Press Release

GenSight Biologics Reports Interim Financial Results for the First Half of 2025

- Optimized cash management results in 8.3% reduction in operating cash outflow compared to the same period in 2024
- Cash runway extended to late Q4 2025 following post-closing financing
- Manufacturing process transfer to Catalent, Inc., on track
- Protocol for the dose-ranging study submitted to the ANSM in mid-August

Paris, France, Monday, September 29, 2025, 11:00 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 2025.

The 2025 half-year financial statements were subject to a limited review by the Company's statutory auditors and approved by the Board of Directors on September 26, 2025. The full interim financial report is available on the Company's website in the Investors section.

"*We have rigorously maintained financial discipline in the first half of 2025, achieving an 8% reduction in cash outflow compared to the prior year period through optimized cash management. The €3.7 million financing we completed last week has extended our cash runway, providing us with sufficient funds until the expected decision of the ANSM with regard to the French Early Access Program,"* noted **Jan Eryk Umiastowski**, Chief Financial Officer of GenSight Biologics. *"While the funds raised position us well for the coming months, we may consider additional capital before year-end, should the evaluation of the dose-ranging study requested by the French authorities extend into the end of Q4 2025."*

2025 Half-Year Financial Results (IFRS)

In million euros	H1 2024	H1 2025
Revenues	1.1	(0.2)
Other income	0.6	0.3
Operating income	1.7	**0.1**
Research and development expenses	(6.3)	(4.3)
Sales, medical and marketing expenses	(0.3)	(0.2)
General and administrative expenses	(2.6)	(2.3)
Operating profit (loss)	(7.4)	**(6.8)**
Financial income (loss)	1.6	**(0.2)**
Net income (loss)	(5.8)	**(7.0)**
EPS (in € per share)	(0.07)	(0.05)
Net cash flows from operating activities	(7.3)	(2.5)
Net cash flows from investment activities	0.0	0.0
Net cash flows from financing activities	12.1	0.3
Net cash flows	+4.8	**(2.2)**
Cash and cash equivalents at closing	6.9	**0.3**

Operating income decreased to €0.04 million from €1.7 million over the period. In the first half of 2025, income mainly reflects the Research Tax Credit (CIR), partly offset by the accounting impact of discounting potential rebate obligations linked to ATUs (GS010/LUMEVOQ®, 2019–2022). These obligations were re-estimated in June 2024, following a revised timeline for the final reimbursement negotiations, which impacted revenue. There was no change in the estimate during the first half of 2025.

The Company has collected the research tax credit (Crédit d'Impôt Recherche), amounting to €0.3 million in the first half of 2025, compared to €0.6 million in the first half of 2024. As of June 30, 2025, the Research Tax Credit (CIR), is lower compared with the same period last year, as eligible expenses are reduced. The Company is expecting to collect an additional €0.2 million in early October 2025.

The main spending was related to preparation of the dose-ranging study requested by the ANSM in the context of assessment of the French Early Access program. The protocol was submitted to the ASNM in mid-August 2025 and is being reviewed under a clear regulatory timeline.

Research and development expenses decreased by 31.8%, or €2.0 million, and amounted to €4.3 million in the first half of 2025 compared to €6.3 million a year earlier. This decrease was essentially driven by a sharp reduction in R&D spending, achieved by focussing mainly on the technology transfer of GS010 manufacturing to our new manufacturing partner, Catalent, Inc., and on essential costs related to preparation of the dose-ranging study.

Sales, medical and marketing expenses decreased by 12.8% in H1 2025 and amounted to €0.2 million in the first half of 2025 compared to €0.3 million a year earlier, reflecting disciplined cost management.

General and administrative expenses fell by 10% in H1 2025, amounting €2.3 million compared to €2.6 million a year earlier, reflecting disciplined cost management. Personnel costs increased following the hiring of a CFO in September 2024, a function that had been outsourced in H1 2024, while professional fees decreased by 38.1%, highlighting the company's effective monitoring of spending.

Operating loss decreased by 8.3%, or €0.6 million, in the first half of 2025, amounting to €(6.8) million compared to €(7.4) million over the same period in 2024. This decrease reflects trends in operating income; R&D expenses; sales, medical and marketing expenses; and G&A expenses as discussed above, partially offset by the reduction in the research tax credit.

Financial income in the first half of 2025 amounted to €(0.2) million compared to €1.6 million over the same period in 2024. In 2024, the financial income is essentially explained by the renegotiation of our financial obligations and the change in derivative financial instrument fair value.

Net loss for the first half of 2025 increased to €(7.0) million compared to €(5.8) million in the first half of 2024. The loss per share (based on the weighted average number of shares outstanding over the period) amounted to €(0.05) and €(0.07) for the first half of 2025 and 2024, respectively.

Net cash flows from operating activities in the first half of 2025 and in 2024 were €(2.5) million and €(7.3) million, respectively. The sharp decrease in 2025 is driven mainly by the decrease in operating expenses. The decrease in income also contributed.

Net cash flows from investment activities amounted to €0.0 million in the first half of 2025 and in 2024, driven mainly by the activity of the Company's liquidity contract.

Net cash flows from financing activities amounted to €0.3 million in the first half of 2025, compared to €12.1 million in the same period of 2025. This reflects capital increases of €0.8 million in 2025 versus €9.3 million in 2024, in line with the company's financing needs and the timing of fundraising activities.

Cash and cash equivalents amounted to €0.3 million as of June 30, 2025, compared to €2.1 million twelve months earlier.

Other Financial Updates

Cash runway

By the end of September 2025, the Company anticipates having cash on hand amounting to a minimum of €3.0 million, taking into account:

- The financing completed on July 1 and July 18, 2025, which raised approximately €4.5 million gross
- The financing secured on September 25, 2025, totaling €3.7 million through equity with 100% warrant coverage from existing investors; the delivery of shares and payments are scheduled for September 30, 2025
- The September Heights Capital Scheduled Installment Payment paid in cash for €0.7 million

Based on current operations, plans, and assumptions, the September funding is expected to extend the Company's operational runway into late Q4 2025. If the French Early Access Program launches as expected, the resulting revenue would further extend the cash runway to the end of May 2026. However, should the regulatory decision for the requested dose-ranging study be delayed until the end of Q4 2025, the Company may require additional financing before year-end.

In June 2025, the Company reached an agreement with the ANSM (the French medicines agency) to expeditiously consider the French Early Access Program following approval of a dose-ranging study. The study protocol was submitted in August 2025, with the regulatory decision expected by the Company between October and November 2025, based on well-defined regulatory timelines. In case of a positive decision, this should enable the launch of revenue-generating programs by year-end.

The Company is actively pursuing opportunities to out-license GS010 in markets outside the USA and Europe, while exploring paid Early Access Programs worldwide. These EAPs and out-license opportunities will allow non-dilutive revenue to be generated, which will partially self-fund subsequent development phases and reduce reliance on equity financing.

Management's Plans and Financing Strategy

Revenue-Driven Runway Extension:

If the ANSM provides a green light to open the French Early Access Program in Q4 2025, it is expected to generate enough revenue to extend operations until end of May of 2026. This will significantly improve the company's liquidity position and provide additional time to secure long-term funding. In the event of an opening in late 2025 or prolonged assessment, the company may require additional financing before the end of the year.

Medium-term Funding Strategy (Beyond May 2026):

The Company has strategically sequenced its operational milestones to create multiple value inflection points and diversified funding opportunities:

Non-dilutive Sources:

- Early Access Program (EAP) reimbursements worldwide
- Licensing and partnership agreements, with enhanced attractiveness as manufacturing and early market access capabilities are demonstrated

Dilutive Sources:

- Additional equity raises, timed to align with operational milestones that reduce execution risk
- Strategic partnerships or merger and acquisition opportunities

This phased approach ensures that each operational success enhances the Company's ability to secure funding for subsequent development phases while progressively reducing dependence on equity markets through revenue generation.

Going Concern Assessment

Key Assumptions

Based on current operations and plans, the Board has prepared the financial statements on a going concern basis based on the following critical assumptions:

- Anticipated opening of the French Early Access program in Q4 2025, generating revenue to help extend operations to end of May 2026. The company may need small complementary financing before the end of the year, should the expected authorization of the requested dose ranging study extend until the end of Q4 2025.
- Securing additional long-term funding (both non-dilutive and dilutive) before mid-2026 to sustain operations through Phase III clinical development and regulatory submission phases
- The respect of payment agreements with suppliers
- The settlement of Height's redemption installments (€0.7M per quarter) in shares rather than cash, which the company is entitled to enforce, provided that the company's share price remains above the contractual floor limit

Material Uncertainty

While the Company believes in its ability to raise additional funds or realize M&A opportunities, no assurance can be given that these objectives will be achieved or that sufficient funds will be secured at acceptable terms. Failure to secure adequate funding could require the Company to severely modify its operating plans, impair its ability to realize its assets and pay its liabilities in the normal course of business, or be forced to enter into insolvency proceedings or cease its operations in whole or in part. Therefore, substantial doubt exists regarding the Company's ability to continue as a going concern.

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About GenSight Biologics

GenSight Biologics S.A. is a clinical-stage biopharma company focused on developing and commercializing 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 help preserve or restore vision in patients suffering from blinding retinal diseases. GenSight Biologics' lead product candidate, GS010 (lenadogene nolparvovec) is in Phase III in Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease that leads to irreversible blindness in teens and young adults. GS010 is currently in clinical development, has not to date been granted marketing authorization in France or any other jurisdiction, and is therefore not available commercially. Using its gene therapy-based approach, GenSight Biologics' product candidates are designed to be administered in a single treatment to each eye by intravitreal injection to offer patients a sustainable 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 completion expected proceeds and anticipated use of proceeds of the Fundraising; the anticipated cash runway of the Company; and 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 and no assurance can be given that the proposed securities offering discussed above will be consummated on the terms described or at all. Completion of the proposed Fundraising and the terms thereof are subject to numerous factors, many of which are beyond the control of the Company, including, without limitation, market conditions, failure of customary closing conditions and the risk factors and other matters set forth in the filings the Company makes with the AMF from time to time. 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.