

GenSight Biologics Reports Interim Financial Results for the First Half of 2026 and Provides Business Updates

- €6.5 million collected from paid early access programs; after recognition of rebates and a €4.3 million non-cash change in accounting estimate, reported IFRS revenue amounted to €(1.2) million.
- Net cash used in operating activities was reduced by 37% to €1.6 million.
- GS010/LUMEVOQ® manufacturing technology transfer to Catalent successfully completed; manufacturing of a new GMP batch for early access programs has started.
- REVISE dose-ranging study is on track, with the last patient scheduled for December 2026.

Paris, France, Tuesday, September 29, 2026, 10:30 pm CEST – GenSight Biologics (Euronext: SIGHT, ISIN: FR0013183985, PEA-PME eligible), a biopharma company focused on developing and commercializing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders, today reported its interim financial results for the first half of 2026 and provided business updates.

The 2026 half-year condensed consolidated financial statements were subject to a limited review by the Company's statutory auditors and approved by the Board of Directors on September 29, 2026. The statutory auditors' review report includes an emphasis of matter paragraph drawing attention to the material uncertainty related to going concern described in Note 3.4 of the condensed consolidated financial statements. The full half-year financial report will be available on the Company's website in the Investors section.

"The first half of 2026 marked a turning point for GenSight: for the first time since 2022, patients received GS010/LUMEVOQ® under authorized paid early access programs, and as a result, we collected €6.5 million over the period," noted Jan Eryk Umiastowski, Chief Financial Officer of GenSight Biologics. "The negative revenue reported for the first half reflects future rebates and a one-off non-cash change in accounting estimate and so does not capture the stronger cash collection the company actually achieved. Early access revenues enabled us to reduce our operating cash burn by 37% to €1.6 million in the first half. With the successful transfer of our manufacturing process to Catalent, our priority now is to secure the structural financing for the RECOVER Phase III trial."

Business Updates

Manufacturing

The technology transfer to Catalent has been completed, with both the upstream and downstream stages successful. As announced on September 8, 2026, the viral genome (vg) titer of the engineering batch drug substance was within target specifications, and its reproducibility indicated that the transferred process would have repeatable yields. The full battery of drug substance test results, received at the end of the summer, has now confirmed the successful transfer of the process.

Manufacturing of a new GMP batch to sustain product supply for the Company's early access programs has started.¹ This manufacturing run is expected to be completed in January 2027, with full release of the drug product batch expected in March 2027.

¹ GS010/LUMEVOQ® is an investigational gene therapy that has not received marketing authorization in any country.

With twice the number of vials needed to satisfy early access needs until release of the new GMP batch, the Company does not currently anticipate a supply interruption.

Clinical Activities

All remaining patients planned for REVISE, the dose-ranging study conducted in France at the request of the French health agency ANSM, have been identified. The last patient is scheduled for December 2026.

RECOVER Phase III Trial

Preparation of the RECOVER Phase III trial is ongoing. The trial is currently expected to start in the second half of 2027, subject to the Company securing the necessary financing.

From a clinical operations standpoint, the Company initiated the selection process for the contract research organization (CRO) in July 2026 and expects to reach the final decision by the end of October 2026. The potential clinical sites are currently being assessed.

From a regulatory standpoint, the next meeting with the U.S. Food and Drug Administration (FDA) to finalize the RECOVER protocol is expected to take place before the end of 2026.

Early Access Programs

In France, patient screening under the authorized named patient early access program (AAC) resumed after the summer break, during which applications had been paused. Treatments have resumed and the related payments, amounting to €1.7 million, were received in early September 2026.

First-half revenue includes the first sale to our partner in Israel, invoiced and collected in June 2026, ahead of the patient's treatment in July. Treatments under paid early access programs in other countries are expected to be carried out in the remainder of 2026.

2026 Half-Year Financial Results (IFRS)

€6.5 million cash collected, €(1.2) million reported revenue

In the first half of 2026, the Company generated €6.5 million of gross revenue under its paid early access programs in France (AAC, from March 2026, at a price of €425,000 per injection) and Israel.

Under IFRS 15, revenue under the French early access framework must be recognized net of the rebates that the Company expects to pay in the future, even though none of these rebates is payable in 2026. Reported revenue therefore amounted to €(1.2) million:

In million euros	H1 2026	Cash impact
Gross revenue from paid early access programs (France, Israel)	6.5	Collected
Rebates accrued on 2026 revenue	(3.4)	No cash outflow in 2026
o/w statutory AAC rebate	(1.9)	Payable in November 2027
o/w estimated CEPS settlement rebate	(1.5)	Payable after marketing authorization and final price negotiation
Net revenue before change in estimate	3.1	
Change in accounting estimate (end of discounting of the legacy ATU refund liability)	(4.3)	One-off, non-cash
Reported revenues	(1.2)	

Figures are rounded; totals may not add up.

Rebates accrued on 2026 revenue (€3.4 million, no cash outflow in 2026). They comprise (i) the statutory AAC rebate, calculated on a progressive scale set by the French authorities on the revenue of the previous year, estimated at €1.9 million for the first half of 2026 and payable in November 2027; and (ii) the estimated CEPS settlement rebate, i.e. the amount the Company may have to repay when the

provisional indemnities received under early access are reconciled with the final price negotiated with the French Economic Committee for Health Products (CEPS). This reconciliation can only take place after marketing authorization and completion of price negotiations. It is based on management's estimate of the final price and may ultimately result in an additional payment or a credit.

One-off, non-cash change in accounting estimate (€(4.3) million). The refund liability relating to indemnities received under the former ATU program (2019–2022) was previously measured on a discounted basis. At June 30, 2026, in light of the resumption of material early access revenue and of the uncertainty surrounding the timing of the final price reconciliation, which depends on the completion of development, financing, the regulatory review of a marketing authorization application and subsequent price negotiations, the Company concluded that the CEPS settlement rebate should be measured at its nominal amount, without discounting. In accordance with IAS 8, this change in accounting estimate was recognized prospectively: the reversal of the discount previously recognized reduced revenue by €4.3 million. It has no impact on cash and does not change management's estimate of the nominal amount ultimately payable; it increased the carrying amount of the refund liability. It also means that no discount unwinding will be charged to revenue in future periods.

Refund liability. As a result, the refund liability amounted to €13.2 million as of June 30, 2026, compared to €5.0 million as of December 31, 2025. It comprises €11.3 million for the CEPS settlement rebate, presented as due in more than five years and not expected to be paid before the conclusion of the price negotiation, and €1.9 million for the statutory AAC rebate payable in November 2027. The refund liability is not financial debt.

Key figures

In million euros	H1 2025	H1 2026
Revenues	(0.2)	(1.2)
Other income	0.3	0.4
Operating income	0.0	(0.9)
Research and development expenses	(4.3)	(4.7)
Sales and marketing expenses	(0.2)	(0.5)
General and administrative expenses	(2.3)	(2.5)
Operating profit (loss)	(6.8)	(8.5)
Financial income (loss)	(0.2)	(1.7)
Net income (loss)	(7.0)	(10.3)
EPS (in € per share)	(0.05)	(0.05)
Net cash flows from operating activities	(2.5)	(1.6)
Net cash flows from investing activities	(0.1)	(0.1)
Net cash flows from financing activities	0.3	1.0
Net cash flows	(2.2)	(0.6)
Effect of exchange rates on cash	0.0	(0.1)
Cash and cash equivalents at closing	0.3	1.7

Figures are rounded; totals may not add up.

Operating income amounted to €(0.9) million in the first half of 2026, compared to €0.0 million in the first half of 2025. It reflects the negative reported revenues of €1.2 million, discussed above, and the positive impact of the research tax credit (CIR).

The research tax credit (Crédit d'Impôt Recherche) amounted to €0.4 million in the first half of 2026, compared to €0.3 million in the first half of 2025, reflecting higher eligible R&D expenditure following the strengthening of the Company's teams and the start of the REVISE study. The 2025 research tax credit of €0.8 million was received on July 30, 2026.

Research and development expenses increased by 9.0%, or €0.4 million, to €4.7 million in the first half of 2026, compared to €4.3 million a year earlier. The increase mainly reflects higher personnel costs following the strengthening of the Company's teams to support the early access programs and the manufacturing technology transfer to Catalent, including the appointment in February 2026 of two senior Regulatory Affairs and Quality executives, as well as higher licensing and intellectual property costs. Subcontracting costs remained stable at €2.6 million and included the engineering run at Catalent and the start of the REVISE study.

Sales and marketing expenses amounted to €0.5 million in the first half of 2026, compared to €0.2 million a year earlier. The increase mainly reflects the commissions paid to an intermediary in connection with the paid named patient early access program in Israel.

General and administrative expenses increased by 9.6%, or €0.2 million, to €2.5 million in the first half of 2026, compared to €2.3 million a year earlier, mainly due to the accelerated depreciation of leasehold improvements ahead of the Company's planned office move before year-end. Professional fees remained stable at €0.9 million, reflecting continued disciplined cost management.

Operating loss amounted to €(8.5) million in the first half of 2026, compared to €(6.8) million in the first half of 2025. The €1.7 million increase reflects the €1.0 million decline in reported revenue, from €(0.2) million to €(1.2) million, and the €0.8 million increase in operating expenses described above, partly offset by the €0.1 million increase in other income. Excluding the €(4.3) million non-cash change in accounting estimate, the operating loss would have amounted to €(4.2) million.

Financial income (loss) amounted to €(1.7) million in the first half of 2026, compared to €(0.2) million a year earlier. The change mainly reflects a lower non-cash gain on the change in fair value of warrants (€0.3 million, compared to €2.2 million in the first half of 2025). Financial expenses mainly include interest and amortized cost on borrowings (€(1.1) million) and the non-cash amortization of the Day-1 loss on warrants (€(0.9) million).

Net loss for the first half of 2026 amounted to €(10.3) million, compared to €(7.0) million in the first half of 2025. The loss per share (based on the weighted average number of shares outstanding over the period) amounted to €(0.05) in both periods.

Net cash flows from operating activities improved to €(1.6) million in the first half of 2026, from €(2.5) million a year earlier. The improvement mainly reflects collections under the early access programs in France and Israel, which offset the increase in operating expenses.

Net cash flows from investing activities amounted to €(0.1) million in both periods.

Net cash flows from financing activities amounted to €1.0 million in the first half of 2026, compared to €0.3 million a year earlier, reflecting €1.4 million of proceeds from share and warrant issuances, mainly in connection with the financing completed in March 2026 with Heights Capital, Invus and UPMC Enterprises, partly offset by lease repayments and interest. No financial debt was repaid in cash during the period.

Cash and cash equivalents amounted to €1.7 million as of June 30, 2026, compared to €2.4 million as of December 31, 2025 and €0.3 million as of June 30, 2025.

Other Financial Updates

Cash position since June 30, 2026

The Company received the 2025 research tax credit of €0.8 million on July 30, 2026. As no AAC treatments were performed in France between late June and early September 2026 due to the summer pause, cash and cash equivalents amounted to €0.6 million as of August 31, 2026. Following the

resumption of treatments, the Company received €1.7 million under the French AAC program in early September 2026.

Funding requirement and cash runway

Based on its current cash position and projected cash flows, the Company's available financial resources are not sufficient to cover its operating requirements over the next twelve months. Over the period to September 30, 2027, total cash requirements are estimated at approximately €41 million. Early access revenues and the research tax credit are expected to more than cover the Company's operating expenses, and the net funding requirement is estimated at approximately €16 million, mainly corresponding to the costs of preparing the RECOVER Phase III trial and the associated manufacturing.

Assuming the Company secures, by the end of November 2026, either a short-term bridge financing of up to €2 million or cash inflows from additional early access treatments beyond those assumed in its projections, its cash resources are sufficient until late March 2027, when the first significant payments for the preparation of the RECOVER trial fall due. Should the structural financing not be obtained by March 2027, the Company would postpone the start of the RECOVER trial; in that case, early access revenues would continue to cover the Company's operating expenses, subject to the timing of treatments and the continuation of the early access programs.

Once the RECOVER trial starts, eligible patients in France are expected to enroll in the trial rather than being treated under the AAC program. Early access revenues would therefore decrease significantly during the enrollment period, expected to last approximately one year, and the structural financing will also need to fund operating expenses during that period.

Financial debt

As of June 30, 2026, the Company's financial debt amounted to €22.6 million in nominal amount (carrying amount: €17.8 million), consisting of:

- EIB loan, Tranche A: €9.5 million (nominal amount plus accrued interest), repayable in a single bullet payment in February 2028;
- Convertible bonds held by Heights Capital: €5.7 million nominal amount, repayable in quarterly installments of €0.7 million, in cash or in shares at the Company's option, until December 2027. The June and September 2026 installments have been deferred to December 2027, and the Company's projections assume that no installment is paid in cash over the next twelve months;
- Bpifrance conditional advances: €7.2 million (nominal amount plus accrued interest), repayable in quarterly installments starting in June 2026. The first installment of €138 thousand was paid on July 7, 2026, and the Company is in discussions with Bpifrance regarding the timing of future repayments, taking into account the delay of the GS030 program.

No principal repayment under the EIB loan falls due before September 30, 2027. Significant payments fall due between November 2027 and February 2028, including the AAC statutory rebate (approximately €4.0 million), the remaining Heights installments and EIB Tranche A (€9.8 million including accrued interest). The Company intends to refinance these debt maturities through a new debt facility, for which discussions are ongoing.

Going Concern Assessment

Key Assumptions

The Board of Directors has prepared the condensed half-year consolidated financial statements on a going concern basis, on the basis of cash flow projections through September 30, 2027 that rely on the following key assumptions:

- *Early access revenues*: the continued execution of the AAC program in France and of other paid early access programs, generating, together with the research tax credit, revenues sufficient to

cover the Company's operating expenses (excluding costs associated with the RECOVER trial). The Company cannot predict precisely the timing of treatments;

- *Amortization of the Heights convertible notes:* Management's base-case cash flow projections assume that scheduled instalment payments falling due during the assessment period will not result in cash outflows, either because they will be settled through the issuance of new ordinary shares or because the Noteholder will elect to defer the relevant scheduled instalment payments in accordance with the contractual terms;
- *Bridge financing or additional EAP treatments:* the availability of a short-term bridge financing of up to €2 million pending the structural financing or, alternatively, a higher number of patients treated under the early access programs than assumed in the projections, in Q4 2026 or early 2027, depending on cash requirements, which are closely monitored;
- *Structural financing:* securing, before the end of March 2027, the net funding requirement described above, from one or more of the following sources: equity financing, debt financing, the expansion of paid early access programs beyond France and Israel, and out-licensing arrangements outside the United States and Europe, partnering or M&A transactions. Failing such financing by that date, the start of the RECOVER trial would be postponed;
- *Manufacturing:* the Company's ability to manage manufacturing campaigns with its contract manufacturing organizations in a timely manner, so as to rebuild product inventories for treatments expected in 2027 and 2028.

Material Uncertainty

While management believes that the Company will be able to raise additional funds and/or complete partnering or M&A transactions, there can be no assurance that such transactions will be completed on a timely basis, in sufficient amounts or on acceptable terms. Failure to secure adequate funding could require the Company to significantly curtail or delay its operating plans, and could ultimately lead to insolvency proceedings or the cessation of all or part of its operations. These events and conditions indicate the existence of a material uncertainty that may cast significant doubt on the Company's ability to continue as a going concern and, therefore, on its ability to realize its assets and discharge its liabilities in the normal course of business.

Contacts

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About GenSight Biologics

GenSight Biologics S.A. is a clinical-stage biopharma company focused on discovering and developing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders. GenSight Biologics' pipeline leverages two core technology platforms, the Mitochondrial Targeting Sequence (MTS) and optogenetics, to develop novel approaches for restoring vision in patients with inherited retinal neurodegenerative diseases.

GenSight Biologics' lead product candidate, GS010, is in Phase III clinical development in Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease that leads to irreversible blindness in teens and young adults. The company's second product candidate, GS030, is in Phase 1/2 clinical development as a mutation-agnostic optogenetic candidate therapy for late-stage Retinitis Pigmentosa, a leading cause of blindness in the world. Using gene therapy-based approaches, GenSight Biologics' product candidates are designed to be administered as one-time intravitreal injections with the potential to provide sustained functional visual recovery.

Forward-Looking Statements

This press release contains forward-looking statements. All statements, other than statements of historical facts, included in this press release are forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the Company's cash runway and funding requirements, its financing and refinancing plans, the expected timing of manufacturing activities, including the completion and release of the GMP batch and the sufficiency of existing product inventory, the progress of its early access programs and the related revenues and rebates, the timing of the REVISE study, the preparation and timing of the RECOVER Phase III trial, including the selection of a CRO and interactions with the FDA, and the future expectations, plans and prospects of the Company. Words such as "anticipates," "believes," "expects," "intends," "projects," and "future" or similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to the inherent uncertainties in predicting future results and conditions, many of which are beyond the control of the Company, including, without limitation, the Company's ability to secure financing, the timing and number of treatments under early access programs, the outcome of price negotiations with the French authorities, manufacturing and regulatory risks, market conditions and the risk factors and other matters set forth in the filings the Company makes with the AMF from time to time, including its 2025 Universal Registration Document. The Company expressly disclaims any obligation to update any forward-looking statements, whether because of new information, future events or otherwise, except as may be required by law.

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As of June 30,	As of December 31,
<i>In thousands of euros</i>	2026	2025
ASSETS		
Non-current assets		
Intangible assets	—	—
Property, plant and equipment	287	427
Other non-current financial assets	2,018	2,847
Total non-current assets	2,305	3,274
Current assets		
Trade accounts receivable	—	—
Other current assets	2,498	2,567
Cash and cash equivalents	1,672	2,415
Total current assets	4,171	4,982
TOTAL ASSETS	6,475	8,256

	As of June 30,	As of December 31,
<i>In thousands of euros</i>	2026	2025
LIABILITIES		
Shareholders' equity		
Share capital	5,886	5,522
Premiums related to the share capital	218,631	217,405
Reserves	(247,849)	(235,833)
Net income (loss)	(10,271)	(12,036)
Total shareholders' equity attributable to equity holders of the Company	(33,603)	(24,942)
Non-current liabilities		
Corporate bonds — non-current portion	1,879	2,382
Derivative liabilities — non-current portion	345	656
Borrowings from Banks — non-current portion	7,413	6,835
Conditional advances — non-current portion	4,320	4,565
Lease liability — non-current portion	—	4
Other liabilities — non-current portion	13,188	4,983
Non-current provisions	1,104	1,104
Total non-current liabilities	28,249	20,529
Current liabilities		
Corporate bonds — current portion	3,179	3,120
Derivative liabilities — current portion	—	—
Borrowings from Banks — current portion	185	176
Conditional advances — current portion	776	396
Lease liability — current portion	181	346
Trade accounts payable	5,408	5,922
Current provisions	—	—
Other current liabilities	2,100	2,708
Total current liabilities	11,829	12,669
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	6,475	8,256

CONDENSED CONSOLIDATED STATEMENT OF INCOME (LOSS)

	For the six-month period ended June 30,	
In thousands of euros	2026	2025
Operating income		
Revenues	(1,210)	(219)
Other income	353	267
Total operating income	(856)	47
Operating expenses		
Research and development	4,672	4,285
Sales and marketing	456	227
General and administrative	2,549	2,326
Total operating expenses	7,678	6,837
Operating profit (loss)	(8,534)	(6,790)
Financial income (loss)	(1,736)	(187)
Income tax	(1)	9
Net income (loss)	(10,271)	(6,967)
Basic and diluted earnings (loss) per share	(0.05)	(0.05)

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (LOSS)

	For the six-month period ended June 30,	
In thousands of euros	2026	2025
Net income (loss)	(10,271)	(6,967)
Actuarial gains and losses on employee benefits, net of income tax	—	—
Foreign currency translation differences, net of income tax	(111)	385
Total comprehensive income (loss)	(10,382)	(6,582)

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

<i>In thousands of euros</i>	For the six-month period ended June 30,	
	2026	2025
Cash flows from operating activities		
Net income (loss)	(10,271)	(6,967)
Operating activities		
Amortization and depreciation	206	172
Retirement pension obligations	—	—
Expenses related to share-based payments	139	237
Other financial items	1,705	(94)
Other non-monetary items	11	—
Operating cash flows before change in working capital	(8,210)	(6,653)
Accounts receivable	—	—
Accounts payable, net of prepayments	575	2,528
Other receivables	(1,513)	544
Other current and non-current liabilities	7,593	1,122
Change in working capital	6,655	4,193
Net cash flows from operating activities	(1,555)	(2,459)
Acquisitions of property, plant and equipment	(66)	—
Acquisitions of intangible assets	—	—
Acquisitions/reimbursement of non-current financial assets	(2)	—
Acquisitions/reimbursement of current financial assets	—	(53)
Net cash flows from investing activities	(68)	(53)
Cash flows from financing activities		
New borrowings obtained	—	—
Interest expenses	(177)	(218)
Repayment of obligation under bond and bank financings	—	—
Repayment of obligation under finance leases	(176)	(354)
Treasury shares	(8)	36
Repayment of borrowings	—	—
Subscription and exercise of share warrants	426	160
Capital increases, net of transaction costs	929	688
Net cash flows from financing activities	994	311
Increase/(decrease) in cash and cash equivalents	(629)	(2,201)
Cash and cash equivalents at beginning of the period	2,415	2,464
Effect of changes in exchange rates on cash and cash equivalents	(114)	8
Cash and cash equivalents at end of period	1,672	270

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

<i>In thousands of euros, except for number of shares</i>	Share Capital		Premiums related to the share capital	Reserves	Net income (loss)	Total Shareholders ' Equity
	Number of shares	Amount				
Balance at January 1, 2026	220,890,398	5,522	217,405	(235,833)	(12,036)	(24,942)
Net income (loss) for the period	—	—	—	—	(10,271)	(10,271)
Cumulative translation adjustment	—	—	—	(111)	—	(111)
Other comprehensive income	—	—	—	0	—	0
Total comprehensive income (loss)	0	0	0	(111)	(10,271)	(10,382)
Allocation of prior period net income (loss)	—	—	—	(12,036)	12,036	0
Allocation to reserves	—	—	—	—	—	0
Capital increase by issuance of ordinary shares	14,153,928	354	871	—	—	1,225
Capital increase transaction costs	—	—	(105)	—	—	(105)
Exercise and subscription of equity instruments	410,000 ⁽¹⁾	10	459	—	—	470
Treasury shares	—	—	—	(8)	—	(8)
Share-based payments	—	—	—	139	—	139
Balance at June 30, 2026	235,454,326	5,886	218,631	(247,849)	(10,271)	(33,603)

⁽¹⁾ In June 2026, 410,000 shares were issued following the vesting of free share plans, and 18,424,392 new warrants and 4,270,464 pre-funded warrants were subscribed but have not yet been exercised.