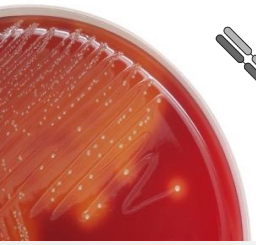
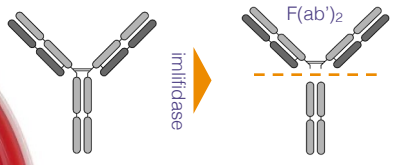
Updated 2024-01-26

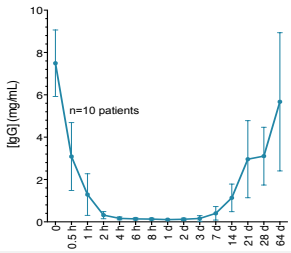
About Hansa Biopharma

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, which can enable kidney transplantation in highly sensitized patients. The Company has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases and gene therapy. Hansa Biopharma is based in Lund, Sweden with operations in Europe and in the U.S.

Imlifidase – A novel approach to eliminating pathogenic IgG







Origins from a bacteria *Streptococcus pyogenes*

- Species of Gram-positive, spherical bacteria in the genus *Streptococcus*
- Usually known from causing a strep throat infection

Imlifidase, a unique IgG antibody-cleaving enzyme

- Interacts with Fc-part of IgG with extremely high specificity
- Cleaves IgG at the hinge region, generating one F(ab')2 fragment and one homo-dimeric Fc-fragment

Imlifidase inactivates IgG in 2-6 hours

- Rapid onset of action that inactivates IgG below detectable level in 2-6 hours
- IgG antibody-free window for approximately one week

Strategic Priorities

Commercialize Idefirix® in first indications and markets

- Successfully launch Idefirix® in Europe
- Secure FDA approval and launch Idefirix® in the U.S.
- Geographical expansion

Advance ongoing imlifidase clinical programs in transplantation and autoimmune diseases

- Achieve approval/usage of imlifidase in follow-on indications
- Broaden our Idefirix® label beyond kidney transplantation

Expand IgG-cleaving enzyme technology platform into new disease areas and indications

- Explore gene therapy opportunity
- Explore opportunities in Oncology and stem cell transplantation (HSCT)
- Develop our next generation IgG-cleaving enzymes to allow for recurring treatment

Achieved and Upcoming Milestones

2023	2024	2025
Q4 2023		
✓ **HNSA-5487 (Lead NiceR candidate):** High-level data readout from Phase 1	- **GBS Phase 2:** Outcome of the comparative efficacy analysis to IGOS data	- **U.S. ConfideS (Kidney tx) Phase 3:** BLA submission
✓ **Long-term follow-up (Kidney tx):** 5-year data readout	- **Genethon Crigler-Najjar Phase 1/2:** Initiate clinical study with imlifidase prior to GNT-0003	- **Anti-GBM disease Phase 3:** Complete enrolment
✓ **GBS Phase 2:** First data readout	- **HNSA-5487 (Lead NiceR candidate):** Further analysis around endpoints to be completed in 2024 incl. lead indication	
✓ **AMR Phase 2:** Full data readout	- **U.S. ConfideS (Kidney tx) Phase 3:** Complete randomization	
✓ **Sarepta DMD pre-treatment Phase 1b:** Commence clinical study		

HANSA BIOPHARMA

Company Facts

Founded	2007
Stock Exchange	NASDAQ Stockholm (HNSA)
Headquarters	Lund, Sweden
Employees	168

Key Executives

Peter Nicklin	Chairman
Søren Tulstrup	President & CEO
Donato Spota	SVP & CFO
Matthew Shaulis	CCO & U.S. President
Hitto Kaufmann	CSO

Market Data (Q4 2023)

Market Cap	USD ~140m (Dec 2023)
52 Week Range	SEK 20-68
Avg. Daily Turnover	vol. 248k shares
Shares Outstanding	52m

Top 5 Shareholders	**(% S/O)**
Redmile Group	18.3%
Nexttobe AB	4.1%
Theodor Jeansson	3.7%
Thomas Olausson	3.6%
Avanza Pension	3.4%

Share Price Graph (12M)

Key Financials

SEKm	2021	2022	FY'23	Q4'23
Revenue	34	155	134	50
R&D cost	(231)	(346)	(411)	(108)
Net loss	(548)	(610)	(834)	(126)
Cash & Short investment	889	1,496	732	732
Operating Cash Flow	(481)	(504)	(756)	(173)
Employees	133	150	168	168

* *Unaudited*

Calender

Feb 6, 2024	Aktiespararna, Falkenberg
Feb 8, 2024	Frankfurt MidCap Seminar, Frankfurt
Feb 14, 2024	Redeye Cell Therapy & Growth Day, Stockholm
Feb 28, 2024	Ökonomisk Ugebrev Life Science Event, Cph
March 4-5, 2024	TD Cowen Healtcare Conference, Boston
March 5, 2024	Life Sciencedagen, Sahlgrenska, Gothenburg
March 10-12, 2024	Carnegie Healthcare Seminar, Stockholm
Mar 20, 2024	Annual Report 2023
April 8-11, 2024	Needham Healthcare Conference (virtual)
April 16-17, 2024	Van Lanschot Kempen Conference, Amsterdam
Apr 17, 2024	Interim Report for January-March 2024
June 27, 2024	2024 Annual General Meeting
July 17, 2024	Half-year Report January-June 2024
Oct 23, 2024	Interim Report for January-September 2024

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Broad Pipeline in Kidney Transplantation, Autoimmune Conditions and Gene Therapy

Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Partner	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients[1,2]								EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	U.S. "ConfIdeS": Kidney transplantation in highly sensitized patients[1,2]								Completion of randomization (64 patients) mid 2024
	GOOD-IDES-02: Anti-GBM antibody disease								Complete enrollment (50 patients)
	16-HMedIdes-12: Active Antibody Mediated Rejection (AMR)								Publication in peer-reviewed journal
	15-HMedIdeS-09: Guillain-Barré Syndrome (GBS)								Comparative efficacy analysis 2024
	Investigator-initiated trial in ANCA-associated vasculitis[3]								Complete enrollment (10 patients)
	SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)		Phase 1b					Sarepta Therapeutics	First patient treated in clinical study
	Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)							Sarepta Therapeutics	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease							AskBio	Preclinical research
	Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome							Genethon	Commence clinical study
HNSA-5487	NICE-01 phase 1: HNSA-5487 – Lead candidate from the NiceR program								Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication

Completed · Ongoing · Planned · Post approval study running in parallel with commercial launch

[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

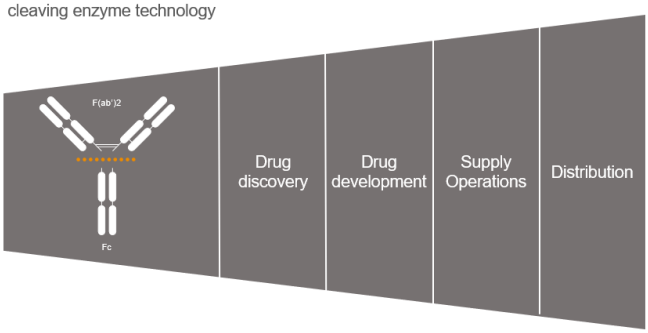
Our Business Model

Growth engine

Leveraging our proprietary antibody cleaving enzyme technology

Value chain

We are controlling the full value chain

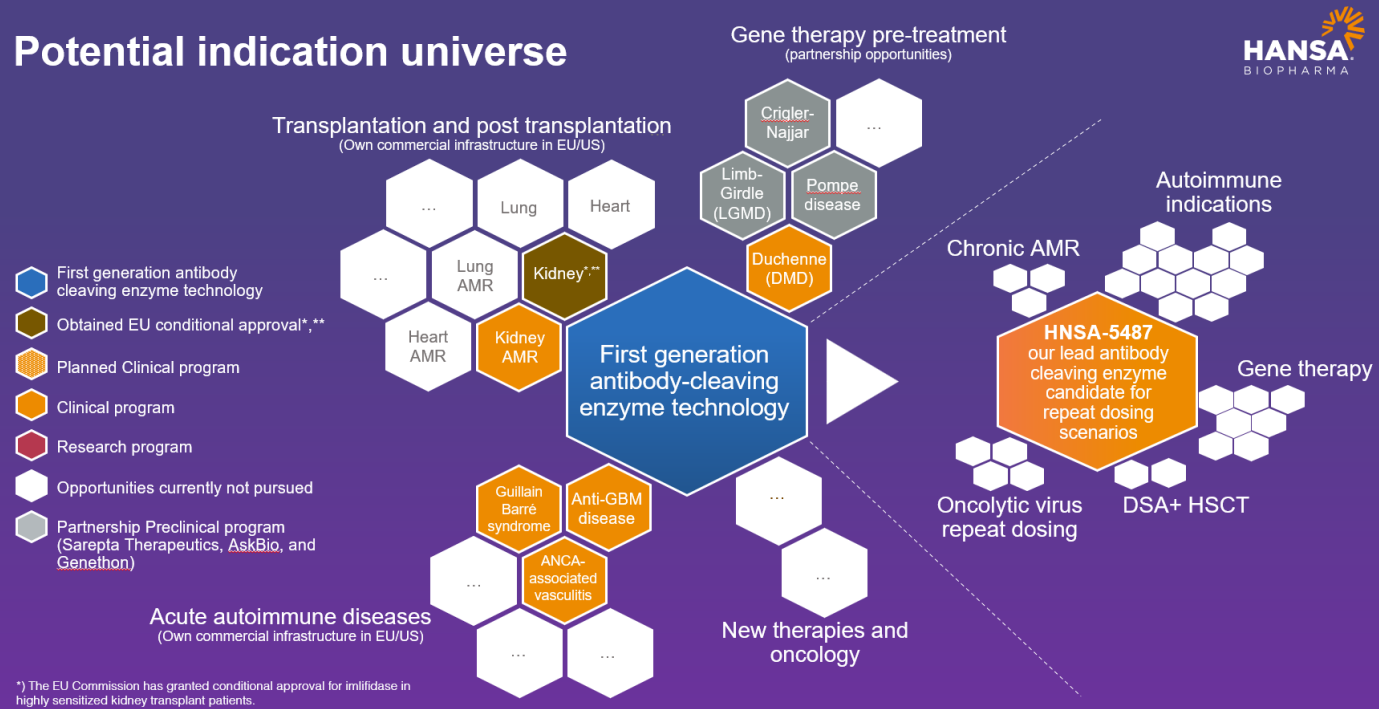


Commercialization

Build-up of franchises	Indications and therapies	Multiple income streams
Own commercial infrastructure	Transplantation	Revenue / sales
	Autoimmune diseases	Upfront payments
Partnership strategy	Gene therapy	Milestone payments
	Oncology	Royalties

Evolution into a fully integrated biopharmaceutical company

Potential indication universe



*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.
**) In the US a new study has commenced targeting a BLA filing in 2024