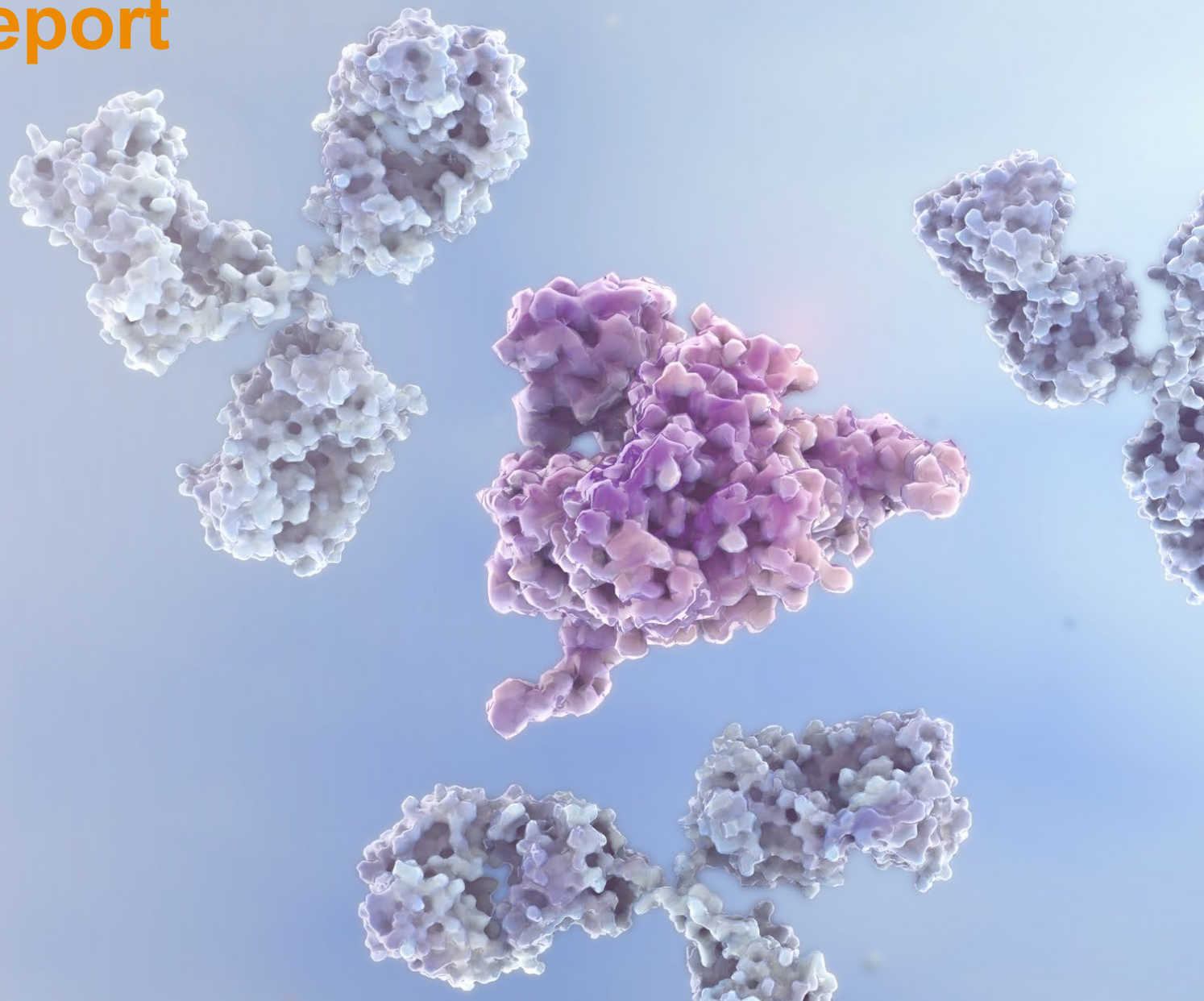
Half Year Report

January – June 2026

HANSA BIOPHARMA



€115 million out-licensing agreement and positive data from European confirmatory trial

Business Update

- Q2 revenues of 48.1 MSEK were in line with prior year Q2 with a slight decrease of 1.0 MSEK or 2% compared to Q2 in 2025 (49.1 MSEK) and a 39% increase over Q1 2026. Q2 Idefirix product revenues totaled 46.8 MSEK, a decrease of 2% as compared to the same period last year (47.8 MSEK). For H1 2026, product revenue amounted to 80.7 MSEK, representing a 29% decrease over H1 2025. European sales in the period were primarily driven by France and Spain.
- On May 19, **Hansa entered into a €115 million out licensing agreement** with SERB Pharmaceuticals (SERB) covering Idefirix for transplantation in Europe, UK and the Middle East and North Africa region (MENA). The agreement strengthens the Company's financial position and supports preparations for a US launch, subject to regulatory approval.
- **The Annual General Meeting** took place in Lund on June 1.
- **Capital Markets Day** was held in New York on June 25, with a focus on kidney transplantation in highly sensitized patients with insights from leading medical experts.
- **Adam Cutler was appointed Chief Financial Officer**, effective June 22, and Fredrik Röök was appointed Vice President Business Development, effective August 17.
- **Subsequent event:** Following receipt of required regulatory approvals, the licensing agreement with SERB was completed on July 1, 2026.

Clinical Pipeline Update

- **ConfIdeS pivotal US Phase 3 Data Presented at the American Transplant Congress (ATC) -** Results from the Phase 3 ConfIdeS trial were shared as an oral presentation at ATC 2026 and selected for inclusion in the 'What's Hot, What's New' plenary session.
- **European confirmatory PAES -** Positive efficacy and safety results from the European post-authorization study of Idefirix in kidney transplantation were reported, including a one-year graft failure-free survival rate of 90%, supporting submission to the European Medicines Agency (EMA) for conversion to full marketing authorization.

Financial Summary

Amounts in MSEK, unless otherwise stated	Q2 2026	Q2 2025	H1 2026	H1 2025
Revenue	48.1	49.1	82.7	115.5
- Including: Product sales	46.8	47.8	80.7	113.5
SG&A expenses	(118.9)	(90.5)	(224.5)	(166.5)
R&D expenses	(67.9)	(95.8)	(125.2)	(160.1)
Loss from operations	(174.1)	(154.5)	(316.6)	(247.9)
Loss for the period	(260.5)	(197.0)	(456.9)	(235.8)
Net cash used in operations	(103.5)	(94.2)	250.5	(230.0)
Cash and short-term investments	552.8	354.4	552.8	354.4
EPS before and after dilution (SEK)	(2.56)	(2.78)	(4.49)	(3.42)
Number of outstanding shares	101,763,222	84,763,222	101,763,222	84,763,222
Weighted average number of shares before and after dilution	101,763,222	70,802,763	101,763,222	68,937,930
Number of employees at period end	131	140	131	140

Upcoming key catalysts

Desensitization Kidney Transplant

- Imlifidase **PDUFA date** December 19, 2026.
- **Publication** of ConfIdeS Phase 3 data in a leading medical journal expected in H2 2026.
- **Submission of application** for conversion to full marketing authorization of Idefirix based on European confirmatory trial PAES expected in Q4 2026.

Desensitization Gene Therapy

- **Phase 2:** Global trial in Crigler-Najjar syndrome with Genethon. Study **enrollment to be completed** by year end following protocol amendment.

Autoimmune Disease

- Submission of IND to FDA before YE 2026 for the clinical development program of HNSA 5487 in GBS.

Out licensing agreement in place and additional strong clinical data reported

Renée Aguiar-Lucander
CEO, Hansa Biopharma

The second quarter was a defining period for Hansa and another important step in our evolution as a leading immunology-focused biotechnology company. We achieved significant strategic, clinical, and operational milestones that strengthened the Company and enhanced our ability to create long-term value for patients, healthcare systems, and shareholders. Most notably, we announced the licensing agreement with SERB Pharmaceuticals (SERB) for Idefirix in Europe, UK and the MENA region, reported positive topline data from our European confirmatory trial (PAES) supporting our application for full marketing authorization in Europe. We also showcased the strength of the ConfIdeS Phase 3 data at an oral presentation at the American Transplant Congress (ATC). These achievements position Hansa for success as we continue to prepare for a potential US launch of imlifidase and advance our broader portfolio.

Revenue for the quarter amounted to SEK 48.1 million, compared with SEK 49.1 million in the corresponding period last year. The development reflects some expected impact from the announcement of the SERB transaction and continued commercial efforts to expand uptake of Idefirix® across European markets, including a positive contribution from the recently secured reimbursement in Catalonia, Spain. We also delivered continued strong performance in France and saw solid demand in the other large European markets such as Germany, Italy and the UK.

Another encouraging development during the quarter was the publication of German expert consensus guidelines providing a framework for the use of Idefirix-enabled transplantation in highly sensitized kidney transplant candidates within the ETKAS program. The publication represents an important step in supporting clinical adoption and awareness of Idefirix in Germany, an important European transplant market. In addition, an independent German law firm published an article with a legal analysis clarifying that desensitization is permitted under all relevant laws and directives in Germany and underscored patients' rights to receive treatment in line with the latest standards. We look forward to seeing increased usage in Germany in the second half of the year as a consequence.

The defining milestone of the quarter was the completion of the licensing agreement with SERB Pharmaceuticals for Idefirix in Europe, UK and the MENA region. I believe this transaction is transformational as it significantly strengthens Hansa's financial position with non-dilutive capital which will enable us to sharpen our focus on key strategic priorities, including a US launch of imlifidase, subject to US approval, and advancement of our broader R&D portfolio.

With its established commercial capabilities in rare and specialty diseases, SERB is well positioned to expand access to Idefirix for appropriate highly sensitized kidney transplant patients. I strongly believe that this transaction ensures enhanced focus and appropriate and experienced resource allocation towards Idefirix, ensuring that it reaches the appropriate patients in Europe. It also enables Hansa to invest appropriately behind its strategic imperatives with a significantly extended runway. Employees associated with the European Idefirix business will, as part of the transaction, be offered the possibility to join SERB's European operations and I would like to express my sincere gratitude to these colleagues whose expertise, dedication and commitment have helped establish Idefirix as an important treatment option for patients with a significant unmet medical need. Hansa will fully support SERB in the filing for conversion to full market authorization and the EMA review process. SERB will also assume responsibility for the long-term PAES follow-up and the ongoing pediatric study post transfer of Marketing Authorization. We are committed to supporting both our employees and SERB throughout this transition process to ensure continuity for patients and customers.

During the quarter, we also generated additional important clinical data, building the momentum created by the ConfIdeS data readout. Positive topline data from the European post-authorization efficacy and safety study (PAES) demonstrated a graft failure-free survival rate of 90% at one year, with patient survival of 98%, and graft survival of 92% with a safety profile consistent with previous clinical experience.

These positive results represent a significant milestone for Idefirix and for Hansa. With this post-authorization requirement successfully fulfilled, we remain on track to submit an application to EMA for conversion to full marketing authorization by the end of 2026.

The quarter also included important scientific engagement activities. At ATC 2026, late-breaking data from our Phase 3 ConfIdeS study were presented by Dr. Robert Montgomery and were selected for the prestigious "What's Hot, What's New" plenary session, highlighting the novelty and scientific significance of the findings. This recognition highlights the strength and clinical relevance of the ConfIdeS data and the potential of imlifidase to address a significant unmet need in highly sensitized kidney transplant patients.

Building on this momentum, Hansa hosted a successful Capital Markets Day in New York on June 25, accessible both in person and virtually. The event focused on kidney transplantation in highly sensitized patients and featured four leading medical experts who discussed their interpretation of the US and European clinical data, real world data outcomes in Europe and limitations of the existing standard of care in US. They also highlighted the unmet medical need and the need for new approved approaches to transform patient outcomes. The strong attendance and engagement from investors, analysts and healthcare stakeholders reinforced our confidence in the long-term opportunity for imlifidase and the significant unmet need that remains in this patient population.

Following the end of the quarter we closed the SERB out-licensing transaction on July 1st and will now focus our internal efforts on ensuring a swift and smooth transition process, while continuing to work diligently on all of the pre-commercial workstreams to prepare for the commercialization of imlifidase in the US. We continue to interact with the FDA in the BLA review process, and we look forward to updating you on any progress regarding potential approval. I would like to thank our shareholders for their continued support and confidence as we execute our strategy and advance Hansa into its next phase of growth.

Imlifidase Commercial, Business and Pipeline Update

Commercial Update

Kidney transplantation in highly sensitized patients

Idefirix continues to progress across European and international markets. Q2 2026 product sales were 2% lower than Q2 2025. H1 product sales were 29% lower compared to the same period in 2025, reflecting weaker performance in the first quarter of 2026.

Commercial execution improved significant (+39%) over Q1, with continued growth in Spain following the achievement of reimbursement in Catalonia and continued strong performance in France. We also saw solid demand in the other large European markets Germany, Italy and the UK.

On June 9, the German expert consensus report, "Risk-adapted HLA delisting and imlifidase-enabled deceased-donor kidney transplantation in highly sensitized kidney transplant candidates," was published in Frontiers. The publication provides practical guidance for the transplantation of highly sensitized patients within the ETKAS program and represents an important step toward broader adoption of Idefirix in Germany. This publication was complemented by an independently published article clarifying that no potential concerns had been identified related to transplantation of highly sensitized patients in the program from a legal perspective. We expect these publications to drive uptake in Germany going forward.

At ATC 2026, data from the US Phase 3 ConfIdeS study were presented by Dr. Robert Montgomery, MD, PhD, of the NYU Langone Transplant Institute during a Clinical Science session. In addition, the ConfIdeS abstract was selected for 'What's Hot, What's New' at ATC's closing plenary session. Hansa also hosted a well-attended satellite symposium, "The Highly Sensitized Patient: Prioritized and Still Waiting," highlighting the significant unmet need in this patient population.

Pre-launch activities in the US continued during the quarter, including the expansion of key commercial and medical capabilities with the recruitment of additional field-based Market Access and Medical Affairs personnel.

Business Update

Out licensing agreement

On May 19th Hansa entered into a €115 million out-licensing agreement with SERB Pharmaceuticals covering development and commercialization of Idefirix in transplantation in the European Union, United Kingdom, Switzerland, Norway, Liechtenstein, Iceland and the MENA region. Hansa receives an upfront payment of €110 million and a €5 million payment upon acceptance of the filing for full approval of Idefirix by the European Medicines Agency (EMA).

Hansa will support SERB in the filing expected to be initiated in Q4 for conversion to full marketing authorization and subsequent EMA review process. SERB will assume responsibility for the long-term PAES follow-up and the ongoing pediatric study upon obtaining Market Authorization Holdership, a transfer process expected to be initiated soon after the closing of the transaction.

Capital Markets Day

Capital Markets Day was held in New York on June 25, with a focus on kidney transplantation in highly sensitized patients and included valuable insights and reflections regarding the imlifidase clinical data, unmet medical need and real world experiences from leading medical experts Matthew Cooper MD, Medical College of Wisconsin, Nassim Kamar, MD, PhD, Toulouse University Hospital, France, Roslyn Mannon, MD, University of Nebraska Medical Center and Annette Jackson, PhD, F(ACHI), Duke University Medical Center.

Pipeline Update

ConfIdeS pivotal US Phase 3 Trial

ConfIdeS Phase 3 abstract titled "Superior 1-year eGFR Among Highly Sensitized Patients Desensitized with Imlifidase Compared to Control" was presented at the ATC meeting in Boston on June 22, 2026.

PAES Confirmatory Trial

Positive results from the Post Authorization Efficacy Study support the planned submission for conversion to full marketing authorization. The study successfully met its primary objective, demonstrating 90% graft failure-free survival at one year.

At one year, mean eGFR was 51.6 mL/min/1.73 m², graft survival was 92%, and patient survival was 98%. Patient retention exceeded 90%, and Idefirix was generally well tolerated with a safety profile consistent with previous clinical studies.

Submission to the EMA for conversion from conditional to full marketing authorization remains planned for Q4, 2026.

Phase 2 Guillain-Barré Syndrome (GBS) Study - 15-HMedIdeS-09

Planned submission of IND to FDA for the clinical development program of HNSA-5487 in GBS before YE 2026.

Focused Pipeline in Desensitization and Autoimmune Diseases

	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Partner	Upcoming Milestone
idefirix (imlifidase)	Desensitization Kidney Transplantation						Filing with EMA for full approval in Q4
imlifidase	Desensitization Kidney Transplantation						PDUFA* date Dec 19, 2026
	Desensitization Gene Therapy (Crigler Najjar)					GENETHON	H2 2026: complete enrollment
	Desensitization Gene Therapy (DMD)					SAREPTA	Discussions ongoing regarding next steps
	Autoimmune AAV Investigator Initiated Trial (IIT)[1]						Follow-up phase concluded
HNSA-5487	Autoimmune GBS						Clinical development plan agreed with FDA in H2 2026

DMD: Duchenne muscular dystrophy
AAV: ANCA-associated vasculitis
GBS: Guillain-Barré Syndrome

[1] Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

*Prescription Drug User Fee Act

Financial Review 2026: Second Quarter & Year to Date

Revenue

Revenue for the second quarter 2026 totaled 48.1 MSEK (Q2 2025: 49.1 MSEK) consisting of Idefirix product sales of 46.8 MSEK (Q2 2026: 47.8 MSEK) and contract revenue of 1.3 MSEK (Q2 2026: 1.4 MSEK). Revenue for the six months ended June 30, 2026, totaled 82.7 MSEK (H1 2025: 115.5 MSEK) consisting of Idefirix product sales of 80,7 MSEK (H1 2025: 113.5 MSEK) and contract revenue of 1.9 MSEK (H1 2025: 2.0 MSEK).

Sales General & Administrative (SG&A) expenses

SG&A expenses for the second quarter 2026 totaled 118.9 MSEK (Q2 2025: 90.5 MSEK) and 224.5 MSEK for the first half of 2026 (H1 2025: 166.5 MSEK).

The year-over-year second quarter expense increase of 28.4 MSEK and reflects increased costs associated with preparation for the expected US market launch, costs associated with the convertible debt and SERB-deal as well as increased costs for Hansa's long-term incentive programs.

Non-cash expenses for the Company's long-term incentive programs (LTIP) were included in SG&A costs and totaled 22.3 MSEK for the first half of 2026 (H1 2025: 4.1 MSEK).

Research & Development (R&D) expenses

R&D expenses for the second quarter of 2026 totaled 67.9 MSEK (Q2 2025: 95.8 MSEK) and 125.2 MSEK for the first half of 2026 (H1 2025: 160.1 MSEK).

Year-over-year second quarter R&D expenses were 27.9 MSEK favorable compared to the prior year mainly due to the finalization of the Confides-study, the anti-GBM study, and the effect of the restructuring made in 2025.

Non-cash expenses related to the Company's LTIP program were included in R&D expense and totaled 7.2 MSEK for the first half of 2026 (H1 2025: 3.4 MSEK).

Other operating income/expenses, net and finance income/expenses, net

Other operating income/expenses, net, primarily included gains or losses from foreign exchange rate fluctuations in operations. In the second quarter of 2026, the Company recorded an expense of 13.0 MSEK compared to an income of 0.7 MSEK in the second quarter of 2025. The change is primarily due to a weakening in the exchange rate of the Swedish Krona primarily against the US dollar and Euro, affecting deferred revenue as well as accounts payable and receivable positions on the balance sheet.

Financial income/expenses, net, for the second quarter of 2026, totaled an expense of 85.8 MSEK (Q2 2025 expense of 55.3 MSEK). The financial expenses, primarily driven by foreign exchange as the Swedish Krona exchange rate compared to the US dollar weakened. This impacted the interest associated with the NovaQuest loan. The financial expenses for the first half of 2026 included non-cash interest expense associated with the Company's long-term loans of 68.6 MSEK (H1 2025: 69.9 MSEK), unfavorable financial foreign exchange fluctuations of 50.8 MSEK (H1 2025 favorable: 132.7 MSEK), a noncash derivative part of the convertible loan of 30.5 MSEK (H1 2025: 0 MSEK) and other items.

Financial results

The loss from operations for the second quarter 2026 totaled 174.1 MSEK (Q2 2025: 154.5 MSEK) and the increase in Hansa's operating loss for the second quarter 2026 compared to the same period previous year was driven by investments in building a commercial US organization.

The second quarter loss for the period totaled 260.5 MSEK (Q2 2025: 197.0 MSEK) and the difference compared to the previous year is due to somewhat higher expenses, but also due to the weakening of the Swedish Krona compared to mainly the US dollar.

Cash flow, cash and investments

Net cash used in operating activities for the second quarter 2026 totaled 103.5 MSEK (Q2 2025: 94.2 MSEK) The change compared to the prior year was driven by higher operating expenses, mainly driven by investments in building a commercial US organization. The new convertible debt increased the cash balance by 271.1 MSEK. The two share issuances completed in 2025 increased cash balances by 847.2 MSEK net of transaction costs.

Cash and cash equivalents totaled 552.8 MSEK on June 30, 2026, compared to 354.4 MSEK for the same period in the previous year and 701.1 MSEK on December 31, 2025.

Parent Company

The parent company's revenue for the second quarter of 2026 totaled 48.1 MSEK (Q2 2025: 49.1 MSEK). The second quarter 2026 parent company loss \ totaled 286.2 MSEK (Q2 2025: 227.8 MSEK).

The parent company shareholders' equity on June 30, 2026, totaled 575.9 MSEK compared to 1,062.1 MSEK on December 31, 2025.

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, 2026, Hansa Biopharma Inc. had twenty-four employees, Hansa Biopharma Ltd had nine employees and Hansa Biopharma S.r.l. had three employees.

Financial Review 2026: Second Quarter & Year to Date (continued)

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, 2026, the Company incurred non-cash equity-based compensation expense under the following LTIP programs: 2020, 2021, 2022, 2023, 2024, 2025 and 2026.

The respective non-cash costs related to the ongoing LTIP programs are summarized in the table below. In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants. For further information on the different LTIP programs, please refer to Hansa Biopharma's 2025 Annual Report which can be found at www.hansabiopharma.com.

Ongoing programs	LTIP 2020	LTIP 2021	LTIP 2023	LTIP 2024	LTIP 2025	LTIP 2026
Maximum number of issuable shares*	568,776	6,500	539,154	1,065,074	8,267,631	594,776
Number of allocated outstanding share rights and options	437,520	5,000	419,575	757,628	5,093,250	1,297,195
Number of allocated outstanding warrants	-	-	-	-	1,693,250	22,000
Estimated total cost including social contributions for outstanding share rights and options, KSEK	25,863	15,473	10,423	27,679	83,837	22,527
Total cost per program, including social contributions as of June 30, 2026 YTD, KSEK	-	-	(1,329)	4,074	26,217	630
Total costs, including social contributions, as of June 30, 2026, YTD, KSEK						**29,592**

Risks and uncertainties

Hansa's business is subject to a variety of external and internal factors that may significantly affect the Company's financial performance and position - many of which are partially or entirely beyond the Company's control. When evaluating the Company's prospects, it is important to consider these risks, alongside the potential for earnings growth to form a balanced and realistic assessment of the Company's expected development.

Since Q4 2022, Hansa has capitalized development costs related to Idefirix following the conditional approval granted by the EMA (see Note 4). In 2023, based on conditional approval, the parent company also revalued the underlying intangible asset related to IDEFIRIX. Both the decision to begin capitalizing development costs and the revaluation of the intangible assets in the parent company were based on the assessment that Hansa is likely to obtain final EMA approval for the commercialization of Idefirix As part of the conditional approval, the EMA required Hansa to conduct two clinical trials to support final approval:

a) A five-year follow-up study of 46 patients previously treated with Idefirix in a Phase 2 trial was performed. This follow-up clinical study was finalized and submitted to EMA in December 2023. In 2024, EMA finalized its review and the study was approved.

b) A post-authorization efficacy and safety (PAES) study, involving 50 highly sensitized kidney transplant patients treated with Idefirix with a non-comparative reference group of 50-100 transplant patients at the same centers not being highly sensitized. Following the treatment, the 50 patients in the trial were monitored for one year to assess the long-term effect of the drug measured by graft failure free survival as measured by kidney function (eGFR). The objective of the study is to confirm the risk / benefit of the drug as assessed at the time of the conditional approval. Hansa read out positive topline data of the trial in May 2026 and plan to file a request for conversion to full approval with the EMA in Q4 2026.

Given the recent positive outcome of the ConfIdeS and PAES studies, Hansa considers the risk of not meeting EMA's specific obligations for full approval to be low.

Risk factors include, among others, uncertainties regarding clinical trials and regulatory approvals, collaborations and partnerships, intellectual property rights, reliance on key products, market dynamics and competition, manufacturing and supply chain challenges, pricing and reimbursement, as well as dependence on key persons and financial risks.

The Company expects its current cash position to support operations well into 2028. A detailed overview of the key risks and uncertainties facing Hansa can be found in the English version of the Company's 2025 Annual Report (pages 34-36).

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 2025 Annual Report have been identified as of the date of this quarterly report.

Financial Review 2026: Second Quarter & Year to Date (continued)

Other information

Contacts

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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, other factors that may affect results are developments within research programs. This is a translated version of the Swedish original.

Financial Calendar 2026

November 5, 2026 Interim Report September 2026
February 11, 2027 Full Year 2026 Report

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares June 30, 2026	101,763,222
Market Cap June 30, 2026	~3.60 BSEK (US ~$370M)
Ticker	HNSA
ISIN	SE0002148817

Top 10 Shareholders as of June 30, 2026

Shareholder Name	Number of Shares	Ownership %
Redmile Group LLC	16,182,328	15.90%
Polar Capital LLP	11,835,910	11.63%
NovaQuest Capital Management LLC	6,257,952	6.15%
Fidelity Investments (FMR)	4,380,154	4.30%
Theodor Jeansson Jr.	3,500,000	3.44%
The Invus Group	2,516,635	2.47%
Handelsbanken Fonder	2,347,246	2.31%
Avanza Pension	2,309,450	2.27%
Thomas Olausson	2,117,000	2.08%
Hansa Biopharma AB	2,029,269	1.99%
All other	49,287,278	47.46%
Total Shares Outstanding	101,763,222	100.00%

Source: Modular Finance compiled and processed data from various sources, including Euroclear, Morningstar, FactSet and the Swedish Financial Supervisory Authority (Finansinspektionen).

Hansa Biopharma had approximately 20,400 shareholders as of June 30, 2026.

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.

Lund, Sweden, July 21, 2026

Peter Nicklin
Chairman of the Board

Mats Blom
Board member

Elisabeth Björk
Board member

Michael Bologna
Board member

Jonas Wikström
Board member

Natalie Berner
Board member

Renée Aguiar-Lucander
President & CEO

This report has not been reviewed by the company's auditors.

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 US Find out more at www.hansabiopharma.com.

Unaudited Condensed Financial Statements

Unaudited condensed consolidated statement of financial position

KSEK	Note	June 30 2026	June 30 2025	December 31 2025
ASSETS				
Non-current assets				
Intangible assets	4	247,054	224,631	230,561
Property and equipment		2,164	3,812	2,945
Non-current receivables & contract assets	2	124,763	134,141	126,249
Right-of-use assets		5,875	10,049	10,401
Total non-current assets		**379,856**	**372,633**	**370,156**
Current assets				
Inventories		7,961	2,944	6,132
Trade receivables	2	65,983	47,178	53,872
Current receivables, non-interest		64,195	40,232	35,524
Cash and cash equivalents		552,807	354,416	701,083
Total current assets		**690,946**	**444,770**	**796,611**
TOTAL ASSETS		**1,070,802**	**817,403**	**1,166,767**
EQUITY AND LIABILITIES				
Shareholders' equity		**(520,239)**	**(460,924)**	**(88,992)**
Non-current liabilities				
Long-term loan (NovaQuest)	3,5	605,494	753,636	790,534
Convertible debt – loan	3,5	120,951	-	-
Convertible debt – derivative	3,5	197,309	-	-
Deferred tax liabilities		247	136	259
Provisions		14,441	4,313	8,838
Lease liabilities		2,162	3,041	2,995
Deferred revenue		3,049	-	1,606
Refund liabilities		92,997	95,130	40,868
Total non-current liabilities		**1,036,649**	**856,256**	**845,100**
Current liabilities				
Short-term loan		300,852	141,472	136,869
Tax liabilities		1,807	2,104	1,827
Lease liabilities		4,338	8,058	8,276
Current liabilities, non-interest bearing		70,571	56,162	66,285
Deferred revenue		-	14,125	-
Refund liabilities		68,991	62,964	76,264
Accrued expenses		107,833	137,185	121,138
Total current liabilities		**554,392**	**422,071**	**410,659**
TOTAL EQUITY AND LIABILITIES		**1,070,802**	**817,403**	**1,166,767**

Unaudited condensed consolidated statement of profit or loss and other comprehensive income (loss)

KSEK	Note	Q2 2026	Q2 2025	H1 2026	H1 2025
Revenue	2	48,096	49,122	82,666	115,471
Cost of revenue		(22,329)	(18,015)	(36,108)	(38,528)
Sales, general and administration expenses		(118,926)	(90,522)	(224,486)	(166,514)
Research and development expenses	4	(67,874)	(95,836)	(125,215)	(160,100)
Other operating income/(expenses), net		(13,028)	734	(13,423)	1,755
Loss from operations		**(174,061)**	**(154,517)**	**(316,566)**	**(247,916)**
Financial income		3,205	49,495	5,759	135,659
Financial expenses	3	(58,478)	(31,664)	(114,393)	(62,941)
Non-cash financial derivative		(30,528)	-	(30,528)	-
Non-cash loss on loan restructuring		-	(59,447)	-	(59,447)
Loss before tax		**(259,862)**	**(196,133)**	**(455,728)**	**(234,645)**
Tax		(677)	(842)	(1,130)	(1,179)
Loss for the period		**(260,539)**	**(196,975)**	**(456,858)**	**(235,824)**
Loss for the period attributable to owners of the parent		(260,539)	(196,975)	(456,858)	(235,824)
Loss per share, basic and diluted (SEK)		(2.56)	(2.78)	(4.49)	(3.42)
Other comprehensive income/(loss)					
Items that have been, or may be reclassified to profit or loss for the period:					
Translation differences		621	(606)	1,274	(2,179)
Other comprehensive income/(loss) for the period		**621**	**(606)**	**1,274**	**(2,179)**
Total comprehensive loss		**(259,918)**	**(197,581)**	**(455,584)**	**(238,003)**

Unaudited condensed consolidated statement of changes in shareholders' equity

KSEK	January-June 2026	January-June 2025	Full Year 2025
Opening balance of shareholders' equity	**(88,992)**	**(589,833)**	**(589,833)**
Result for the period	(456,858)	(235,824)	(534,110)
Translation reserve	1,274	(2,179)	(2,970)
Net comprehensive loss	**(455,584)**	**(238,003)**	**(537,080)**
Transactions with the group's owner			
Proceeds from new share issuance, net[1]	-	218,492	847,216
Proceeds from restructuring of debt	-	141,472	141,472
Long term incentive programs	23,915	6,948	30,848
Long term incentive program option contribution[2]	422	-	18,385
Total transactions with the group's owner	**24,337**	**366,912**	**1,037,921**
Closing balance of shareholders' equity	**(520,239)**	**(460,924)**	**(88,992)**

[1] Total share issue costs in Q2 2025 amounted to SEK 14,703 and in Q4 2025 to 41,681 KSEK.
[2] In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants.

Unaudited condensed consolidated statement of cash flow

KSEK	Q2 2026	Q2 2025	January-June 2026	January-June 2025
Cash Flows from Operating Activities				
Loss from operations	(174,061)	(154,517)	(316,566)	(247,916)
Adjustment to reconcile net income to net cash flows from operating activities				
Interest received	1,675	87	1,959	372
Interest paid	(3,338)	(135)	(3,466)	(341)
Income taxes paid	(536)	(941)	(1,436)	(1,655)
Depreciation and amortization expenses	11,668	9,503	22,788	18,132
Loss on restructuring of loan	-	(9,530)	-	(9,530)
Expenses related to incentive programs	19,690	3,176	29,517	7,001
Accrued interest and unrealized currency differences	4,788	(4,570)	20,162	(16,677)
Total adjustments to net cash flows	**(140,115)**	**(156,927)**	**(247,042)**	**(250,614)**
Changes in working capital:				
(Increase)/decrease of trade receivables and unbilled revenues	2,373	2,249	(10,625)	(36,354)
(Increase)/decrease of other operating assets	(22,918)	(495)	(26,627)	(5,549)
Increase/(decrease) trade payables	25,276	6,927	3,445	4,158
Increase/(decrease) of other operating liabilities	31,882	54,053	30,366	58,331
Total changes in working capital:	36,613	62,734	(3,441)	20,586
Net cash used in operating activities	**(103,502)**	**(94,193)**	**(250,483)**	**(230,028)**
Capitalized development cost	(18,544)	(17,508)	(28,546)	(33,546)
Net cash (used in) from investing activities	**(18,544)**	**(17,508)**	**(28,546)**	**(33,546)**
Cash Flows from Financing activities				
Proceeds from new loans	-	218,492	271,108	
Proceeds from issue of new share issue, net of transaction cost[1]		-	-	218,492
Amortization of loans	-	-	(136,869)	-
Payment of lease liabilities	(2,398)	(1,961)	(4,771)	(3,891)
Proceeds from incentive program option contribution	**323**	-	422	-
Net cash (used in) from financing activities	**(2,074)**	**216,531**	**129,889**	**214,601**
Net change in cash and cash equivalents	(124,120)	104,830	(149,139)	(48,974)
Cash and cash equivalents at beginning of the period	676,462	250,200	701,083	405,280
Effects of movements in exchange rate on cash held	466	(614)	864	(1,891)
Cash and cash equivalents at end of period	**552,807**	**354,416**	**552,807**	**354,416**

[1] Total share issue costs in Q2 2025 amounted to SEK 14,703 and in Q4 2025 to 41,681 KSEK.

Parent Company - Unaudited condensed statement of financial position

KSEK	Note	March 31 2026	March 31 2025	December 2025
ASSETS				
Non-current assets				
Intangible assets	4	1,318,100	1,414,616	1,361,141
Property and equipment		2,164	3,812	2,945
Right-of-use assets		5,875	10,049	10,401
Non-current receivables & contract assets	2	124,763	134,141	126,249
Investment in subsidiaries		53,287	34,363	43,224
Total non-current assets		**1,504 189**	**1,596,981**	**1,543,960**
Current assets				
Inventories		7,961	2,944	6,132
Trade receivables & unbilled revenues	2	65,983	47,178	53,872
Current receivables, non-interest		62,571	39,230	32,715
Cash and cash equivalents		534,578	342,206	681,145
Total current assets		**671,093**	**431,558**	**773,864**
TOTAL ASSETS		**2,175,282**	**2,028,539**	**2,317,824**
EQUITY AND LIABILITIES				
Shareholders' equity		**575,895**	**743,334**	**1,062,142**
Non-current liabilities				
Long-term loan	3,5	605,494	753,636	790,534
Convertible debt – loan		120,951	-	-
Convertible debt – derivative		197,309	-	-
Provisions		14,441	4,313	8,838
Lease liabilities		2,162	3,041	2,995
Deferred revenue		3,049	-	1,606
Refund liabilities		92,997	95,130	40,868
Total non-current liabilities		**1,036,402**	**856,120**	**844,841**
Current liabilities				
Short-term part of loan		300,852	141,472	136,869
Tax liabilities		458	1,091	358
Lease liabilities		4,338	8,058	8,276
Liabilities, group companies		25,354	16,232	12,979
Current liabilities, non-interest bearing		70,220	56,168	66,168
Deferred revenue		-	14,125	-
Refund liabilities		68,991	62,964	76,264
Accrued expenses		92,772	128,975	109,927
Total current liabilities		**562,985**	**429,085**	**410,841**
TOTAL EQUITY AND LIABILITIES		**2,175,282**	**2,028,539**	**2,317,824**

Parent Company - Unaudited condensed statement of profit or loss and other comprehensive income (loss)

KSEK	Note	Q2 2026	Q2 2025	H1 2026	H1 2025
Revenue	2	48,096	49,122	82,666	115,471
Cost of revenue		(52,120)	(47,807)	(95,691)	(98,112)
Sales, general and administration expenses		(128,898)	(92,960)	(233,831)	(170,988)
Research and development expenses	4	(66,140)	(94,691)	(122,106)	(158,384)
Other operating income/(expenses), net		(1,192)	596	(2,229)	1,314
Loss from operations		**(200,254)**	**(185,740)**	**(371,191)**	**(310,699)**
Financial income		3,205	49,495	5,759	135,659
Financial expenses	3	(58,442)	(31,651)	(114,355)	(62,927)
Non-cash loss on loan restructuring		-	(59,447)	-	(59,447)
Non-cash financial derivative		(30,528)	-	(30,528)	-
Loss before tax		**(286,019)**	**(227,343)**	**(510,315)**	**(297,414)**
Income tax		(212)	(490)	(343)	(560)
Loss for the period		**(286,231)**	**(227,833)**	**(510,658)**	**(297,974)**
Other comprehensive loss for the period		-	-	-	-
Total comprehensive loss for the period		**(286,231)**	**(227,833)**	**(510,658)**	**(297,974)**

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

KSEK	June 30 2026	June 30 2025	12 Months 2025
Opening balance of shareholders' equity	**1,062,142**	**674,449**	**674,449**
Result for the period	(510,658)	(297,974)	(649,361)
Other comprehensive income/(loss) for the		-	-
Net comprehensive loss	**(510,658)**	**(297,974)**	**(649,361)**
Proceeds from new share issuance, net[1]	-	218,492	847,216
Proceeds from restructuring of debt	-	141,472	141,472
Long term incentive programs	23,989	6,895	29,981
Long term incentive program option	422	-	18,385
Total other transactions	24,411	**366,859**	**1,037,054**
Closing balance of shareholders' equity	**575,895**	**743,334**	**1,062,142**

1 Total share issue costs in Q2 2025 amounted to SEK 14,703 and in Q4 2025 to 41,681 KSEK.

2 In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants

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 US Find out more at www.hansabiopharma.com.

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 for 2025 was published on March 26, 2026, 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.

Reclassification of Consolidated Statement of Cash Flows

In preparing the condensed consolidated interim financial statements for the six months ended June 30, 2026, management identified that capitalized development costs of 66,637 KSEK for the year ended December 31, 2024, and 33,546 KSEK for the year ended December 31, 2025, and 33,546 KSEK, for the six-month period ended June 30, 2025, had been classified as cash outflows from operating activities in the previously issued consolidated statements of cash flows. These costs related to the internal generation of intangible assets recognized on the statement of financial position and should have been classified as cash flows from investing activities, as they represent expenditures that result in a recognized asset in the statement of financial position.

The Company has corrected this by retrospectively reclassifying the affected comparative periods presented. The reclassified amounts noted above from "Net cash used in operating activities" to "Cash flow from investing activities" for each period presented. The reclassification has no effect on total net cash flow, on the consolidated statements of financial position, profit or loss, or comprehensive income for any period presented, as it is a presentation-only correction within the statement of cash flows.

The following tables present the effect of the reclassification on the previously issued consolidated statements of cash flows for the six months ended June 30, 2024, the year ended December 31, 2024, the year ended December 31, 2025.

	Year Ended December 31, 2024 As previously reported		
KSEK	As previously reported	Reclassification	As Restated
Cash flows from operating activities:			
Capitalized development costs (reclassified)	(66,637)	66,637	-
Other operating activities	-	-	-
Increase to net cash used in operating activities	(66,637)	66,637	-
Cash flows from investing activities:			
Capitalized development costs (reclassified)	-	(66,637)	(66,637)
Other investing activities	-	-	-
Decrease to net cash used in investing activities	-	(66,637)	(66,637)

	Year Ended December 31, 2025 As previously reported		
KSEK	As previously reported	Reclassification	As Restated
Cash flows from operating activities:			
Capitalized development costs (reclassified)	(51,584)	51,584	-
Other operating activities	-	-	-
Increase to net cash used in operating activities	(51,584)	51,584	-
Cash flows from investing activities:			
Capitalized development costs (reclassified)	-	(51,584)	(51,584)
Other investing activities	-	-	-
Decrease to net cash used in investing activities	-	(51,584)	(51,584)

	Year Ended June 30, 2025 As previously reported		
KSEK	As previously reported	Reclassification	As Restated
Cash flows from operating activities:			
Capitalized development costs (reclassified)	(33,546)	33,546	-
Other operating activities	-	-	-
Increase to net cash used in operating activities	(33,546)	33,546	-
Cash flows from investing activities:			
Capitalized development costs (reclassified)	-	(33,546)	(33,546)
Other investing activities	-	-	-
Decrease to net cash used in investing activities	-	(33,546)	(33,546)

Note 2 Revenue

Income per significant category of income	Q2		12M	
KSEK	2026	2025	2026	2025
Group				
Revenue				
Product sales	46,825	47,772	80,797	113,450
Contract revenue, Axis-Shield agreement	565	673	1,130	1,344
Cost reimbursement, Axis-Shield agreement	706	677	799	677
	48,096	**49,122**	**82,666**	**115,471**
Parent Company				
Revenue				
Product sales	46,825	47,772	80,737	113,450
Contract revenue, Axis-Shield agreement	565	673	1,130	1,344
Cost reimbursement, Axis-Shield agreement	706	677	799	677
	48,096	**49,122**	**82,666**	**115,471**

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Variable Consideration

For healthcare facilities where payment for Idefirix is contingent upon product usage in a kidney transplant, and where there is no established payment history, the Company recognizes product revenue at the transaction price upon transfer of control of the product.

Variable consideration related to vials that may not ultimately be used in a transplant is estimated using the expected value method, based on the median wait time for a kidney transplant of highly sensitized patients on a wait list. Due to the extended duration of transplant wait times, the Company does not initially record variable consideration at the time revenue is recognized.

Variable consideration, with a corresponding reserve, is recorded when it becomes probable that the healthcare facility will not use the product, resulting in a reduction of product revenue and the recognition of a liability in the consolidated balance sheets. The estimate of variable consideration is reassessed at each reporting date, and any changes are recognized on a cumulative catch-up basis.

Trade Receivables

In certain European markets, payment is contingent on when the healthcare facility uses Idefirix in a successful transplantation of a highly sensitized patient and may be subject to outcome-based or post-transplant reconciliation with healthcare authorities. In these situations, patients typically experience extended waiting periods for kidney transplantation, which may be in excess of one year. Accordingly, a portion of the Company's trade receivable balances are classified as non-current. The Company reassesses the classification of trade receivable at each reporting date based on updated expectations regarding the timing of transplantation and payment.

Significant Financing Component

The Company does not recognize a significant financing component due to the uncertainty of the expected period between customer payment and the transfer of Idefirix at contract inception.

Note 3 Long-term loan

On July 18, 2022, the Company entered into a USD 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 agreement.

The net proceeds from the funding agreement totaled USD 69.2 million after the deduction of transaction costs.

In June 2025, Hansa and NovaQuest entered into agreements (the Note Restructuring agreement) to restructure their existing debt agreement. As part of the restructuring, and in connection with the Q2 2025 Directed Share Issue, Hansa offset approximately USD 14.875 million of its outstanding debt through the issuance of new shares at the same price as in the Directed Share Issue (the "First Tranche"). The First Tranche was resolved by the Company's Board of Directors under the authorization granted at the Annual General Meeting held on June 27, 2024, and with deviation from the shareholders' preferential rights.

On January 31, 2026, Hansa paid NovaQuest USD 14.875 million (Second Tranche) as part of the June 2025 Note Restructuring agreement.

The remaining debt will be paid in three fixed cash payments scheduled for June 2027, June 2028 and January 2029. In addition, previously agreed approval-related payments will be eliminated. Under the restructured terms, total payments from Hansa to NovaQuest will be capped at USD 150.5 million, an increase from the original agreement cap of USD 140.0 million. The accounting assessment of the NovaQuest debt restructuring actions was deemed to be non-substantial.

An updated version of the original security agreement entered into under the initial debt agreement remains in place under which the Company has granted NovaQuest a broad security interest in certain assets, proceeds and intellectual property rights related to imlifidase for use in kidney transplantation in highly sensitized patients and in the treatment of anti-GBM disease.

The new debt amendment resulted in modification of the original debt agreement. As a result, the debt was remeasured based on the net present value of the revised cash flows, discounted using a fair value effective interest rate. This remeasured amount was compared to the previous carrying value of the original debt, with the difference recognized as a non-cash loss of 59.4 MSEK in the financial statements. Transaction costs incurred in connection with the new amendment were also recognized as part of a gain or loss calculation on the modification.

The Company records 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 for each reporting period until the debt obligation has been satisfied.

On June 30, 2026, the loan totaled 897.6 MSEK, including 478.7 MSEK in total accrued interest.

Note 4 Intangible assets - Internally-generated intangible assets

Expenditures related to research activities are recognized as expenses in the period in which they are 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 assets 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 met all the above criteria as of Q4 2022.

As of June 30, 2026, the total capitalized development expenses related to fulfilling the Idefirix EMA post-approval commitments amount to 296.3 MSEK, with 33.9 MSEK capitalized during 2026. These capitalized development costs are subject to regular amortization over their useful life, which is projected to extend until the end of 2032. Total accumulated amortization at June 30, 2026, was 65.2 MSEK.

Note 5 Senior unsecured convertible note

On March 19, 2026, the Company entered into a USD 30.0 million convertible note (“the Note or Notes”) purchase agreement with Athyrium Capital Management, L.P. The Note is senior unsecured with a fixed interest rate of 3.0% payable semi-annually in cash beginning on September 15, 2026. The Note has a conversion premium of 25% based on the 30-day volume-weighted average price of ordinary shares ending on March 18, 2026. The Note maturity date is 5 years from the closing date, anticipated to be March 2031.

Subsequent event

On May 19, 2026, Hansa executed an exclusive licensing agreement with SERB S.A (Serb Pharmaceuticals or Serb) for development and commercialization of Idefirix in the European Union, United Kingdom, Switzerland, Norway, Liechtenstein, Iceland, Middle East and North Africa (MENA) regions (the Territory). On July 8 Hansa received an upfront payment of 110.0 million EUR and will receive another 5.0 million EUR payment upon acceptance of the filing for full approval of Idefirix by the European Medicines Agency (EMA). The Company will support SERB in the filing and EMA review process following the reporting of the Post-Authorization Efficacy Study (PAES) topline data. SERB will assume responsibility for the long-term PAES follow-up and the ongoing pediatric study upon obtaining Market Authorization Application (MAA), a process expected to be initiated immediately following the closing of the transaction. The close of the transaction was subject to customary conditions, including required foreign direct investment (FDI) regulatory approval. Following receipt of required regulatory approval, the licensing agreement with SERB was completed on July 1, 2026.

As a result of the exclusive licensing agreement, Hansa will no longer have product sales in the Territory after June 30, 2026. The Company will also completely write down the development of intangible assets associated with EMA approval which was reported at 23.2 million USD as of December 31, 2025.

In conjunction with the execution of the license agreement with SERB, Hansa restructured and amended the funding agreement with NovaQuest. Under the terms of the amended funding agreement, 15.0 million USD will be accelerated in exchange for the waiver of certain covenants. In addition, the Company paid a release fee of 3.0 million USD in consideration for discharge of liens, security interests and other incumbrancers related to the Licensee’s assets

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 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 a comprehensive submission to the Food and Drug Administration (FDA) to obtain approval to market 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.

FDA or US FDA
US Food and Drug Administration.

Guillain-Barré syndrome
Guillain-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 substance 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 clinical results are convincing and 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.

Prescription Drug User Fee Act (PDUFA)
The Prescription Drug User Fee Act (PDUFA), established by the US Congress in 1992, authorizes the FDA to collect fees from companies that submit applications for approval or are the marketing authorization holders of certain human prescription drug and biological products.

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.