42.6m). Recorded non-cash cost for the company's employee long-term incentive programs (LTIP 2016, LTIP 2018 and LTIP 2019) amounting to SEK 1.6m (SEK 0.8) for the first quarter 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, performing 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.

## Financial result

The operating result for the first quarter 2020 amounted to SEK -91.4m (SEK -72.7m).

Net loss for the first quarter 2020 amounted to SEK -93.4m (SEK -72.5m).

## Cash flow, cash and investments

Cash flow from operating activities for the first quarter 2020 amounted to SEK -121.2m (SEK -101.6m). Compared to the previous year, the higher cash consumption is due to preparatory activities throughout the organization related to a potential commercial launch of imlifidase.

Cash and cash equivalents including short term investments amounted to SEK 476.9m on March 31, 2020 as compared to SEK 601.1m at the end of the year 2019.

## Shareholders' equity

On March 31, 2020, equity amounted to SEK 473.9m compared to SEK 562.8m at the end of the year 2019.

## Parent Company

The parent company's net revenue for the first quarter 2020 amounted to SEK 0.9m (SEK 0.9m).

Loss for the parent company for the first quarter 2020 amounted to SEK -93.6m (SEK -72.6).

On March 31, 2020, cash and cash equivalents including short term investments amounted to SEK 471.8m compared to SEK 596.1m at the end of the year 2019.

The parent Company's equity amounted to SEK 473.6m as per March 31, 2020, as compared to SEK 562.9m at the end of 2019.

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



*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.*

## Long-term incentive programs

Hansa Biopharma's past Annual General Meetings have resolved to adopt share-based long-term incentive programs (LTIPs). As of March 31, 2020 the following LTIPs were ongoing: LTIP 2016, LTIP 2018 and LTIP 2019.

The respective cost for Q1-2020 related to such ongoing programs are indicated in below table. For further information to the different LTIP programs please refer to Hansa Biopharma's 2019 Annual Report which can be found at [www.hansabiopharma.com](http://www.hansabiopharma.com).

Ongoing programs	LTIP 2016	LTIP 2018	LTIP 2019
Maximum number of issuable shares*	45,997	789,321	1,154,463
Number of allocated and outstanding share rights and options	35,000	238,368	455,451
Number of acquired and outstanding warrants	-	6,701	11,000
Estimated total cost including social contributions, KSEK	2,848	20,383	29,535
Cost including social contributions Q1-2020, KSEK	237	1,684	2,574

*\*Includes issuable shares to cover social contributions under the LTIPs*

## Risks and uncertainties

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

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

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

## Other information

### Financial calendar 2020

June 23, 2020 – Annual General Meeting

July 16, 2020 - Interim report for Jan - Jun. 2020

October 22, 2020 – Interim report for Jan - Sep 2020

### Contacts

Klaus Sindahl, Head of Investor Relations

Hansa Biopharma

Mobile: +46 (0) 709–298 269

E-mail: [klaus.sindahl@hansabiopharma.com](mailto:klaus.sindahl@hansabiopharma.com)

### Legal disclaimer

This financial report includes statements that are forward looking, and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are 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 March 31, 2020	SEK 3.1bn
Ticker	HNSA
ISIN	SE0002148817

### Top 10 shareholders as of March 31, 2020

Name	Number of shares	Ownership in pct
NXT2B	5 755 379	14.4
Invesco	2 116 818	5.3
Consonance Capital Management LP	2 088 285	5.2
Thomas Olausson	1 713 474	4.3
Gladiator	1 530 014	3.7
Avanza Pension	1 372 236	3.3
Third Swedish National Pension Fund	1 316 470	3.2
Fourth Swedish National Pension Fund	1 112 044	2.7
Vanguard	930 811	2.2
ClearBridge, LLC	691 486	1.7
Other	21 444 910	53.5
<b>Outstanding shares in total</b>	<b>40 026 107</b>	<b>100.0</b>

*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 March 31, 2019, Hansa Biopharma had 13,062 shareholders.

*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.*

# 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 April 28, 2020

**Ulf Wiinberg**  
Chairman of the Board

**Birgit Stattin Norinder**  
Board member

**Eva Nilsagård**  
Board member

**Mats Blom**  
Board member

**Andreas Eggert**  
Board member

**Anders Gersel Pedersen**  
Board member

**Søren Tulstrup**  
President & CEO

*Hansa Biopharma is leveraging its proprietary 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.*



## Condensed unaudited financial statements

### Consolidated statement of comprehensive income

	Q1		Year
KSEK	2020	2019	2019
Revenue	885	917	3 364
Cost of revenue	-423	-401	-866
<b>Gross profit</b>	<b>462</b>	<b>516</b>	<b>2 498</b>
Other operating income	-	60	166
Sales, general and administration expenses	-38 670	-29 448	-167 310
Research and development expenses	-52 545	-42 581	-192 949
Other operating expenses	-598	-1 229	-2 073
<b>Operating profit/loss</b>	<b>-91 351</b>	<b>-72 682</b>	<b>-359 668</b>
Financial income/expenses	-2 029	350	76
<b>Profit/loss for the period before tax</b>	<b>-93 380</b>	<b>-72 332</b>	<b>-359 592</b>
Tax	11	-147	-417
<b>Net profit/loss for the period</b>	<b>-93 369</b>	<b>-72 479</b>	<b>-360 009</b>
Attributable to:			
Parent company shareholders	-93 369	-72 479	-360 009
<b>Earnings per share (EPS)</b>			
Before dilution (SEK)	-2,33	-1,81	-9,00
After dilution (SEK)	-2,33	-1,81	-9,00
<b>Other comprehensive income</b>			
Items that have been, or may be reclassified to profit or loss for the period			
Translation differences	90	129	143
Changes in fair value on available-for-sale financial assets	-	-	207
Items that cannot be reclassified to profit or loss for the year			
Shares valued to fair value as comprehensive income		42 441	49 597
<b>Other comprehensive income for the year</b>	<b>90</b>	<b>42 570</b>	<b>49 947</b>
<b>Total net comprehensive income</b>	<b>-93 279</b>	<b>-29 908</b>	<b>-310 062</b>

## Consolidated balance sheet

	March 31		December 31
KSEK	2020	2019	2019
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	33 210	33 199	33 348
Property, plant and equipment	5 884	4 408	6 035
Leased assets	8 153	15 432	9 109
Financial assets	-	81 970	-
<b>Total non-current assets</b>	<b>47 247</b>	<b>135 008</b>	<b>48 493</b>
<b>Current assets</b>			
Current receivables, non-interest bearing	15 334	3 795	14 650
Short-term investments	327 747	419 301	419 397
Cash and cash equivalents	149 159	339 929	181 697
<b>Total current assets</b>	<b>492 240</b>	<b>763 025</b>	<b>615 743</b>
<b>TOTAL ASSETS</b>	<b>539 486</b>	<b>898 032</b>	<b>664 236</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>473 946</b>	<b>835 074</b>	<b>562 815</b>
<b>Non-current liabilities</b>			
Deferred tax liabilities	505	510	507
Provisions	958	10 196	818
Lease liabilities	4 711	8 548	4 827
Contingent consideration	760	740	730
<b>Total non-current liabilities</b>	<b>6 934</b>	<b>19 993</b>	<b>6 881</b>
<b>Lease liabilities</b>	<b>3 852</b>	<b>5 938</b>	<b>4 632</b>
Current liabilities, non-interest bearing	25 295	24 114	57 513
Accrued expenses and deferred income	29 459	12 914	32 395
<b>Total current liabilities</b>	<b>58 606</b>	<b>42 965</b>	<b>94 540</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>539 486</b>	<b>898 032</b>	<b>664 236</b>

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	Q1		Year
	2020	2019	2019
Opening shareholders' equity	562 815	859 876	859 876
Result for the period	-93 369	-72 479	-360 009
Other comprehensive income for the period	90	42 570	49 947
<b>Net comprehensive income</b>	<b>-93 279</b>	<b>-29 908</b>	<b>-310 062</b>
<b>Transactions with the group's owner</b>			
New share issue	-	2 309	716
Expenses attributable to new share issue	-	-10	-7 646
Sales own shares	-	877	877
Issued warrants	-	14	193
Long term incentive programs	4 410	1 915	17 268
Treasury shares acquired			-716
By employees redeemed stock options	-		2 309
<b>Total transactions with the group's owner</b>	<b>4 410</b>	<b>5 106</b>	<b>13 001</b>
<b>Closing shareholders' equity</b>	<b>473 946</b>	<b>835 074</b>	<b>562 815</b>

## Consolidated cash flow statement

KSEK	Q1		Year
	2020	2019	2019
<b>Operating activities</b>			
Operating profit/loss	-91 351	-72 682	-359 668
Adjustment for items not included in cash flow <sup>[1]</sup>	5 528	3 375	14 613
Interest received and paid, net	-122	-324	-337
Income taxes paid	-	-	-123
<b>Cash flow from operations before change in working capital</b>	<b>-85 944</b>	<b>-69 631</b>	<b>-345 516</b>
Change in working capital	-35 235	-31 969	10 743
<b>Cash flow from operating activities</b>	<b>-121 180</b>	<b>-101 600</b>	<b>-334 775</b>
<b>Investing activities</b>			
Acquisition of intangible assets	-	-	-729
Acquisition of property, plant and equipment	-138	-23	-2 699
Proceeds from sale of equipment	-	87	87
Sale of short term investments	89 741	-	-
Proceeds from sale of Genovis	-	-	89 125
<b>Cash flow from investing activities</b>	<b>89 602</b>	<b>64</b>	<b>85 784</b>
<b>Financing activities</b>			
Issue of warrants	-	2 309	-
Cost of share issue	-	-10	-7 646
Sale of treasury shares	-	877	877
Issue of warrants	-	-	2 309
Repayment of lease liabilities	-1 155	-1 257	-4 424
<b>Cash flow from financing activities</b>	<b>-1 154</b>	<b>1 920</b>	<b>-8 884</b>
<b>Net change in cash</b>	<b>-32 733</b>	<b>-99 616</b>	<b>-257 875</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>181 697</b>	<b>439 441</b>	<b>439 441</b>
Currency exchange variance, cash and cash equivalents	195	104	131
<b>Cash and cash equivalents, end of period</b>	<b>149 159</b>	<b>339 929</b>	<b>181 697</b>

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

## Parent company - Statement of comprehensive income

KSEK	Q1		Year
	2020	2019	2019
Revenue	885	917	3 364
Cost of revenue	-423	-401	-866
<b>Gross profit</b>	<b>462</b>	<b>516</b>	<b>2 498</b>
Other operating income	-	60	166
Sales, general and administration expenses	-38 972	-29 535	-168 515
Research and development expenses	-52 445	-42 825	-192 548
Other operating expenses	-597	-1 206	-2 074
<b>Operating profit/loss</b>	<b>-91 553</b>	<b>-72 990</b>	<b>-360 474</b>
Result from sales of financial fixed assets	-	-	-
Result from short term financial receivables	-1 910	548	511
Other financial expenses	-119	-198	-435
Loss for the period before tax	-93 582	-72 640	-360 398
Income tax benefit/expense	-	-	-
<b>Loss for the period after tax</b>	<b>-93 582</b>	<b>-72 640</b>	<b>-360 398</b>
Other comprehensive income for the period	-	42 441	49 804
<b>Total net comprehensive income</b>	<b>-93 582</b>	<b>-30 199</b>	<b>-310 594</b>

## Parent company - Changes in equity

KSEK	March 31		December 31
	2020	2019	2019
<b>Opening shareholders' equity</b>	<b>562 763</b>	<b>833 270</b>	<b>833 270</b>
Justering för retroaktiv tillämpning/ändring	-	-	-
Justerat eget kapital 2012-01-01	562 763	833 270	833 270
Change in accounting principle	-	-	-
Opening shareholders' equity	-	-	-
Result for the period	-93 582	-72 640	-360 398
Other comprehensive income for the period	-	42 441	49 804
Net comprehensive income	-93 582	-30 199	-310 594
Change in accounting principle	-	27 030	27 029
New share issue <sup>[1]</sup>	-	2 309	0
Expenses attributable to new share issue <sup>[2]</sup>	-	-10	-7 646
Sales and purchase own shares <sup>[1]</sup>	-	877	877
Issued warrants	-	14	193
Long term incentive programs	4 410	1 741	17 324
By employees redeemed stock options	-	-	2 309
New share issue under registration	-	-	-
<b>Total transactions with the group's owner</b>	<b>4 410</b>	<b>31 961</b>	<b>40 086</b>
<b>Closing shareholders' equity</b>	<b>473 592</b>	<b>835 029</b>	<b>562 763</b>

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.

2) 2019 expenses relate to the directed share issue in 2018 (KSEK -7,596) and the LTIPs (KSEK -60)

## Parent company - Balance sheet

KSEK	March 31		December 31
	2020	2019	2019
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	29 398	30 024	29 522
Property, plant and equipment	5 884	4 407	6 035
Leased assets	8 153	15 432	9 109
Investment in subsidiaries	5 095	5 095	5 095
Investment in Genovis	-	81 970	-
Receivables, group companies	2 359	-	2 244
<b>Total non-current assets</b>	<b>50 889</b>	<b>136 928</b>	<b>52 005</b>
<b>Current assets</b>			
Receivables, group companies	926	-	1 061
Current receivables, non-interest bearing	14 836	5 217	14 369
Short-term investments	327 747	419 301	419 397
Cash and cash equivalents	144 079	335 213	176 715
<b>Total current assets</b>	<b>487 588</b>	<b>759 731</b>	<b>611 542</b>
<b>TOTAL ASSETS</b>	<b>538 477</b>	<b>896 659</b>	<b>663 547</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>473 592</b>	<b>835 029</b>	<b>562 763</b>
<b>Non-current liabilities</b>			
Liabilities, group companies	-	-	-
Provisions/DTL	958	10 173	818
Lease liabilities	4 711	8 548	4 827
Contingent consideration	759	740	730
<b>Total non-current liabilities</b>	<b>6 428</b>	<b>19 461</b>	<b>6 375</b>
<b>Current liabilities</b>			
Lease liabilities	3 852	5 938	4 632
Liabilities, group companies	1 700	-	2 793
Current liabilities, non-interest bearing	24 968	23 350	56 883
Accrued expenses and deferred income	27 937	12 880	30 102
<b>Total current liabilities</b>	<b>58 457</b>	<b>42 168</b>	<b>94 410</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>538 477</b>	<b>896 659</b>	<b>663 547</b>

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 2019 was published on April 2, 2020 and is available on [www.hansabiopharma.com](http://www.hansabiopharma.com). Disclosures in accordance with IAS 34.16A are as applicable in the notes or on the pages before the consolidated income statement.

### Change in accounting principles for the Parent Company

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

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

### Effects of the change to IFRS 9

The change to IFRS 9 led to an increase in the opening balance of equity as per 1 January 2019 amounting to SEK 27,030k. The change to IFRS 9 led to an increase in other comprehensive income of SEK 42,441k for Q1-2019 and 49,804k for the full year 2019, while profit and loss changed by -76,626k for the full year 2019.

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

The change led to an increase in the balance sheet of investment in in Genovis AB at 31 March 2019 amounting to SEK 42,441k and the contra entry was recorded in other comprehensive income.

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

There was no change in the statement of cash flows.

### Effects of the change to IFRS 16

The change to IFRS 16 led to the parent company recognizing leasing liabilities of SEK 13,354k and right-of-use assets of SEK 13,354k as per 1 January 2019. Per 31 December 2019, the leasing liabilities amounted to SEK 8,975k and right-of-use assets to SEK 9,109k.

The change to IFRS 16 led to the parent company recognizing leasing liabilities of SEK 14,486k and right-of-use assets of SEK 15,432k as per 31 March 2019.

The change to IFRS 16 led to an impact on the statement of profit or loss for the parent company for the full year 2019 of depreciation amounting to SEK -4,784k and interest expenses amounting to SEK -392k and partly offset by lease expenses amounting SEK 4,708k for the full year 2019.

The change to IFRS 16 led to an impact on the statement of profit or loss for the parent company for Q1 2019 of depreciation amounting to SEK -1,243k and interest expenses amounting to SEK -122k and partly offset by lease expenses amounting SEK 1,167k in the first quarter of 2019.

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

## Note 2 Net revenue

Income per significant category of income KSEK		Q1		Year
		2020	2019	2019
Group				
Net revenue:				
	Royalty and license revenue	582	566	2 265
	Milestone revenue	-	-	573
	Patent reimbursement	302	351	526
		885	917	3 364
Parent company				
Net revenue:				
	Royalty and license revenue	582	566	2 265
	Milestone revenue	-	-	573
	Patent reimbursement	302	351	526
		885	917	3 364

## Note 3 Fair value of financial instruments

The Group measures its investments in interest funds and its financial liability for contingent consideration at fair value. The fair value of interest funds at March 31, 2020 amounted to SEK 327.7 million (Q4'19: SEK 419.3 million) and belonged to level 2 in the fair value hierarchy. The fair value of the financial liability for contingent consideration at March 31, 2020 amounted to SEK 0.8 million (Q4'19: SEK 0.7 million) and belongs to level 3 in the fair value hierarchy. All other financial instruments are measured at amortized cost. The carrying values of those instruments are considered reasonable approximations of their fair values.

# Glossary

## AMR

Antibody mediated rejection of a transplanted organ.

## Antibody

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

## Anti-GBM disease (Goodpasture syndrome)

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

## Autoimmune disease

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

## B-cells

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

## Biologics License Application (BLA)

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

## Biopharmaceutical

A pharmaceutical drug that is manufactured using biotechnology.

## Biotechnology

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

## Clinical Phase 1

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

## Clinical Phase 2

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

## Clinical Phase 3

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

## Donor specific antibodies (DSA)

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

## Enzyme

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

## Guillian-Barré syndrome (GBS)

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

## Heparin Binding Protein (HBP)

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

## Human Leukocyte Antigen (HLA)

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

## Immunoglobulin G (IgG)

Immunoglobulin G is the predominant type of antibody in serum.

## Imlifidase

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

## International Non-proprietary Name (INN)

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

## Marketing Authorization Application (MAA)

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

*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.*