Press release

GenSight Biologics Reports Full Year 2023 Consolidated Financial Results

- Efforts to reduce operational expenses confirming the cash runway until the end of April 2024
- Mobilization of resources aimed at releasing the batch of LUMEVOQ® Drug Product expected in Q3 2024 to ensure the resumption of compassionate access
- Active discussions regarding a new financing and strategic options, including potential partnership opportunities

Paris, France, March 22, 2024, 6:00 pm 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 its full year 2023 consolidated financial results, as approved by the Board of Directors on March 21, 2024. Audit procedures on the Company's 2023 consolidated financial statements were completed by the Company's statutory auditors. Final certification will take place after the completion of procedures required before the Universal Registration Document is filed with the French market authority (*Autorité des Marchés Financiers*)[1].

"The Company has implemented significant measures in 2023, the full effect of which is expected in 2024, to reduce its operational expenses and extend its cash runway" commented Laurence Rodriguez, CEO of GenSight Biologics. "We are now dedicating all our resources to making LUMEVOQ® doses available, which should enable us to resume our compassionate access programs in France, expected in the third quarter of 2024, as well as to discussions around new financing options with our investors and strategic partners that will fund our activities until this resumption."

Annual Consolidated Financial Statements (IFRS) for the Year Ending December 31, 2023 and December 31, 2022

In million euros	As of December 31,	
	2022	2023
Cash and cash equivalent	10.6	2.1
Total assets	25.9	9.1
Total shareholders' equity	(15.3)	(30.7)
Total liabilities	41.2	39.8

In million euros	2022	2023
Operating income	4.9	3.0
Research and development expenses	(19.3)	(19.4)
Sales and marketing expenses	(8.0)	(7.9)
General and administrative expenses	(5.4)	(5.4)

[1] Subject to the finalization of their audit procedures, the Auditors plan to issue an unqualified opinion on the annual and consolidated financial statements and to include a paragraph concerning the significant uncertainty related to the going concern detailed in the notes to the annual and consolidated financial statements.

Operating profit (loss)	(27.8)	(29.7)
Financial profit (loss)	0.2	3.5
Net profit (loss)	(27.6)	(26.2)
EPS (in € per share)	(0.60)	(0.54)
Net cash flows from operating activities	(33.8)	(24.7)
Net cash flows from investing activities	0.2	0.2
Net cash flows from financing activities	0.1	15.9
Net cash flows	**(33.5)**	**(8.6)**
Cash and cash equivalents at closing	**10.6**	**2.1**

The variation in the Company's **operating income**, from €4.9 million as of December 31, 2022, to €3.0 million as of December 31, 2023, is primarily attributable to the absence of revenue in 2023 from named Patient Temporary Use Authorizations (ATU) for LUMEVOQ® granted by the French National Agency for the Safety of Medicines (ANSM). Following production issues encountered at the Company's partner, the last available doses had been used up by March 2022, generating revenue of €2.6 million in the first quarter of 2022. The Company plans to resume product availability under the Compassionate Use Authorization (AAC, formerly ATU) in France in Q3 2024, upon product availability.

The decrease in Research Tax Credit (CIR), from €2.2 million in 2022 to €1.7 million in 2023, directly stems from the reduction in clinical development expenses for LUMEVOQ®, as the Company is currently engaged in discussions with the EMA, MHRA, and FDA to determine the optimal regulatory pathway for LUMEVOQ®, while designing the protocol for its new phase III clinical trial, RECOVER, to incorporate feedback received from these regulatory agencies.

From 2022 to 2023, the Company's **research and development expenses** remained stable, at €19.3 million in 2022 and €19.4 million in 2023. The decrease of €(0.9) million (or -20%) in personnel expenses excluding share-based payments and the decrease of €(1.5) million in subcontracting and collaboration expenses of the Company were offset by an increase in "non-cash" expenses, notably by a €1.1 million increase in share-based payment charges. The Company is currently actively designing the protocol for its phase III study RECOVER and maintaining its efforts in Chemistry, Manufacturing, and Controls (CMC) activities to ensure product supply for this new clinical trial and the resumption of Compassionate Use Authorizations.

Sales and marketing expenses reached €7.9 million in 2023 and €8.0 million in 2022, reflecting the intensification of strategic marketing and market access activities in preparation for the commercial launch of LUMEVOQ® in Europe. The Company had begun establishing its local presence in key European countries, including France, Germany, the United Kingdom, Italy, and Spain, by setting up local commercial subsidiaries. From mid-2023 onwards, sales and marketing expenses gradually decreased following 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.

The Company's **general and administrative expenses** also remained stable and amounted to €5.4 million in 2022 and 2023. The overall decrease in overhead expenses, including a €(0.4) million or -14% decrease in personnel costs excluding share-based payments and a €(1.9) million decrease in consultancy fees, was offset by a €2.0 million increase in share-based payment expenses.

The Company's **operating loss** amounted to €(29.7) million in 2023 compared to €(27.8) million in 2022. This €1.9 million increase is primarily attributed to a €(1.9) million decrease in operating income and a €4.0 million increase in "non-cash" expenses related to share-based payments, shifting from a €3.4 million profit in 2022 due to the cancellation of certain free shares plans to a €0.5 million expense in 2023. This increase was partially offset by a general decrease in external and internal expenses as the Company implemented significant cash preservation measures in 2023, including a 40% reduction in its workforce,

primarily in commercial teams. This substantial reduction in operating expenses will primarily benefit 2024 and subsequent years.

The **financial result** amounted to €0.2 million and €3.5 million in 2022 and 2023 respectively. The financial result in 2023 is primarily composed of a "non-cash" financial gain of €6.8 million related to the fair value change of derivative financial instruments pertaining to the conversion option and warrants attached to the bond financing with Heights and the loan contracted with the European Investment Bank (EIB). This financial gain is offset by interest expenses of €(3.0) million related to the Company's bond financing, bank loans, and state-guaranteed loan, based on the effective interest rate.

The Company's net loss amounted to €(27.6) million in 2022 compared to a loss of €(26.2) million in 2023. The weighted average number of shares outstanding increased from 46.3 million in 2022 to 48.3 million in 2023, thereby reducing the loss per share from (€0.54) in 2023 to (€0.60) in 2023. Adjusting for "non-cash" charges related to share-based payments and the revaluation of the fair value of financial instruments, the adjusted net loss amounted to €32.4 million in 2023, compared to €32.7 million in 2022.

Net cash flows from operating activities amounted to €(24.7) million in 2023, compared to €(33.8) million a year earlier. Excluding changes in working capital, net cash flows from operating activities decreased by €2.7 million despite no revenues being generated during the year, reflecting an overall decrease in operating expenses. This decrease is further accentuated by a significant decrease in working capital needs, amounting to €2.5 million in 2023 compared to €(3.9) million in 2022, mainly due to the progress of development projects and other studies by the end of 2023 compared to the end of 2022..

Net cash flows from investment activities remained stable in 2023 compared to 2022 at €0.2 million and primarily relate to the Company's liquidity contract activity.

Net cash flows from financing activities amounted to €15.9 million and primarily consist of the first tranche of the credit line from the EIB received in February 2023 for €8 million, the two tranches of the bridge financing signed in August 2023 for a total of €10 million, and the repayment of financial debts amounting to €(1.1) million.

Cash and cash equivalents totaled €2.1 million as of December 31, 2023, compared to €10.6 million as of December 31, 2022.

Cash runway

As of December 31st, 2023, the Company available cash and cash equivalents amounted to €2.1 million.

Including the gross proceeds of the capital increase completed in February 2024 for €5 million, the Company does not have sufficient net working capital required to meet its obligations over the next 12 months but only until end of April 2024.

The net funding requirement for the next 12 months is estimated at €9 million (including the anticipated income from the resumption of the AAC/AAP program in France in Q3 2024), in view of the Company's need to finance its ongoing activities notably the launch of the new RECOVER Phase III clinical trial and the continuation of its CMC activities.

Consequently, the Company needs to seek other sources of financing, including via debt or equity financing or partnership opportunities, in order to extend its cash runway until the receipts from the first revenue of the early access program in France (AAC/AAP). This resumption is expected in Q3 2024 when LUMEVOQ® becomes available and the authorization from the ANSM has been obtained.

Detailed information regarding the Company, including its business, financial information, results, perspectives and related risk factors are contained (i) in the Company's 2022 Universal Registration Document filed with the AMF on May 10, 2023 under number D.23-0406 (the "2022 URD"), and (ii) the amendment to the 2022 URD filed with the AMF on November 21, 2023 under number D.23-0406-A01 (the "Amendment to the 2022 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 2022 URD and in chapter 2 of the Amendment to the 2022 URD, in particular the liquidity risk presented in the chapter 2.2.1 of the Amendment to the 2022 URD.

GenSight Biologics will report its cash position as of March 31, 2024 on April 4 2024.

Contacts

GenSight Biologics
Chief Financial Officer
Ivan Tortet
itortet@gensight-biologics.com

LifeSci Advisors
Investor Relations
Guillaume van Renterghem
gvanrenterghem@lifesciadvisors.com
+41 (0)76 735 01 31

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, LUMEVOQ® (GS010; lenadogene nolparvovec), is an investigational compound and has not been registered in any country at this stage, 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. 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.