Press Release

GenSight Biologics Reports Interim Financial Results for the First Half of 2023

- Cash runway extended through October 2023 with the 1st tranche of a €10 million financing in August, and to December 2023 with drawing down the 2nd tranche expected in October
- Operating expenses significantly reduced going forward, limiting financing needs in 2024
- Manufacturing of 3 GMP batches started as planned in August; results expected through September and October

Paris, France, Friday September 15, 2023, 5:45 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 2023. The 2023 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 14, 2023. The full interim financial report will be available on September 19, 2023, on the Company's website in the Investors section.

"We are heartened by our investors' confidence, as reflected once again in the financing we have succeeded in securing in August," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"After navigating the challenges at the beginning of the year, we are now focused on manufacturing the LUMEVOQ GMP batches, which will enable us to resume early access programs and progress towards commercialization. Providing access to LUMEVOQ for all eligible LHON patients is a primary objective that continues to animate our activities."*

2023 Half-Year Financial Results (IFRS)

In million euros	H1 2022	H1 2023
Revenues	3.1	1.6
Other income	1.2	1.2
Operating income	**4.3**	**2.7**
Research and development expenses	(9.9)	(12.0)
Sales, medical and marketing expenses	(4.0)	(4.8)
General and administrative expenses	(2.3)	(3.0)
Operating profit (loss)	**(12.0)**	**(17.1)**
Financial income (loss)	**1.3**	**5.1**
Net income (loss)	**(10.7)**	**(12.0)**
EPS (in € per share)	(0.23)	(0.26)
Net cash flows from operating activities	(16.7)	(16.2)
Net cash flows from investment activities	0.1	0.2
Net cash flows from financing activities	(3.3)	6.4
Net cash flows	**(19.9)**	**(9.6)**

Cash and cash equivalents at closing	**24.1**	**1.0**

The Company's **operating income** decreased by 36.1% to €2.7 million from €4.3 million over the period. This decrease was essentially driven by a single quarter of revenues generated in 2022 by LUMEVOQ® in France through the supply of named patient Temporary Authorizations for Use ("*ATU nominative*"). Following manufacturing issues at the Company's partner, all available vials were used up by March 2022 leading to no revenues being recognized in the subsequent reporting quarters. As a result, there was no revenue from ATUs in the first half of 2023. Revenues recognized in 2023 only relates to the change in valuation of the refund liability and the potential rebates obligations resulting from the current regulatory framework for ATUs, following the Company's decision to withdraw its EMA application in April 2023. The Company expects to resume supply of AAC (*Autorisation d'Accès Compassionnel*, or Early Access Authorisation, formerly known as ATU) in France in Q1 2024 as soon as LUMEVOQ® becomes available.

The Company also generated research tax credit (*Crédit d'Impôt Recherche* or CIR), amounting to €1.2 million in the first half of 2023, stable over the same period in 2022.

Research and development expenses increased by 21.0% amounting to €12.0 million in the first half of 2023 compared to €9.9 million a year earlier. This increase was essentially driven by the Company maintaining its efforts in Chemistry, Manufacturing and Controls (CMC) activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP) and notably the production of validation batches.

Sales, medical and marketing expenses increased by 19.4% to €4.8 million in the first half of 2023 from €4.0 million over the same period in 2022, reflecting the ramp up of key strategic marketing and market access activities in preparation for the commercial launch of LUMEVOQ® in Europe expected at that time. Given the Company's decision to withdraw its EMA application in April 2023, sales and marketing expenses are expected to decrease drastically from the second half of 2023 onwards.

General and administrative expenses increased by 27.8% to €3.0 million in the first half of 2023 compared to €2.3 million over the same period in 2022. This increase was mainly driven by higher personnel expenses, due primarily to the decrease of the share-based income, resulting, in the first half of 2022 and 2023, from the cancellations of performance share plans whose conditions were unlikely to be met following manufacturing issues at the Company's partner in the United States and subsequent EMA application withdrawal. Excluding this non-recurring and non-cash IFRS2 item, general and administrative expenses amounted to €3.4m, stable over the period.

The Company's **operating loss** increased by 41.9% in the first half of 2023, amounting to €(17.1) million compared to €(12.0) million over the same period in 2022, both driven by the reduction in revenues generated by ATUs of LUMEVOQ® in France due to lack of product availability, as well as the increase in CMC expenses and the ramp up of sales, medical and marketing expenses over the period to support the Marketing Authorisation and the subsequent commercial launch in Europe. Given the Company's decision to withdraw its EMA application in April 2023, operating expenses, and notably sales and marketing expenses, are expected to decrease significantly from the second half of 2023 onwards.

The **financial income** in the first half of 2023 amounted to €5.1 million compared to €1.3 million over the same period in 2022. This increase was essentially explained by the change in derivative financial instrument fair value booked for an amount of €6.5 million as of June 30, 2023, versus €2.0 million as of June 2022. These financial incomes are non-cash and represent primarily, in the first half of 2023, the change in the fair value of the convertible option of the bond financing with Heights Capital for €3.3 million and of share warrants attached to the bank financing with EIB for €3.2 million.

The Company's **net loss** for the first half of 2023 amounted to €(12.0) million compared to €(10.7) million in the first half of 2022. The loss per share (based on the weighted average number of shares outstanding over the period) amounted to €(0.26) and €(0.23) for the first halves of 2023 and 2022, respectively.

Net cash flows from operating activities in the first halves of 2023 and 2022 were €(16.2) million and €(16.7) million, respectively. The limited variation in 2023 is mainly driven by the increase in operating expenses to support the Marketing Authorisation and the subsequent planned commercial launch of LUMEVOQ® in Europe, the decrease of revenues with no ATUs supplied in 2023, and the non-cash change in derivative financial instruments' fair values related to Heights' convertible bonds and the EIB's warrants, offset by a decrease in non-cash expenses related to share-based payments due to performance shares plans cancelled in 2022 and a positive change in working capital over the period.

Net cash flows from investment activities amounted to €0.2 million in the first half of 2023 compared to €0.1 million in 2022, mainly driven by the activity of the Company's liquidity contract.

Net cash flows from financing activities amounted to €6.4 million in the first half of 2023, compared to €(3.3) million in the same period of 2022, reflecting the proceeds from the €8.0 million Tranche A of the EIB financing received in February 2023, partly offset by the reimbursement of capital and payment of interests of the state-guaranteed loan for €(1.2) million and the €(0.5) million reimbursement related to finance leases and the application of the IFRS 16 standard.

Cash and cash equivalents as of June 30, 2023, amounted to €1.0 million.

Financial Update

Following the decision to withdraw its EMA application in April 2023, GenSight instituted cash preservation measures, including a 40% headcount reduction mainly in Commercial teams, leading to a significant reduction equalling approximately 40% of its initially planned 2023 operating expenses. The Company was also able to retrieve its 2022 Research Tax Credit amounting to €2.2 million in July 2023, much earlier than in normal operating conditions where this tax credit is usually received towards the end of the year.

This significant reduction of cash burn will mostly benefit 2024 and the following years until the Company can reach European Medicines Agency (EMA) approval and launch LUMEVOQ® in Europe.

In August 2023, GenSight signed a €10 million financing agreement with Sofinnova Partners, Invus and UPMC Enterprises[1], and drew the first tranche of €6 million in the form of convertible bonds with a conversion price of 0.7122 euros. The second tranche is conditioned to either the successful production of at least two successive GMP (Good Manufacturing Practice) batches of LUMEVOQ® or unanimous approval of the three investors, no later than October 30, 2023

As of today, the Company is financed through October 2023. The cash runway would be extended to December 2023 with the drawdown of the second tranche of the August financing for an amount of €4 million. GenSight expects to seek other sources of debt or equity financing to fund its operations beyond December 2023.

In parallel, the Company is also advancing a number of discussions with potential partners on strategic opportunities, including a merger or acquisition, assessed as one of the options to move forward.

[1] https://www.gensight-biologics.com/2023/08/03/gensight-biologics-obtains-funding-of-e10-million-from-sofinnova-partners-invus-and-upmc-enterprises/

Manufacturing Update

GenSight has continued to work closely with its manufacturing partner in the United-States to improve documentation, training and supervision of operating teams ahead of the new manufacturing campaign launched in August 2023.

Given the decision to withdraw its EMA application, there is no immediate need for a validation (PPQ) campaign until a new Marketing Authorisation Application (MAA) is submitted. Consequently, the Company decided to manufacture 3 GMP batches as planned, using the commercial process but outside the context of a validation campaign[2], to generate more batch data for a future MAA filing and provide more experience with the manufacturing process to operating teams, while fulfilling the immediate requirement of supplying product for a possible new clinical trial and for the resumption of an early access program for patients in Q1 2024.

The manufacturing of these 3 GMP batches started as planned in August, and results are expected through September and October 2023. Assuming the 1st batch is successfully manufactured with a vg titer within the required range, full quality control tests would then be undertaken, leading to full release of the product for human use in Q1 2024.

Regulatory Update

As planned, GenSight requested a Scientific Advice meeting with the EMA to discuss a new regulatory pathway for LUMEVOQ® in Europe, including the potential need for generating additional clinical data. A written response from EMA is now expected before end of September.

In addition, GenSight is expecting to meet the UK MHRA in November 2023 to discuss a possible regulatory pathway for LUMEVOQ® in the United Kingdom.

GenSight Biologics will report on October 26, 2023, its cash position as of September 30, 2023.

Contacts

GenSight Biologics
Chief Financial Officer
Thomas Gidoin
tgidoin@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

[2] A validation campaign, or Process Performance Qualification (PPQ) campaign, consists of at least 3 successful GMP (Good Manufacturing Practice, required standards for human use outside of a clinical trial) batches manufactured sequentially to demonstrate and document the robustness, control, consistency and reproducibility of the commercial manufacturing process at the designated commercial facility. This exercise is required only as part of a Marketing Authorisation Application with the EMA and a Biologics License Application (BLA) with the FDA.

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.