INTERIM REPORT JANUARY-SEPTEMBER 2020

HANSA BIOPHARMA

Hansa Biopharma advances to commercial stage following conditional EU approval of Idefirix; Positive high-level data from investigator-initiated phase 2 trial with imlifidase in anti-GBM

Highlights for the third quarter 2020

- The EU Commission granted conditional approval for Idefirix(R) (imlifidase) in highly sensitized kidney transplant patients in the European Union. Idefirix is the Company's first approved drug and will transform Hansa Biopharma into a commercial stage biopharmaceutical company.
- Entered exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications. The agreement with Sarepta includes an upfront payment and will potentially generate milestone payments to Hansa totaling up to USD 397.5m plus royalties on imlifidase enabled gene therapy sales. All imlifidase sales will be booked by Hansa.
- Anti-GBM antibody disease: Reported positive high-level data from investigator-initiated phase 2 trial with imlifidase in anti-GBM antibody disease, with two-thirds of patients achieving dialysis independence six months after treatment. The positive data marks an important milestone for the Company's expansion of imlifidase outside transplantation.
- US trial in kidney transplantation: Recruitment of first patient expected in H1 2021, given the continued impact of the COVID-19 pandemic in the US and the timeline to finalize the study protocol. Potential BLA submission by 2023 under the accelerated approval path.
- Pipeline: Patient enrollment into phase 2 studies in GBS and AMR have been temporarily halted for the past months due to the COVID-19 pandemic. Reinitiation of enrollment expected in Q4 2020 under a risk-based site-by-site approach. Completion of enrollment in both studies is expected in the second half of 2021.
- Hansa Biopharma AB certified as a Great Place to Work® following the results of a company-wide employee survey and a review of policies.
- Max Sakajja, VP Corporate Development, appointed to a new role as VP International Markets to prepare Hansa Biopharma's expansion strategy outside the EU. The role reports into the CCO and is part of Hansa's broader leadership team.
- SEK 1.1bn (USD 121m) raised 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. The capital raised will help finance the development and advancement of the Company's R&D pipeline as well as fund the launch and commercialization of imlifidase in kidney transplantation.
- Investments in R&D and SG&A increased in the third quarter to SEK 71m (Q3'19: SEK 47m) and SEK 52m (Q3'19: SEK 46m), respectively. Cash position was SEK 1,476m at the end of September 2020 (Q3'19: SEK 680m). Cash flow from operating activities for the third quarter ended at SEK 5m (Q3'19: SEK -80m).

Financial Summary

SEKm, unless otherwise stated - unaudited	Q3 2020	Q3 2019	9M 2020	9M 2019
Revenue	0.8	0.7	2,3	2.2
SG&A expenses	-51.7	-45.9	-139,8	-113.9
R&D expenses	-71.3	-47.2	-176,8	-135.3
Other operating income/expenses	-0.9	-0.5	-1,6	-1.8
Operating profit/loss	**-123,4**	**-93.2**	**-316,6**	**-249.6**
Net profit/loss	-122.4	-94.3	-315,0	-249.2
Cash flow from operating activities	4.8	-80.2	-193,8	-259.8
Cash and short-term investments	1,476.2	680.2	1,476,2	680.2
Shareholders' equity	1,338.2	668.1	1,338.2	668.1
EPS before and after dilution (SEK)	-2.77	-2.36	-7.61	-6.23
Number of outstanding shares	44,473,452	40,026,107	44,473,452	40,026,107
Weighted average number of shares before and after dilution	44,135,067	40,026,107	41,405,758	40,018,515
Number of employees	80	64	80	64

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving 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. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth 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, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

Søren Tulstrup, President and CEO, comments

"Hansa Biopharma's evolution into a fully integrated, commercial stage biopharmaceutical company took a major step forward in the third quarter following the conditional approval of IdefirixTM (imlifidase) by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

The European approval serves as a validation of the potential of our proprietary drug development platform and will transition Hansa Biopharma into the next growth phase as a commercial stage biopharmaceutical company that brings lifesaving and life altering therapies to patients with rare diseases who need them and generates value to society at large.

We are very excited about the European Commision's decision to approve Idefirix in highly sensitized kidney transplant patients. This is the first approved drug for Hansa Biopharma and will bring hope to the thousands of highly sensitized patients across Europe waiting for a lifesaving kidney transplant.

We are also excited about the progress of our efforts beyond transplantation. In July, we 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 for Duchenne muscular dystrophy and Limb-girdle muscular dystrophy in patients with neutralizing antibodies (NAbs) to adeno-associated virus (AAV).

Sarepta is a leading player in the field of gene therapy for neuromuscular dystrophies and we are obviously excited about their commitment in partnering up with us 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. The agreement with Sarepta is exclusive for the use of imlifidase in Duchenne and and Limb-girdle indications and serves as a validation of the potential of our enzyme technology beyond transplantation.

Late Septermber, we also announced positive high-level data from an investigator-initiated phase 2 trial with imlifidase in anti-GBM antibody disease, evaluating safety, tolerability and efficacy of imlifidase in 15 patients with severe anti-GBM antibody disease. Data from the trial shows that imlifidase leads to rapid clearance of anti-GBM antibodies, with two-thirds of patients achieving dialysis independence six months after treatment.

We are very encouraged by the positive outcome from the phase 2 trial in anti-GBM antibody disease. Anti-GBM is the first IgG-mediated disease outside transplantation where imlifidase has been shown to stop an immunologic attack.

Our strong progress across our platform of immunomodulatory enzymes has also been recognized by our investors, as our investor base has continued to expand in Sweden and internationally. End of September, the number of shareholders has increased to more than 18,000 investors, with 45% of the shares now owned by international investors and institutions. We see this as a testimony to our recent progress and a strong and growing international interest in Hansa Biopharma.

While an exciting and transformative year has impacted us in a positive way, we are still seeing negative effects from the COVID-19 pandemic. Patient enrollment into the phase 2 studies in GBS and AMR has been temporarily halted for the past months. We now expect to reinitiate enrollment in both studies in the fourth quarter 2020 under a risk-based, site-by-site approach. Enrollment in both AMR and GBS is expected to be completed in the second half of 2021, with high-level data readout for both studies in the second half of 2022.

In the US, a proposed study protocol for a randomised, controlled trial (RCT) targeting highly-sensitized kidney patients was submitted to the US Food and Drug Administration (FDA) in June, 2020. Discussions are currently ongoing with the FDA and, once the final protocol has been agreed upon, we will proceed to set up centers in the US and start to enroll patients.

Given the continued impact of the COVID-19 pandemic in the US and the timeline for finalization of the study protocol, we expect recruitment of the first patient to be in the first half of 2021, with a potential BLA submission in 2023 under the accelerated approval path.

Lastly, I also want to highlight that Hansa Biopharma AB recently got certified as a Great Place to Work® following the results of a company-wide employee survey and a review of policies. This certification reflects our efforts to build a strong organization through attracting, developing and retaining the very best talent in the industry as we continue our growth trajectory and development into a fully integrated biopharmaceutical company.

I look forward to keeping you updated on the progress of our journey – now as a commercial stage biopharmaceutical company focused on bringing lifesaving and life altering therapies to patients with rare diseases who need them and generating value to society at large."

Søren Tulstrup
President and CEO, Hansa Biopharma

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving 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. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth 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, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

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]				→		*)	EU: Commercial launch Q4 2020
	US: Kidney transplantation in highly sensitized patients[1,2]				**)			First patient dosed 1H 2021
	Anti-GBM antibody disease[3]							Next step is to engage with regulators and agree on a path forward toward BLA/MAA in anti-GBM
	Antibody mediated kidney transplant rejection (AMR)							Complete enrollment of 30 patients in H2 2021
	Guillain-Barré syndrome (GBS)							Complete enrollment of 30 patients in H2 2022
	Limb-Girdle (LGMD) & Duchenne (DMD) (Pre-treatment ahead of gene therapy with Sarepta)							Research phase
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

*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch

**) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients. Given the continued impact of the COVID-19 pandemic and the timeline for the finalization of the study protocol Hansa expect recruitment of the first patient to be in H1 2021

Imlifidase - Clinical programs and Regulatory interactions

Enabling kidney transplantation for highly sensitized patients

On August 26, 2020 Idefirix™ (imlifidase) was granted conditional approval by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.The EU approval serves as a landmark milestone for Hansa Biopharma, as Idefirix™ will be the Company's first approved drug and will transform Hansa Biopharma into a commercial stage biopharmaceutical company.

The first treatments with Idefirix is expected to be available to patients in selected European countries during the fourth quarter 2020 and a post-approval study study is expected to commence in the second half of 2021 following ongoing site selection and alignment on country specific requirements.

In the US, the proposed study protocol for a randomised controlled trial (RCT) targeting highly-sensitized kidney patients was submitted to the US Food and Drug Administration (FDA) in June, 2020. Discussions are currently ongoing with the FDA and, once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients.

Given the continued impact of the COVID-19 pandemic in the US affecting patient enrollment, and the timeline for finalization of the study protocol, Hansa Biopharma expects recruitment of the first patient to be in the first half of 2021. Completion of enrollment is still expected to be in 2022 with a potential Biologics License Application (BLA) submission in 2023 under the accelerated approval path.

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving 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. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth 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, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

Beyond the four completed phase 2 studies in kidney transplantation, Hansa Biopharma is also conducting a prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration. The 2-year follow-up data demonstrates graft survival of 90% for 31 patients post imlifidase treatment with a median eGFR of 61.5 ml/min and an AMR frequency that was comparable 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.

On September 24, 2020 positive high-level data from investigator-initiated phase 2 trial with imlifidase to treat anti-GBM disease with two-thirds of patients achieving dialysis independence six months after treatment. The positive data marks an important milestone for expansion of imlifidase outside transplantation.

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 DSAs in the treatment of active episodes of acute AMR in kidney transplant patients in comparison to plasma exchange.

Due to the widespread impact from the COVID-19 pandemic, the enrollment in the phase 2 program in Antibody-mediated kidney transplant rejection (AMR) was temporarily halted for the past months. Hansa Biopharma expects to reinitiate enrollment in Q4 2020 under a risk-based, site-by-site approach. The enrollment in the AMR study is expected to be completed in the second 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 halted over the past months following the COVID-19 virus pandemic but is expected to be reinitiated in Q4 2020 under a risk-based, site-by-site approach. Enrollment in the GBS study is still expected to be completed in the second half of 2021, as previously guided. High-level data readout for both studies are now expected in the second half of 2022.

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

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

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

4 http://www.irodat.org.

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Preclinical programs

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.

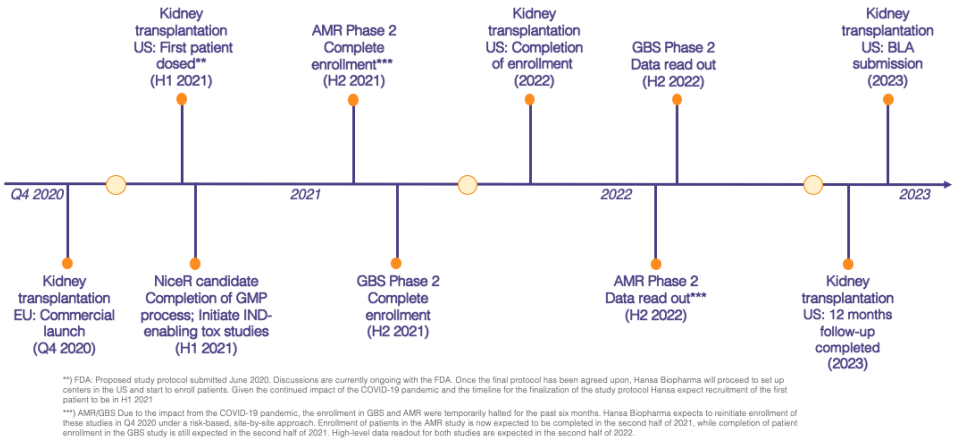
The first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development has been selected. Development of a GMP-manufacturing process for the lead NiceR candidate has since been initiated and preparations for toxicology studies and a clinical Phase 1 study are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



**) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients. Given the continued impact of the COVID-19 pandemic and the timeline for the finalization of the study protocol Hansa expect recruitment of the first patient to be in H1 2021

***) AMR/GBS Due to the impact from the COVID-19 pandemic, the enrollment in GBS and AMR were temporarily halted for the past six months. Hansa Biopharma expects to reinitiate enrollment of these studies in Q4 2020 under a risk-based, site-by-site approach. Enrollment of patients in the AMR study is now expected to be completed in the second half of 2021, while completion of patient enrollment in the GBS study is still expected in the second half of 2021. High-level data readout for both studies are expected in the second half of 2022.

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

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Financial review January – September 2020

Revenue

Revenue for the third quarter 2020 amounted to SEK 0.8m (Q3'19: SEK 0.7m) and to SEK 2.3m for the first nine months of 2020 (first 9 months'19 SEK 2.2m) and comprises of royalty income from Axis-Shield Diagnostics (Abbott group) and patent cost reimbursements. The company received USD 10M (SEK 89,9M) upfront payment in July 2020 related to the License agreement with Sarepta Therapeutics. The upfront payment will be recognized over time as Hansa fulfils its performance obligations under the contract. No revenue has been recognized as of 30 September 2020.

Other operating income and expenses

No other operating income was recorded for the third quarter 2020 (Q3'19: SEK 0.0m) and no other operating income was recorded for the first nine months of the year 2020 (9 monhts'19: SEK 0.2). The other operating income 2019 comprise of a research grant from Vinnova. Other operating expense was SEK -0.9M for the third quarter 2020 (Q3'19: SEK -0.5m) and to SEK -1.6m for the first nine months of 2020 (first 9 months'19: SEK -2.0m).

SG&A expenses

Sales, general and administration expenses for the third quarter 2020 amounted to SEK 51.7m (Q3'19: SEK 45.9m) and to SEK 139.8m for the first nine months of 2020 (first 9 months '19: SEK 113.9m). 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 third quarter (LTIP 2016, LTIP 2018, LTIP 2019 and LTIP 2020) amounted to SEK 12.3m (Q3'19: SEK 2.5m) and SEK 19.7m for the first nine months of 2020 (first 9 monhts '19: SEK 2.9m) is included in above SG&A expenses.

R&D expenses

Research and development expenses for the third quarter 2020 amounted to SEK 71.2m (Q3'19: SEK 47.2m) and to SEK 176,8m for the first nine months of 2020 (first 9 months'19: SEK 135.3m) . 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. Recorded non-cash cost for the company's employee long-term incentive programs (LTIP 2016, LTIP 2018, LTIP 2019 and 2020) amounting to SEK 6.1m for the third quarter (Q3'19: SEK 0.9m) is included in above R&D expenses and to SEK 10.2m for the first nine months of 2020 (first 9 months '19: SEK -0.6m).

Financial result

The operating result for the third quarter 2020 amounted to SEK -123.4m (Q3'19: SEK -93.2m) and to SEK -316.6m for the first nine months of 2020 (first 9 months'19: SEK -249.6m).

Net loss for the third quarter 2020 amounted to SEK -122.4m (Q3'19: SEK -94.3m) and to SEK -315.0m for the first nine months of 2020 (first nine months '19: -249.2m).

Cash flow, cash and investments

Cash flow from operating activities for the third quarter 2020 amounted to SEK 4.8m (Q3'19: SEK -80.2m) and to SEK -193.8m for the first nine months of 2020 (first 9 months '19: -259.8m).

Compared to the previous year, the lower cash consumption is mainly driven by upfront payment of SEK 89.9m related to the Sarepta agreement. Eliminating this one time effect the operating cash consumption increased primarily due to preparatory activities throughout the organization related to a potential commercial launch of imlifidase and increased investments in ongoing R&D activities.

On 8 July 2020 the company announced the successful completion of its 4.4M share issuance resulting in net cash proceeds of SEK 1.1bn.

Cash and cash equivalents including short term investments amounted to SEK 1,476.2m on September 30, 2020 as compared to SEK 601.1m at the end of the year 2019.

Shareholders' equity

On September 30, 2020, equity amounted to SEK 1,338.2m as compared to SEK 562.8m at the end of the year 2019.

Parent Company

The parent company's net revenue for the third quarter of 2020 amounted to SEK 0.8m (Q3'19: SEK 0.7m) and to SEK 2.3m for the first nine months of 2020 (first 9 months '19: SEK 2.2m).

Loss for the parent company for the third quarter 2020 amounted to SEK -122.5m (Q3'19: SEK -94.1) and to SEK -315.7m for the first nine months of 2020 (first nine months '19: SEK -249.4m).

On September 30, 2020, cash and cash equivalents including short term investments amounted to SEK 1,470.5m compared to SEK 596.1m at the end of the year 2019.

The parent Company's equity amounted to SEK 1,377.7m as per September 30, 2020, as compared to SEK 562.8m at the end of year 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 three employees at the end of September 2020. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had two employees at the end of September 2020.

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Long-term incentive programs

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

The respective cost 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	LTIP 2020
Maximum number of issuable shares*		789 321	1 154 463	1 011 376
Number of allocated and outstanding share rights and options		229 773	446 077	919 076
Number of acquired and outstanding warrants	-	6 701	11 000	-
Estimated total cost including social contributions, KSEK		25 481	42 141	120 739
Total cost per program, including social contributions as of 30 September 2020 YTD, KSEK	395	7 960	13 133	8 385

**Includes issuable shares to cover social contributions under the LTIP*

Total costs, including social contributions, as of 30 September 2020 YTD, KSEK	29 872

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

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Financial calendar 2020

October 29, 2020 Hansa Biopharma Capital Markets Day, Copenhagen (virtual)
February 4, 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

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	45,894,909 (44,473,452 A-shares and 1,421,457 C-shares)
Market Cap Sep 30, 2020	SEK 11bn (USD ~1.25bn)
Ticker	HNSA
ISIN	SE0002148817

Top 10 shareholders as of September 30, 2020

Name	Number of shares	Ownership in pct
Consonance Capital Management LP	2 655 009	6.0
Redmile Group	2 323 708	5.2
NXT2B	2 155 379	4.8
Invesco	1 938 841	4.4
Thomas Olausson	1 750 474	3.9
Fourth Swedish National Pension Fund	1 536 624	3.5
Avanza Pension	1 387 380	3.1
Handelsbanken Fonder AB	1 329 744	3.0
Gladiator	1 025 000	2.3
ClearBridge, LLC	1 012 786	2.3
Other	27 358 507	61.5
Outstanding shares in total	44,473,452	100.0

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

As of September 30, 2020, Hansa Biopharma had approximately 18,000 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, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving 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. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth 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, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and 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 October 22, 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, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving 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. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth 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, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

Translation from the Swedish original

Review report

To the Board of Directors of Hansa Biopharma AB

Corp. id. 556734-5359

Introduction

We have reviewed the condensed interim financial information (interim report) of Hansa Biopharma AB as of 30 September 2020 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Malmö 22 October 2020

KPMG AB

Jonas Nihlberg

Authorized Public Accountant

Condensed unaudited financial statements

Consolidated income statement

	Q3		January-September	
KSEK	2020	2019	2020	2019
Revenue	762	652	2 270	2 161
Cost of revenue	-285	-208	-824	-706
Gross profit	**477**	**444**	**1 446**	**1 455**
Other operating income	-	-	-	166
Sales, general and administration expenses	-51 726	-45 936	-139 753	-113 888
Research and development expenses	-71 250	-47 155	-176 758	-135 290
Other operating expenses	-946	-545	-1 556	-1 999
Operating profit/loss	**-123 445**	**-93 192**	**-316 621**	**-249 556**
Financial income/expenses	1 027	-947	1 568	648
Profit/loss for the period before tax	**-122 418**	**-94 139**	**-315 053**	**-248 908**
Tax	10	-125	31	-246
Net profit/loss for the period	**-122 408**	**-94 264**	**-315 022**	**-249 154**
Attributable to:				
Parent company shareholders	-122 408	-94 264	-315 022	-249 154
Earnings per share (EPS)				
Before dilution (SEK)	-2,77	-2,36	-7,61	-6,23
After dilution (SEK)	-2,77	-2,36	-7,61	-6,23
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	164	76	13	154
Changes in fair value on available-for-sale financial assets		967	-	967
	164	1 043	13	1 121
Items that cannot be reclassified to profit or loss for the period				
Shares valued to fair value as comprehensive income		-		49 598
Other comprehensive income for the period	**164**	**1 043**	**13**	**50 719**
Total net comprehensive income	**-122 244**	**-93 221**	**-315 009**	**-198 435**

Consolidated statement of financial position

	September 30		December 31
KSEK	2020	2019	2019
ASSETS			
Non-current assets			
Intangible assets	33 104	33 497	33 348
Property, plant and equipment	5 486	4 962	6 035
Leased assets	5 713	11 124	9 109
Total non-current assets	44 303	**49 583**	**48 493**
Current assets			
Current receivables, non-interest bearing	5 979	5 607	14 650
Short-term investments	237 978	420 805	419 397
Cash and cash equivalents	1 238 188	259 359	181 697
Total current assets	1 482 145	**685 771**	**615 743**
TOTAL ASSETS	1 526 448	**735 355**	**664 236**
EQUITY AND LIABILITIES			
Shareholders' equity	**1 338 180**	**668 115**	**562 815**
Non-current liabilities			
Deferred tax liabilities	450	451	507
Provisions	11 199	3 096	818
Lease liabilities	1 445	5 310	4 827
Deferred revenue	59 933	-	-
Contingent consideration	672	778	730
Total non-current liabilities	73 699	**9 635**	**6 881**
Current liabilities			
Lease liabilities	4 782	5 098	4 632
Current liabilities, non-interest bearing	34 033	28 508	57 513
Deferred revenue	29 967	-	-
Accrued expenses and deferred income	45 787	23 999	32 395
Total current liabilities	114 569	57 605	94 540
TOTAL EQUITY AND LIABILITIES	**1 526 448**	**735 355**	**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, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving 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. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth 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, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and the U.S.

Consolidated statements of changes in shareholders' equity

KSEK	January-September 2020	January-September 2019	Year 2019
Opening balance of shareholders' equity as reported	**562 815**	**859 876**	**859 876**
Adjustment of the opening balance	-304		
Adjusted opening balance of shareholders's equity	**562 511**	**859 876**	**859 876**
Result for the period	-315 022	-249 154	-360 009
Other comprehensive income for the period	-173	50 719	49 947
Net comprehensive income	**-315 195**	**-198 435**	**-310 062**
Transactions with the group's owner			
Proceeds from new share issuance, net	1 071 331	-5 337	-6 930
Issued warrants	-	111	193
Long term incentive programs	19 533	11 023	17 268
Treasury shares acquired			-716
Treasury shares sold	-	877	877
Issuance of ordinary shares upon exercise of stock options	-		2 309
Total transactions with the group's owner	**1 090 864**	**6 674**	**13 001**
Closing balance of shareholders' equity	**1 338 180**	**668 115**	**562 815**

Consolidated statement of cash flow

KSEK	Q3 2020	Q3 2019	January-September 2020	January-September 2019
Operating activities				
Operating profit/loss	-123 445	-93 192	-316 621	-249 556
Adjustment for items not included in cash flow [1]	19 703	6 149	34 690	8 825
Interest received and paid, net	-87	-122	-235	-370
Income taxes paid	-	-156	-	-339
Cash flow from operations before change in working capital	**-103 829**	**-87 321**	**-282 166**	**-241 440**
Changes in working capital	108 661	7 113	88 414	-18 349
Cash flow from operating activities	**4 834**	**-80 208**	**-193 753**	**-259 789**
Investing activities				
Acquisition of intangible assets	-	-723	-	-723
Acquisition of property, plant and equipment	-	-407	-294	-1 331
Proceeds from sale of equipment			-	87
Sale of short term investments	14 913		182 828	
Proceeds from sale of shares in Genovis	-		-	89 125
Cash flow from investing activities	**14 913**	**-1 130**	**182 534**	**87 158**
Financing activities				
Proceeds from new share issuance, net	**1 071 330**	-60	**1 071 330**	-7 646
Sale of treasury shares [2]	-	-	-	877
Exercise of Stock options	-	10		2 309
Loans raised	-	24		24
Repayment of lease liabilities	-1 173	-1 515	-3 491	-3 303
Cash flow from financing activities	**1 070 157**	**-1 541**	**1 067 839**	**-7 739**
Net change in cash	1 089 903	-82 879	1 056 620	-180 370
Cash and cash equivalents, beginning of period	148 377	342 076	181 697	439 441
Currency exchange variance, cash and cash equivalents	-92	162	-129	288
Cash and cash equivalents, end of period	**1 238 188**	**259 359**	**1 238 188**	**259 359**

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.

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Parent company – Income statement

	Q3		January-September	
KSEK	2020	2019	2020	2019
Revenue	762	652	2 270	2 161
Cost of revenue	-285	-208	-824	-706
Gross profit	**477**	**444**	**1 446**	**1 455**
Other operating income	-	-	-	166
Sales, general and administration expenses	-51 810	-45 963	-140 025	-114 042
Research and development expenses	-71 330	-47 155	-177 033	-135 660
Other operating expenses	-948	-504	-1 535	-1 942
Operating profit/loss	**-123 611**	**-93 178**	**-317 148**	**-250 023**
Result from sales of financial fixed assets				
Result from short term financial receivables	2 137	-819	1 615	1 071
Other financial expenses	-1 066	-129	-138	-424
Loss for the period before tax	-122 540	-94 126	-315 671	-249 376
Income tax benefit/expense	-	-	-	-
Loss for the period after tax	**-122 540**	**-94 126**	**-315 671**	**-249 376**
Other comprehensive income				
Change in fair value of financial assets	**0**	967	**0**	50 564
Total other comprehensive income for the period	**-122 540**	**-93 159**	**-315 671**	**-198 812**

Parent company – Statement of changes in shareholders' equity

	September 30		December 31
KSEK	2020	2019	2019
Opening shareholders' equity as reported	562 905	**833 270**	**833 270**
Adjustment of the opening balance due to change in accounting policy	-350	**27 030**	**27 030**
Adjusted opening balance of shareholders's equity	562 555	860 300	860 300
Result for the period	-315 671	-249 379	-360 398
Other comprehensive income for the period		**50 564**	**49 804**
Net comprehensive income	-315 671	-198 815	-310 594
New share issue	1 071 331	-7 646	-6 930
Issued warrants	-	111	193
Long term incentive programs	19 533	11 082	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	1 090 864	6 733	13 057
Closing shareholders' equity	**1 337 749**	**668 218**	**562 763**

Parent company – Statement of financial position

	30-Sep		December 31
KSEK	2020	2019	2019
ASSETS			
Non-current assets			
Intangible assets	29 651	29 651	29 522
Property, plant and equipment	5 486	4 962	6 035
Leased assets	5 713	11 124	9 109
Investment in subsidiaries	5 095	5 095	5 095
Receivables, group companies	2 165	-	2 244
Total non-current assets	**48 110**	**50 832**	**52 005**
Current assets			
Receivables, group companies	4 496	5 748	1 061
Current receivables, non-interest bearing	5 461	5 448	14 369
Short-term investments	237 978	420 805	419 397
Cash and cash equivalents	1 232 489	253 312	176 715
Total current assets	**1 480 424**	**685 313**	**611 542**
TOTAL ASSETS	**1 528 534**	**736 145**	**663 547**
EQUITY AND LIABILITIES			
Shareholders' equity	**1 337 749**	668 218	562 763
Non-current liabilities			
Provisions	**11 396**	2 096	818
Lease liabilities	**1 445**	5 310	4 827
Deferred revenue	**59 933**		
Contingent consideration	672	778	730
Total non-current liabilities	**73 446**	**8 184**	**6 375**
Current liabilities			
Lease liabilities	4 782	**5 098**	**4 632**
Liabilities, group companies	4 453	**3 604**	**2 793**
Current liabilities, non-interest bearing	34 545	**27 173**	**56 883**
Deferred revenue	29 967		
Accrued expenses and deferred income	43 592	23 867	30 102
Total current liabilities	**117 339**	**59 742**	**94 410**
TOTAL EQUITY AND LIABILITIES	**1 528 534**	**736 145**	**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, gene therapy and cancer. The Company's lead product candidate, imlifidase, is an antibody cleaving 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. Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth 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, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in EU and 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 967k for Q3-2019 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 10,408k and right-of-use assets of SEK 11,124k as per 30 September 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 Q3 2019 of depreciation amounting to SEK -1,194k and interest expenses amounting to SEK -94k and partly offset by lease expenses amounting SEK 1,175k in the third quarter of 2019.

The change to IFRS 16 led to an impact on the statement of profit or loss for the parent company for the first nine months of 2019 of depreciation amounting to SEK -3,745k and interest expenses amounting to SEK -329k and partly offset by lease expenses amounting SEK 3,518k in the first nine months 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		Q3		9M	
KSEK		2020	2019	2020	2019
Group					
Net revenue:					
	Royalty and license revenue	582	566	1 747	1 699
	Patent reimbursement	180	85	523	462
		762	652	2 270	2 161
Parent company					
Net revenue:					
	Royalty and license revenue	582	566	1 747	1 699
	Patent reimbursement	180	85	523	462
		762	652	2 270	2 161

The company received USD 10M (SEK 89,9M) upfront payment in July 2020 related to the License agreement with Sarepta Therapeutics. The upfront payment will be recognized over time as Hansa fulfils its performance obligations under the contract. No revenue has been recognized as of 30 September 2020.

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 September 30, 2020 amounted to SEK 238.0 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 September 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.

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.

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