Newsletter to Shareholders

January 2026

Contents

EDITORIAL

Laurence Rodriguez
CEO GenSight Biologics

Dear Shareholders,

As we begin 2026, I would like to take a moment to look back on the past year and highlight the significant progress we have made, progress made possible by the commitment and professionalism of our teams.

By staying true to its strategic roadmap, GenSight has reached an inflection point in its journey, marking the beginning of a new chapter for the company.

Financial Management

Throughout the year, the company maintained strict control over its operating expenses. We successfully refinanced GenSight five times. This reflects the continued trust of our long-standing investors, whom I warmly thank, and demonstrates the confidence of new investors who recognized GenSight's potential.

These refinancing operations allowed us to secure the tech transfer of our manufacturing process and set up the various early-access programs now underway.

Technology Transfer

In early 2025, we announced the change of manufacturing site for GS010/LUMEVOQ®, a crucial step to ensure the continuation of our activities over the longer term.

The key milestones in this ambitious transfer have now been completed and will soon enable the start of commercial-scale production. This technology transfer also included an upgrade of our testing procedures.

Early Access Programs

At the end of the year, we obtained several early access authorizations, paving the way for the initiation of patient treatments in the United States, France, and Israel. Treatments are expected soon across participating countries. Vials are available as of now to meet incoming requests.

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Other Achievements

The protocol for the REVISE dose-ranging study has been approved, and enrollment of the first patients will begin in January 2026.

We are also continuing to follow patients with retinitis pigmentosa who were treated with GS030, our optogenetic therapy candidate, as part of the Phase I/II PIONEER trial.
The year 2025 was truly an exceptional one. We stayed firmly on course toward our goal of making GS010/LUMEVOQ® available to patients as early as possible.

Looking Ahead to 2026

The year 2026 will build on this renewed momentum. Alongside the resumption of treatments through early access programs, we will focus our efforts on recruiting patients for the REVISE dose-ranging study and finalizing the protocol of the pivotal clinical trial, RECOVER. We also plan to engage shortly with the regulatory teams at the UK agency to define the optimal regulatory pathway for Lumevoq.

At the same time, GS030 will continue to advance along its clinical development plan. We are maintaining discussions with potential partners regarding strategic opportunities that could accelerate this development plan and strengthen our long-term positioning.

Closing Thoughts

I would like to express my profound gratitude for the trust you have placed in us and for your continued show of commitment alongside us. Our exchanges have led to greater transparency in our communication, and I thank you for that.

I extend my warmest wishes for good health, success, and fulfillment in all your personal and professional endeavors.

Wishing all of you an excellent year in 2026!

Laurence Rodriguez

J.P. Morgan Healthcare Conference 2026

Jan Eryk Umiastowski
Chief Financial Officer

I am pleased to announce that GenSight was a resounding success at the J.P. Morgan Healthcare Conference 2026 held in San Francisco.

A Week of Exceptional Engagement

This year's trip proved to be particularly productive, characterized by an energizing atmosphere and excellent conditions that facilitated meaningful connections throughout the week. I maintained an intensive schedule of meetings from 7am to 5pm daily, followed by evening networking events.

Strategic Partnerships and Collaborations

My presence in San Francisco provided invaluable opportunities to strengthen existing relationships and forge new ones across our entire ecosystem:

- **Suppliers:** I engaged in substantive discussions with current and potential suppliers, reinforcing our supply chain partnerships and exploring innovative solutions to support our development and commercialization objectives.
- **Current Partners:** I deepened my relationships with existing strategic partners, aligning on shared goals and discussing next steps in our joint initiatives.
- **Future Partners:** I began several promising conversations with prospective partners who share our vision and could play instrumental roles in accelerating our progress.
- **Investors:** I connected with both current and potential investors, presenting GenSight's progress and strategic direction. The level of interest and engagement was encouraging, reflecting growing confidence in our approach and potential.

Looking Ahead

The relationships seeded and strengthened at JPM 2026 set GenSight up in a favorable position as we advance toward our ultimate goal: successfully delivering our therapies to the patients who need them. The intense yet rewarding week has energized our team and reinforced our commitment to executing on our mission.

I look forward to updating you on the concrete outcomes of these discussions in the coming months as we continue to build momentum in 2026.

Screening Patients in the REVISE Study

Magali Taiel
Chief Medical Officer

Initiation and First Patient Pathway

The REVISE study, previously approved by the ANSM and ethic committee, started in January 2026 after these two key steps were completed:

1. Activation of the 15-20 Hospital as the investigator site managing the REVISE study. The activation of an investigator site requires the completion of various files and documentation.
2. Shipment of lenadogene nolparvovec vials, which are now on site and ready for clinical use

Patient Selection and Enrollment Process

The process of selecting patients for the clinical study follows these standard steps:

- Physicians/ophthalmologists/neuro-ophthalmologists may request their patients be enrolled in the REVISE study if they fulfill the selection criteria of the study.
- They then refer their patients to the Principal Investigator of the 15-20 Hospital center, who will confirm the eligibility of the patients at their screening visits.
- After that, the patients are treated and followed in the REVISE study.

Accordingly, locally-based patients already followed by the 15-20 Hospital who fulfill the selection criteria may be accepted into the REVISE study.

Importantly, before any examination or visit in the study can be performed, the patient who is willing to participate in the study must sign and date the Informed Consent Form specific to the study. This consent form outlines the study's objectives, procedures, risks and benefits, as well as the rights of participants.

Next Milestone

As of now, the first patient of the study is planned to get his screening visit and then be selected in the study at the end of this month.

GS010/LUMEVOQ® and GMO regulations

Magali Gibou
Chief Regulatory and Quality Assurance Officer

Why is gene therapy linked to GMOs?

GS010/LUMEVOQ® uses a viral vector (AAV) to bring the therapeutic gene to the cells in the retina. In Europe, these vectors are classified as "genetically modified organisms" (GMOs). This means that use of the product must comply with specific regulations.

What do European regulations require?

These rules are guided by two main objectives: protecting patients' health and protecting the environment. In practice, before any use (clinical trial, compassionate use, or market access), GenSight must file notifications or obtain approvals in each country where the product will be administered.

Depending on the context, there are two types of procedures:

- Contained use: when the product is handled in a controlled setting (e.g., the manufacturing site, a hospital during clinical trials). Safety measures are put in place to avoid any contact with the environment.
- Deliberate release: for any activity involving the GMO that does not fall under contained use. In this case, an environmental risk assessment is required.

How does it work in France?

In France, the ANSM (the French medicines safety agency) oversees the notification and authorization procedures for the use of GMOs. GenSight must submit a technical dossier including a risk assessment for health and the environment. The ANSM may consult expert committees before issuing its opinion.

What about GS010/LUMEVOQ® specifically?

The good news is that the AAV vector used in GS010/LUMEVOQ® is well-characterized and has a very low risk profile. It is classified in Group 1 (no or negligible risk), which corresponds to the lowest level of containment needed. This classification simplifies administrative procedures while ensuring the safety of both patients and the environment.

Securing the GS010 Cold (Supply) Chain

Scott Jeffers
Chief Technical Officer

GS010/LUMEVOQ® clinical trials and early access supply must fulfill one core promise: that every vial leaves the freezer, which is at -80°C, and arrives at the injection room in the same pristine condition, ready to go into a patient's eye.

Why The Cold Chain Is So Critical

GS010 is manufactured as a frozen gene therapy drug product that must be stored and transported at tightly controlled low temperatures to preserve its potency and safety. If temperatures rise above the allowed band, the viral vector's ability to deliver the therapy can become degraded, which would put both efficacy and patient safety at risk. Any excursion can mean that vials may not be able to be used and so patients are not treated as scheduled.

Securing the Cold Chain During Storage and Shipment

For GS010 clinical and early access supply, the path from the manufacturing site to the hospital looks roughly like this:

- Frozen GS010 vials are released from the manufacturing site after full quality control testing.
- Vials are stored in qualified low temperature storage (central or regional), which are tested and continually monitored until an order for a specific patient is confirmed.
- The vials are packed into validated cold-chain shipping boxes that have been tested to maintain the required temperature, then shipped on pre-qualified routes to the treating hospital or eye center, with temperature probes continuously monitoring the shippers throughout the journey.

On arrival, pharmacy or clinical staff immediately check:

- The integrity of the cold-chain shipping container and any tamper evidence seals.
- The temperature report showing whether the product stayed within the acceptable range for the entire journey.
- The identity of the vials against the trial or early access documentation so the right product is at the right site for the right patient.

Only then is the shipment accepted into the hospital's own monitored freezer for storage until the scheduled injection day.

A Note on the Differences between Clinical Trial vs Early Access Supply Chains

In Phase 3 studies like REFLECT and future RECOVER, GS010 has been or will be shipped to a limited number of highly specialized ophthalmology centers across Europe, the US, and other regions, each trained in handling and administering the gene therapy. Early access programs, such as the planned named early access program (AAC) in France and individual early access in countries like Israel, follow the same principles but are organized under national early access rules and timelines.

Because early access often serves patients outside a formal trial, quantities are limited, and every vial is reserved for a specific patient or center once the competent authority has authorized treatment. The cold chain therefore must be reliable, since replacing a lost or temperature abused shipment may not be possible within the time window when the patient is eligible for treatment.

The Work to Secure the Cold Chain Before Shipments Begin

Given the demand for tight control over the quality of the product throughout its path from manufacturing site to treatment center, GenSight plans and qualifies the complete cold chain for clinical trials and named early access programs before the first patient is ever treated at a center. This process includes identifying validated freezers, qualified shippers, which maintain temperature and protect the vials from shocks that could break them , and continuous temperature monitoring devices that create a permanent record for each shipment and batch.

To keep every GS010 vial in pristine condition all the way to injection, several layers of protection work together:

- Validated packaging and routes so that even with flight delays or customs checks, the internal temperature stays within the defined range for longer than the worst-case transit time.
- Qualified depots and hospital freezers with alarms, backup power, and documented temperature monitoring, so storage is as tightly controlled as transport.
- Well-defined standard operating procedures and associated training for GenSight, logistics partners, and clinical sites that define exactly how long vials can be exposed during unpacking, preparation, and thawing before injection.
- Complete documentation and traceability so that each vial can be tracked from manufacturing batch release through shipment, receipt, storage, and administration to an individual patient.

If any deviation occurs, the data from the temperature loggers and chain of custody records allow GenSight and the treatment center to decide whether the vial remains acceptable, or if it must be discarded to protect the patient. For patients entering a GS010 clinical trial or early access program, that invisible, carefully managed cold chain is what ensures that the therapy in the syringe on injection day is exactly the therapy that left the manufacturing site.

NEWSFLOW

EVENTS & PUBLICATIONS

Retrospective

CEO in Pharma BoardRoom

October 2025 | Paris

GenSight's CEO, Laurence Rodriguez was featured in a PharmaBoardRoom interview.

CEO Joins the Board of France Biotech

December 2025 | Paris

GenSight's CEO, Laurence Rodriguez, joined France Biotech as a Board's Director, within the Biotech college.

44th Annual J.P. Morgan Healthcare Conference

January 2026 | San Francisco, California

GenSight's CFO, Jan Eryk Umiastowski was at the J.P. Morgan Healthcare Conference in 2026.

Extraordinary General Meeting (EGM)

January 2026 | Paris

GenSight held an EGM in its Paris offices.

Upcoming Events

Annual Financial Results

March 2026

GenSlight will publish its annual results.

GS010/LUMEVOQ® Papers

March 20-24 - Boston, USA

North American Neuro-Ophthalmology Society 2026

2026 Q1 Cash Position

April 7, 2026

GenSight will publish its cash posiiton for the first quarter of 2026.

GS010/LUMEVOQ® Papers

April 18-22, 2026 - Chicago, USA

American Academy of Neurology 2026

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