Half Year Report

January – June 2024

HANSA BIOPHARMA

Randomization completed for US ConfIdeS trial; Continued strong IDEFIRIX® sales performance in EU; GOOD-IDES-02 trial at >70% enrollment in anti-GBM disease

Business Highlights Q2 2024

- **US ConfIdeS trial (kidney transplantation**): Hansa's US Phase 3 pivotal trial for imlifidase has completed randomization at the early end of guidance enrolling 64 patients. The ConfIdeS trial is an open label, randomized, controlled trial of imlifidase in kidney transplantation. Data from the study is expected to provide the basis for a Biologics License Application (BLA) with the US Food and Drug Administration (FDA) to seek accelerated approval in the second half of 2025.
- **Strong commercial performance continues**. Second quarter 2024 sales of IDEFIRIX totaled 47.1 MSEK offset by a provision totaling 19.9 MSEK that was established for potential credits related to volume discounts and refunds related to sales in previous periods. Net of the provision, second quarter 2024 IDEFIRIX sales were 27.2 MSEK.

  Year-to-date revenue from the sale of IDEFIRIX totaled 94.6 MSEK and was offset by the aforementioned provision for total year-to-date IDEFIRIX sales of 74.7 MSEK (net of the provision). Second quarter 2024 product sales came from all European markets including France, UK, Spain, Germany, and most recently initial sales in Italy.

  Excluding the provision, this marks the third consecutive quarter of strong IDEFIRIX sales across Europe and represents a solid first half for 2024 sales.

Clinical Pipeline Update

- **GOOD-IDES-02 Phase 3 trial (anti-GBM disease):** More than 70 percent of patients have been enrolled in this global trial (36 of targeted 50) for anti-glomerular basement membrane (anti-GBM) disease. Enrolment is expected to be completed in the first half of 2025 with data readout in the second half of 2025.
- **Post Approval European Study (PAES) (kidney transplantation**): Over 70 percent of patients have been enrolled in this post approval, Phase 3 study in kidney transplantation (37 of targeted 50). The study will support full marketing authorization in Europe and data readout is expected in 2025.

Subsequent Events

- **The European Medicines Agency (EMA)** has published a revised and approved new Summary of Product Characteristic (SmPC) for imlifidase. This was in line with, and part of the Company's Special Obligation timeline for final approval. The description noted data from the long term follow up study, 17-HMedIdeS-14 pooled with data from four Phase 2 trials. The updated information noted the long-term follow-up of 46 transplanted patients from the submitted Phase 2 study data that at five years after transplantation, overall graft survival (death censored) was 85 percent and patient survival was 92 percent.

Financial Summary

MSEK, unless otherwise stated – unaudited	Q2 2024	Q2 2023	H1 2024	H1 2023
Revenue	34.3	36.7	90.3	60.8
- thereof: Product sales[1] *(Q2 product sales 47.1 MSEK less provision 19.9 MSEK = 27.2 MSEK)*	27.2	29.6	74.7	43.9
SG&A expenses	(88.2)	(129.5)	(179.5)	(232.8)
R&D expenses	(91.7)	(114.7)	(194.6)	(207.5)
Loss from operations	(187.4)	(228.5)	(346.8)	(410.8)
Loss for the period	(207.9)	(251.2)	(426.5)	(456.6)
Net cash used in operations	(189.2)	(181.9)	(378.3)	(388.9)
Cash and short-term investments	705.0	1,102.5	705.0	1,102.5
EPS before and after dilution (SEK)	(3.30)	(4.79)	(7.38)	(8.71)
Number of outstanding shares	67,814,241	52,443,962	67,814,241	52,443,962
Weighted average number of shares before and after dilution	62,929,675	52,443,962	57,800,736	52,443,962
No of employees at the end of the period	146	162	146	162

[1] *Product sales in the second quarter 2024 totaled 47.1 MSEK. Sales were offset by a provision totaling 19.9 MSEK for potential credits associated with volume discounts and potential refunds. First half 2024 product sales totaled 94.6 MSEK and were offset by the provision totaling 19.9 MSEK. Net of the provision, first half product sales totaled 74.7 MSEK.*

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabiopharma.com.

CEO Comments

"The completed randomization of patients in the US ConfIdeS pivotal Phase 3 trial at the early end of guidance is an important milestone for Hansa and more importantly for highly sensitized kidney transplant patients."

Søren Tulstrup
President and CEO, Hansa Biopharma

"The completed randomization of patients in the US ConfIdeS pivotal Phase 3 trial at the early end of guidance is a significant milestone for Hansa and more importantly for highly sensitized kidney patients in the United States waiting for a potentially lifesaving transplant. Data from the study is expected to support our submission of a BLA under the accelerated approval pathway to the US FDA in the second half of 2025.

IDEFIRIX product sales in Q2 were 47.1 MSEK and for the first half of 2024 product sales totaled 94.6 MSEK. Product sales for the second quarter and year to date were offset by a provision of 19.9 MSEK. Net of the provision, Q2 and year-to-date IDEFIRIX sales were 27.2 MSEK and 74.7 MSEK, respectively. The provision was established to account for potential credits related to volume discounts and refunds related to sales in previous periods in Europe since the launch of IDEFIRIX in 2020.

Excluding the provision, this marks the third consecutive quarter of strong IDEFIRIX sales across Europe and represents a solid first half for 2024 sales.

IDEFIRIX performance in the first half of 2024 was a result of utilization in key transplant centers in larger markets, including France, Germany, and the UK, as well as expansion into new markets. Of note, in Q2 we secured our first sales in Italy following achievement of reimbursement status in key regions. Additionally, we have started to see growing repeat usage in several key transplant centers in the wake of positive first experiences, further validating the important role that IDEFIRIX can play in desensitization in kidney transplantation. We expect to see further utilization in markets across Europe and greater clinical adoption throughout the remainder of 2024.

During the last several quarters, patient enrollment in the European Post Approval Efficacy Study (PAES) has continued at pace, and the study has now enrolled more than 70 percent of patients (37 of targeted 50) in the trial. The study is a post-marketing requirement under the European conditional marketing authorization. Data from the study will generate important clinical data on the use of IDEFIRIX as a desensitization therapy in highly sensitized kidney transplant patients.

The Company also advanced important Phase 2 and Phase 3 trials with imlifidase in autoimmune diseases. Of note, the GOOD-IDES-02 Phase 3 study in anti-GBM disease has now enrolled more than 70 percent of patients (36 of targeted 50) and we expect to complete enrollment and deliver data in 2025. This is important progress that brings hope to patients suffering from this serious disease that can lead to rapid destruction of the kidneys and lungs.

Looking ahead to the second half of 2024, we look forward to sharing further data from the 15-HMedIdes-09 Phase 2 trial in Guillain-Barré Syndrome (GBS) and results from the exploratory endpoints for the NICE-01 Phase 1 study for HNSA-5487, the lead candidate from the NiceR program for repeat dosing.

As previously mentioned, earlier in the quarter we completed a financing round that will extend our cash runway into 2026. The financing round was led by Hansa's largest shareholder Redmile and supported by new leading international specialist healthcare investors and resulted in gross proceeds of ~372 MSEK (US ~$34.6M). This financing will help prepare for the US commercial launch of imlifidase in kidney transplantation, strengthen ongoing product development in autoimmune indications and support the continued development of HNSA-5487.

In the second half of 2023, Hansa initiated a restructuring program to better focus on key clinical development and commercial priorities. Restructuring actions have resulted in decreased external service costs and a reduction in company staffing levels across the organization.

Finally, we concluded our 2024 Annual General Meeting on June 27th where two new board members - Jonas Wikström, former fund manager at Catella Fondförvaltning, and Founder/CEO of WR Capital, and Florian Reinaud, Managing Director at Redmile, Hansa's largest shareholder, were elected. At the same time, Andreas Eggert resigned from the board, and we thank him for his many significant contributions to Hansa over the past years."

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Hansa's Pipeline Progress

[1] Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)
[2] Lorant et al., American Journal of Transplantation and 03+04 studies (Jordan et al., New England Journal of Medicine)
[3] Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

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Imlifidase - Commercial, Clinical & Regulatory Update

EU: Kidney transplantation in highly sensitized patients

In August 2020, IDEFIRIX was granted conditional approval by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch antibodies against an available deceased donor.

Commercial launch activities and market access efforts for IDEFIRIX in Europe continue to progress as planned. The product now has commercial access in 15 European countries, including France, Germany, Italy, Spain, the UK, and others.

Desensitization strategies and utilization continue to advance within the clinical community. In April, the European Society of Organ Transplantation (ESOT) published a consensus paper, entitled *European Consensus on the Management of Sensitized Kidney Transplant Recipients: A Delphi Study* recommending imlifidase as a desensitization strategy for deceased kidney transplantation in selected patients for whom no other treatment options are available.

Additionally, Eurotransplant's desensitization program is helping identify patients eligible for IDEFIRIX. To date, the program has transplanted five patients and identified additional candidates. This validates that transplant centers are now receiving IDEFIRIX-designated kidneys. Eurotransplant is an international allocation system responsible for the allocation of donor organs across eight countries: Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, and Slovenia.

Post Authorization Efficacy and Safety Study (PAES) - 20-HMedIdes-19

In parallel with the company's commercial launch of IDEFIRIX, Hansa is conducting a post authorization efficacy and safety study as part of its obligation under European conditional marketing authorization. The study will be used to further investigate long-term graft survival in 50 highly sensitized kidney transplant patients treated with IDEFIRIX and support full marketing authorization. Data readout is expected in 2025.

ConfIdeS US Phase 3 Trial - 20-HMedIdeS-17

Randomization of the ConfIdeS Phase 3 clinical trial was completed in May 2024. The ConfIdeS trial is evaluating imlifidase as a potential desensitization therapy compared to treatment according to standard of care (SoC) to enable kidney transplantation in highly sensitized patients waiting for a deceased donor kidney. A total of 64 highly sensitized (cPRA ≥99.9 percent) patients on the wait list for kidney transplantation were randomized on a 1:1 basis to either (i) desensitization with imlifidase or (ii) SoC. Hansa plans to submit a BLA to the US FDA in the second half of 2025 to seek accelerated approval.

Long-term follow-up trial of kidney transplant patients - 17-HMedIdeS-14

The 17-HMedIdes-14 study is 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.

On October 17, 2023, Hansa announced data from the 17-HMedIdeS-14 trial pooled with data from four Phase 2 trials. The data showed sustained positive outcomes out to five years in the majority of highly sensitized patients who received an imlifidase-enabled kidney transplant. Patient survival was 90 percent (death censored) and graft survival was 82 percent, in line with outcomes seen at three years post-transplant. The five-year extended pooled analysis is a continuation of the analysis at three years of crossmatch positive only patients and will be submitted to a peer reviewed journal in 2024. This data was presented at the American Society of Transplantation's annual congress in June.

Global Phase 3 Anti-GBM trial - GOOD-IDES-02

The GOOD-IDES-02 Phase 3 trial is moving at pace and has enrolled over 70 percent of patients (36 out of 50 targeted). Enrollment is expected to be completed in 2025 followed by a data readout in the second half of 2025. The trial is an open label, controlled, randomized, multi-center trial evaluating renal function in patients with severe anti-GBM disease using imlifidase plus SoC versus SoC only.

Anti-GBM disease is an acute autoimmune disease in which 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 ultrarare and very severe disease that affects approximately 1.6 people per million, annually. Many patients lose their kidney function, requiring chronic dialysis and/or kidney transplantation.[1,2]

Global Phase 2 AMR trial - 16-HMedIdes-12

In December 2023, Hansa announced full data from the 16-HMedIdes-12 trial, demonstrating statistically significant superior reduction of donor-specific antibodies (DSAs) by imlifidase to rapidly reduce levels of DSAs compared to plasma exchange in the five days following the start of the treatment. The secondary endpoint investigated overall kidney function following treatment.

The imlifidase arm demonstrated a 74 percent six-month graft survival and eGFR of 30mL/min/1.73m^2. A 100 percent six-month graft survival and eGFR of 33mL/min/1.73m2 was observed in the Plasma Exchange arm.

Data for the Phase 2 clinical trial has been accepted for publication in a peer reviewed journal.

Phase 2 GBS Trial - 15-HMedIdeS-09

In December 2024, Hansa communicated positive high-level data from the 15-HMedIdeS-09 trial. Imlifidase was safe and well tolerated when administered prior to the SoC including rapid improvement in disease-related efficacy measures. The trial is an open-label, single arm, multi-center study evaluating the safety, tolerability, and efficacy of imlifidase in GBS patients in combination with SoC intravenous immunoglobulin (IVIg). Further analysis of efficacy data will be communicated in 2024.

GBS is a disease which is caused by an acute autoimmune attack on the peripheral nervous system, which affects approximately 1-2 in 100,000 people annually.[3]

HNSA-5487 Phase 1 Trial – NICE-01

In October 2023, Hansa announced high-level results from the NICE-01 trial with HNSA-5487, the company's lead candidate in the NiceR program. The data showed it was safe and well tolerated with fast and complete depletion of immunoglobulin G (IgG) antibodies observed with increasing doses in all subjects. Pharmacokinetics (PK) were in line with expectations and pharmacodynamics (PD) (efficacy on IgG cleavage) showed a fast and complete cleavage of IgG to F(ab')$_2$ and Fc-fragments with increasing doses. The trial included a total of 36 healthy male and female adult participants. Further analysis of other endpoints will be completed in 2024, including the clinical development pathway.

[1] Kluth et al.. J Am Soc Nephrol. 1999 Nov;10(11):2446-53
[2] Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12
[3] McGrogan A, et al. Neuroepidemiology. 2009; 32(2):150-63.

Hansa is developing novel, IgG-degrading enzymes with the objective of enabling repeat dosing in autoimmune conditions, oncology, gene therapy and transplantation, where patients may benefit from more than one dose of an IgG-modulating enzyme.

Duchenne Muscular Dystrophy (DMD) Trial - SRP-9001-104 Phase 1b

In December 2023, a clinical study (Phase 1b) commenced using imlifidase as a pre-treatment to Sarepta's ELEVIDYS (SRP-9001) gene therapy in DMD. Enrollment in the trial was paused due to a protocol amendment and data will be available in 2025. In June, Sarepta communicated that it is working hard to expand into antibody positive patients. ELEVIDYS received US FDA accelerated approval in June 2023, as a one-time treatment in ambulatory pediatric patients aged four through five years suffering from DMD. In June 2024 ELEVIDYS received expanded US FDA approval to include individuals with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene who are at least four years of age. Confirming the functional benefits, the FDA granted traditional approval for ambulatory patients. The FDA granted accelerated approval for non-ambulatory patients.

Between 5 percent and 70 percent of gene therapy patients carry antibodies against AAV vectors that act as a barrier for treatment eligibility. Up to 20 percent of patients affected by DMD might not be able to receive treatment due to the presence of anti-AAV antibodies. Imlifidase as pre-treatment to gene therapy may give those patients access to ELEVIDYS.

In July 2020, Hansa entered into an exclusive agreement with Sarepta Therapeutics to develop imlifidase as a potential pre-treatment to gene therapy in DMD and Limb-Girdle Muscular Dystrophy (LGMD) in patients with antibodies against the vector AAVrh74. Under the terms of the agreement, Hansa received a US $10 million upfront payment and will book all future sales of imlifidase. Hansa is also eligible for up to US $397.5 million in development, regulatory and sales milestones, as well as royalties on any Sarepta gene therapy sales enabled through pre-treatment with imlifidase in antibody-positive patients. The program with imlifidase as pre-treatment ahead of gene therapy in LGMD is still in preclinical research stage. For further information about Sarepta's programs please refer to www.sarepta.com.

Preclinical Programs

AskBio - pre-treatment ahead of gene therapy in Pompe disease

At the American Society of Gene and Cell Therapy's (ASGCT) annual meeting in May, AskBio delivered an oral presentation on pre-clinical data, as part of the Hansa-AskBio partnership. It evaluated the potential use of imlifidase as a pre-treatment to gene therapy. The data demonstrated that imlifidase can help keep AAVs in circulation for a longer time period, thus allowing a longer window for gene therapy transduction.

In January 2022, Hansa and AskBio announced a collaboration agreement designed to evaluate the potential use of imlifidase as a pre-treatment, prior to the administration of AskBio's gene therapy in Pompe disease. The evaluation will be performed in a preclinical and clinical feasibility study aimed at enabling gene therapy for patients with pre-existing antibodies against the adeno-associated viral vector used in AskBio's gene therapy.

For further information regarding AskBio's programs please refer to www.askbio.com.

Genethon - pre-treatment ahead of gene therapy in Crigler-Najjar syndrome

On April 27, 2023, Hansa announced a collaboration agreement with Genethon, a French non-profit organization and pioneer in the discovery and development of gene therapies for rare diseases.

The collaboration will evaluate the safety and efficacy of Hansa's antibody cleaving enzyme, imlifidase, as a pre-treatment prior to the administration of Genethon's gene therapy product candidate, GNT-0003, in patients with Crigler-Najjar syndrome and pre-formed antibodies to adeno-associated virus serotype 8 (AAV8).

GNT-0003 is currently being evaluated in a pivotal clinical study in France, Italy, and the Netherlands and has received PRIME (PRIority MEdicines) status from the EMA. Through this collaboration, patients with Crigler-Najjar syndrome and pre-formed antibodies will be enrolled in a study where imlifidase is evaluated as a pre-treatment to enable gene therapy treatment with GNT-0003. The study is planned to commence in 2024.

Progress to date and what's next

	Progress to date	What's next 2H '24	Looking ahead - 2025
EARLY DEV	• **COMPLETED NICE-01 Ph 1** safety/tolerability for HNSA-5487	• **HNSA-5487 Ph 1** data on exploratory endpoints and clinical development path	• **HNSA-5487** clinical development
TRANSPLANT	• **FULL RANDOMIZATION ConfIdeS** Ph 3 trial	• **15-HMedIdeS-14** data publication in peer reviewed journal	• **ConfIdeS Ph 3** 12 month follow up and BLA submission in 2H • **Post Approval Efficacy Study** readout
GENE THERAPY	• **STUDY INITIATED: SRP 9001-104** Ph 1 study (DMD) • Genethon (Crigler-Najjar) preclinical • AskBio (Pompe) preclinical	• **Genethon** trial initiated (Crigler-Najjar)	• **SRP 9001-104 Ph 1 study** (DMD) initial data readout
AUTOIMMUNE	• **TRIAL COMPLETED 15-MedIdeS-09 (GBS)** Ph 2 trial • **70% ENROLLED GOOD-IDES-12** Ph 3 (anti-GBM) trial	• **15-MedIdeS-09 Ph 2 (GBS)** data contextualization (IGOS) • **16-MedIdeS-12 Ph 2 (AMR)** data publication	• **GOOD-IDES-12 Ph 3 (anti-GBM)** 1H full enrolment; 2H data readout

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Financial Review June 2024: Second Quarter & Year to Date

Revenue

Revenue for the second quarter 2024 totaled 54.2 MSEK (Q2 2023: 36.7 MSEK) consisting of IDEFIRIX product sales of 47.1 MSEK (Q2 2023: 29.6 MSEK) and contract revenue of 7.1 MSEK (Q2 2023: 7.1 MSEK) primarily related to the recognition of an upfront payment the Company received under its partnership agreement with Sarepta. Product sales were offset by a provision of 19.9 MSEK. Including the provision, total revenue and product sales were 34.3 MSEK and 27.2 MSEK, respectively. The provision was established to account for potential credits related to volume discounts and refunds related to sales in previous periods in European since the launch of IDEFIRIX in 2020.

Revenue for the six months ended June 30, 2024, totaled 110.2 MSEK (H1 2023: 60.8 MSEK) consisting of IDEFIRIX product sales of 94.6 MSEK (H1 2023: 43.9 MSEK) and contract revenue of 15.6 MSEK (H1 2023: 17.0 MSEK) primarily from an upfront payment the Company received under its partnership agreement with Sarepta. Including the aforementioned provision of 19.9 MSEK, total revenue and product sales for the six months ended June 30, 2024 were 90.3 MSEK and 74.7 MSEK, respectively.

Sales General & Administrative (SG&A) expenses

SG&A expenses for the second quarter 2024 totaled 88.2 MSEK (Q2 2023: 129.5 MSEK) and 179.5 MSEK for the first half of 2024 (H1 2023: 232.8 MSEK). SG&A expenses were impacted by the establishment of a restructuring reserve totaling 3.5 MSEK. Restructuring activities reduced total SG&A expenses as compared to prior quarters. Non-cash expenses for the Company's long-term incentive programs (LTIP) were included in SG&A costs and totaled 16.0 MSEK for the first six months of 2024 (H1 2023: 24.1 MSEK).

Research & Development (R&D) expenses

R&D expenses for the second quarter of 2024 totaled 91.7 MSEK (Q2 2023: 114.7 MSEK) and 194.6 MSEK for the first half of 2024 (H1 2023: 207.5 MSEK). R&D expenses include a restructuring reserve totaling 6.6 MSEK. Compared to the same period in 2023, the decrease in expense was primarily driven by the savings associated with restructuring activities offset by the ongoing US ConfIdeS study, EMA post-approval commitments, the ongoing anti-GBM Phase 3 clinical study and CMC development expense for HNSA-5487. Non-cash expenses for the Company's LTIP program were included in R&D expense and totaled 6.5 MSEK for the first half of 2024 (H1 2023: 11.3 MSEK).

Other operating income/expenses and financial income/expenses

Other operating income/expenses primarily include gains or losses from foreign exchange rate fluctuations in operations. In the second quarter 2024, these expenses totaled 1.3 MSEK, compared to 2.2 MSEK in expense in the second quarter of 2023. For the first half of 2024, the total expense was 4.3 MSEK compared to 3.0 MSEK in the first half of 2023. The change in expenses is primarily due to fluctuations in the US dollar exchange rate against the Swedish Krona, affecting deferred revenue as well as accounts payable and receivable positions on the balance sheet.

Financial income/expenses, net, for the second quarter of 2024, amounted to an expense of 20.5 MSEK, compared to an expense of 22.6 MSEK in the second quarter 2023. For the first half of 2024, the expense totaled 79.7 MSEK compared to 45.3 MSEK for the first half of 2023. The difference compared to 2023 is mainly driven by negative foreign exchange variances associated with Hansa's US dollar denominated long-term loan (see Note 4 below), partially offset by positive foreign exchange variances associated with US dollar denominated bank deposits.

Financial results

The loss from operations for the second quarter 2024 totaled 187.4 MSEK (Q2 2023: 228.5 MSEK) and 346.8 MSEK for the first half of 2024 (H1 2023: 410.8 MSEK). The decrease in Hansa's operating loss compared to the first half of 2023 was driven by increased sales as well as lower overall expenses.

The second quarter loss for the period totaled 207.9 MSEK (Q2 2023: 251.2 MSEK) and for the first half of 2024 the loss for the period totaled 426.5 MSEK (H1 2023: 456.6 MSEK).

Cash flow, cash and investments

Net cash used in operating activities for the second quarter 2024 totaled 189.1 MSEK (Q2 2023: 182.9 MSEK) and 378.3 MSEK for the first half of 2024 (H1 2023: 389.8 MSEK). The change compared to the first half in 2023 was driven by higher sales and lower operating expenses offset by the negative impact associated with changes in working capital. The share issue completed during Q2 increased cash balances by 354.3 MSEK net of transaction costs.

Cash and cash equivalents totaled 705.0 MSEK at June 30, 2024, compared to 732.1 MSEK at December 31, 2023.

Parent Company

The parent company's revenue for the second quarter of 2024 totaled 34.3 MSEK (Q2 2023: 36.7 MSEK) and for the first half of 2024 90.3 MSEK (HI 2023: 60.8 MSEK).

The second quarter 2024 parent company loss for the period totaled 238.7 MSEK (Q2 2023: income of 43.8 MSEK) and for the first half of 2024 the loss for the period totaled 485.8 MSEK (H1 2023: loss of 161.5 MSEK). The parent company loss for the second quarter 2023 was affected by a deferred tax income credit of 294.6 MSEK related to the write-up of Intellectual Property (IP) in the quarter.

Parent company shareholders' equity at June 30, 2024 totaled 1,106.0 MSEK compared to 1,216.9 MSEK at December 31, 2023.

The Group consists of the parent company, Hansa Biopharma AB, and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc., Hansa Biopharma Italy S.r.l. and Hansa Biopharma Australia PTY LTD. On June 30, 2024, Hansa Biopharma Inc. had 12 employees, Hansa Biopharma Ltd six employees and Hansa Biopharma S.r.l. four employees.

Long-term incentive programs

At Hansa Biopharma's previous Annual General Meetings, shareholders resolved to adopt various share-based LTIP programs. As of June 30, 2024, the Company incurred non-cash equity-based compensation expense under the following LTIP programs: 2019, 2020, 2021, 2022 and 2023.

The respective non-cash costs related to the ongoing LTIP programs are summarized in the table below. For further information on the different LTIP programs, please refer to Hansa Biopharma's 2023 Annual Report which can be found at www.hansabiopharma.com.

Ongoing programs	LTIP 2019	LTIP 2020	LTIP 2021	LTIP 2022	LTIP 2023
Maximum number of issuable shares*	193,892	633,776	468,000	1,054,690	1,369,810
Number of allocated outstanding share rights and options	149,148	487,520	360,000	811,300	1,066,000
Estimated total cost including social contributions for outstanding share rights and options, KSEK	-	7	105	55,063	28,090
Total cost per program, including social contributions, recognized in profit/loss as of June 30, 2024, YTD, KSEK	-	328	7,732	9,703	4,777

*As of June 30, 2024, the table includes shares issued to cover estimated social contributions under the LTIP.

Total costs, including social contributions, recognized in profit/loss as of June 30, 2024, YTD, KSEK	**22,540**

Risks and uncertainties

Hansa'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 consider these risks.

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

In the 2023 Annual Report (pages 53-56 English version), the risks and uncertainties which are considered to have greatest significance for Hansa Biopharma are described in more detail.

On a regular basis, Hansa's Board of Directors and senior management review the development of these risks and uncertainties. No material changes from the presentation in the 2023 Annual Report have been identified as of the date of this quarterly report.

Other information

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Legal disclaimer

This financial report includes statements that are forward-looking, and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are developments within research programs.

Financial calendar 2024/2025

October 24, 2024	Interim Report for January – September 2024
February 6, 2025	Full-year Report for January – December 2024
April 17, 2025	Interim Report for January – March 2025

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares June 30, 2024[1]	67,814,241
Market Cap June 30, 2024	~3.14 BSEK (US ~$298M)
Ticker	HNSA
ISIN	SE0002148817

Top 10 Shareholders as of June 30, 2024

Shareholder Name	Number of Shares	Ownership %
Redmile Group, LLC	13,156,700	19.4%
Braidwell, L.P.	8,247,600	12.2%
Jeansson, Theodor	2,730,000	4.0%
Hansa Biopharma AB	2,214,267	3.3%
Nexttobe AB	2,155,400	3.2%
Fjärde AP-Fonden (AP 4)	2,094,000	3.1%
Försäkrings AB Avanza Pension	1,929,985	2.8%
Olausson, Thomas	1,917,000	2.8%
Tredje AP-Fonden (AP 3)	1,389,600	2.0%
Sphera Funds Management, LTD	1,107,000	1.6%
All other	30,872,689	45.5%
Total Shares Outstanding	67,814,241	100.0%

Source: S&P Global compiled and processed data from various sources, including Euroclear, Morningstar, FactSet and the Swedish Financial Supervisory Authority (Finansinspektionen).

Hansa Biopharma had approximately 20,000 shareholders as of June 30, 2024.

1. Following execution of a directed share issue in the second quarter 2024, the number of outstanding shares increased to 67,814,241 shares.

Assurance

The Board of Directors and the Chief Executive Officer 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. This Report has not been reviewed by the company's auditors.

Lund July 18, 2024

Peter Nicklin
Chairman of the Board

Hilary Malone
Board member

Eva Nilsagård
Board member

Mats Blom
Board member

Florian Reinaud
Board member

Anders Gersel Pedersen
Board Member

Jonas Wikström
Board member

Søren Tulstrup
President & CEO

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabiopharma.com.

Unaudited Condensed Financial Statements

Unaudited condensed consolidated statement of financial position

KSEK	Not	June 30 2024	June 30 2023	December 31 2023
ASSETS				
Non-current assets				
Intangible assets	5	166,363	95,938	135,817
Property and equipment		5,551	7,666	6,343
Right-of-use assets		16,949	23,966	20,730
Total non-current assets		**188,863**	**127,570**	**162,890**
Current assets				
Inventories		2,117	2,501	1,513
Trade receivables & unbilled		99,329	70,557	78,025
Current receivables, non-interest		34,068	59,381	43,553
Cash and cash equivalents		704,999	1,102,514	732,060
Total current assets		**840,513**	**1,234,953**	**855,151**
TOTAL ASSETS		**1,029,376**	**1,362,523**	**1,018,041**
EQUITY AND LIABILITIES				
Shareholders' equity		**(218,794)**	**182,183**	**(167,876)**
Non-current liabilities				
Long-term loan	4	956,352	840,908	844,903
Deferred tax liabilities		364	418	367
Provisions		4,173	5,531	4,454
Lease liabilities		10,554	17,683	14,362
Deferred revenue		-	13,347	-
Contingent consideration	3	930	862	843
Total non-current liabilities		**972,373**	**878,749**	**864,929**
Current liabilities				
Tax liabilities		1,420	981	1,599
Lease liabilities		7,576	7,257	7,503
Current liabilities, non-interest		54,927	57,267	86,966
Deferred revenue		30,015	42,955	41,473
Refund liabilities		86,167	47,907	49,266
Accrued expenses		95,692	145,224	134,181
Total current liabilities		**275,797**	**301,591**	**320,988**
TOTAL EQUITY AND LIABILITIES		**1,029,376**	**1,362,523**	**1,018,041**

Unaudited condensed consolidated income statement

KSEK	Note	Q2 2024	Q2 2023	H1 2024	H1 2023
Revenue	2	34,334	36,652	90,315	60,846
Cost of revenue		(40,528)	(18,715)	(58,686)	(28,361)
Sales, general and administration expenses		(88,207)	(129,470)	(179,457)	(232,762)
Research and development expenses	5	(91,678)	(114,736)	(194,643)	(207,527)
Other operating income/(expenses), net		(1,306)	(2,182)	(4,305)	(2,995)
Loss from operations		**(187,385)**	**(228,451)**	**(346,776)**	**(410,799)**
Financial income		5,970	3,253	11,206	5,927
Financial expenses	4	(26,514)	(25,865)	(90,877)	(51,256)
Loss before tax		**(207,929)**	**(251,063)**	**(426,447)**	**(456,128)**
Tax		(14)	(119)	(75)	(475)
Loss for the period		**(207,943)**	**(251,182)**	**(426,522)**	**(456,603)**
Loss for the period attributable to owners of the parent		(207,943)	(251,182)	(426,522)	(456,603)
Loss per share, basic and diluted (SEK)		(3.30)	(4.79)	(7.38)	(8.71)
Other comprehensive income/(loss)					
Items that have been, or may be reclassified to profit or loss for the period:					
Translation differences		(39)	439	732	489
Other comprehensive income/(loss) for the period		**(39)**	**439**	**732**	**489**
Total comprehensive income/(loss)		**(207,982)**	**(250,743)**	**(425,790)**	**(456,114)**

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Unaudited condensed consolidated statement of changes in shareholder's equity

KSEK	January-June 2024	January-June 2023	Full year 2023
Opening balance of shareholders' equity	**(167,876)**	**602,912**	**602,912**
Result for the period	(426,522)	(456,603)	(831,720)
Translation reserve	732	489	(422)
Net comprehensive income/(loss)	**(423,865)**	**(456,114)**	**(832,142)**
Transactions with the group's owner			
Proceeds from new share issuance, net[1]	354,308	-	-
Long term incentive programs	20,564	35,385	61,354
Total transactions with the group's owner	**374,872**	**35,385**	**61,354**
Closing balance of shareholders' equity	**(218,794)**	**182,183**	**(167,876)**

[1] Total share issue cost amounted to SEK 17,845 KSEK.

Unaudited condensed consolidated statement of cash flow

KSEK	Q2 2024	Q2 2023	H1 2024	H1 2023
Cash Flows from Operating Activities				
Loss for the period	(207,943)	(251,182)	(426,522)	(456,603)
Adjustment for items not included in cash flow[1]	14,144	36,100	95,757	65,247
Interest received and paid, net	437	(1,975)	892	386
Income taxes paid	(137)	334	(283)	(22)
Cash flow from operations before change in working capital	**(193,499)**	**(216,723)**	**(330,156)**	**(390,992)**
Changes in working capital	4,359	33,842	(48,127)	1,151
Net cash used in operating activities	**(189,140)**	**(182,881)**	**(378,283)**	**(389,841)**
Investing activities				
Acquisition of property and equipment	-	(155)	(116)	(689)
Cash flow from investing activities	**-**	**(155)**	**(116)**	**(689)**
Financing activities				
Proceeds from new share issue, net of transaction cost[2]	354,308	-	354,308	-
Payment of lease liabilities	(1,876)	(1,783)	(3,735)	(3,551)
Cash flow from financing activities	**352,432**	**(1,783)**	**350,573**	**(3,551)**
Net change in cash	163,292	(184,820)	(27,826)	(394,081)
Cash and cash equivalents at beginning of period	541,465	1,286,820	732,060	1,496,179
Currency exchange variance, cash and cash equivalents	242	514	765	416
Cash and cash equivalents, end of period	**704,999**	**1,102,514**	**704,999**	**1,102,514**

[1] Values are mainly costs of share-based incentive programs including social contributions and depreciation, partly offset by certain capitalized development costs (see further in note 5).
[2] Total share issue cost amounted to SEK 17,845 KSEK.

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Parent Company – Unaudited condensed statement of financial position

KSEK	Note	June 30 2024	June 30 2023	December 31 2023
ASSETS				
Non-current assets				
Intangible assets	5,6	1,475,250	1,523,720	1,504,277
Property and equipment		5,552	7,666	6,343
Right-of-use assets		16,949	23,966	20,730
Investment in subsidiaries		33,646	27,107	30,044
Total non-current assets		**1,531,39**	**1,582,45**	**1,561,394**
Current assets				
Inventories		2,117	2,501	1,513
Trade receivables & unbilled revenues		99,329	70,557	78,025
Current receivables, non-interest bearing		33,744	59,059	43,205
Cash and cash equivalents		689,395	1,086,007	715,538
Total current assets		**824,585**	**1,218,12**	**838,281**
TOTAL ASSETS		**2,355,98**	**2,800,58**	**2,399,675**
EQUITY AND LIABILITIES				
Shareholders' equity	6	**1,105,98**	**1,625,09**	**1,216,945**
Non-current liabilities				
Long-term loan	4	956,352	840,908	844,903
Provisions		4,173	5,531	4,454
Lease liabilities		10,554	17,683	14,362
Deferred revenue		-	13,347	-
Contingent consideration	3	930	862	843
Total non-current liabilities		**972,009**	**878,331**	**864,562**
Current liabilities				
Tax liabilities		1,221	981	1,409
Lease liabilities		7,577	7,256	7,503
Liabilities, group companies		9,851	2,086	7,089
Current liabilities, non-interest bearing		55,433	56,841	86,966
Deferred revenue		30,015	42,955	41,473
Refund liabilities		86,167	47,907	49,266
Accrued expenses		87,727	139,129	124,462
Total current liabilities		**277,991**	**297,155**	**318,168**
TOTAL EQUITY AND LIABILITIES		**2,355,98**	**2,800,58**	**2,399,675**

Parent Company – Unaudited condensed income statement

KSEK	Note	Q2 2024	Q2 2023	H1 2024	H1 2023
Revenue	2	34,334	36,652	90,315	60,846
Cost of revenue		(70,320)	(18,715)	(118,269)	(28,361)
Sales, general and administration		(87,472)	(128,196)	(177,185)	(231,356)
Research and development expenses	5	(93,548)	(115,578)	(196,803)	(208,514)
Other operating income/(expenses), net		(1,159)	(2,183)	(4,147)	(2,996)
Loss from operations		**(218,165)**	**(228,019)**	**(406,089)**	**(410,381)**
Financial income		5,960	3,253	11,196	5,927
Financial expenses	4	(26,502)	(25,859)	(90,866)	(51,256)
Loss before tax		**(238,707)**	**(250,625)**	**(485,759)**	**(455,710)**
Income tax	6	(16)	294,384	(87)	294,202
Loss for the period		**(238,723)**	**43,759**	**(485,846)**	**(161,508)**
Other comprehensive income/(loss) for the period		-	-	-	-
Total comprehensive income/(loss) for the		**(238,723)**	**43,759**	**(485,846)**	**(161,508)**

Parent Company – Unaudited condensed statement of changes in shareholders' equity

KSEK	Q2 2024	Q2 2023	Full year 2023
Opening balance of shareholders' equity	**1,216,945**	**615,799**	**615,799**
Result for the period	(485,846)	(161,508)	(595,536)
Other comprehensive income/(loss) for the period	-	-	-
Net comprehensive income/(loss)	**(485,846)**	**(161,508)**	**(595,536)**
IP write-up, net	-	1,135,420	1,135,421
Proceeds from new share issuance, net[1]	354,308	-	-
Long term incentive programs	20,575	35,385	61,261
Total other transactions	**374,883**	**1,170,806**	**1,196,682**
Closing balance of shareholders' equity	**1,105,982**	**1,625,097**	**1,216,945**

[1] Total share issue cost amounted to SEK 17,845 KSEK.

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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. Hansa's Annual Report 2023 was published on March 21, 2024, and is available at 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.

Note 2 Revenue

Income per significant category of income	Q2		January-June	
KSEK	2024	2023	2024	2023
Group				
Revenue				
Product sales[1] *(Q2 product sales 47.1 MSEK less provision 19.9 MSEK = 27.2 MSEK)*	27,219	29,576	74,667	43,882
Contract revenue, Axis-Shield agreement	651	644	1,302	1,288
Cost reimbursement, Axis-Shield agreement	80	-	581	286
Contract revenue, Sarepta, AskBio agreement	6,384	6,432	13,765	15,390
	34,334	**36,652**	**90,315**	**60,846**
Parent Company				
Revenue				
Product sales	27,219	29,576	74,667	43,882
Contract revenue, Axis-Shield agreement	651	644	1,302	1,288
Cost reimbursement, Axis-Shield agreement	80	-	581	286
Contract revenue, Sarepta, AskBio agreement	6,384	6,432	13,765	15,390
	34,334	**36,652**	**90,315**	**60,846**

[1] *Actual product sales in Q2 2024 amounted to 47.1 MSEK. Sales were offset by a provision totaling 19.9 MSEK for expected credits associated with volume discounts and potential refunds. First half 2024 product sales totaled 94.6 MSEK and were offset by the provision totaling 19.9 MSEK. Net of the provision, first half product sales totaled 74.7 MSEK.*

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 the financial liability for contingent consideration at June 30, 2024 totaled 0.9 MSEK (December 31, 2023: 0.8 MSEK) and belongs to Level 3 in the fair value hierarchy. The Group does currently not hold any interest funds. 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 Long-term loan

On July 18, 2022, the Company entered into a US $70.0 million funding agreement with NovaQuest. The funding was accounted for as a liability and classified as debt because the Company has an unavoidable obligation to settle the agreement in cash. The debt will be accounted for over the life of the funding agreement.

The net proceeds from the funding agreement totaled US $69.2 million after the deduction of transaction costs. The transaction costs were capitalized and offset against the carrying value of the debt and will be amortized over the term of the debt.

Under the terms of the funding agreement, the Company will make quarterly mid-single-digit royalty payments to NovaQuest on future worldwide annual net sales of imlifidase, commencing upon approval by the US FDA of imlifidase in kidney transplantation or anti-GBM. In addition, Hansa will make certain milestone payments to NovaQuest upon FDA approval of imlifidase in kidney transplantation or anti-GBM disease. The agreement also provides for time-based catch-up payments if specified payment amounts have not been received by NovaQuest by specified dates. Under the agreement, repayments must begin no later than January 31, 2026, regardless of whether the aforementioned approvals were achieved, with the final potential catch-up payment due on January 31, 2029. The company is obligated to repay a total of US $140.0 million in the form of milestones, royalty payments and/or catch-up payments.

Hansa has also entered into a security agreement under which the Company has pledged and provided a broad security interest to NovaQuest in, and to, certain assets, proceeds and IP rights related to imlifidase in kidney transplantation in highly sensitized patients and anti-GBM disease.

The Company will record the difference between the principal and the total payments as interest expense over the term of the debt by applying the effective-interest-rate method. Based on the progress of the payments, the Company will recalculate the effective interest each reporting period until the debt obligation has been satisfied.

On June 30, 2024, the loan totaled 956.4 MSEK, including 222.4 MSEK in accrued interest.

Note 5 Intangible assets – Internally generated intangible assets

Expenditures related to research activities are recognized as expense in the period in which it is incurred. An internally-generated intangible asset arising from development (or from the development phase of an internal project) is recognized only if all the following criteria have been demonstrated in accordance with IAS 38:

- *the technical feasibility of completing the intangible asset so that it will be available for use or sale;*
- *the intention to complete the intangible asset and use or sell it;*
- *the ability to use or sell the intangible asset;*
- *how the intangible asset will generate probable future economic benefits;*
- *the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and*
- *the ability to measure reliably the expenditure attributable to the intangible asset during its development.*

The amount initially recognized for internally-generated intangible assets is the sum of the expenditures incurred from the date when the intangible asset first meets all the recognition criteria listed above. Development expenses, for which no internally-generated intangible asset can be identified, are expensed in the statement of profit and loss and other comprehensive income in the period in which they are incurred.

The Company determined that IDEFIRIX and its conditional approval by EMA to enable kidney transplantation in highly sensitized patients meet all the above criteria as of Q4 2022.

As of June 30, 2024, the total capitalized development expenses related to fulfilling the IDEFIRIX EMA post-approval commitments amount to 158.6 MSEK, with 39.0 MSEK capitalized during 2024. These capitalized development costs are subject to regular amortization over their useful life, which is projected to extend until end of 2032. Total accumulated amortization at June 30, 2024 was 14.1 MSEK.

Note 6 Intangible assets – Recognition of write-up

As of June 30, 2023, Hansa recognized a write-up of 1,430.0 MSEK in intangible assets in the statutory financial statements of the parent company Hansa Biopharma AB, in accordance with Chapter 4, Section 6 of the Swedish Annual Accounts Act (1995:1554) and RFR 2.

The write-up relates to IDEFIRIX, which has received a conditional market authorization in the European Union (EU)/EEA and United Kingdom (UK) for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Following the write-up, the asset will have a gross value of 1,500.0 MSEK in Hansa Biopharma AB's financial statements. The write-up increased the restricted shareholder equity in Hansa Biopharma AB by 1,430.0 MSEK. It also created a taxable temporary difference, leading to the recognition of a deferred tax liability of 294.6 MSEK, which decrease restricted shareholder equity. As a result of recognizing the deferred tax liability, Hansa recognized a deferred tax asset of 294.6 MSEK through profit or loss, increasing unrestricted shareholder equity, related to previously unrecognized tax losses.

The intangible asset will be subject to regular amortization over its estimated useful life of 12 years.

As of June 30, 2024, the Company recorded an accumulated amortization of 119.2 MSEK in its statutory financial statements, thereby reducing the previously recorded intangible asset by the same amount. As a result, the Company has recorded an adjustment of 24.5 MSEK to its previously recorded deferred tax assets and tax liabilities due to amortization.

The write-up and subsequent amortization of the intangible asset does not impact the consolidated IFRS financial statements of the Hansa Group.

Glossary

Adeno-associated virus (AAV)
AAV is a versatile viral vector technology that can be engineered for very specific functionality in gene therapy applications.

Allogeneic hematopoietic stem cell transplantation (HSCT)
Allogeneic HSCT, also known as “bone-marrow” transplantation, involves transferring the stem cells from a healthy person (the donor) to the patient’s body after high-intensity chemotherapy or radiation. The donated stem cells can come from either a related or an unrelated donor.

AMR
Antibody mediated transplant rejection.

Antibody
One 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 antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

Autoimmune disease
Diseases that occur when the body’s immune system reacts against the body’s own structures.

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.

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

Clinical studies
Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical phase 1
The first time a drug under development is administered to humans. Phase I 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.

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

EMA
The European Medicines Agency (EMA) is an EU agency for the evaluation of medicinal products.

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

ESOT
The European Society for Organ Transplantation (ESOT) is an umbrella organsation which overlooks how transplantations are structured and streamlined.

FDA or US FDA
U.S. Food and Drug Administration.

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

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

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

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

Imlifidase
Imlifidase, is the immunoglobulin G-degrading enzyme of Streptococcus pyogenes, 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.

IND
Investigational New Drug (IND) application is required to get approval from the FDA to administer an investigational drug or biological product to humans.

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

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

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

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

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.

Neutralizing Antibodies (NAbs)
NAb is an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically.

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

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

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

Randomized Control Trial (RCT)
RCT is a study design where the trial subject is randomly allocated to one of two or more study cohorts to test a specific intervention against other alternatives, such as placebo or standard of care.

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

Standard of Care (SOC)
Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals.