

# GenSight Biologics Reports Estimated Full-Year 2024 Consolidated Financial Results<sup>1</sup>

- Review of LUMEVOQ® dossier to resume compassionate access program in France is ongoing; in parallel, work continues on the new RECOVER Phase III clinical trial and marketing application to the MHRA
- Cash runway extended to early April 2025 thanks to active cash management and the expected collection of Research Tax Credit (CIR) in March
- Resumption of the Compassionate Access Program (AAC) is now expected to occur in April 2025

Paris, France, February 27, 2025, 7:30 am CET – 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 estimated full-year 2024 consolidated financial results 1, as reviewed by the Audit Committee and approved by the Board of Directors on February 26, 2025. The Board of Directors will approve the final accounts on March 18, 2025, and the final certification by the auditors will take place after completion of the required procedures to file the universal registration document with the *Autorité des Marchés Financiers ( AMF)*.

"2024 was a year of strategic transformation for GenSight Biologics. Despite challenges including management transition, implementation of an additional blending step in LUMEVOQ manufacturing, and extended timelines for the French paid compassionate access program (AAC), we have successfully built a more resilient foundation for the business," commented Jan Eryk Umiastowski, CFO of GenSight Biologics. "We extended our cash runway through disciplined operational expense management, gained investor confidence with four funding rounds totaling €18.6 million, and successfully renegotiated our financial obligations. As we progress through the final stages of ANSM regulatory review, we remain focused on our clear pathway forward and are optimistic about our future prospects and strategic direction."

### Estimated Annual Consolidated Financial Statements (IFRS) for the FY 2024<sup>1</sup>

In william access	As of Dec	As of December 31,		
In million euros	2023	2024		
Cash and cash equivalent	2.1	2.5		
Non-current assets	2.6	5.4		
Other Current assets	4.4	2.9		
Total assets	9.1	10.8		
Total shareholders' equity	(30.7)	(26.9)		
Non-current liabilities	14.5	15.1		
Current liabilities	25.3	22.6		
Total liabilities	39.8	37.7		
Total Shareholders' equity and liabilities	9.1	10.8		

<sup>&</sup>lt;sup>1</sup> See paragraph Estimated Full-Year 2024 Consolidated Financial Results at the end of this Press Release.

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In million euros	2023	2024	% Change	€ Change
Operating income	3.0	2.6	(11.4%)	(0.3)
Research and development expenses	(19.4)	(12.4)	(36.1%)	(7.0)
Sales and marketing expenses	(7.9)	(0.7)	(91%)	(7.3)
General and administrative expenses	(5.4)	(5.4)	0.6%	0.0
Operating profit (loss)	(29.7)	(15.8)	(46.7%)	(13.9)
Financial profit (loss)	3.5	1.8	(47.3%)	(1.6)
Net profit (loss)	(26.2)	(14.0)	(46.6%)	(12.2)
EPS (in € per share)	(0.54)	(0.15)	(73.1%)	0.4
Net cash flows from operating activities	(24.7)	(12.9)	(47.5%)	11.7
Net cash flows from investing activities	0.2	0.0	(91.7%)	(0.2)
Net cash flows from financing activities	15.9	13.5	(14.6%)	(2.3)
Net cash flows	(8.6)	0.6		
Cash and cash equivalents at closing	2.1	2.5		

Operating income decreased by 11.4% to €2.6 million from €3.0 million over the period. This €0.3 million decrease is primarily attributable to the €0.6 million decrease in the research tax credit (*Crédit d'impôt recherche*), amounting to €1.1 million at the end of 2024 compared to €1.7 million a year before. This stems from the reduction in clinical development expenses for LUMEVOQ®. It was partly offset by a €0.2 million increase in revenue. Revenues recognized in 2023 and 2024 only relate to the change in valuation of the refund liability and the potential rebate obligations resulting from the current regulatory framework for ATU.

Research and development expenses decreased by 36.1%, or €7.0 million, and amounted to €12.4 million in FY 2024 compared to €19.4 million in FY 2023. This decrease was essentially driven by a sharp reduction in R&D spending in the GS030 program, in order to focus on the LUMEVOQ® project and by lower expenses in Chemistry, Manufacturing and Controls (CMC) activities following the manufacturing of the two batches of LUMEVOQ® Drug Substance in late 2023.

Sales and marketing expenses amounted to €0.7 million in FY 2024 compared to €7.9 million in FY 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 remained stable year-over-year, €5.4 million in FY 2024 and FY 2023. They include recurring costs related to the company's stock market listing and, for the first six months of the year, costs associated with the outsourcing of the CFO function prior to the arrival of the new CFO in September.

Operating loss amounted to €15.8 million in FY 2024 compared to €29.7 million loss in FY 2023. This €13.9 million decrease in losses, or 46.7%, reflects trends in Operating income; R&D expenses; Sales, medical and marketing expenses; and G&A expenses, as discussed above.

Financial result amounted to €1.8 million at end of 2024 compared to €3.5 million at end of 2023. The financial result in 2024 is primarily composed of a "non-cash" financial gain of €3.1 million related to the fair value change of derivative financial instruments pertaining to the conversion option relating to the convertible bond financing with Heights and warrants granted to the European Investment Bank (EIB) in connection with its loan and warrants issued in connection with capital increase in May, November and



December 2024. This financial gain is offset mainly by interest expenses of €(1.5) million related to the financial debts based on the effective interest rate.

Net loss amounted to €14.0 million in FY 2024 compared to a loss of €26.2 million in FY 2023, a decrease of €12.2 million or 46.6%. The weighted average number of shares outstanding increased from €48.3 million in FY 2023 to €95.8 million in FY 2024, also contributing to a reduction in loss per share from (€0.54) in FY 2023 to (€0.15) in FY 2024.

Net cash flows from operating activities amounted to €(12.9) million in FY 2024, compared to €(24.7) million a year earlier. Excluding changes in working capital, net cash flows from operating activities decreased by €13.3 million despite no revenues being generated during the year, reflecting an overall decrease in operating expenses. Changes in working capital contributed €0.8 million to cash flow this year, compared to €2.5 million in FY2023. This variation is mainly due to a lower research tax credit (*CIR*) resulting from reduced R&D expenses, as well as the recognition of provisions related to older advances and down payments.

**Net cash flows from investment activities** was neutral this year, as it only reflects movements related to the Company's liquidity contract activity.

Net cash flows from financing activities amounted to €13.5 million and were mainly driven by capital increases of €18.6 million before transaction costs and by the conversion of convertible bonds by Heights for €3.2 million. It also includes the repayment of the state-guaranteed loan (PGE) for €2.1 million.

Cash and cash equivalents totaled €2.5 million as of December 31, 2024, compared to €2.1 million as of December 31, 2023. The Company completed successful offerings in February, May, November and December 2024, through capital increases for gross amounts of approximately €5.0 million, €9.3 million, €2.8 million and €1.5 million, respectively, limited to specialized investors.

#### **Cash runway**

The Company currently has sufficient net working capital until early April 2025, but not for the next 12 months. This cash runway extension primarily reflects active cash management and the expected collection of Research Tax Credit (*CIR*) in March. Should the Company experience delays in collecting the *CIR*, a small bridge financing will be necessary in March.

On February 17, 2025, the Company received follow-up questions from the French medicines safety agency (ANSM - Agence Nationale de Sécurité des Médicaments et produits de santé) regarding the compassionate access dossier for LUMEVOQ®. It expects to submit the responses in the coming days.

The French Compassionate Access Program (AAC) is now expected to resume in April 2025, rather than February 2025 as previously announced. Once operational, this program will extend the Company's cash runway beyond the next 12 months and finance ongoing CMC, clinical and regulatory activities necessary for upcoming milestones, including the initiation of the new RECOVER Phase III clinical trial and UK MHRA marketing application for LUMEVOQ<sup>®</sup>.

To address the potential gap between the AAC program resumption and receipt of the first AAC payments, the Company is in an active discussion for bridge financing contingent upon ANSM approval of its AAC program. It has also negotiated an accounts receivable assignment agreement with a bank, ensuring receipt of 80% of the value of hospital invoices within days of billing.

Looking further ahead, the Company is scheduled to pay annual rebates on the 2025 AAC program in November 2026, amounting to approximately 40% of the AAC indemnities generated throughout 2025. Consequently, to supplement working capital requirements and fund ongoing operating expenses, it will need to pursue additional debt or equity financing or explore partnering or M&A opportunities before the second half of 2026.



#### Update on the liquidity risk

#### OCA amortization

On June 28, 2024, the Company resumed payment of the quarterly amortization of the convertible bonds issued on December 28, 2022, to Heights Capital (the "2022 OCAs") by issuing new shares. Since then, quarterly amortization of the 2022 OCAs was also executed through the issuance of new shares in October and December 2024. Two additional amortizations in shares occurred on August 30 and December 3<sup>rd</sup>, 2024, in accordance with the additional amortization rights mechanism contained in the amended and restated terms and conditions of June 2024. The March 2025 amortization will also be settled in shares.

#### Discussion with existing creditors

In December 2024, the Company initiated discussions with its banking partners to extend the final maturity date of certain loans. As a result, €0.5 million of these loans remained unpaid as of December 31, 2024. No lender has issued a notice of default or demanded payment of the last outstanding installments. Discussions with the banking partners are ongoing to resolve this situation. Consequently, no event of default was recorded as of December 31, 2024.

To date, the Company has also deferred interest payments without receiving any notices of default from its lenders. As negotiations continue, no event of default has been recorded, and no debt is currently due for immediate repayment.

As a result to these payment delays, financial debts have been classified as current debt on the Company balance sheet. These include a state-guaranteed loan, an EIB loan and Heights Capital convertible notes for a total of €13.3 million (€17.7 million undiscounted amount).

#### Accounting Principles for the Preparation of the Estimated Consolidated Financial Information

The estimated consolidated financial information has been prepared assuming the Company will continue as a going concern. No adjustments have been made to the financial statements relating to the recoverability and classification of asset carrying amounts or classification of liabilities that might be necessary, should the Company not be able to continue as a going concern.

The estimated consolidated financial information has been prepared on a going concern basis as of December 31, 2024, based on the following key assumptions:

- 1. Implementation of a small bridge financing in March 2025 if the Research Tax Credit (*CIR*) is not collected in a timely manner in March.
- 2. ANSM approval of our AAC program and its resumption in April 2025.
- 3. A potential bridge financing following ANSM approval of our AAC program to address any gap between program resumption and receipt of the first AAC payment.
- 4. Successful negotiation with banks and financial partners to address potential default on contractual obligations.
- 5. The Company's ability to raise funds before the end of H1 2026 to finance operations and rebate payments in H2 2026.

However, given the uncertainties related to these assumptions, no assurance can be given at this stage regarding the Company's ability to achieve its objectives in the short or medium term, or to obtain sufficient additional funding on favorable terms. This situation could result in the Company having to significantly modify its operating plans, being unable to realize its assets and pay its liabilities in the normal course of



business or being forced into receivership or ceasing operations in whole or in part. These circumstances give rise to significant uncertainty regarding the Company's ability to continue as a going concern.

#### **Financial Agenda**

GenSight Biologics will report its cash position as of March 31, 2025, on April 7, 2025.

#### **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. 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. 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, 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*. 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.

#### **Estimated Full-Year 2024 Consolidated Financial Results**

The Group's financial information relating to the financial year ended December 31, 2024 included in this document have been prepared using a process similar to that adopted for the preparation of the Group's annual consolidated financial statements but are not yet audited. This estimated accounting and financial data have been reviewed by the company's statutory auditors. However, Gensight has not yet obtained assurance from its auditors that the financial statements will be certified without qualification. The Board of Directors of Gensight has examined at its February 26, 2025 meeting the Group's final financial information for the financial year ended December 31, 2024, and has approved their communication. The Group's financial statements, which will be approved by the Board of Directors in the meeting to be held on March 18, 2025, shall include any material events previously unknown by the Group and of which it becomes aware or which may occur after February 26, 2025. Therefore, the financial information presented shall be qualified as estimated financial results.

#### **Detailed information**

Detailed information regarding the Company, including its business, financial information, results, perspectives and related risk factors are contained (i) in the Company's 2023 Universal Registration Document filed with the AMF on April 17, 2024, under number D.24-0299 (the "2023 URD"), and (ii) the amendment to the 2023 URD filed with the



AMF on May 7, 2024, under number D.24-0299-A01 (the "Amendment to the 2023 URD"). These documents, as well as other regulated information and all of the Company's press releases, can be accessed on the Company's website (www.gensight-biologics.com) and/or AMF (www.amf-france.org). Your attention is drawn to the risk factors related to the Company and its activities presented in chapter 3 of its 2023 URD and in chapter 2 of the Amendment to the 2023 URD, in particular the liquidity risk presented in the chapter 2.2.1 of the Amendment to the 2023 URD.



### Estimated Full-Year 2024 Consolidated Financial Results <sup>2</sup> **BALANCE SHEET**

In thousands of Euros	2024	2023
ASSETS		
Non-current assets		
Intangible assets	57	75
Property, plant and equipment	933	2 025
Other non-current financial assets	4 424	502
Total non-current assets	5 413	2 603
Current assets		
Trade accounts receivable	1	1
Other current assets	2 878	4 394
Cash and cash equivalents	2 464	2 134
Total current assets	5 343	6 529
TOTAL ASSETS	10 756	9 132

In thousands of Euros	2024	2023
LIABILITIES		
Shareholders' equity		
Share capital	3 119	1 633
Premiums related to the share capital	206 606	190 937
Reserves	(222 644)	(197 051)
of which cumulative translation adjustment	(152)	33
Net income (loss)	(14 001)	(26 220)
Total shareholders' equity	(26 920)	(30 702)
Non-current liabilities		
Corporate bonds—non-current portion	0	0
Derivative liabilities – non-current portion	3 960	559
Borrowings from Banks—non-current portion	0	0
Conditional advances—non-current portion	4 700	5 107
Lease liability—non-current portion	514	1 048
Other liability – non-current portion	4 718	6 572
Non-current provisions	1 166	1 258
Total non-current liabilities	15 058	14 543
Current liabilities		
Corporate bonds—current portion	6 973	9 131
Derivative liabilities – Current portion	0	0
Borrowings from Banks—current portion	6 341	7 474
Conditional advances—current portion	0	396
Lease liability—current portion	585	775
Trade accounts payable	6 357	5 634
Current provisions	0	0
Other current liabilities	2 362	1 880
Total current liabilities	22 618	25 290
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	10 756	9 132

 $<sup>^2</sup>$  See paragraph  $\it Estimated Full-Year 2024 Consolidated Financial Results.$ 



**Total comprehensive income (loss)** 

# Estimated Full-Year 2024 Consolidated Financial Results $^{\circ}$ Profit & Loss 2024

In thousands of Euros	2024	2023	VAR			
Operating income						
Revenues	1 500	1 267	233	18,4%		
Other income	1 125	1 697	(572)	-33,7%		
Total operating income	2 625	2 963	(338)	-11,4%		
Operating expenses						
Research and development	12 368	19 360	(6 992)	-36,1%		
General and administrative	5 386	5 352	34	0,6%		
Sales and marketing	685	7 947	(7 262)	-91,4%		
Total operating expenses	18 438	32 659	(14 221)	-43,5%		
Operating profit (loss)	(15 813)	(29 696)	13 883	-46,7%		
Financial income (loss)	1 833	3 475	(1 643)	-47,3%		
Income tax	(21)	0	(21)			
Net income (loss )	(14 001)	(26 220)	12 219	-46,6%		
Basic and diluted earnings (loss) per share	(0.15)	(0.54)	0.40	-73,1%		
In thousands of Euros						
Net income (loss) Actuarial gains and losses on employee benefits, net of income	(14 001)	(26 220)				
tax	14	6				
Foreign currency translation differences, net of income tax	(184)	103				
Other comprehensive income	-	-				

(14 172)

(26 111)

 $^3$  See paragraph Estimated Full-Year 2024 Consolidated Financial Results.



## Estimated Full-Year 2024 Consolidated Financial Results <sup>4</sup> CASHFLOW STATEMENT

In thousands of Euros	2024	2023
Cash flows from operating activities		
Net income (loss)	(14 001)	(26 220)
Operating activities		
Amortization and depreciation	1 059	2 179
Retirement pension obligations	22	25
Expenses related to share-based payments	784	587
Other financial items	(1 674)	(3 689)
Other non-monetary items		
Operating cash flows before change in working capital	(13 810)	(27 118)
Accounts receivable	0	(1)
Accounts payable, net of prepayments	155	(2 234)
Other receivables	2 028	7 886
Other current and non-current liabilities	(1 310)	(3 197)
Change in working capital	873	2 454
Net cash flows from operating activities	(12 937)	(24 663)
Net cash flows from investment activities	17	209
Net cash flows from financing activities	13 542	15 859
Increase/(decrease) in cash and cash equivalents	623	(8 595)
Cash and cash equivalents at the beginning of the period	2 134	10 610
Effect of changes in exchange rates on Cash and cash equivalent	(293)	119
Cash and cash equivalents at the close of the period	2 464	2 134

<sup>&</sup>lt;sup>4</sup> See paragraph *Estimated Full-Year 2024 Consolidated Financial Results*.



# Estimated Full-Year 2024 Consolidated Financial Results $^{5}$ CHANGE IN EQUITY

	Share capital		Premium		Net income	Total
In thousands of Euros, except for number of shares	Number of shares	Amount	related to share capital	Reserves	(loss)	shareholders' equity
At January 1, 2024	65 309 073	1 633	190 937	(197 051)	(26 220)	(30 702)
Net income (loss)	_	_	_	_	(14 001)	(14 001)
Cumulative translation adjustment	_	_	_	(184)	_	(184)
Other comprehensive income	_	_	_	14	_	14
Total comprehensive income (loss)	0	0	0	(171)	(14 001)	(14 172)
Allocation of prior period net income (loss)	_	_	_	(26 220)	26 220	0
Allocation to reserves	_	_	_	_	_	0
Capital increase by issuance of ordinary shares	59 465 372	1 245	14 569	_	_	15 813
Capital increase transaction costs	_	_	(1 816)	_	_	(1 816)
Exercise and subscription of equity instruments	0	242	2 916	_	_	3 158
Treasury shares	_	_	_	(27)	_	(27)
Share-based payments	_	_	_	784	_	784
Other impact				41		41
At December 31, 2024	124 774 445	3 119	206 605	(222 643)	(14 001)	(26 920)

<sup>&</sup>lt;sup>5</sup> See paragraph Estimated Full-Year 2024 Consolidated Financial Results.

