

GenSight Biologics Reports Full Year 2021 Consolidated Financial Results

- Strong demand of LUMEVOQ® ATUs in France generating €5.3 million revenues in 2021 despite COVID; +20.1% vs 2020
- Ramp up of sales & marketing actions and investments to drive commercial launch of LUMEVOQ® in Europe in 2023
- Cash runway confirmed to early Q1 2023

Paris, France, Friday April 8, 2022, 7:30 am 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 full year 2021 consolidated financial results, as approved by the Board of Directors on April 7, 2022. Audit procedures on the Company’s 2021 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*).

*“We are now focusing our efforts and resources in 2022 on addressing our manufacturing challenges while preparing for the commercial launch of LUMEVOQ and advancing GS030 as a pioneering optogenetics treatment,”*¹ commented **Thomas Gidoïn**, Chief Financial Officer of GenSight Biologics. *“With a current cash runway to early Q1 2023, we are assessing several financing options, non or as little dilutive as possible, to ensure a successful European commercial launch of LUMEVOQ in 2023.”*

Annual Consolidated Financial Statements (IFRS) for the Year Ending December 31, 2021

In million euros	2020	2021
Operating income	7.4	7.7
Research and development expenses	(22.4)	(22.9)
Sales and marketing expenses	(2.0)	(5.5)
General and administrative expenses	(8.0)	(7.4)
Operating profit (loss)	(24.9)	(28.1)
Financial profit (loss)	(9.1)	(0.5)
Net profit (loss)	(34.0)	(28.6)
EPS (in € per share)	(0.97)	(0.63)
Net cash flows from operating activities	(15.0)	(17.1)
Net cash flows from investing activities	(0.4)	(0.0)
Net cash flows from financing activities	33.9	23.7
Net cash flows	18.4	6.6
Cash and cash equivalents at closing	37.9	44.3

¹ See press release issued on April 7, 2022

The Company's **operating income** increased by 3.6% to €7.7 million in 2021 from €7.4 million in 2020. This increase was essentially driven by revenues generated by LUMEVOQ® in France through the named patient Temporary Authorization for Use ("*ATU nominative*") granted by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) significantly progressing by 20.1% to €5.3 million in 2021 compared to €4.4 million a year earlier. The Company also generated research tax credit (*Crédit Impôt Recherche* or CIR), amounting to €2.4 million in 2021 compared to €2.8 million in 2020.

Research and development expenses remained stable year-on-year amounting to €22.9 million in 2021 compared to €22.4 million in 2020. While Phase III clinical trials of LUMEVOQ® – RESCUE, REVERSE and REFLECT – are now completed and patients entered long term follow-up, the Company maintains 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 as required to complete the Marketing Authorisation Application (MAA) in Europe.

Sales and marketing expenses sharply increased to €5.5 million in 2021 from €2.0 million in 2020 to reflect the ramp up of key strategic marketing and market access activities in preparation for the expected commercial launch of LUMEVOQ® in Europe in 2023. The Company is also building its local presence in the main European countries, France, Germany, the United Kingdom, Italy and Spain by setting up commercial affiliates.

General and administrative expenses reduced by 7.4% to €7.4 million in 2021 compared to €8.0 million in 2020. This decrease was mainly driven by the reversal of the social contribution provision on the 2020 Performance Shares plan, which was partly voided due to a performance criterion not being met within the required timeline.

The Company's **operating loss** was contained in 2021 amounting to €28.1 million compared to €24.9 million in 2020, after having been significantly reduced from 2019. This 12.8% increase was driven by the ramp up of sales and marketing expenses over the period in preparation for the expected commercial launch of LUMEVOQ® in Europe in 2023.

The **financial loss** in 2021 amounted to €0.5 million compared to €9.1 million in 2020. The amount in 2020 was essentially composed of the change in derivative financial instrument fair value of the convertible option and share warrants attached to the bond financing with Kreos between December 31, 2019 and 2020, which was recognized in profit or loss in accordance with IFRS9. The related €7.4 million non-cash and non-recurring financial expense in 2020 was mainly driven by the share price increase over the period.

The Company's **net loss** in 2021 amounted to €28.6 million compared to €34.0 million in 2020. The average weighted number of shares increased to 45.2 million in 2021 from 35.1 million in 2020 leading the loss per share to decrease by 34.5% to €(0.63) in 2021 from €(0.97) in 2020. Excluding both share-based compensation (IFRS2) and financial Kreos-related (IFRS9) non-cash expenses, the adjusted net loss amounted to €24.0 million in 2021 compared to €22.5 in 2020.

Net cash flows from operating activities decreased over the period at €(17.1) million in 2021 compared to €(15.0) million a year earlier, primarily as a result of building the commercial infrastructure and preparing for the launch of LUMEVOQ® in Europe partially offset by revenues generated by ATUs of LUMEVOQ® in France.

Net cash flows from investment activities amounted to €(16) thousand in 2021 compared to €(0.4) million in 2020, mainly driven by the activity of the Company's liquidity contract.

Net cash flows from financing activities amounted to €23.7 million in 2021, reflecting the net proceeds from the private placement in March for €28.1 million partially offset by the amortized repayment of the state-guaranteed loan (*Prêt Garanti par l'État* or PGE) and the bond financing from Kreos. In 2020, these financing activities amounted to €33.9 million, reflecting the private placement in October 2020 for €23.1 million, the PGE obtained for a total of €6.8 million, as well as the Tranche B of the bond financing from Kreos, for an amount of €3.9 million.

Cash and cash equivalents totaled €44.3 million as of December 31, 2021, compared to €37.9 million as of December 31, 2020. The amounts of expected future cash flows related to the reimbursement of our financial debts were €4.6 million at less than one year and €12.4 million at more than one year.

GenSight Biologics will report its cash position as of March 31, 2022 on April 21, 2022.

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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, LUMEVOQ® (GS010; lenadogene nolparvovec), has been submitted for marketing approval in Europe 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.