

## GenSight Biologics Reports Interim Financial Results for the First Half of 2024, Provides Business Updates

- Optimized cash management, renegotiation of financial obligations and ongoing financial discipline result in 60% reduction in cash outflow compared over the same period in 2023
- Cash runway extended to mid-November 2024 based on current operations; potential extension to Q3 2025 if, as expected, AAC resumes in autumn.
- LUMEVOQ<sup>®</sup> drug product expected to be released for human use in mid-October 2024, with proceeds from the restart of early access program expected from November 2024 onwards

**Paris, France, Monday, September 23, 2024, 6:00 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 2024, and provided business updates since June.

The 2024 half-year financial statements were subject to a limited review by the Company's statutory auditors<sup>1</sup> and approved by the Board of Directors on September 19, 2024. The certification report will be issued once the requisite filing procedures for the Half Year Report have been completed. It will be available in the coming days and before end of September 2024, on the Company's website in the Investors section.

"The team's achievements under a regime of financial discipline while pursuing its strategic objectives have been impressive," noted **Jan Eryk Umiastowski**, the newly appointed Chief Financial Officer of GenSight Biologics. "Investor confidence is evident through two successful capital increases in the first half of 2024. Renegotiated financial obligations and optimized cash management have reduced the monthly burn rate to €1.2 million and extended the cash runway into Q3 2025, if, as expected, the Early Access (AAC) Program resumes this autumn."

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<sup>1</sup> Subject to the completion of their limited review procedures, the Statutory Auditors intend to issue an unqualified opinion on the condensed interim financial statements, and to insert a paragraph relating to the significant going concern uncertainty detailed in the notes to the interim consolidated financial statements.

## 2024 Half-Year Financial Results (IFRS)

In million euros	H1 2023	H1 2024
Revenues	1.6	1.1
Other income	1.2	0.6
<b>Operating income</b>	<b>2.7</b>	<b>1.7</b>
Research and development expenses	(12.0)	(6.3)
Sales, medical and marketing expenses	(4.8)	(0.3)
General and administrative expenses	(3.0)	(2.6)
<b>Operating profit (loss)</b>	<b>(17.1)</b>	<b>(7.4)</b>
<b>Financial income (loss)</b>	<b>5.1</b>	<b>1.6</b>
<b>Net income (loss)</b>	<b>(12.0)</b>	<b>(5.8)</b>
EPS (in € per share)	(0.26)	(0.07)
Net cash flows from operating activities	(16.2)	(7.3)
Net cash flows from investment activities	0.2	0.0
Net cash flows from financing activities	6.4	12.1
<b>Net cash flows</b>	<b>(9.6)</b>	<b>+4.8</b>
<b>Cash and cash equivalents at closing</b>	<b>1.0</b>	<b>6.9</b>

**Operating income** decreased by 36.4% to €1.7 million from €2.7 million over the period. Revenues recognized in 2024 and 2024 only relates to the change in valuation of the refund liability and the potential rebate obligations resulting from the current regulatory framework for ATUs, following the Company's decision to withdraw its EMA application in April 2023. The discounting update comes from rescheduling the date of the final reimbursement negotiation. This update was implemented as of June 30, 2024.

The Company also generated research tax credit (Crédit d'Impôt Recherche), amounting to €0.6 million in the first half of 2024, compared to €1.2 million in the first half of 2023.

**Research and development expenses** decreased by 47.6%, or €5.7 million, and amounted to €6.3 million in the first half of 2024 compared to €12.0 million a year earlier. This decrease was essentially driven by a sharp reduction in R&D spending on the GS030 program in order to focus on the LUMEVOQ® project and lower expenses in Chemistry, Manufacturing and Controls (CMC) activities following the release of two batches of LUMEVOQ® Drug Substance in September and November 2023.

**Sales, medical and marketing expenses** decreased by 94.6%, or €4.6 million, to €0.3 million in the first half of 2024 compared to €4.8 million over the same period in 2023, reflecting the Company's withdrawal of its marketing authorization application with the EMA for LUMEVOQ® and the concomitant decision to terminate activities related to preparing for a commercial launch in Europe.

**General and administrative expenses** decreased by 13.5% to €2.6 million in the first half of 2024 compared to €3.0 million over the same period in 2023. This decrease is mainly driven by the decrease of share-based income, resulting from the cancellations of performance share plans whose conditions were unlikely to be met following the EMA application withdrawal. Excluding this non-recurring and non-cash IFRS2 item, general and administrative expenses decreased by €0.9 million over the period.

**Operating loss** decreased by 56.7%, or €9.7 million, in the first half of 2024, amounting to €(7.4) million compared to €(17.1) million over the same period in 2023. This decrease reflects trends in Operating income, R&D expenses, Sales, medical and marketing expenses and G&A expenses as discussed above.

**Financial income** in the first half of 2024 amounted to €1.6 million compared to €5.1 million over the same period in 2023. In 2023, the fair value of derivative financial instrument had declined sharply in connection with the evolution of the market price. En 2024, the financial income is essentially explained

by the context of the renegotiation of our financial obligations and the change in derivative financial instrument fair value.

**Net loss** for the first half of 2024 decreased to €5.8 million compared to €12.0 million in the first half of 2023. The loss per share (based on the weighted average number of shares outstanding over the period) amounted to €0.07 and €0.26 for the first halves of 2024 and 2023, respectively.

**Net cash flows from operating activities** in the first half of 2024 and 2023 were €(7.3) million and €(16.2) million, respectively. The sharp decrease in 2024 is driven mainly by the decrease in operating expenses following the EMA application withdrawal, in income and in non-cash expenses related to share-based payments.

**Net cash flows from investment activities** amounted to €0.0 million in the first half of 2024 compared to €0.2 million in 2023, mainly driven by the activity of the Company's liquidity contract.

**Net cash flows from financing activities** amounted to €12.1 million in the first half of 2024, compared to €6.4 million in the same period of 2023, reflecting the proceeds from the capital increases conducted in the first half of 2024 and the subscription and exercise of share warrants.

**Cash and cash equivalents** amounted to €6.9 million as of June 30, 2024, compared to €1.0 million twelve months earlier.

### **Other Financial Updates**

On June 28, 2024, the Company resumed payment of the quarterly redemptions of the 2022 OCAs by issuing new shares in the Company. Payment of its next quarterly due date at the end of September 2024 will also be in shares.

As of today, the Company is financed through mid-November 2024. The Company expects to begin receiving revenues from the restarted AAC program in November 2024. This will extend the cash runway to Q3 2025.

In the event of a significant delay between the resumption of compassionate access and the receipt of the first compensation payments, the company may need to implement temporary financing solutions, such as the sale of receivables, to secure its cash position during this transitional period. If timely resumption of the AAC program is not achieved, refinancing would be required before mid-November 2024.

GenSight Biologics expects to pursue other sources of financing or partnerships, including M&A opportunities, to secure its ongoing activities, such as the launch of the new RECOVER Phase III clinical trial, and to supplement its working capital requirements.

### **Business Updates: Manufacturing, Preparing for Resumption of Early Access (AAC) Program**

Over the summer, the LUMEVOQ® drug product batch manufactured in July 2024 has undergone the quality control tests required to be released for use with patients. To date, the batch has passed all safety tests, enabling the vials to be shipped to the distribution facility in France, where packaging operations have been completed. A final series of tests is currently underway. The Company is preparing for the pharmaceutical release of the batch in mid-October, rather than in September as [previously announced](#).

Preparations for resuming the AAC program in France are advancing, in close coordination with the Quinze-Vingts hospital in Paris and the Agence Nationale de Sécurité du Médicament et des Produits de



Santé (ANSM), within a timetable compatible with the various stakeholders. The first proceeds are expected to be received from November 2024 onwards.

### **Management Team Update: New Chief Financial Officer**

GenSight Biologics appointed **Jan Eryk Umiastowski** as Chief Financial Officer, effective September 16, 2024. Mr. Umiastowski brings over 26 years of expertise in corporate finance, fundraising, financial management and M&A to the role. Prior to joining GenSight, Mr. Umiastowski served as Chief Investment Officer at CEGEDIM for 16 years. His wide-ranging background encompasses responsibilities as an M&A director at a Swiss family office specializing in fashion and luxury and as a small-cap equity fund manager for European and US funds.

"I'm thrilled to join GenSight Biologics at this pivotal moment," commented Mr. Umiastowski. "I am excited to bring my multifaceted experience, along with my deep understanding of listed companies and the healthcare sector, to the challenge of developing and implementing robust financial strategies that will fuel the company's innovative journey."

"Jan Eryk's appointment underscores GenSight's commitment to strengthening its financial leadership as it advances its innovative gene therapies in a challenging environment," said **Laurence Rodriguez**, Chief Executive Officer of GenSight Biologics. "He is an outstanding addition to our team."

GenSight Biologics will report its cash position as of September 30, 2024, on October 24, 2024.

### **Contacts**

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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. 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. GenSight Biologics' lead product candidate, LUMEVOQ® (GS010; lenadogene nolparvovec), an investigational compound that has not been registered in any country at this stage, was developed for the treatment of Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease affecting primarily teens and young adults that leads to irreversible blindness. The company is also developing an optogenetics product candidate, GS030, for the treatment of rare inherited diseases, such as Retinitis Pigmentosa, that cause degeneration of photoreceptors.

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding product development prospects and financial projections. These statements do not constitute guarantees of future performance and involve risks and uncertainties. A further list and description of risks and uncertainties that could cause actual results to differ materially from those set forth in the forward-looking statements in this press release can be found in GenSight Biologics' regulatory filings with the French Autorité des Marchés Financiers ("AMF"). Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak



only as of the date hereof. Other than as required by applicable law, GenSight Biologics undertakes no obligation to update or revise the information contained in this press release.