Newsletter to shareholders

July 2025

EDITORIAL

Dear Shareholders,

As GenSight Biologics continues to move forward in its development, we would like to share the progress made over the past six months. These milestones reflect our steadfast commitment to fulfilling our mission and creating long-term value.

GenSight recently reached an agreement with the French medicines safety agency (ANSM) regarding the opening of the Named Early Access Program (AAC). Constructive discussions with the Agency are ongoing. The launch of the program is contingent upon approval of a dose-ranging study involving approximately ten patients. A preliminary study design has been submitted to the ANSM, and we plan to finalize the protocol in the third quarter of 2025. We are actively working to define the patient eligibility criteria for both the study and the AAC program. This agreement sets out a clear regulatory pathway for GenSight and for the patient community who has been awaiting access that maintains the highest standards of quality, safety, and efficacy.

As announced at our Annual General Meeting on May 13, 2025, the technology transfer to Catalent, a global leader in viral vector manufacturing, is progressing well. This critical step aims to secure long-term production capacity, ensure that LUMEVOQ® meets international standards, and increase batch yields.

On the clinical front, we are finalizing the protocol for the Phase III RECOVER study. Regulatory interactions with both the FDA and EMA are planned in due time. The pivotal trial, developed in close collaboration with regulatory authorities, will support global marketing authorization submissions for our gene therapy in Leber Hereditary Optic Neuropathy (LHON).

We expect to submit the regulatory dossier to the MHRA in the second half of 2026, following the completion of the manufacturing module.

In parallel, we continue to hold discussions with potential industry partners to reinforce our strategic positioning and accelerate patient access to our innovative therapies.

In the face of persistent budget pressures and a challenging financing environment for the biopharmaceutical sector, we are maintaining a disciplined approach to financial management. Our recent refinancing reflects the strength of our asset portfolio and the long-term commitment of our existing shareholders.

We sincerely thank you for your continued trust and loyalty. Significant progress has been made in recent months, and broadening access to treatment for patients remains at the core of our strategic priorities.

Warm regards,

Laurence Rodriguez
CEO, GenSight Biologics

2025 Annual General Meeting

GenSight strengthens its governance and secures its financing

Our 2025 Annual General Meeting was held in an atmosphere of strong shareholder trust, marking a key milestone in GenSight's development. For the first time, the AGM was broadcast live in full, strengthening our connection with the wider investor community.

A strong endorsement from our shareholders

All resolutions were approved with overwhelming support, with several exceeding 92% and indeed reaching up to 99% support. This trust reflects our investors' support for GenSight's strategy and vision.

Strategic reinforcement of our governance

World-class scientific expertise

The appointment of Professor José-Alain Sahel to GenSight's Board of Directors is a major asset for the Company. His nomination brings the insight of a globally recognized leader in ophthalmology:

- **An exceptional career:** from the Institut de la Vision in Paris to the UPMC Vision Institute in Pittsburgh.
- **International recognition:** author of over 700 scientific publications and recipient of numerous prestigious awards.
- **Targeted expertise:** a pioneer in the treatment of retinal diseases through gene therapy and optogenetics.

Continuity and international diversity

The renewal of four Board member mandates affirms our ongoing commitment to diverse and international governance:

- **Elsy Boglioli** (France)
- **Maritza McIntyre** (United States)
- **Simone Seiter** (Germany)
- **Sofinnova Partners**

Securing Our Financing Capabilities

Enhanced financial flexibility

The approval of financing-related resolutions gives us the tools needed to seize growth opportunities. These authorizations are essential in an environment where capital increases remain a vital source of funding for biotech firms.

Diversifying sources of funding

We are actively exploring new non-dilutive financing solutions, including:

- **Licensing agreements** outside Europe and the United States.
- **Strategic partnerships** to accelerate the development of our programs.

These initiatives align with our strategy to preserve long-term shareholder value while financing the Company's growth.

▶ Outlook

The 2025 Annual General Meeting marks a turning point for GenSight, with a strengthened Board of Directors, enhanced financial flexibility, and continued strong shareholder support. We are well-positioned to pursue our mission: to revolutionize the treatment of LHON.

Note → A full replay of our Annual General Meeting is available on our website. We thank all our shareholders for their renewed trust.

GS030 Update

The PIONEER Clinical Trial

The ongoing Phase I/II study evaluating the safety and preliminary efficacy of GS030 continues to progress. The international research team — including renowned scientists such as Prof. Botond Roska, Prof. José-Alain Sahel, and Prof. Isabelle Audo — is preparing to submit a new scientific publication analyzing data from the 10 patients treated in the PIONEER study. Submission to a leading peer-reviewed journal is expected in Q3 2025.

Technology Transfer

Late-Stage Technology Transfer: Moving House for Advanced Therapy Medicinal Products (ATMPs)

Each advance in gene therapy brings with it a major challenge: how can complex manufacturing processes be transferred from one site to another without compromising the quality of a treatment that is vital for patients? Late-stage technology transfer in gene therapy can be compared to moving house: it's about making sure that all the essential elements arrive at their destination intact and work perfectly in their new environment. In the pharmaceutical industry, transferring manufacturing processes or analytical tests to another site means rigorously demonstrating that the final product remains identical.

Why do companies undertake such a step?

Several strategic reasons may lead companies to carry out such a complex technology transfer:

- **Regulatory requirements:** Some countries require certain tests to be performed locally (onshoring) to ensure direct oversight and compliance with national standards.
- **Facility changes:** Manufacturing sites may close, be sold, or become unavailable, forcing companies to relocate their operations.
- **Scaling up production:** As demand grows, companies need larger, better-equipped facilities to meet patient needs.
- **Strategic partnerships:** Companies may transfer their production to specialized contract manufacturers with in-depth expertise in specific types of gene therapy.

In our case, all of these factors are relevant. To commercialize a gene therapy in Europe, all tests must be conducted within EU member states. The recent closure of one of our subcontracted production sites made the process transfer necessary. The transfer also represents a key step in preparing for a successful commercial launch while strengthening our strategic partnerships.

A critical issue for patients

A successful technology transfer has a direct impact on patients' access to life-saving treatments. When the transfer is executed well:

- Production capacity increases, enabling more patients to be treated.
- Costs are reduced, thanks to more efficient manufacturing.
- Supply chains become more resilient, as production and/or testing sites are diversified.
- Innovation accelerates, as teams can focus on developing new therapies instead of resolving manufacturing bottlenecks.

Why is a technology transfer in gene therapy so complex?

Gene therapies differ fundamentally from conventional drugs. Instead of relying on stable chemical compounds, they are often based on:

- **Living cells**, which require strict control of temperature, pH, and nutrients. The LUMEVOQ® manufacturing process uses cells to produce the viral vector.
- **Viral vectors** (modified viruses) that deliver the therapeutic gene but which are particularly sensitive to environmental changes. LUMEVOQ® must be manufactured in the same way, regardless of the production site.
- **Biological materials**, which pose a double challenge: they cannot be sterilized using conventional methods (such as heat or chemical agents), and their natural variability requires

rigorous control. For LUMEVOQ®, this means using aseptic processing and sterile filtration to eliminate any risk of bacterial contamination. In addition, biological raw materials introduced into the process, such as DNA, must be compared to those in previous batches to ensure consistent production.

The stakes are especially high: this transfer is costly and takes several months. The most critical requirement is the scientific demonstration that the new site can produce an equivalent product — this is known as the comparability demonstration.

The technology transfer process in four phases

The industry has developed a structured approach to secure and standardize these transfers:

Phase 1: Planning and assessment
Teams conduct thorough feasibility studies, establish quality agreements between the facilities involved, and define specific success criteria. This step is essential — akin to inspecting your future home before moving in, to ensure it meets all your needs.

Phase 2: Knowledge sharing
Teams at both the sending and receiving facilities exchange detailed information on equipment specifications, manufacturing procedures, quality control processes, and personnel/training requirements. They identify potential problems and develop mitigation strategies before any physical transfer begins.

Phase 3: Implementation
This is where the actual transfer happens: analytical methods and manufacturing processes are transferred, and pilot batches are produced to verify that everything works correctly. Several validation batches are generally required to demonstrate the process' reproducibility and robustness.

Phase 4: Documentation and comparability demonstration
Teams prepare comprehensive documentation to demonstrate a successful transfer to the regulatory authorities. This includes rigorous comparability studies showing that the product manufactured at the new facility is equivalent to that from the original in terms of identity, safety, purity, and efficacy.

Regulatory oversight: Patient safety above all

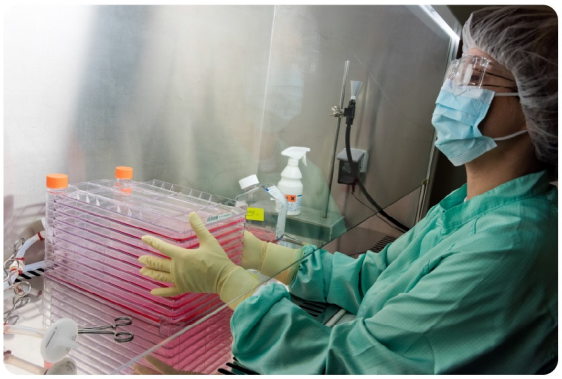
Before, during, and after the transfer, GenSight ensures that regulatory authorities are kept fully informed so that they can fulfill their mission of protecting patients. For example, scientific advice meetings are often held when process changes are implemented.

We must provide robust evidence that LUMEVOQ® maintains all of its therapeutic properties and quality throughout the technology transfer. Regulators understand that biological products are inherently more variable than chemical drugs, but nonetheless, they require rigorous demonstration.

The future of technology transfer in gene therapy

The gene therapy sector is maturing, and transfer processes are becoming more standardized, more reliable, and able to be executed in less time. As a result, innovative treatments can reach patients more quickly while the highest safety standards are maintained.

For patients waiting for breakthrough treatments like LUMEVOQ®, this progress in technology transfer is a source of hope: it opens the way to faster access to therapies and a future where every scientific advance can follow a clear, reliable, and accelerated path from the lab to the patient. The bridge between innovation and care is becoming stronger every day.



NEWSFLOW

EVENTS & PUBLICATIONS

Retrospective

PUBLICATION

JAMA Ophthalmology

"Five-Year Results of Lenadogene Nolparvovec Gene Therapy in Leber Hereditary Optic Neuropathy". JAMA Ophthalmology, Vol. 143, No. 2 – doi:10.1001/jamaophthalmol.2024.5375

March 10–12, 2025

IOC 2025 3rd Edition of International Ophthalmology Conference | March 10-12, 2025 | Rome, Italy

International Ophthalmology Conference – 3rd Edition

Dr. Magali Taiel, CMO – LUMEVOQ® for LHON

LUMEVOQ® gene therapy for Leber's hereditary optic neuropathy

March 15–20, 2025

2025 NANOS 51st ANNUAL MEETING

North American Neuro-Ophthalmology Society Annual Meeting – Tucson, AZ (USA)

Dr. Sergott (USA) – OCT analyses
Dr. Yu-Wai Man (UK) – Indirect comparison vs. idebenone and natural history
Dr. Moster (USA) – Compassionate use
Dr. Newman (USA) – 5-year REFLECT data

April 5–9, 2025

AAN 2025 Annual Meeting

American Academy of Neurology

Dr. Newman (USA) – Latest data on GS010 in LHON
Dr. Biousse (USA) – Contralateral effect evidence from autopsy case reportse

May 4–8, 2025

ARVO 2025 May 4 – 8 | Salt Lake City, Utah

ARVO Annual Meeting

Dr. Carelli (Italie) – Contralateral effect evidence from autopsy case reports
Dr. Barboni (Italie) – OCT results
Dr. Sahel (France/USA) – Indirect comparison vs. idebenone and natural history
Dr. Borgia (Italie) – Compassionate use
Dr. Yu-Wai Man (UK) – 5-year REFLECT

May 10–12, 2025

Société Française d'Ophtalmologie 131e CONGRÈS INTERNATIONAL 10-12 MAI 2025 Palais des Congrès de Paris

French Society of Ophthalmology – 131st Congress

Dr. Biousse (USA) – 2025 LHON gene therapy update

May 10–12, 2025

AOS 2025 MAY 10-12 NAPLES, FLORIDA

American Ophthalmological Society – 161st Meeting

Dr. Newman (USA) – LUMEVOQ® in LHON

May 28–29, 2025

3rd Annual Gene Therapy Potency Assay Summit

Gene Therapy Potency Assay Summit – 3rd Edition

Scott Jeffers, GenSight Biologics CTO
Potency assays & mitochondrial targeting

June 7–9, 2025

SOE 2025 LISBON • PORTUGAL 7 – 9 JUNE 2025

European Society of Ophthalmology (SOE)
161st Annual Meeting

Dr. Yu-Wai Man (UK) – Compassionate use
Dr. Biousse (USA) – Contralateral effect evidence from autopsy case reports
Dr. Newman (USA) – GS010 development progress

Upcoming

September 19–20, 2025

Patient Association Conference– Madrid, Spain

October 7–9, 2025

4th Annual Operationalise: Early Access Programmes Summit EUROPE

October 9–11, 2025

EVER European Association for Vision and Eye Research

October 17–20, 2025

AMERICAN ACADEMY OF OPHTHALMOLOGY

CONTACT • GenSight Biologics • investor-relations@gensight-biologics.com