GenSight BIOLOGICS

NEWSLETTER
July 2026

NEWSLETTER TO SHAREHOLDERS

Solid, disciplined operational momentum

GenSight Biologics closed a strong second quarter in 2026, with eligible LHON patients now receiving early access treatment in a number of countries and the technology transfer of its manufacturing process nearing completion, all as the Company prepares for its pivotal RECOVER Phase III trial. Inside, the quarter in full.

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EDITORIAL

Laurence Rodriguez
CHIEF EXECUTIVE OFFICER

THE QUARTER IN REVIEW

A look back at Q2

Dear Madam, Dear Sir, Dear Shareholders,

We close this second quarter with solid, disciplined operational momentum.

EARLY ACCESS

Early access now possible in three countries

We have accelerated the treatment of the first patients benefiting from early access. Patients, who suffer from Leber Hereditary Optic Neuropathy (LHON) and are showing the first signs of vision loss, have been treated in the United States, Israel or France. Under cross-border agreements, France can also, subject to certain eligibility conditions, take in patients from other European Union member states, if the treatments are funded by the home countries. The 15-20 National Hospital in Paris has thus received several European patients alongside French ones. This arrangement allows many patients facing an unmet medical need to gain earlier access to our candidate drug GS010/LUMEVOQ®. It also reflects the excellence of the French scientific and medical environment.

MANUFACTURING

Securing the process with Catalent

As indicated at our General Meeting in May, we are pursuing the final stage of the technology transfer with our manufacturing partner Catalent in the United States. In practical terms, this involves reproducing and securing our manufacturing process to prepare for the next stage in manufacturing. The engineering run batch, which verifies that the process works at full scale, is being finalized.

CLINICAL

Preparing the RECOVER Phase III trial

In parallel, we are preparing the protocol for the Phase III RECOVER clinical trial and are in discussions with the hospital centers that may take part, which were identified during our feasibility study. The protocol, together with the data from the technology transfer, will be presented to the regulatory agencies, whom we hope to meet in the second half of the year. These advances demonstrate our ability to execute our strategic plan with rigor and consistency and reflect the strong commitment of our teams. To sustain this momentum, we plan to reinforce our expertise in key areas, particularly in pharmaceutical operations, quality assurance and regulatory affairs, and, in the near future, clinical operations.

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CONTINUED

ADVOCACY

Standing up for French and European innovation

The start of the year has also been marked by my personal involvement in several professional organizations, guided by the French and European model of innovation. France has a scientific, medical and entrepreneurial ecosystem of great quality, but it is one that is subject to growing constraints that hold back patients' access to innovation. In the current pre-election context, it is essential to engage in education and outreach and to put forward concrete proposals.

> **To make the voice of biotechnology companies heard, and to defend the French and European model of innovation.**

france biotech	leem les entreprises du médicament	ELSC
GOVERNING BODY	GOVERNING BODY	WITH INVEST EUROPE
Joining its governance to be the voice of biotechnology companies, whose growth depends on a favorable regulatory and economic framework.	Contributing to the work of LEEM to advance patients' access to innovation.	Supporting the European Life Sciences Coalition, which unites investors and research bodies to strengthen European life sciences venture capital.

This commitment is essential to protect our industry and our model of innovation, but also to support the development of a sector that creates value for Europe, for companies and for patients.

Your support and the quality of our exchanges continue to be very precious to us. I sincerely thank you for your trust, and look forward to reconnecting with you in September. I wish you a wonderful summer.

Yours sincerely,

Laurence Rodriguez

CHIEF EXECUTIVE OFFICER · GENSIGHT BIOLOGICS

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FINANCIAL UPDATE

Jan Eryk Umiastowski
CHIEF FINANCIAL OFFICER

HALF-YEAR 2026

A revenue-generating half-year

The first half of 2026 marked a real turning point: GenSight is now a revenue-generating company.

€6.8M	€4.3M	€1.7M	28/28
H1 EARLY-ACCESS PROCEEDS (FRANCE & ISRAEL)	OF WHICH COLLECTED IN Q2	CASH & EQUIVALENTS AT 30 JUNE 2026	AGM RESOLUTIONS APPROVED · 19 MAY

EARLY-ACCESS PROCEEDS · CUMULATIVE

From first revenue to €6.8M

Proceeds were received between mid-March and mid-June 2026, reflecting the programs' successful ramp-up to provide early access in multiple geographies.

CROSS-BORDER ACCESS

Treatment in Paris under the French Early Access Program started in mid-March 2026 and is also open, under certain conditions, to patients from other European countries, several of whom have already been treated. We expect this momentum to continue in the second half, and we are evaluating the opening of Early Access Programs in other parts of the world.

ANNUAL GENERAL MEETING

Held on 19 May, our Annual General Meeting saw all resolutions adopted, most by a large majority, giving the Company the financial flexibility to move forward, in particular to secure the resources for RECOVER, the pivotal Phase III trial of GS010/LUMEVOQ®.

NEXT PUBLICATION

GenSight will publish its half-year 2026 results, together with the half-year financial report, on 29 September 2026.

We wish you an excellent summer, and look forward to keeping you informed of our progress in September.

Jan Eryk Umiastowski
CHIEF FINANCIAL OFFICER · GENSIGHT BIOLOGICS

03

MEDICAL, CLINICAL & ACCESS

Dr Magali Taiel
CHIEF MEDICAL OFFICER

PATIENT ACCESS

Reaching patients in multiple countries

Providing access to GS010 is where our mission becomes concrete. In a disease that progresses as rapidly as LHON, early access programs allow eligible patients to receive treatment — and this quarter, treatments are underway across three geographies.

EARLY ACCESS · OPERATIONAL UPDATE

Three regulatory routes to early access

Europe
Paris · 15-20 National Hospital

Israel
Jerusalem · Hadassah UMC

United States
Individual patient centers

EUROPE

Named Patient Early Access (AAC)

Authorized by **ANSM** (Dec 2025); PUT-SP posted March 2026. Reviewed patient-by-patient.

Open, under certain conditions, to eligible patients across EU member states, not only to French residents.

ISRAEL

Named Patient Program

Authorized by the **Israeli Ministry of Health** and Ethics Committee.

First patient treated in 2026 via our partner K.S. Kim International (SK-Pharma); a second has been approved.

UNITED STATES

Expanded Access (Individual IND)

Each patient individually cleared by the **FDA** and the **IRB**.

A second patient was cleared in January 2026, building on the first (IND cleared October 2025).

ANSM: French medicines regulator · PUT-SP: Therapeutic Use and Patient Follow-up Protocol · FDA: US Food and Drug Administration · IRB: Institutional Review Board · IND: Investigational New Drug · EMA: European Medicines Agency

Across the three geographies the guiding principles are the same: access is granted on a named-patient basis, for patients who meet specific eligibility criteria, and only after review and approval by the competent health authority and ethics committee. In France, the AAC program is open to patients who are not eligible for the ongoing REVISE study.

A CROSS-BORDER PATHWAY

Treatment in Paris under the French Early Access Program (AAC) is open to eligible patients from across the European Union, not only to French residents. They are referred to the 15-20 National Hospital and treated with GS010/LUMEVOQ®, with their care funded by their home country. In the first half of 2026, the Company treated its first patients from other European countries.

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CLINICAL STUDY · REVISE

REVISE progressing on schedule

PHASE	DESIGN	CENTER	POPULATION
Phase II Open-label	**Dose-ranging** Two dose levels of GS010	**Single site** 15-20, Paris	***ND4*-LHON** Recent vision loss
ONSET WINDOW	**TARGET ENROLMENT**	**FIRST PATIENT**	**REQUESTED BY**
6 mo – 1.5 yr Vision loss at treatment	**14** *ND4*-LHON patients	**Jan 2026** Enrolment continued into spring	**ANSM** During the AAC review

REVISE is currently the only ongoing clinical study involving GS010 in Europe. When a patient is eligible for both REVISE and the AAC program, the clinical study takes priority, in accordance with Good Clinical Practices. Each patient is followed per protocol across both dose levels. Registered on ClinicalTrials.gov (NCT07303296).

PEER-REVIEWED PUBLICATION

BRITISH JOURNAL OF OPHTHALMOLOGY · APRIL 2026

Matching-adjusted indirect comparison of GS010 and idebenone in *ND4*-LHON

A peer-reviewed comparison against the only therapy currently approved for LHON

The article reported two matching-adjusted indirect comparisons of GS010 and idebenone in patients carrying the *ND4* mutation, using individual patient data from REFLECT and aggregated idebenone data. GS010 showed a statistically higher rate of clinically relevant visual recovery at 24 months in the LEROS-versus-REFLECT analysis; no statistically significant difference was seen for time to initial clinically relevant recovery, or for change from baseline in best-corrected visual acuity at 24 months.[1]

Read the article on the journal's website →

1 Yu-Wai-Man P, Newman NJ, Carelli V, et al. Efficacy of lenadogene nolparvovec gene therapy versus idebenone in Leber hereditary optic neuropathy due to the m.11778G>A *MT-ND4* variant: two matching-adjusted indirect comparisons. *Br J Ophthalmol* 2026;0:1–9.

03

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SCIENTIFIC CONGRESS

EUROMIT 2026 · ANGERS, FRANCE

A global gathering for mitochondrial medicine

From 30 May to 4 June, the international mitochondrial-medicine community gathered in Angers for Euromit 2026, the leading congress on mitochondrial diseases. Held every three years and hosted by France for only the second time, it drew more than 850 clinicians, researchers, patients and families. For us, it was a valuable chance to engage with the LHON community and share the science behind GS010.

THE SCIENCE BEHIND GS010

A mitochondrial targeting platform

GS010 is built on a proprietary mitochondrial targeting sequence (MTS) platform: a functional copy of the affected gene is expressed within the cell, and the resulting protein is transported directly into the mitochondria, where the disease originates. It is precisely this ability to act inside the mitochondria that makes the platform such a promising foundation for treating mitochondrial diseases like LHON.

Three days of mitochondrial science · Euromit 2026

NEXT STEPS · SECOND HALF OF 2026

We will continue to make GS010 available to eligible patients through early access programs; pursue enrolment and follow-up in REVISE; and finalize the RECOVER Phase III protocol in consultation with the FDA and EMA, with a view to initiating RECOVER in Q2 2027, subject to regulatory approvals. RECOVER is the study that will deliver the controlled, additional clinical evidence for GS010, and getting it ready is our foremost clinical objective.

As always, I remain committed to keeping you informed of these developments with the transparency and rigor they deserve.

Dr Magali Taiel

CHIEF MEDICAL OFFICER · GENSIGHT BIOLOGICS

04

CALENDAR

RECENT & UPCOMING

Events & publications

RETROSPECTIVE

11 May 2026 Press release — PUBLICATION

MAIC of GS010 & idebenone in LHON

Two matching-adjusted indirect comparisons, in the British Journal of Ophthalmology.

19 May 2026 Paris, France — GOVERNANCE

Combined General Meeting

All 28 resolutions submitted to shareholders were approved.

30 May – 4 Jun Angers, France — CONGRESS

Euromit 2026

International congress on mitochondrial diseases; 850+ attendees.

4 – 6 Jun 2026 Milan, Italy — CONGRESS

EUNOS 2026

Congress of the European Neuro-Ophthalmology Society.

8 Jul 2026 Press release — FINANCIAL

Cash position as of 30 June 2026

Cash position and business updates, including early-access proceeds.

UPCOMING

29 Sep 2026 Press release — FINANCIAL

2026 half-year results

Half-year results and half-year financial report.

9 – 12 Oct 2026 New Orleans, USA — CONGRESS

AAO 2026

American Academy of Ophthalmology Annual Meeting (KOL participation).

15 – 17 Oct 2026 Florence, Italy — CONGRESS

EVER 2026

European Association for Vision and Eye Research (KOL participation).

GenSight BIOLOGICS

Our teams wish you a wonderful summer. We look forward to reconnecting with you in September.

FOLLOW OUR STORY

Subscribe to the newsletter

Our press releases announce the news; our newsletter tells the story behind them, with an inside view of the projects driving GenSight forward each quarter.

SCAN TO SUBSCRIBE

GENSIGHT BIOLOGICS

A biopharmaceutical company specializing in the development and commercialization of innovative gene therapies for neurodegenerative retinal diseases and central nervous system disorders.

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Forward-looking statements: This newsletter contains forward-looking statements regarding GenSight Biologics' clinical development, regulatory strategy and business outlook. Such statements are subject to risks and uncertainties that could cause actual results to differ materially; the Company undertakes no obligation to update them except as required by law. GS010/LUMEVOQ® has not received marketing authorization in any jurisdiction and is not commercially available.