Interim report January–March **2019**

HANSA BIOPHARMA

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# MAA filing of IDEFIRIX (imlifidase) in Europe marks a milestone in Hansa's evolution into a commercial stage biopharmaceutical company

**January – March 2019 Highlights**

- The European Medicines Agency (EMA) accepted Hansa's Marketing Authorization Application (MAA) for review of IDEFIRIX (imlifidase). This acceptance marks the beginning of the regulatory review process for IDEFIRIX in the European Union (EU). IDEFIRIX has both EU Orphan Drug Designation and PRIority MEdicine (PRIME) designation. An opinion of the EMA Committee for Medicinal Products for Human Use (CHMP) is expected within 210 days plus potential clock stops for applicant responses.
- In Hansa's most recent meeting with the U.S. Food and Drug Administration (FDA) in December 2018, the agency provided overall positive feedback on the data generated on imlifidase to date and acknowledged the high unmet medical need of highly sensitized patients who currently can't access kidney transplantation. Hansa has now decided to do complementary analyses with respect to transplantability for highly sensitized patients, based on data from the successfully completed Phase 2 studies of imlifidase and matched controls from the U.S. transplant registry (SRTR/OPTN). We believe these analyses will help further illustrate the value of imlifidase in the U.S. healthcare system. As soon as the analyses are concluded, Hansa will schedule a subsequent meeting with the FDA, expected to take place in the second half of 2019. In this meeting, the dialogue with the FDA will be continued to determine the path forward for regulatory filing and approval in the U.S. for imlifidase in kidney transplantation of highly sensitized patients.
- The Company has selected a lead candidate from its NiceR program (Novel IgG Cleaving Enzymes for Repeat dosing). The new drug candidate may have broader value as a potential treatment for unmet needs that would benefit from repeat dosing, including relapsing autoimmune diseases, chronic transplant rejection, oncology and gene therapy. This is the first IgG eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development.

The Company's Phase 2 study of imlifidase in acute Antibody-Mediated Rejection (AMR) in Kidney Transplantation has received Clinical Trial Application and Ethics Committee approvals. The study will enroll approximately 30 patients at eight clinical trial centers in France, Sweden, Austria, Australia and the United States.

- The Company has continued to expand its leadership team as Hansa transforms into commercial-stage biopharmaceutical company. Donato Spota has been appointed the Company's new Chief Financial Officer, effective May 15, 2019 and Anne Säfström Lanner has been appointed Vice President, Global Human Resources. Mr. Spota is a senior executive with more than 20 years of strategic and operational experience in the global pharmaceutical industry, including investor relations and international capital markets transactions. Mrs. Lanner has over 15 years of broad human resources experience in international growth companies.

**Significant events after the end of the reporting period**

- Hansa Biopharma received Clinical Trial Application and Ethics Committee approvals in Europe for its Phase 2 study of imlifidase in Guillain Barré Syndrome (GBS). The study will enroll up to 30 patients at approximately ten clinical trial centers in France, U.K and the Netherlands over the next 18 months.
- Hansa Biopharma divested its entire equity holding in Genovis AB (NASDAQ Stockholm: GENO). The transaction generated gross proceeds of SEK 89 million ($9.6 million). The proceeds will be used as working capital not only to expedite further the clinical development program of imlifidase in transplant rejection (AMR) and autoimmune diseases, but also to ramp up preparations for clinical studies with the recently selected lead in the NiceR-program, Hansa's program for the development of novel IgG-cleaving enzymes for repeat dosing.

## Financial summary – First quarter

| | Q1 | | Year |
|---|---|---|---|
| KSEK, unless otherwise stated | 2019 | 2018 | 2018 |
| Net revenue | 917 | 588 | 3,358 |
| Operating profit/loss | -72,682 | -46,622 | -246,498 |
| Net profit/loss | -72,479 | -46,498 | -247,974 |
| Earnings per share before and after dilution (SEK) | -1.81 | -1.23 | -6.47 |
| Shareholders' equity | 835,074 | 591,805 | 859,876 |
| Cash flow from operating activities | -101,602 | -44,094 | -204,560 |
| Cash and cash equivalents including short term invesments | 759,230 | 575,049 | 858,187 |

# CEO statement

It is now twelve months since I joined Hansa, and I'm extremely proud of all we accomplished this past year to demonstrate the potential of our immunomodulatory enzyme technology and imlifidase. Our main priority is getting our lead compound imlifidase to market to enable lifesaving kidney transplants for highly sensitized patients, who currently cannot receive this standard of care treatment. At the same time, we continue developing our proprietary enzymology platform in other rare, life-threatening diseases.

In February, EMA accepted our MAA for review of IDEFIRIX (imlifidase). This acceptance marks the beginning of the regulatory review process for IDEFIRIX in the EU. In our most recent meeting the FDA in December 2018, the agency provided overall positive feedback on the data generated on imlifidase to date and acknowledged the high unmet medical need of highly sensitized patients who currently can't access kidney transplantation. Hansa has now decided to do complementary analyses with respect to transplantability for highly sensitized patients, based on data from the successfully completed Phase 2 studies of imlifidase and matched controls from the U.S. transplant registry (SRTR/OPTN). We believe these analyses will help further illustrate the value of imlifidase in the U.S. healthcare system. As soon as the analyses are concluded, Hansa will schedule a subsequent meeting with the FDA, expected to take place in the second half of 2019. In this meeting, the dialogue with the FDA will be continued to determine the path forward for regulatory filing and approval in the U.S. for imlifidase in kidney transplantation of highly sensitized patients.

Imlifidase may have potential applications in transplantation of other organs and tissue as well as an array of acute autoimmune indications, including Acute Kidney Antibody Mediated Rejection (AMR) post transplantation. In March, we received Clinical Trial Application and Ethics Committee approvals for our Phase 2 study of imlifidase in acute 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. In April we got a similar approval for the initiation of a Phase 2 Study of imlifidase in Guillain Barré Syndrome (GBS). GBS is a rare, acute inflammatory disease of the peripheral nervous system that affects 1-2 in 100,000 people annually.

Our program of next generation IgG-cleaving enzymes, NiceR, also advanced recently with the selection of a lead candidate for clinical development. The new drug candidate may have broader value as a potential treatment for unmet needs that may benefit from repeat dosing, including relapsing autoimmune diseases, chronic transplant rejection, oncology and gene therapy.

Mid-April we divested our shareholding in Genovis to a group of Swedish institutional investors. The transaction provides a profitable exit for Hansa Biopharma, and the funds generated will be used as working capital to further expedite our promising clinical pipeline of potential treatments for rare IgG-mediated diseases.

As part of the ongoing expansion of our organization, we appointed Mr. Donato Spota as new Chief Financial Officer, effective May 15, 2019, and Ms. Anne Säfström Lanner as Vice President, Global Human Resources. We are delighted to welcome Donato and Anne as we grow Hansa Biopharma into a global commercial-stage biopharma company. They will be very valuable additions to our team as we continue the transformation of Hansa and grow our operations and organization.

Based on the progress so far this year, I believe we are poised for continued success in 2019, with a growing body of clinical evidence supporting the efficacy of imlifidase, multiple opportunities in additional indications, and a potential pipeline of next-generation drug candidates. I look forward to updating you on our continued progress.

**Søren Tulstrup**
President and CEO of Hansa Biopharma
Lund, Sweden, April 29, 2019

# Hansa Biopharma in brief

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 of 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.

# Business overview

**Imlifidase** is a novel enzyme that specifically and rapidly cleaves immunoglobulin G (IgG), thereby eliminating immunological barriers and enabling treatment of IgG-mediated diseases. Imlifidase, proposed product name IDEFIRIX, is in late-stage clinical development for kidney transplantation. Imlifidase is also being evaluated in IgG-mediated autoimmune disorders.

**NiceR** is a program developing novel IgG-inactivating drug candidates for repeat dosing, which may enable broader usage in relapsing autoimmune diseases and oncology. In the first quarter of 2019, a lead candidate was selected for preparation for clinical development from the NiceR program.

**EnzE** is a preclinical research and development program under which the combined use of approved antibody-based cancer treatments with IgG-modulating enzymes is explored in order to potentially increase the efficacy of presently available antibody-based cancer therapies.

## Pipeline (as per April 29, 2019)

| Candidate/ Method/Project | Indication | Research/ Preclinical | Phase 1 [1] | Phase 1/2 | Phase 2 | Reg. interactions | Registration |
|---|---|---|---|---|---|---|---|
| THERAPEUTICS | | | | | | | |
| **Imlifidase** | Kidney transplantation in highly sensitized patients | | | | | | |
| | Anti-GBM antibody disease | | | | | | |
| | Antibody mediated kidney transplant rejection (AMR) | | | | | | |
| | Guillain-Barré syndrome (GBS) | | | | | | |
| **NiceR** | Recurring treatment in autoimmune disease, transplantation and oncology | | | | | | |
| **EnzE** | Cancer immunotherapy | | | | | | |
| DIAGNOSTICS | | | | | | | |
| **HBP-assay (IVD)** [2] | Prediction of severe sepsis | | | | | | |

In planning  Ongoing  Completed

[1] Present and future imlifidase Phase 2 studies to be based on the same Phase 1 study. Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7).
[2] Out-licensed to Axis-Shield Diagnostics Ltd.

## Imlifidase

**Imlifidase – A novel therapeutic approach**

Hansa Biopharma's lead drug candidate, imlifidase, represents a unique and novel approach to rapidly and effectively eliminate IgG-antibodies. Imlifidase cleaves immunoglobulin G (IgG) with a high degree of specificity. Several rare autoimmune diseases are characterized by pathogenic IgG-antibodies and, in organ and tissue transplantation, IgG-antibodies can prohibit patients from being transplanted or cause rejection after transplantation. Hansa is developing imlifidase as a single intravenous treatment for fast and effective elimination of IgG-antibodies in transplantation and acute autoimmune diseases.

**Overview of imlifidase clinical program**

The Company's lead clinical development program for imlifidase is focused on treatment with imlifidase prior to kidney transplantation. The long-term vision for Hansa is to establish imlifidase as a therapy for fast and efficient elimination of IgG in several transplant-related indications and acute autoimmune diseases.

Imlifidase has been evaluated in a Phase 1 study[1] in healthy subjects and in four Phase 2 studies in sensitized patients awaiting kidney transplantation[2, 3]. The results from these studies demonstrate that imlifidase is highly effective in reducing donorspecific antibodies (DSAs) to levels that enable transplantation, and that imlifidase is well-tolerated. Based on the successful outcome from these five clinical studies, Hansa is seeking a path towards regulatory approval in Europe and the U.S.

An investigator-initiated Phase 2 study evaluating imlifidase in anti-GBM antibody disease, an ultra-rare and acute autoimmune kidney disease, is ongoing at several European nephrology clinics with Professor Mårten Segelmark at the university hospital in Lund as principal investigator. Also, a Phase 2 study in kidney transplant antibody mediated rejection (AMR) has been initiated as well as a Phase 2 with imlifidase in the rare neurological disease Guillain-Barré syndrome (GBS) following ethical review board and regulatory approvals.

**Imlifidase – enabling kidney transplantation for highly sensitized patients**

Highly sensitized patients have high levels of anti-HLA antibodies, which are likely to target and significantly compromise a transplanted organ. The more antibodies, the lower the likelihood of finding a donor organ that will be a match. Many highly sensitized patients will indefinitely remain in a debilitating disease state on long-term dialysis treatment, which is associated with high cost, a poor quality of life and an increased mortality rate.

In September 2018, Hansa announced the successful completion of the third and fourth Phase 2 studies evaluating imlifidase in kidney transplantation for highly sensitized patients. The Hansa sponsored, multi-center Highdes study enrolled 18 patients at five sites in the U.S., France and Sweden; the U.S. investigator-initiated study enrolled 17 patients at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center, Los Angeles.

Across both studies, treatment with imlifidase successfully enabled transplantation for all 35 patients. At study completion, six months post-transplantation, graft survival was 91%. Thirty-two patients were off dialysis with good kidney function with estimated glomerular filtration rates (eGFR) within the expected range. Three patients experienced graft loss unrelated to the treatment with imlifidase. Results demonstrate favorable safety profile after six months follow-up.

The trials were single-arm, open-label studies designed to assess the safety and efficacy of imlifidase for patients transplanted with either a deceased or living donor kidney. The 35 highly sensitized patients had either failed previous attempts of desensitization or were highly unlikely to receive a compatible kidney transplant.

***Latest developments***

The Company submitted a Marketing Authorisation Application (MAA) for review of IDEFIRIX (imlifidase) with the EMA on February 5, 2019. On February 28, 2019 EMA accepted the submission of the MAA. An opinion of the EMA Committee for Medicinal Products for Human Use (CHMP) is expected within 210 days (plus any clock-stops for the applicant to provide answers to questions which may arise during the review). After adoption of a CHMP opinion, a final decision regarding the MAA for IDEFIRIX is made by the European Commission.

Hansa's dialogue with the FDA to determine the path forward for the U.S regulatory approval is ongoing and the Company will provide updated guidance regarding the timeline for a potential BLA filing following its next meeting with the agency.

A separate long-term observational prospective follow-up study is ongoing since mid 2018. This study will seek to enroll all imlifidase treated transplant patients in order to evaluate graft survival across a five-year time frame. The study aims to encompass all patients from the four Phase 2 studies of imlifidase in sensitized kidney transplantation patients. Interim results will be available on a regular basis. The objective of the study is to collect long-term outcome data to provide further support to future prescribers, payers and patients.

**Imlifidase – Treatment of anti-GBM antibody disease**

Anti-GBM antibody disease, also known as Goodpasture's disease, is a rare, acute autoimmune disease where autoantibodies directed against type IV collagen cause acute inflammation of the kidney and/or the lungs. In severe anti-GBM, the disease may progress to renal failure or death. Anti-GBM antibody disease affects one in a million patients annually[4], and less than one third of the patients survive with preserved kidney function after six-months follow-up[5].

An open-label, investigator-initiated Phase 2 study in severe anti-GBM antibody disease with imlifidase is ongoing. Currently eight 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.

Both FDA and the European Commission, following the recommendation from EMA, have granted Orphan Drug Designation for imlifidase for the treatment of anti-GBM. Orphan Drug Designation qualifies the sponsor of the drug for various development incentives and up to seven years of marketing exclusivity in the U.S. and ten years in EU from time of marketing approval.

***Latest developments***

To date, eight patients have been treated with imlifidase in the anti-GBM Phase 2 study. Although limited follow up data is available at this point, the patients have responded favorably, and imlifidase appears to be well-tolerated. Additional sites have been added to this study which will continue to actively recruite patients with this ultra-rare disease. Completion of patient enrollment to this study is anticipated for 2019.

**Imlifidase- Treatment of acute kidney transplant antibody-mediated rejection (AMR)**

There is no approved therapy for the treatment of acute AMR. In heart, lung and kidney transplants, acute AMR occurs in 10–20 percent[6] of patients and remains a significant unmet medical need associated with loss of graft function. Imlifidase is highly effective in inactivating IgG and has the potential to halt progression of AMR and be an effective treatment in acute cases.

***Latest developments***

In the first quarter of 2019, Hansa initiated a Phase 2 study, which will recruit approximately 30 patients from eight sites in the U.S., France, Sweden, Austria and Australia over the next 12 months. The study is a randomized, open-label, multi-center, active control study 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.

**Imlifidase - Treatment of Guillain-Barré syndrome (GBS)**

GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG-antibodies. It affects one in 100,000 people annually[7]. While patients are typically treated with either IVIg or plasmapheresis, there remains a significant unmet medical need. In February 2018, imlifidase received Orphan Drug Designation from the FDA for the treatment of GBS.

***Latest developments***

Hansa received Clinical Trial Application and Ethics Committee approvals for the company's Phase 2 study of imlifidase in Guillain Barré Syndrome (GBS) in the beginning of the second quarter 2019. The Phase 2 study will recruit up to 30 patients from approximately ten European sites over the next 18 months. The study 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).

# Completed and ongoing clinical studies with imlifidase

## Overview

| Type of study | ClinicalTrials.gov Identifier | Subjects | Status | Results | Publication |
|---|---|---|---|---|---|
| Phase 1 in healthy subjects | NCT01802697 | 29 | Completed | Imlifidase is efficacious and well tolerated with a favorable safety profile. | PLOS ONE (2015)[1] |
| Phase 2 in sensitized patients | NCT02224820 | 8 | Completed | Imlifidase treatment resulted in HLA levels acceptable for transplantation in all patients. | American Journal of Transplantation (2018)[2] |
| Phase 2 in sensitized patients | NCT02475551 | 10 | Completed | Imlifidase enabled kidney transplantation for all patients with a favourable safety profile. | The New England Journal of Medicine (2017)[3] |
| Phase 2 in highly sensitized patients | NCT02426684 | 17 | Completed | The imlifidase treatment enabled life-saving transplants in all 17 patients. Graft survival at study completion, six months post-transplantation, was 94%. | The New England Journal of Medicine (2017)[3] |
| Multicenter Phase 2 in highly sensitized patients (Highdes) | NCT02790437 | 18 | Completed | The imlifidase treatment enabled life-saving transplants in all 18 patients. Graft survival at study completion, six months post-transplantation, was 89%. | |
| Observational follow-up study (US, France, Sweden) | NCT 03611621 | 46 | Enrolling. Transplanted patients to be followed up to five years | | |
| Phase 2 in Anti-GBM disease (GOOD-IDES) | NCT03157037 | Approx. 15 | Enrolling | | |
| Phase 2 in AMR | NCT03897205 | Approx. 30 | Enrolling | | |
| Phase 2 in GBS | NCT not yet assigned | Approx. 30 | Clinical Trial Application approved and clearance from ethical review board | | |

**Manufacturing of imlifidase**
Imlifidase manufacturing has been transferred to contract manufacturers suitable for producing imlifidase for commercialization. The manufacturing processes has been optimized, and the product for commercialization is a lyophilized product, which provides the advantages of easy off-the-shelf use and efficient global distribution. The first GMP batch for further validation was produced in late 2017. Full process characterization and validation for commercial supply was completed during 2018

**Regulatory strategy for imlifidase to enable kidney transplantation in highly sensitized patients**
The recently completed Phase 2 studies have enrolled highly sensitized patients who had either failed previous attempts of transplantation or were highly unlikely to receive a compatible kidney transplant. Based on the results from these successfully completed Phase 2 studies, Hansa is seeking a path towards regulatory approval.

In May 2017, the EMA granted imlifidase access to its PRIority MEdicines (PRIME) scheme for highly sensitized kidney transplant patients. PRIME is based on enhanced interaction and early dialogue with developers of promising medicines, to optimize development plans and speed up evaluation so these medicines can reach patients earlier.

In October 2018 the FDA granted imlifidase Fast Track Designation for the investigation of imlifidase for transplantation. The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical need. Fast Track designation provides a company more frequent communication with the FDA regarding the investigational drug's development plan and also provides eligibility for priority review if certain criteria are met.

In February 2019 the EMA accepted Hansa's MAA for review of IDEFIRIX (imlifidase). Hansa's dialogue with the FDA to determine the path forward for the U.S regulatory approval is ongoing and the Company will provide updated guidance regarding the timeline for a potential BLA filing following its next meeting with the agency.

## Preclinical development projects

**NiceR – Novel Immunoglobulin 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 benefit from more than one dose of an IgG- modulating enzyme. The Company has developed and patented several novel immunoglobulin cysteine endopeptidases.

Significant progress was made during 2018 in the NiceR-project and in March 2019 Hansa announced that a lead candidate for clinical development was selected. This is the first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development. Development of a GMP-manufacturing process for the lead NiceR candidate has since been initiated and preparations for toxicology studies and a clinical Phase 1 study are now ongoing.

**EnzE – Enzyme-based antibody Enhancement**
Published findings[8] 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-clearing agent (e.g. imlifidase or the selected NiceR-lead) as a pretreatment for cancer. 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. The EnzE program is in the pre-clinical research phase.

## Out-licensed royalty generating programs

**HBP – Prediction of severe sepsis**
The HBP-assay for measurement of heparin-binding protein (HBP) in plasma is a novel diagnostic method originally developed and patented by Hansa to assist in predicting severe sepsis in patients with infectious disease symptoms at emergency departments[9]. Hundreds of thousands of patients die every year due to severe sepsis as a complication of infections, e.g. urinary tract infection and pneumonia. Many of these infections can be effectively treated with antibiotics in order to prevent progression to severe sepsis, although early prediction of risk patients is crucial for successful treatment. Severe sepsis affects 300 of 100,000 people annually[10]. The HBP-assay has been out-licensed by Hansa to UK-based Axis-Shield Diagnostics, a subsidiary to Abbott, and Hansa holds the right to royalty payments from Axis-Shield. Axis-Shield is engaged in further product development and clinical development with the HBP-assay.

# Financial review January–March 2019

## Net revenue

Net revenue for the first quarter 2019 amounted to SEK 0.9 m (0.6) and is comprised of royalty income from Axis-Shield Diagnostics and patent reimbursements.

## Other operating income and expenses

Other operating income amounted to SEK 0.1 m (0.2) for the first quarter 2019 and is comprised of grant from Vinnova. Other operating expense, comprised of net currency differences, amounted to SEK 1.2 m (0.4) for the first quarter 2019.

## Sales, general and administration expenses

Sales, general and administration (SG&A) expenses for the first quarter 2019 amounted to SEK 29.5 m (15.5). The increase of the expenses reflects the continuing activities to build the organization for drug approval and commercial launch and include recorded non-cash costs for the company's employee long-term incentive programs (LTIP 2016 and LTIP 2018) amounting to SEK 0.4 m (4.9). 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 is marginal for the first quarter 2019.

## Research and development expenses

Research and development (R&D) expenses amounted to SEK 42.6 m (31.5) for the first quarter 2019 and include non-cash costs for the company's long-term incentive programs amounting to SEK 0.8 m (0.4). Compared with the previous year, the higher expenses are due to intensified activities within medical affairs and the development of that organization prior to the planned launch. 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 is marginal for the first quarter 2019.

## Financial result

Operating result for the first quarter 2019 amounted to SEK -72.7 m (-46.6). Profit/loss for the first quarter 2019 amounted to SEK -72.5 m (-46.5).

## Cash flow and investments

Cash flow from operating activities amounted to SEK -101.6 m (-44.1) for the first quarter 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 1.0 m 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 759.2 m on March 31, 2019, as compared with SEK 858.2 m at the end of 2018.

Investments for the first quarter 2019 amounted to SEK 0.1 m (0.3). Cash flow from financing activities amounted to SEK 1.9 m (3.4) for the first quarter 2019.

## Shareholders' equity

On March 31, 2019 equity amounted to SEK 835.1 m compared with SEK 591.8 m at the end of the corresponding period 2018.

## Parent company

The parent company's net revenue for the first quarter 2019 amounted to SEK 0.9 m (0.7). Profit/loss for the parent company amounted to SEK -72.6 m (-46.8) for the first quarter. On March 31, 2019, cash and cash equivalents including short term investments amounted to SEK 754.5 m compared with SEK 852.6 m at the end of 2018.

The parent company's equity amounted to SEK 765.6 m as per March 31, 2019, as compared with SEK 582.7 m 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 (former Immago Biosystems Ltd) and Hansa Medial Inc. Hansa Medical Inc was registered in May 2018 and includes operations for medical affairs and market access. At the end of March 2019 the company had three employees. Hansa Biopharma Ltd is owner of patent rights to the EnzE concept and had at the end of March 2019 one employee.

## Financial summary – First quarter

| | Q1 | | Year |
|---|---|---|---|
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| Net profit/loss | -72,479 | -46,498 | -247,974 |
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| Shareholders' equity | 835,074 | 591,805 | 859,876 |
| Cash flow from operating activities | -101,602 | -44,094 | -204,560 |
| Cash and cash equivalents including short term invesments | 759,230 | 575,049 | 858,187 |

# Shareholder information

The Hansa Biopharma share is listed on NASDAQ Stockholm, under the ticker HNSA and included in several indexes including:
- OMX Nordic Mid Cap
- OMX Nordic Health Care index
- OMX Stockholm Benchmark Index
- OMX Stockholm Health Care
- OMX Stockholm Pharmaceuticals & Biotechnology
- MSCI Global Small Cap

## Brief facts, the Hansa Biopharma-share

| | |
|---|---|
| Listing | Nasdaq OMX Stockholm |
| Number of shares | 40,731,654 (40,026,107 A-shares and 705,547 C-shares) |
| Market capitalization March 31, 2019 | SEK 9,165 m |
| Ticker | HNSA |
| ISIN | SE0002148817 |

## 15 largest shareholders, March 31, 2019

| Name | Number of shares | Share (%) |
|---|---|---|
| Nexttobe AB | 5,755,379 | 14.1 |
| Oppenheimer | 2,310,614 | 5.7 |
| Thomas Olausson | 1,613,474 | 4.0 |
| Handelsbanken Funds | 1,546,766 | 3.8 |
| Avanza Pension | 1,226,685 | 3.0 |
| Norron Funds | 1,075,774 | 2.6 |
| Third Swedish National Pension Fund | 1,068,523 | 2.6 |
| Polar Capital | 1,030,321 | 2.5 |
| Fourth Swedish National Pension Fund | 958,044 | 2.4 |
| AFA Insurance | 953,734 | 2.3 |
| Gladiator | 902,000 | 2.2 |
| Vanguard | 768,945 | 1.9 |
| Canaccord Genuity Wealth Management | 666,000 | 1.6 |
| BlackRock | 639,463 | 1.6 |
| BWG Invest Sàrl (William Gunnarsson) | 600,370 | 1.5 |
| Other | 19,615,562 | 48.2 |
| **In total** | **40,731,654** | **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).*

According to the shareholder register maintained by Euroclear Sweden AB, as of March 31, 2019, Hansa Biopharma had 12,543 shareholders. On March 31, 2018, Hansa Biopharma had 13,828 shareholders. Information regarding shareholders and shareholdings is updated each quarter on the company's website, www.hansabiopharma.com.

# Other information

## Employees and organization

The number of employees at the end of the first quarter 2019 was 57, compared to 35 at the end of corresponding period 2018.

## Share warrant program

On June 2, 2015, Hansa Biopharma's Annual General Meeting adopted a share warrant program for the company's employees. 355,000 warrants have been acquired by the company's employees during 2015 and 2016. Each warrant entitles the holder to subscribe for one new share in Hansa Biopharma. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018 to June 15, 2019. The warrants were sold to the company's employees on market terms at a price established based on an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute. The option program is subsidized by the company, and the employees, except the former CEO, have been given a one-time bonus as part of the stock option purchase. The options are linked to continued employment with the company only in the sense that, if the employment would be terminated, the stock option owner shall offer the warrants to the company and repay the resulting subsidy. The subsidy will affect the company's results proportionately during the option period in accordance with the same principles as in IFRS 2.

As of March 31, 2019, 355,000 out of 355,000 warrants have been exercised for subscription of shares at the subscription price SEK 44.15-46.19 per share.

## Long-term incentive program (LTIP 2016)

The Hansa Biopharma's Extraordinary General Meeting November 21, 2016 resolved to adopt a long-term incentive program (LTIP 2016) in the form of a performance-based share program for all employees of the Hansa Biopharma Group, meaning that not more than 30 individuals within the group may participate. The rationale for LTIP 2016 is to create conditions for motivating and retaining competent employees of the Hansa Biopharma group and for the alignment of the targets of the employees with those of the shareholders and the company, as well as to increase the motivation of meeting and exceeding the company's financial targets. A maximum of 305,000 rights may be allotted to participants under LTIP 2016. 289,750 rights have been allocated in total, of which 91,500 rights previously allocated have been excluded due to accelerated vesting or terminated, so remaining allocated rights as of March 31, 2019 are 198,250. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. The rights allocated are divided into two vesting periods, the first of which ends November 28, 2019 and the second May 18, 2020.

The general meeting further resolved, to implement LTIP 2016 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 401,000 Class C shares to a participating bank, of which a maximum of 96,000 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. The directed share issue of the 401,000 Class C-shares and the repurchase were executed in May 2018. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2016 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2016, mainly social security costs. Not more than 305,000 ordinary shares can be transferred to participants under LTIP 2016 and 96,000 ordinary shares can be used to cover any social security contributions due to the LTIP 2016, which means a dilution of 0.8 percent of the ordinary shares and votes in the company.

LTIP 2016 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost of LTIP 2016, calculated in accordance with IFRS 2, including social security contributions is expected to amount to approximately SEK 26.4 m, of which SEK 0.2 m is included in the results for the parent company and the group for the first quarter 2019. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

## Long-term incentive program (LTIP 2018)

The Hansa Biopharma's Annual General Meeting May 29, 2018 resolved to adopt a long-term incentive program (LTIP 2018). Not more than 52 individuals within the Hansa Biopharma group may participate in the program and are given the opportunity to acquire warrants at market value and/or receive so called performance-based share awards free of charge which, provided that certain conditions are met, may give the right to acquire shares in the Company. The rationale for LTIP 2018 is to create conditions for motivating and retaining competent employees of the Hansa Biopharma group and for the alignment of the targets of the employees with those of the shareholders and the company, as well as to increase the motivation of meeting and exceeding the company's financial targets. A maximum of 491,419 warrants or 297,902 share rights may be allotted to participants under LTIP 2018.

6,701 warrants have been acquired by the participants in LTIP 2018 as of March 31, 2019. Each warrant entitles the holder to subscribe for one new share in Hansa Biopharma. The warrants were sold to the company's employees on market terms at a price established based on an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute. For participants who have not yet joined the Hansa Biopharma-group, acquisitions must be made at the current market value on the day of allocation. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 12, 2021 through June 12, 2022. The subscription price will be the market value of the share at the offer for subscription of the warrants with an annual enumeration of 7 percent. This means that the subscription price after three years will amount to approximately 122.5 percent of the current market value of one ordinary share, and after four years amount to approximately 131.1 percent. Except for the CEO, all participants will be offered a subsidy to partially finance the acquisition of warrants. The subsidy will be equal to 25 percent of the warrant investment (after tax). The options are linked to continued employment with the company only in the sense that, if the employment would be terminated, the

stock option owner shall offer the warrants to the company and repay the resulting subsidy. The subsidy will affect the company's results proportionately during the option period in accordance with the same principles as in IFRS 2. At a maximum allocation of warrants, 491,419 warrants will be acquired by the participants, which means a dilution effect of approximately 1.2 percent of the number of shares and votes in the company.

178,131 share rights have been totally allocated during the year, of which 6,575 have been excluded, remaining allocated rights as of March 31, 2019 are 171,756. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. A share right may be exercised provided that the participant, with certain exceptions, from the date of the start of LTIP 2018 for each participant, up until and including the date three years thereafter (the "Vesting Period"), maintains his or her employment within the Hansa Biopharma-group. The latest start date to receive Share Awards shall be the day prior to the Annual General Meeting 2019. The rights allocated are divided into two vesting periods, the first of which ends June 15, 2021 and the second November 30, 2021.

The general meeting further resolved, to implement LTIP 2018 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 391,503 Class C shares to a participating bank, of which a maximum of 93,601 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. The new share issue of 391,503 Class C shares and the repurchase was performed in October 2018. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2018 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2018, mainly social security costs. Not more than 297,902 ordinary shares can be transferred to participants under LTIP 2018 and 93,601 ordinary shares can be used to cover any social security contributions due to the LTIP 2018, which means a dilution of 1.0 percent of the ordinary shares and votes in the company.

The cost for the share rights in LTIP 2018 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost calculated in accordance with IFRS 2 including social security contributions (based on social security tax of 31.42 percent), for the share rights allocated as of March 31, 2019, is expected to amount to approximately SEK 23.6 m, of which SEK 1.0 m is included in the results for the parent company and the group for the period ending March 31, 2019.

The number of warrants and share rights allocated to the participants will vary depending on how the participants choose to allocate their Participant Values. Consequently, the dilution, costs and effect on key ratios will vary consequently. The maximum dilution effect of LTIP 2018, which combines two program types, occurs if all of participants choose to solely subscribe for warrants.

## Committee for the 2019 Annual General Meeting

Hansa Biopharma AB's Nomination Committee for the AGM 2019 will consist of Erika Kjellberg Eriksson representing Nexttobe AB, Astrid Samuelsson representing Handelsbanken Funds and Sven Sandberg representing Thomas Olausson and Gladiator. It also includes the chairman of the board Ulf Wiinberg as convener.

## Financial calendar

| | |
|---|---|
| Annual General Meeting | May 22, 2019 |
| Interim report for January–June 2019 | July 18, 2019 |
| Interim report for January–September 2019 | October 31, 2019 |

## 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 in preclinical and clinical trials, the impact of competing research programs, the effect of economic conditions, the effectiveness of the company's intellectual property rights and preclusions of potential third party's intellectual property rights, technological development, exchange rate and interest rate fluctuations and political risks.


## Address

Hansa Biopharma AB (publ)
Scheelevägen 22
SE-223 63 Lund, Sweden

## Postal address

P.O. Box 785
SE-220 07 Lund, Sweden

## Registration number

556734-5359

# Condensed financial statements

## Consolidated statement of comprehensive income

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2019 | 2018 | 2018 |
| Net revenue | 917 | 588 | 3 358 |
| Direct cost of net revenue | -401 | -50 | -916 |
| **Gross profit** | **516** | **538** | **2 442** |
| | | | |
| Other operating income | 60 | 214 | 725 |
| Sales, general and administration expenses | -29,448 | -15,470 | -90,837 |
| Research and development expenses | -42,581 | -31,537 | -154,558 |
| Other operating expenses | -1,229 | -367 | -4,720 |
| **Operating profit/loss** | **-72,682** | **-46,622** | **-246,498** |
| | | | |
| Financial income/expenses | 350 | 114 | -1,516 |
| **Profit/loss before tax** | **-72,332** | **-46,508** | **-248,014** |
| Tax | -147 | 10 | 40 |
| **Net profit/loss for the period** | **-72,479** | **-46,498** | **-247,974** |
| | | | |
| **Attributable to** | | | |
| Parent company shareholders | -72,479 | -46,498 | -247,974 |
| | | | |
| **Earnings per share** | | | |
| Before dilution (SEK) | -1.81 | -1.23 | -6.47 |
| After dilution (SEK) | -1.81 | -1.23 | -6.47 |
| | | | |
| **Other comprehensive income** | | | |
| Items that have been, or may be reclassified to profit or loss for the period translation differences | 129 | 123 | 65 |
| Changes in fair value on available-for-sale financial assets | – | 3,549 | – |
| Items that cannot be reclassified to profit or loss for the year | | | |
| Shares valued to fair value as comprehensive income | 42,441 | – | 21,029 |
| **Other comprehensive income for the period** | **42,570** | **3,672** | **21,094** |
| | | | |
| **Total net comprehensive income** | **-29,908** | **-42,826** | **-226,880** |

# Consolidated balance sheet

| | March 31 | | December 31 |
|---|---|---|---|
| KSEK | 2019 | 2018 | 2018 |
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible fixed assets | 33,199 | 33,769 | 33,197 |
| Tangible fixed assets | 4,408 | 4,032 | 5,876 |
| Leased fixed assets | 15,432 | – | – |
| Financial fixed assets | 81,970 | 22,049 | 39,528 |
| **Total non-current assets** | **135,008** | **59,850** | **78,601** |
| | | | |
| **Current assets** | | | |
| Current receivables, non-interest bearing | 3,795 | 12,534 | 8,033 |
| Short-term investments | 419,301 | 474,957 | 418,746 |
| Cash and cash equivalents | 339,929 | 100,092 | 439,441 |
| **Total current assets** | **763,025** | **587,583** | **866,220** |
| | | | |
| **TOTAL ASSETS** | **898,032** | **647,433** | **944,821** |
| | | | |
| **EQUITY AND LIABILITIES** | | | |
| **Shareholders' equity** | **835,074** | **591,805** | **859,876** |
| | | | |
| **Long term liabilities** | | | |
| Deferred tax liabilities | 510 | 560 | 511 |
| Other provisions | 10,196 | 5,384 | 10,948 |
| Long term leasing liabilities, interest bearing | 8,548 | – | – |
| Other long term liabilities, interest bearing | 740 | 652 | 1,155 |
| **Total long term liabilities** | **19,993** | **6,596** | **12,614** |
| | | | |
| **Current liabilities** | | | |
| Current liabilities, non-interest bearing | 24,114 | 15,204 | 46,089 |
| Current leasing liabilities, interest bearing | 5,938 | – | – |
| Accrued expenses and deferred income | 12,914 | 33,828 | 26,242 |
| **Total current liabilities** | **42,965** | **49,032** | **72,331** |
| | | | |
| **TOTAL EQUITY AND LIABILITIES** | **898,032** | **647,433** | **944,821** |

# Consolidated changes in equity

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2019 | 2018 | 2018 |
| **Opening shareholders' equity** | **859,876** | **630,661** | **630,661** |
| Result for the period | -72,479 | -46,498 | -247,974 |
| Other comprehensive income for the period | 42,570 | 3,672 | 21,094 |
| **Net comprehensive income** | **-29,908** | **-42,826** | **-226,880** |
| **Transactions with the group's owner** | | | |
| New share issue [1] | 2,309 | – | 453,075 |
| Expenses attributable to new share issue | -10 | -1,070 | -20,711 |
| Repurchase/Sales own shares [1] | 877 | 4,473 | 4,473 |
| Issued warrants | 14 | 29 | 354 |
| Long term incentive program | 1,915 | 538 | 5,390 |
| By employees redeemed stock options | – | – | 13,514 |
| **Total transactions with the group's owner** | **5,106** | **3,970** | **456,095** |
| **Closing shareholders' equity** | **835,074** | **591,805** | **859,876** |

[1] 1) Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares. In Q1, 2019 50,000 shares where issued due to the TO 2015 program and 16,217 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program.

# Consolidated cash flow statement

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2019 | 2018 | 2018 |
| **Operating activities** | | | |
| Operating profit/loss | -72,682 | -46,622 | -246,498 |
| Adjustment for items not included in cash flow [1] | 3,373 | 1,713 | 13,444 |
| Interest received and paid, net | -324 | -207 | -210 |
| **Cash flow from operations before change in working capital** | **-69,633** | **-45,116** | **-233,264** |
| Change in working capital | -31,969 | 1,022 | 28,704 |
| **Cash flow from operating activities** | **-101,602** | **-44,094** | **-204,560** |
| **Investing activities** | | | |
| Investments in intangible fixed assets | – | -25 | -127 |
| Investments in tangible fixed assets | -23 | -275 | -2,366 |
| Divestment of tangible fixed assets | 87 | – | – |
| Short term investments | – | -449,995 | -493,984 |
| Divestment short term investments | – | 10,000 | 109,000 |
| **Cash flow from investing activities** | **64** | **-440,295** | **-387,477** |
| **Financing activities** | | | |
| New share issue [2] | 2,309 | – | 453,075 |
| Issue expenses | -10 | -1,070 | -20,712 |
| Disposal of own shares [2] | 877 | 4,473 | 4,473 |
| Issued warrants | – | – | 13,514 |
| Repayment of leasing liabilities | -1,257 | – | -44 |
| **Cash flow from financing activities** | **1,920** | **3,403** | **450,307** |
| **Net change in cash** | **-99,618** | **-480,986** | **-141,730** |
| Cash and cash equivalents, beginning of period | 439,441 | 581,078 | 581,078 |
| Currency exchange variance, cash and cash equivalents | 104 | – | 93 |
| **Cash and cash equivalents, end of period** | **339,927** | **100,092** | **439,441** |

[1] Values are mainly costs of share based incentive programs including social contributions.
[2] Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares. In Q1 2019 50,000 shares where issued due to the TO 2015 program and 16,217 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program.

# Consolidated key ratios and other information

| | Q1 | | Year |
|---|---|---|---|
| KSEK, unless other stated | 2019 | 2018 | 2018 |
| **Profit numbers** | | | |
| Net revenue | 917 | 588 | 3,358 |
| Operating profit/loss | -72,682 | -46,622 | -246,498 |
| Net profit/loss | -72,479 | -46,498 | -247,974 |
| | | | |
| **Per share data** | | | |
| Earnings/loss per share before and after dilution (SEK) | -1.81 | -1.23 | -6,47 |
| Shareholders' equity per share (SEK) | 20.50 | 15.62 | 21.52 |
| | | | |
| **Other information** | | | |
| Equity ratio (%) | 93 | 91 | 91 |
| Cash and cash equivalents including short term invesments | 759,230 | 575,049 | 858,187 |
| | | | |
| Number of outstanding shares at the end of the period | 40,026,107 | 37,878,125 | 39,959,890 |
| Weighted average number of shares before and after dilution | 40,003,078 | 37,921,800 | 38,326,098 |

# Parent company – Statement of comprehensive income

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2019 | 2018 | 2018 |
| Net revenue | 917 | 685 | 3,603 |
| Direct cost of net revenue | -401 | -50 | -916 |
| **Gross profit** | **516** | **635** | **2,687** |
| | | | |
| Other operating income | 60 | 214 | 725 |
| Sales, general and administration expenses | -29,538 | -15,463 | -85,938 |
| Research and development expenses | -42,836 | -31,575 | -159,137 |
| Other operating expenses | -1,229 | -367 | -4,720 |
| **Operating profit/loss** | **-73,027** | **-46,556** | **-246,383** |
| | | | |
| Result from other securities and receivables which are fixed assets | 548 | 3 | 52 |
| Other financial expenses | -76 | -252 | -1,966 |
| **Profit/loss for the period (before and after taxes)** | **-72,555** | **-46,805** | **-248,297** |
| | | | |
| **Other comprehensive income for the period** | **–** | **–** | **–** |
| | | | |
| **Total net comprehensive income** | **-72,555** | **-46,805** | **-248,297** |

# Parent company – Balance sheet

| | March 31 | | December 31 |
|---|---|---|---|
| KSEK | 2019 | 2018 | 2018 |
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible fixed assets | 30,024 | 30,570 | 30,163 |
| Tangible fixed assets | 4,407 | 4,032 | 5,290 |
| Financial fixed assets | 17,594 | 17,317 | 17,594 |
| **Total non-current assets** | **52,025** | **51,919** | **53,047** |
| | | | |
| **Current assets** | | | |
| Current receivables non-interest bearing | 6,274 | 13,113 | 10,869 |
| Short-term investments | 419,301 | 474,997 | 418,746 |
| Cash and cash equivalents | 335,213 | 97,811 | 433,875 |
| **Total current assets** | **760,788** | **585,921** | **863,490** |
| | | | |
| **TOTAL ASSETS** | **812,813** | **637,840** | **916,537** |
| | | | |
| **EQUITY AND LIABILITIES** | | | |
| **Shareholders' equity** | **765,646** | **582,693** | **833,270** |
| | | | |
| **Long-term liabilities** | | | |
| Other provisions | 10,196 | 5,384 | 10,948 |
| Long term liabilities, non-interest bearing | 740 | 652 | 679 |
| **Total long-term liabilities** | **10,936** | **6,036** | **11,627** |
| | | | |
| **Current liabilities** | | | |
| Liabilities to group companies | – | 98 | – |
| Current liabilities, non-interest bearing | 23,350 | 15,204 | 45,428 |
| Accrued expenses and deferred income | 12,880 | 33,809 | 26,212 |
| **Total current liabilities** | **36,230** | **49,111** | **71,640** |
| | | | |
| **TOTAL EQUITY AND LIABILITIES** | **812,813** | **637,840** | **916,537** |

# Parent company – Changes in equity

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2019 | 2018 | 2018 |
| **Opening shareholders' equity** | **833,270** | **625,528** | **625,528** |
| Result for the period | -72,555 | -46,805 | -248,297 |
| New share issue [1] | 2,309 | – | 453,467 |
| Expenses attributable to new share issue | -10 | -1,070 | -20,712 |
| Sales own shares [1] | 877 | 4,473 | 4,082 |
| Issued warrants | 14 | 29 | 354 |
| Long term incentive program | 1,741 | 538 | 5,334 |
| By employees redeemed stock options | – | – | 13,514 |
| **Total transactions with the group's owner** | **4,931** | **3,970** | **456,039** |
| **Closing shareholders' equity** | **765,646** | **582,693** | **833,270** |

[1)] Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares. In Q1, 2019 50,000 shares where issued due to the TO 2015 program and 16,217 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program.

# 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. 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.

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 asset 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 1.0m since the leasing fees' amortization part is reported as payment in the financing activities. The discount rate used is 3.4%.

| | 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** |

## Note 2 Net revenue

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2019 | 2018 | 2018 |
| **Income per significant category of income** | | | |
| **Group** | | | |
| Net revenue | | | |
| Royalty and license revenue | 566 | 503 | 2,071 |
| Milestone revenue | – | – | 621 |
| Patent reimbursement | 351 | 85 | 666 |
| **TOTAL** | **917** | **588** | **3,358** |
| | | | |
| **Parent company** | | | |
| Net revenue | | | |
| Royalty and license revenue | 566 | 503 | 2,071 |
| Milestone revenue | – | – | 621 |
| Patent reimbursement | 351 | 85 | 911 |
| **TOTAL** | **917** | **588** | **3,603** |

Hansa Biopharma has developed a method for HBP analysis that is used to predict severe sepsis in emergency clinics. The product has been licensed out to the partner Axis-Shield Diagnostics. According to the agreement with Axis-Shield, Hansa Biopharma is entitled to continuously receive minimum royalty of USD 250k annually until the underlying patent expires. Received payments of minimum royalty is thus accrued and recognized as income during the period to which the royalty refers.

In addition, additional compensation may apply when Axis-Shield conduct a sale where the developed method for HBP analysis is included or in cases where Axis-Shield achieves certain milestones in developing. The Group only recognizes revenue when it is clear that the Group has the right to receive the compensation.

The Company has received compensation for maintaining patents. This compensation is called patent reimbursement. Patent reimbursement has been recognized as revenue as the services are executed.

## Note 3 Fair value of financial instruments

The reported value is assessed as being a fair approximation of the fair value for all the Group's financial instruments except investments in short term commercial papers, which have been measured at amortized cost. The financial instruments reported at fair value in the balance sheet are comprised partly of holdings of interest rate funds consisting of investments in interest-bearing securities and other interest-rate instruments of high-rating and partly of the Group's holding of shares in Genovis, which are listed on Nasdaq First North.

The fair value of the holdings based on the closing price at the balance sheet date in KSEK:

| Financial instrument | Valuation hierarchy | Mar 31, 2019 | Mar 31, 2018 |
|---|---|---|---|
| Interest funds | Level 2 | 419,301 | 429,960 |
| Shares | Level 1 | 69,471 | 22,409 |
| Commercial papers | Level 1 | – | 44,995 |

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# Glossary

**AMR**
Antibody mediated transplant rejection.

**Antibody**
One type of proteins 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. The different isotypes have slightly different structures and they play different roles in the immune system. Immunoglobulin G, IgG, is the most common type in the blood and tissue and provides the majority of antibodybased immunity against invading pathogens. IgA is mainly found in mucosal areas and prevents colonization by pathogens. IgD mainly functions as receptor on B-cells that have not yet been activated. IgE binds to allergens and is involved in allergy. IgM is mainly found in the blood and is part of the first response against an infection.

**Anti-GBM disease (Goodpasture syndrome)**
Anti-GBM antibody disease is a disorder in which circulating antibodies 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.

**CD20 B-lymphocyte antigen**
CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

**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 administeredto 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.

**DSA**
Donor specific antibodies. 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.

**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.

**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.

**IgG**
IgG, Immunoglobulin G, is the predominant type of antibody in serum.

**Imlifidase**
imlifidase (INN), also known as IdeS, Immunoglobulin G-degrading enzyme of Streptococcus pyogenes, 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.

**INN**
International Nonproprietary Name (INN) is a generic and nonproprietary name to facilitate the identification of a pharmaceutical substances or active pharmaceutical ingredient. Each INN is a unique name that is globally recognized and is public property. The INN system has been coordinated by the World Health Organization (WHO) since 1953.

***In vitro***
Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

***In vivo***
Term within biomedical science to indicate that experiments or observations are made on living organisms.

**IVD**
IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

**Pivotal trial**
A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat lifethreatening or severely debilitating conditions.

**PRA**
Panel Reactive Antibody (PRA) is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via preexisting antibodies.

**Preclinical development**
Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

**Sepsis**
Diagnosed or suspected infection in combination with the patient being in a systemic inflammatory state (SIRS). Clinical symptoms of systemic inflammation may be a combination of fever, increased heart rate and increased respiratory rate.

**Severe sepsis**
Sepsis is progressing into severe sepsis when the patient may suffer circulatory effects and reduced functions of vital organs such as the brain, heart, lungs, kidneys or liver.

***Streptococcus pyogenes***
A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

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