INTERIM REPORT JANUARY-JUNE 2020

HANSA BIOPHARMA

Hansa Biopharma reaches two landmark milestones: Idefirix (imlifidase) receives positive CHMP opinion in EU; Gene therapy partnership with Sarepta Therapeutics in select indications

Highlights for the second quarter 2020

- CHMP/EMA has adopted a positive opinion, recommending conditional approval of Idefirix (imlifidase) for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. An approval by the European Commission is expected in Q3 2020.
- In the US, Hansa Biopharma submitted the proposed study protocol for the randomized controlled study with imlifidase in kidney transplant to the FDA on June 17, 2020. The trial is planned to be initiated in Q4 this year.
- Pipeline: The first data read-out from the phase 2 study in anti-GBM is expected in Q3 2020 as previously guided. In the AMR and GBS phase 2 studies, 4 of the targeted 30 patients have been enrolled in each of the respective studies. Enrollment in the AMR and GBS studies is expected to be completed in H1 2021 and H2 2021, respectively.
- On June 1, 2020 Achim Kaufhold, M.D. was announced as new Chief Medical Officer and member of the Executive Committee of Hansa Biopharma. Dr. Kaufhold is a highly experienced senior leader in immunology, infectious diseases and oncology and will support the Company´s expansion outside transplantation.
- Hansa hosted its 2020 Annual General Meeting on June 23, 2020. All resolutions except articles 18b and 19b were approved, and the entire board of directors was re-elected for the period until the end of the next AGM.
- Investments in R&D and SG&A increased in the second quarter to SEK 53m (Q2'19: SEK 46m) and SEK 49m (SEK 39m), respectively. Cash position was SEK 400m at the end of June 2020. Cash flow from operating activities for the second quarter ended at SEK -77m (SEK -78m).

Events after the end of the reporting period

- On July 2, 2020 Hansa announced an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications. The agreement with Sarepta triggers a USD 10 million upfront payment and will potentially generate milestone payments to Hansa totaling up to USD 397.5m plus royalties on the sales of Sarepta gene therapy products enabled by imlifidase. All imlifidase sales will be booked by Hansa.
- On July 8, 2020 Hansa Biopharma raised SEK 1.1bn (USD 121m) in a directed share issue of 4.4 million ordinary shares. The share issue was multiple times oversubscribed due to high demand from US, European and Swedish institutional investors including Redmile, Consonance, HBM and Fonden TIN Ny Teknik.The capital raised will help finance the development and expansion of the Company's R&D pipeline as well as to fund the potential launch and commercialization of imlifidase in kidney transplantation.

Financial Summary

SEKm, unless otherwise stated - unaudited	Q2 2020	Q2 2019	H1 2020	H1 2019
Revenue	0.6	0.6	1.5	1.5
SG&A expenses	-49.4	-38.5	-88.0	-68.0
R&D expenses	-53.0	-45.6	-105.5	-88.1
Other operating income/expenses	-0.0	-0.1	-0.6	-1.2
Operating profit/loss	**-101.8**	**-83.7**	**-193.2**	**-156.4**
Net profit/loss	-99.2	-82.4	-192.6	-154.9
Cash flow from operating activities	-77.4	-78.0	-198.6	-179.6
Cash and short-term investments	**400.2**	**762.7**	**400.2**	**762.7**
Shareholders' equity	378.1	755.4	378.1	755.4
EPS before and after dilution (SEK)	-2.48	-2.06	-4.81	-3.87
Number of outstanding shares	40,026,107	40,026,107	40,026,107	40,026,107
Weighted average number of shares before and after dilution	40,026,107	40,026,107	40,026,107	40,014,056
Number of employees	78	60	78	60

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

Søren Tulstrup, President and CEO, comments

"Hansa Biopharma's evolution into a fully integrated commercial stage biopharmaceutical company has taken a major step forward with the achievement of two landmark milestones.

On June 25, 2020 Hansa Biopharma received a positive opinion from the CHMP of the European Medicines Agency (EMA), recommending conditional approval of Idefirix (imlifidase) in highly sensitized kidney patients for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

We are very excited about this recognition from the CHMP/EMA. The recommendation by the CHMP and the expected launch of imlifidase towards the end of this year brings hope to the thousands of highly sensitized patients across Europe waiting for a life-saving kidney transplant and takes Hansa Biopharma a major step forward to becoming a commercial stage biopharmaceutical company.

A week later, on July 2, 2020, Hansa Biopharma announced the achievement of another landmark milestone with the exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy in Duchenne muscular dystrophy and Limb-girdle muscular dystrophy in patients with neutralizing antibodies (NAbs) to adeno-associated virus (AAV).

Under the terms of the agreement, Hansa will receive a USD 10m upfront payment, will book all sales of imlifidase and be eligible for up to USD 397.5m in development, regulatory and sales milestones to Hansa as well as royalties on any Sarepta gene therapy sales enabled through pre-treatment with imlifidase in NAb-positive patients.

We are very excited to partner with Sarepta, a leading player in the field, to use the unique features of imlifidase to potentially enable gene therapy treatment in patients who today aren't eligible for these breakthrough therapies due to pre-existing neutralizing antibodies in two conditions with a very high unmet medical need. The agreement with Sarepta also serves as a validation of our enzyme technology as we expand beyond transplantation and acute autoimmune diseases.

Hansa's strong progress across our platform of immunomodulatory enzymes has been well received by investors. On July 8, 2020 Hansa Biopharma carried out a capital raise of SEK 1.1bn (USD 121m) in a directed share issue of 4.4 million ordinary shares, which was significantly oversubscribed due to high demand from U.S., UK, Swiss and Swedish institutional investors. This funding will enable the Company to accelerate commercial preparations for launch of imlifidase in kidney transplant and to continue advancing the development of our other pipeline projects.

In the US, the proposed study protocol for the randomized controlled trial in kidney transplant was submitted to the FDA on June 17, 2020. The trial is expected to include 45 highly sensitized kidney patients with a cPRA score of 99.9% or above and we plan to initiate recruitment in the first centers in Q4 this year. As communicated earlier, we believe this study could support a future BLA submission in the US by 2023.

While we have overall been able to maintain a high level of productivity despite the impact from COVID-19 pandemic, our patient recruitment into the ongoing AMR and GBS phase 2 studies has been negatively impacted as no patients were enrolled during the second quarter. The impact from the pandemic is expected to delay recruitment timelines by 3-6 months as communicated earlier and we expect to reinitiate enrollment in both studies during the third quarter. In the anti-GBM phase 2 study, we completed enrollment in the investigator sponsored program back in January this year and expect the first data read-out in the third quarter, as communicated earlier.

Lastly, I also want to highlight how we continue to build a high-performance organization while adding new competences. In June we announced the recruitment of Achim Kaufhold, M.D. as our new Chief Medical Officer. Dr. Kaufhold brings extensive experience as a senior leader in immunology, infectious diseases and oncology and will support the Company´s expansion outside transplantation.

I look forward to keeping you updated on the progress of Hansa Biopharma's journey as we take the next steps towards commercialization of imlifidase in Europe and the transformation of Hansa Biopharma into a global biopharmaceutical company that brings lifesaving and life altering therapies to patients with rare diseases who need them and generate value to society at large. I look forward to updating you on our continued progress."

Søren Tulstrup
President and CEO, Hansa Biopharma

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.

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
Imlifidase	EU: Kidney transplantation in highly sensitized patients[1,2]	■	■	■	→	*)		Conditional Approval to be adopted by the EU Commission Q3 2020
	US: Kidney transplantation in highly sensitized patients[1,2]	■	■	■	**)			First patient dosed Q4 2020
	Anti-GBM antibody disease[3]	■	■	□				Data read-out Q3 2020
	Antibody mediated kidney transplant rejection (AMR)	■	■	□				Complete enrollment of 30 patients in H1'2021
	Guillain-Barré syndrome (GBS)	■	■	□				Complete enrollment of 30 patients in H2 2022
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	□						Development of CMC process / Tox studies
EnzE	Cancer immunotherapy	□						Research phase

■ Completed □ Ongoing

[1] Results from the Phase 1 study have been published, Winstedt el 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)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund
*) EMA: Positive CHMP opinion received in June 2020 for a conditional approval – Formal adoption by the EU Commission expected Q3 2020, while a post-approval study will commence in parallel with the launch
**) FDA: Agreement with the FDA on a regulatory path forward in the US. New clinical study could support BLA submission by 2023. Safety review of an Investigational New Drug application (IND) expected in Q3 2020, while the study is expected to be initiated Q4'20

Clinical studies with imlifidase

Enabling kidney transplantation for highly sensitized patients

On June 25, 2020 Hansa Biopharma announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had adopted a positive opinion, recommending conditional approval of Idefirix (imlifidase) for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

The positive opinion serves as a landmark milestone for the Company as Hansa Biopharma transform into a commercial-stage biopharmaceutical company. Endorsement of the positive opinion and approval by the European Commission is expected in the third quarter of 2020 and the Company expects to launch Idefirix (imlifidase) in the first leading European transplantation centers in the fourth quarter.

In the US, Hansa Biopharma submitted the study protocol to the FDA on June 17, 2020. The randomized, controlled clinical study with imlifidase in kidney transplantation is planned to be initiated in Q4 this year.

The Company aims to recruit 45 highly sensitized patients with a cPRA level of 99.9% or above, who are waiting for a deceased donor transplantation. Patients 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. The study could support a future BLA submission in the US by 2023, as communicated earlier.

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

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration.

At the American Transplant Congress (ATC), on May 30 to June 1, 2020, Hansa Biopharma presented two-year follow-up data on imlifidase in highly sensitized patients. The data demonstrated graft survival of 90% for 31 patients post imlifidase treatment with a median eGFR of 61.5 ml/min. Despite varying levels of donor specific antibody (DSA) rebound among these imlifidase-desensitized patients, the AMR frequency was comparable with those reported in other studies with less 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[1], 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[2] or approximately 3,200[3] new patients annually[4] and is a significant challenge to long term graft survival.

In 2019, Hansa Biopharma initiated a randomized, open-label, multi-center, controlled study in AMR. The study is designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in the treatment of active episodes of acute AMR in kidney transplant patients in comparison to plasma exchange.

The recruitment process was impacted following the COVID-19 virus pandemic but is expected to be reinitiated in Q3 2020. By the end of Q2 2020 4 of the targeted 30 patients were recruited in the AMR trial across centers in the US, Europe and Australia. Completion of enrollment is expected in the first half of 2021.

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

GBS is an acute autoimmune attack on the peripheral nervous system, which affects 1 in 100,000. In 2019, Hansa Biopharma initiated an open-label, single arm, multi-center study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients in combination with standard of care intravenous immunoglobulin (IVIg).

The recruitment process was impacted following the COVID-19 virus pandemic but is expected to be reinitiated in Q3 2020. By the end of Q2 2020 4 of the targeted 30 patients were recruited in the GBS trial across centers in France, UK and the Netherlands. Completion of enrollment is expected in the second half of 2021.

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

2 Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.

3 Jordan et al., British Medical Bulletin, 2015, 114:113-125.

4 http://www.irodat.org.

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

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.

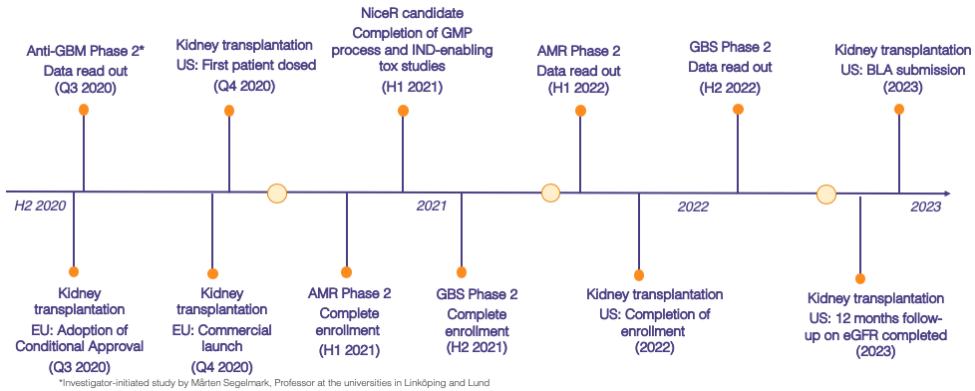
The first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development has been selected. Development of a GMP-manufacturing process for the lead NiceR candidate has since been initiated and preparations for toxicology studies and a clinical Phase 1 study are 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[5] demonstrate how pre-treatment with imlifidase in tumor animal models can increase the efficacy of currently available antibody-based cancer therapies. This treatment concept is currently being investigated under the project name EnzE, Enzyme-based antibody Enhancement.

The research results demonstrate the potential of an IgG-cleaving agent (e.g. imlifidase or the selected NiceR-lead) as a pretreatment for cancer therapy. High levels of plasma IgG have been shown to limit the efficacy of therapeutic antibodies, as plasma IgG can saturate the receptors of the patient' s immune cells, preventing them from efficiently killing the tumor cells. Removing the inhibiting IgG antibodies with imlifidase or a novel IgG-clearing enzyme prior to dosing the patient with a therapeutic antibody can potentially increase the efficacy of the given cancer therapy.

Upcoming milestones and news flow



*Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

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 enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

Financial review January – June 2020

Revenue

Revenue for the second quarter 2020 amounted to SEK 0.6m (Q2'19: SEK 0.6m) and to SEK 1.5m for the first half 2020 (H1'19 SEK 1.5m) 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 second quarter 2020 (Q2'19: SEK 0.1m) and no other operating income was recorded for the first half of the year 2020 (H1'19 SEK 0.2). The other operating income 2019 comprise of a research grant from Vinnova. No other operating expense was recorded for the second quarter 2020 (Q2'19: SEK 0.2m) and to SEK 0.6m (H1'19: SEK 1.5m) for the first half 2020.

SG&A expenses

Sales, general and administration expenses for the second quarter 2020 amounted to SEK 49.4m (Q2'19: SEK 38.5m) and to SEK 88.0m (H1'19 SEK 68.0m) for the first half of 2020. The increase in expenses reflects the continuing activities related to preparing for a commercial launch of imlifidase. Recorded non-cash cost for the company's employee long-term incentive programs for the second quarter (LTIP 2016, LTIP 2018 and LTIP 2019) amounting to SEK 4.6m (Q2'19: SEK 0.0m) and SEK 7.5m (1H'19: SEK 0.4m) for the first half is included in above SG&A expenses.

R&D expenses

Research and development expenses for the second quarter 2020 amounted to SEK 53.0m (Q2'19: SEK 45.6m) and to SEK 105.5m (H1'19: SEK 88.1m) for the first half. Recorded non-cash cost for the company's employee long-term incentive programs (LTIP 2016, LTIP 2018 and LTIP 2019) amounting to SEK 2.5m (Q2'19: SEK -2.3m) for the second quarter is included in above R&D expenses and to SEK 4.1m (1H'19: SEK -1.5m) for the first half. 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 commercial launch of imlifidase.

Financial result

The operating result for the second quarter 2020 amounted to SEK -101.8m (Q2'19: SEK -83.7m) and to SEK -193.2m (H1'19 SEK 156.4m) for the first half 2020.

Net loss for the second quarter 2020 amounted to SEK -99.2m (Q2'19 SEK -82.4m) and to SEK -192.6m (H1'19: 154.9) for the first half 2020.

Cash flow, cash and investments

Cash flow from operating activities for the second quarter 2020 amounted to SEK -77.4m (Q2'19: SEK -78.0m) and to SEK -198.6m (H1'19: 179.6m) for the first half 2020.

Compared to the previous year, the higher cash consumption is mainly due to preparatory activities throughout the organization related to a potential commercial launch of imlifidase and increased investments in ongoing R&D activities.

Cash and cash equivalents including short term investments amounted to SEK 400.2m on June 30, 2020 as compared to SEK 601.1m at the end of the year 2019.

Shareholders' equity

On June 30, 2020, equity amounted to SEK 378.1m 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 0.6m (Q2'19: SEK 0.6m) and to SEK 1.5m (1H'19 1.5m) for the first half 2020.

Loss for the parent company for the second quarter 2020 amounted to SEK -99.6m (Q2'19: SEK -82.6) and to SEK -193.1m (1H'19 -155.3m) for the first half.

On June 30, 2020, cash and cash equivalents including short term investments amounted to SEK 394.6m compared to SEK 596.1m at the end of the year 2019.

The parent Company's equity amounted to SEK 377.8m as per June 30, 2020, as compared to SEK 562.8m 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 June 2020. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had two employees at the end of June 2020.

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

Long-term incentive programs

Hansa Biopharma's past Annual General Meetings have resolved to adopt share-based long-term incentive programs (LTIPs). As of June 30, 2020, the following LTIPs were ongoing: LTIP 2016, LTIP 2018 and LTIP 2019.

The respective cost for Q2-2020 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.

Ongoing programs	LTIP 2016	LTIP 2018	LTIP 2019
Maximum number of issuable shares*	-	789,321	1,154,463
Number of allocated and outstanding share rights and options	-	235,768	446,077
Number of acquired and outstanding warrants	-	6,701	11,000
Estimated total cost including social contributions, KSEK	-	22,314	35,147
Cost including social contributions Q2-2020, KSEK	237	4,206	7,081

**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' future development is described in more detail.

Other information

Financial calendar 2020

October 22, 2020 - Interim report for Jan - Sep 2020
February 2, 2021 - Interim report for Jan - Dec 2020
April 8, 2021 - Annual Report 2020
April 22, 2021 - Interim report for Jan - Mar 2021
July 15, 2021 - Interim report for Jan - Jun 2021
October 21, 2021 – Interim report for Jan – Sep 2021

Contacts

Klaus Sindahl, Head of Investor Relations
Hansa Biopharma
Mobile: +46 (0) 709–298 269
E-mail: 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 June 30, 2020	SEK 7.2bn (USD 720m)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of June 30, 2020

Name	Number of shares	Ownership in pct
NXT2B	5 755 379	14.4
Consonance Capital Management LP	2 478 177	6.2
Invesco	1 999 188	5.0
Thomas Olausson	1 713 474	4.3
Avanza Pension	1 396 176	3.5
Gladiator	1 260 631	3.1
Fourth Swedish National Pension Fund	1 112 044	2.8
Third Swedish National Pension Fund	1 066 470	2.7
Vanguard	938 933	2.3
ClearBridge, LLC	741 306	1.9
Other	21 564 329	54.0
Outstanding shares in total	40 026 107	100.0

Source: Q4 Inc Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

As of June 30, 2020, Hansa Biopharma had 14,716 shareholders.

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

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 July 16, 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 enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

Condensed unaudited financial statements

Consolidated statement of comprehensive income

	Q2		H1	
KSEK	2020	2019	2020	2019
Revenue	623	592	1 508	1 509
Cost of revenue	-116	-97	-539	-498
Gross profit	**507**	**495**	**969**	**1 011**
Other operating income	-	106	-	166
Sales, general and administration expenses	-49 357	-38 505	-88 027	-67 952
Research and development expenses	-52 963	-45 554	-105 508	-88 135
Other operating expenses	-12	-225	-610	-1 454
Operating profit/loss	**-101 825**	**-83 683**	**-193 176**	**-156 364**
Financial income/expenses	2 570	1 245	541	1 595
Profit/loss for the period before tax	**-99 255**	**-82 438**	**-192 635**	**-154 769**
Tax	10	26	21	-121
Net profit/loss for the period	**-99 245**	**-82 412**	**-192 614**	**-154 890**
Attributable to:				
Parent company shareholders	-99 245	-82 412	-192 614	-154 890
Earnings per share (EPS)				
Before dilution (SEK)	-2,48	-2,06	-4,81	-3,87
After dilution (SEK)	-2,48	-2,06	-4,81	-3,87
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	-241	-51	-151	78
	-241	-51	-151	78
Items that cannot be reclassified to profit or loss for the year				
Shares valued to fair value as comprehensive income	-	7 157	-	49 598
Other comprehensive income for the year	**-241**	**7 106**	**-151**	**49 676**
Total net comprehensive income	**-99 486**	**-75 306**	**-192 765**	**-105 214**

Consolidated balance sheet

	June 30		December 31
KSEK	2020	2019	2019
ASSETS			
Non-current assets			
Intangible assets	32 757	32 930	33 348
Property, plant and equipment	5 760	5 041	6 035
Leased assets	6 933	12 319	9 109
Total non-current assets	**45 450**	**50 290**	**48 493**
Current assets			
Current receivables, non-interest bearing	14 149	4 789	14 650
Short-term investments	251 797	420 651	419 397
Cash and cash equivalents	148 378	342 076	181 697
Total current assets	**414 324**	**767 516**	**615 743**
TOTAL ASSETS	**459 773**	**817 806**	**664 236**
EQUITY AND LIABILITIES			
Shareholders' equity	**378 082**	**755 395**	**562 815**
Non-current liabilities			
Deferred tax liabilities	458	461	507
Provisions	4 249	5 152	818
Lease liabilities	2 649	6 389	4 827
Contingent consideration	721	741	730
Total non-current liabilities	**8 077**	**12 743**	**6 881**
Current liabilities			
Lease liabilities	4 751	5 136	4 632
Current liabilities, non-interest bearing	30 505	21 510	57 513
Accrued expenses and deferred income	38 358	23 022	32 395
Total current liabilities	**73 614**	**49 668**	**94 540**
TOTAL EQUITY AND LIABILITIES	**459 773**	**817 806**	**664 236**

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

Consolidated changes in equity

	H1		Year
KSEK	2020	2019	2019
Balance of opening shareholders' equity as reported	562 815	859 876	859 876
Adjustment of the opening balance	-302	-	-
Adjusted opening balance of shareholders's equity	**562 513**	**859 876**	**859 876**
Result for the period	-192 614	-154 890	-360 009
Other comprehensive income for the period	-151	49 676	49 947
Net comprehensive income	**-192 765**	**-105 214**	**-310 062**
Transactions with the group's owner			
New share issue	-	-	716
Cost of new share issue	-	-7 596	-7 646
Issued warrants	-	27	193
Long term incentive programs	8 334	5 116	17 268
Treasury shares acquired	-	-	-716
Treasury shares sold	-	877	877
Issuance of ordinary shares upon exercise of stock options	-	2 309	2 309
Total transactions with the group's owner	**8 334**	**734**	**13 001**
Closing balance of shareholders' equity	**378 082**	**755 395**	**562 815**

Consolidated cash flow statement

	Q2		H1	
KSEK	2020	2019	2020	2019
Operating activities				
Operating profit/loss	-101 825	-83 683	-193 176	-156 364
Adjustment for items not included in cash flow [1]	9 459	-697	14 987	2 676
Interest received and paid, net	-26	76	-148	-248
Income taxes paid	-	-183	-	-183
Cash flow from operations before change in working capital	**-92 392**	**-84 487**	**-178 337**	**-154 119**
Changes in working capital	14 988	6 507	-20 247	-25 462
Cash flow from operating activities	**-77 402**	**-77 980**	**-198 585**	**-179 581**
Investing activities				
Acquisition of property, plant and equipment	-156	-901	-294	-924
Proceeds from sale of equipment			-	87
Sale of short term investments	78 174		167 915	
Proceeds from sale of shares in Genovis	-	89 125	-	89 125
Cash flow from investing activities	**78 017**	**88 224**	**167 621**	**88 288**
Financing activities				
Cost of share issue		-7 576	-	-7 586
Sale of treasury shares [2]		-	-	877
Exercise of Stock options		-10		2 299
Repayment of lease liabilities	-1 163	-531	-2 318	-1 788
Cash flow from financing activities	**-1 163**	**-8 117**	**-2 318**	**-6 198**
Net change in cash	-549	2 127	-33 282	-97 491
Cash and cash equivalents, beginning of period	149 159	339 927	181 697	439 441
Currency exchange variance, cash and cash equivalents	-232	22	-37	126
Cash and cash equivalents, end of period	**148 378**	**342 076**	**148 378**	**342 076**

1) Values are mainly costs of share based incentive programs including social contributions and depreciation.
2) In Q1 2019 50,000 shares where issued due to the TO 2015 program and 16,217 of the C-shares where converted to ordinary shares partly transferred and partly divested in the market due to the LTIP 2016 program.

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

Parent company - Statement of comprehensive income

	Q2		H1	
KSEK	2020	2019	2020	2019
Revenue	623	592	1 508	1 509
Cost of revenue	-116	-97	-539	-498
Gross profit	**507**	**495**	**969**	**1 011**
Other operating income	-	106	-	166
Sales, general and administration expenses	-49 243	-38 545	-88 215	-68 080
Research and development expenses	-53 258	-45 680	-105 703	-88 505
Other operating expenses	9	-232	-588	-1 438
Operating profit/loss	**-101 985**	**-83 856**	**-193 538**	**-156 846**
Result from sales of financial fixed assets				
Result from short term financial receivables	1 388	1 342	-522	1 890
Other financial expenses	1 047	-97	928	-295
Loss for the period before tax	**-99 550**	**-82 611**	**-193 132**	**-155 251**
Income tax benefit/expense	-	-	-	-
Loss for the period after tax	**-99 550**	**-82 611**	**-193 132**	**-155 251**
Other comprehensive income for the period	**0**	**7 157**	**0**	**49 597**
Total net comprehensive income	**-99 550**	**-75 454**	**-193 132**	**-105 654**

Parent company - Changes in equity

	June 30		December 31
KSEK	2020	2019	2019
Opening balance of shareholders' equity as reported	562 905	833 270	833 270
Adjustment of the opening balance due to change in accounting policy	-142	26 942	27 030
Adjusted opening balance of shareholders's equity	**562 763**	**860 212**	**860 300**
Result for the period	-193 339	-155 166	-360 398
Other comprehensive income for the period		49 597	49 804
Net comprehensive income	**-193 339**	**-105 569**	**-310 594**
New share issue	-	-	716
Cost of new share issue	-	-7 596	-7 646
Issued warrants	-	27	193
Long term incentive programs	8 335	4 670	17 324
Treasury shares acquired	-	-	-716
Treasury shares sold	-	877	877
Issuance of ordinary shares upon exercise of stock options	-	2 309	2 309
Total transactions with the group's owner	**8 335**	**287**	**13 057**
Closing balance of shareholders' equity	**377 759**	**754 930**	**562 763**

Parent company - Balance sheet

	June 30		December 31
KSEK	2020	2019	2019
ASSETS			
Non-current assets			
Intangible assets	29 273	29 884	29 522
Property, plant and equipment	5 760	5 042	6 035
Leased assets	6 933	12 319	9 109
Investment in subsidiaries	5 095	5 095	5 095
Receivables, group companies	2 280	-	2 244
Total non-current assets	**49 341**	**52 340**	**52 005**
Current assets			
Receivables, group companies	3 731	4 108	1 061
Current receivables, non-interest bearing	13 711	4 573	14 369
Short-term investments	251 797	420 651	419 397
Cash and cash equivalents	142 846	336 895	176 715
Total current assets	**412 085**	**766 227**	**611 542**
TOTAL ASSETS	**461 426**	**818 567**	**663 547**
EQUITY AND LIABILITIES			
Shareholders' equity	**377 759**	754 930	562 763
Non-current liabilities			
Provisions	**4 249**	5 104	818
Lease liabilities	**2 649**	6 389	4 827
Contingent consideration	721	741	730
Total non-current liabilities	**7 619**	**12 234**	**6 375**
Current liabilities			
Lease liabilities	4 751	**5 136**	**4 632**
Liabilities, group companies	3 555	**2 683**	**2 793**
Current liabilities, non-interest bearing	30 353	**20 596**	**56 883**
Accrued expenses and deferred income	37 389	22 987	30 102
Total current liabilities	**76 048**	**51 402**	**94 410**
TOTAL EQUITY AND LIABILITIES	**461 426**	**818 567**	**663 547**

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

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. 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 7 157k for Q2-2019 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 investment in Genovis was sold in April 2019.

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 9,459k and right-of-use assets to SEK 9,109k.

The change to IFRS 16 led to the parent company recognizing leasing liabilities of SEK 11,525k and right-of-use assets of SEK 12,319k as per 30 June 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 Q2 2019 of depreciation amounting to SEK -1,307k and interest expenses amounting to SEK -122k and partly offset by lease expenses amounting SEK 1,175k in the second quarter of 2019.

The change to IFRS 16 led to an impact on the statement of profit or loss for the parent company for H1 2019 of depreciation amounting to SEK -2,550k and interest expenses amounting to SEK -235k and partly offset by lease expenses amounting SEK 2,342k in the first half of 2019.

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

Note 2 Revenue

Income per significant category of income	Q2		H1	
KSEK	2020	2019	2020	2019
Group				
Revenue:				
Royalty and license revenue	582	566	1 164	1 133
Patent cost reimbursement	41	26	344	376
	623	592	1 508	1 509
Parent company				
Revenue:				
Royalty and license revenue	582	566	1 164	1 133
Patent cost reimbursement	41	26	344	376
	623	592	1 508	1 509

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 June 30, 2020 amounted to SEK 251.8 million (Q4'19: SEK 419.4 million) and belonged to level 2 in the fair value hierarchy. The fair value of the financial liability for contingent consideration at June 30, 2020 amounted to SEK 0.7 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.

Note 4 Events after the end of the reporting period

On July 2, 2020 Hansa announced an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications. The agreement with Sarepta triggers a USD 10 million upfront payment and will potentially generate milestone payments to Hansa totaling up to USD 397.5m plus royalties on the sales of Sarepta gene therapy products enabled by imlifidase. All imlifidase sales will be booked by Hansa.

On July 8, 2020 Hansa Biopharma raised SEK 1.1bn (USD 121m) in a directed share issue of 4.4 million ordinary shares. The share issue was multiple times oversubscribed due to high demand from US, European and Swedish institutional investors including Redmile, Consonance, HBM and Fonden TIN Ny Teknik.The capital raised will help finance the development and expansion of the Company's R&D pipeline as well as to fund the potential launch and commercialization of imlifidase in kidney transplantation.

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

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 sur- face of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

Immunoglobulin G (IgG)
Immunoglobulin G is the predominant type of antibody in serum.

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

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

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 enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.The Company's lead product candidate, imlifidase, is an antibodycleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020. Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.