

Sensorion Reports Full-Year 2025 Results, Provides Corporate Update and Announces Release of Annual Report

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- GJB2-GT (SENS-601) CTA/IND-enabling studies progress, supported by regulatory interactions with FDA and EMA since Q3 2025, and on track for CTA submission in H1 2026
- SENS-501 Audiogene trial ongoing; six-month efficacy data expected in Q1 2026
- Strengthened balance sheet and shareholder registry via €60m financing in January 2026, including a €20m strategic investment from Sanofi; cash runway extended to end of H1 2027

MONTPELLIER, France--(BUSINESS WIRE)-- Regulatory News:

Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company specializing in the development of novel therapies to restore, treat and prevent hearing loss disorders, today reported its full-year 2025 results, provided a corporate update, and announced the availability of the annual report.

“This past year has been an exceptional period of progress across our pipeline and on the corporate development front.” commented **Amit Munshi, Chairman and Interim Chief Executive Officer of Sensorion**. “Our GJB2 gene therapy program continued to advance toward CTA/IND submission, supported by regulatory interactions with the FDA and EMA, targeting the largest cause of genetic congenital deafness, responsible for approximately 50% of autosomal recessive non-syndromic congenital hearing loss. With no approved gene therapy currently available for GJB2-related hearing loss, SENS-601 has the potential to be the first-in-human gene therapy addressing GJB2 mutations. On the financial side, we executed a successful financing totaling over €60 million, led by a strategic investment from Sanofi with participation from existing and new investors, strengthening our balance sheet and shareholder registry to finance the next steps of our gene therapy development. We welcome Sanofi, a renowned pharmaceutical player active in the gene-therapy space, and some of the healthcare sector’s leading institutional investors to our shareholder registry. I would like to thank former CEO, Nawal Ouzren, for her contributions to

Sensorion. The Board and management team remain fully focused on execution and we head into 2026 well positioned to deliver on our clinical and corporate plan, and on behalf of the entire team, I extend my gratitude to our longstanding shareholders, to the patients, and to the physicians for their continued support as we remain committed to bringing transformative therapies for patients suffering from hearing disorders.”

Pipeline Highlights and Upcoming Milestones

Gene Therapies for Hereditary Monogenic Hearing Loss

In 2025, Sensorion advanced its portfolio of gene therapies developed in collaboration with the Institut Pasteur. The Company achieved several notable milestones with SENS-501, for the treatment of hearing loss caused by otoferlin deficiency.

SENS-501: Gene therapy program to restore hearing in OTOF patients

Sensorion's SENS-501 dual vector AAV (adeno-associated virus) gene therapy product aims to restore hearing in patients with mutations in OTOF gene who suffer from severe to profound sensorineural prelingual non syndromic hearing loss. Otoferlin related hearing loss is responsible for up to 8% of all cases of congenital hearing loss, with around 20,000 people affected in the US and Europe¹.

Following the completion of the first Cohort enrollment in December 2024, the Audiogene Phase 1/2 clinical trial of SENS-501 received a positive recommendation from the Data Monitoring Committee (DMC) in February 2025 after a review of initial safety data. Preliminary results announced in July 2025 confirmed that the intracochlear administration of a low dose of SENS-501 (1.5E11 vg/ear) was well-tolerated in infants and toddlers aged 6 to 31 months, with no serious adverse events reported, and early clinical efficacy signals were observed, including positive ABR and PTA responses in Cohort 1.

Sensorion completed enrollment for the second Cohort in July 2025 and received a further positive DMC safety recommendation. As announced in December 2025, early directional improvements were observed in Cohort 2, with two of the three treated patients showing hearing threshold gains by Month 3 reaching approximately 60 and 70 dB HL at best-performing frequencies respectively.

The Company announced it will review the upcoming six-month efficacy data and will communicate during Q1 2026 once the dataset has reached sufficient maturity.

GJB2-GT: Gene therapy program to restore hearing in GJB2 patients

Sensorion's AAV-based GJB2 gene therapy program developed in collaboration with the Institut Pasteur, has the potential to address three pathologies related to GJB2 mutations: pediatric congenital deafness, progressive forms of hearing loss in children, and early onset of presbycusis in adults.

The Company first released GJB2-GT Proof-of-Concept data at the European Society of Cell & Gene Therapy (ESGCT), which took place in October 2024, in Rome, Italy, and has since been advancing the program towards the clinic.

In September 2025, as part of its half year results announcement, the Company indicated that to support the CTA submission, Sensorion started preliminary discussions with the American and European regulatory agencies in Q3 2025. The CTA enabling studies are progressing well and the program is on track for CTA filing during H1 2026.

SENS-401, Sensorion's small molecule for the treatment and prevention of hearing loss

SENS-401 (Arazasetron) is a small molecule that Sensorion develops in three indications: (i) to treat Sudden Sensorineural Hearing Loss SSNHL (Phase 2b completed), (ii) to prevent residual hearing loss following cochlear implantation, in partnership with Cochlear Limited (Phase 2a completed), and (iii) to prevent Cisplatin-Induced Ototoxicity (Phase 2a completed). SENS-401 is orally available and aims to protect and preserve the inner ear tissue from damage, responsible for hearing impairment. SENS-401 has been granted Orphan Drug Designation by in Europe for the treatment of SSNHL, and in the U.S. for the prevention of Cisplatin-Induced Ototoxicity in pediatric population.

In 2019, the French government awarded the PATRIOT consortium a Structuring Research and Development Project for Competitiveness ("Projet de recherche et développement Structurant pour la Compétitivité" - PSPC) non-dilutive funding for the development of the SENS-401 program for the treatment of SSNHL. As such, Bpifrance granted Sensorion a repayable advance and a grant in connection with its participation, as part of a consortium, in the "PATRIOT" Project. During the second half of 2025 following a request by the consortium to adjust the project scope, Bpifrance and the consortium were unable to reach agreement on revised terms, resulting in the conclusion of the project and its related funding. In January 2026, a review of eligible expenses under the project identified an amount of €0.3 million, to be returned by Sensorion. Sensorion is currently in discussions with Bpifrance regarding the terms for the repayment of the €1.3 million repayable advance received (net of the above adjustment).

SENS-401 to prevent Cisplatin-Induced Ototoxicity (CIO)

Cisplatin and other platinum compounds are essential chemotherapeutic agents for many malignancies. Unfortunately, platinum-based therapies cause ototoxicity, or hearing loss, which is permanent, irreversible and particularly harmful to 50-60% of adult patients and 90% of pediatric patients who survive cancer.

The NOTOXIS Phase IIa trial is an exploratory, multicenter, randomized, controlled, open-label study designed to characterize the natural history of cisplatin-induced ototoxicity, to document oncologist prescribing practices, and explore whether SENS-401 may have a potential role in preventing ototoxicity in adult patients with neoplastic disease four weeks after completion of cisplatin-based chemotherapy.

End of study data confirmed the favourable safety profile in all patients treated with cisplatin with no new adverse event or serious adverse events related to SENS-401 reported after 23 weeks of twice-daily oral exposure. Primary analysis showed comparable change in hearing thresholds from baseline to the end of treatment in both arms. Subgroup and post hoc analyses reproduced the trend observed at the World Congress of Audiology (WCA) 2024, suggesting a potential benefit of SENS-401 in patients exposed to the highest cumulative cisplatin doses. These insights are intended to inform potential next steps for the overall development plan for SENS-401.

Board of Directors and senior leadership

On April 2, 2025, Sensorion announced the appointment of Amit Munshi as Chairman of the Board and Independent Director, succeeding John Furey who stepped down as Independent Board Member. Mr. Munshi also replaced Khalil Barrage, who had served as interim Chairman since March 31, 2023 and continued as a Board director. This appointment was performed by way of co-optation and subsequently ratified by shareholders at the Company's General Meeting in May 2025.

Mr. Munshi brings over 35 years of healthcare industry experience, with a track record of leading biotech companies through transformational growth and landmark exits. He most recently served as CEO of Orna Therapeutics (and previously ReNAGade Therapeutics, acquired by Orna in May 2024). As President and CEO of Arena Therapeutics (Nasdaq: ARNA) from 2016, he led the company's transformation into a late-stage clinical organization culminating in its \$6.7 billion acquisition by Pfizer in March 2022, having also spun-out assets into Longboard Therapeutics (Nasdaq: LBPH; acquired by Lundbeck for \$2.6 billion). Earlier, as co-founder and Chief Business Officer of Kythera Biopharmaceuticals (Nasdaq: KYTH), he identified the lead asset Kybella®, led multiple financing rounds, and completed a \$370 million ex-North America license with a Bayer division, before KYTH's \$2.1 billion acquisition by Allergan in June 2015. Mr. Munshi also held leadership roles at Amgen Inc., including General Manager of European Nephrology based in Switzerland. He holds an MBA from The Peter Drucker Graduate School of Management at Claremont Graduate University and a BA in History and BS in Quantitative Economics from UC Riverside.

On February 17, 2026, Sensorion announced that Nawal Ouzren, Sensorion's Chief Executive Officer and a Director on the Company's Board, was stepping down from both roles due to a personal matter incompatible with serving as Chief Executive Officer. Amit Munshi, who is serving as the Chairman of Sensorion is also assuming the role of Interim Chief Executive Officer and Ms. Ouzren will remain temporarily as a consultant to the Company to ensure

an effective transition. The Board has commenced its search for a permanent Chief Executive Officer.

Strengthening Sensorion's capital position

On January 28, 2026, Sensorion announced a €60 million offering reserved to specific categories of investors through the issuance of 214,285,714 new ordinary shares of the Company at a price per New Share of €0.28 to the benefit of Sanofi for €20 million, and Redmile Group, Artal, which is advised by Invus, and Sofinnova Partners, existing shareholders, and other investors including Cormorant Asset Management, Coastlands Capital and Sphera Healthcare, for €40 million.

Expected future milestones and estimated timelines

- Q1 2026 – SENS-501: Cohort two 6-months follow-up data of Phase 1/2 Audiogene trial
- H1 2026 – SENS-601 (GJB2-GT): Clinical Trial Application Submission

Full Year 2025 financial highlights

- **Cash Position**

Cash & Cash Equivalents amounted to c. €47.5m as of December 31, 2025, compared to €77.0m as of December 31, 2024, which included at year-end 2024 a €10.2m short-term deposit classified as other current assets.

- **Research And Development (R&D) Expenses**

R&D expenses increased by 12 % from €25.7 million in 2024 to €28.8 million in 2025.

- **General And Administrative (G&A) Expenses**

G&A expenses were €7.7 million in 2025, compared to €9.4 million in 2024.

- **Net Loss**

Net loss was -€29.4 million in 2025, compared to -€26.0 million in 2024.

- **Financial guidance**

Based on cash and cash equivalents of €47.5 million as of December 31, 2025, and a private placement of €60 million, with net proceeds of around €56 million (received on January 30, 2026) announced on January 28, 2026, at the date of the closing of the accounts, the Company has sufficient net working capital to meet its cash requirements beyond the next twelve months, i.e. until the end of June 2027.

Financial results

The annual accounts as of December 31, 2025, were prepared according to IFRS standards and approved by the

Board of Directors on March 17, 2026.

The simplified income statement as of December 31, 2025, is as follows:

In thousands of Euros – IFRS standards	31.12.2025	31.12.2024
Operating income	5,814	6,653
Research & Development expenses	-28,840	-25,664
General & Administrative expenses	-7,727	-9,390
Total operating expenses	-36,567	-35,054
Operating loss	-30,753	-28,401
Financial result	1,328	2,555
Corporate Income Tax	-4	-126
Net loss	-29,429	-25,972

The simplified balance sheet as of December 31, 2025, is as follows:

In thousands of Euros – IFRS standards	31.12.2025	31.12.2024
Non-current Assets	2,997	3,574
Other Current Assets	7,433	18,934
Of which short term deposit	-	10 214
Cash & cash equivalent	47,457	66,769
Total Assets	57,887	89,277
Equity	44,479	72,138
Non-current Liabilities	1,441	3,486
Current Liabilities	11,966	13,653
Total Liabilities	57,887	89,277

2025 certified accounts

On March 17, 2026, the Board of Directors approved the Company's full year results as of December 31, 2025. The Full Year Report can be found on Sensorion's website (<https://www.sensorion.com/en/home/>) in the investor section under financial information. The full year accounts of 2025 have been subject to an audit by the Company's statutory auditors, and an unqualified report is being issued.

About SENS-501

SENS-501 (OTOF-GT) is an innovative gene therapy program developed to treat a specific form of congenital deafness linked to mutations in the OTOF (otoferlin) gene. This gene plays a key role in the transmission of auditory signals between the hair cells of the inner ear and the auditory nerve. When this gene is defective, affected individuals are born with severe to profound hearing loss.

The aim of SENS-501 (OTOF-GT) is to restore hearing by introducing a functional copy of the OTOF gene directly into hair cells via viral vector technology (AAV). This therapy aims to restore the normal process of converting sound into electrical signals, enabling patients to regain their hearing ability. Currently in the clinical research phase, this gene therapy program represents significant hope for families affected by this rare form of genetic deafness. SENS-501 (OTOF-GT) embodies a commitment to scientific innovation in the field of hearing, with the potential to dramatically improve the quality of life of patients suffering from genetic deafness. This gene therapy for patients suffering from otoferlin deficiency has been developed in the framework of RHU AUDINNOVE, a consortium composed of Sensorion with the Necker Enfants Malades Hospital, the Institut Pasteur, and the Fondation pour l'Audition. The project is partially financed by the French National Research Agency, through the "investing for the future" program (ref: ANR-18-RHUS-0007).

About the Audiogene Trial

Audiogene aims to evaluate the safety, tolerability and efficacy of intra-cochlear injection of SENS-501 for the treatment of OTOF gene-mediated hearing loss in infants and toddlers aged 6 to 31 months at the time of gene therapy treatment. By targeting the first years of life, when brain plasticity is optimal, the chances of these young children with pre-linguistic hearing loss acquiring normal speech and language are maximized. The study comprises two cohorts of two doses followed by an expansion cohort at the selected dose. While safety will be the primary endpoint of the first part of the dose escalation study, auditory brainstem response (ABR) will be the primary efficacy endpoint of the second part of the expansion. Audiogene will also evaluate the clinical safety, performance and ease-of-use of the delivery system developed by Sensorion.

About SENS-401

SENS-401 (Arazasetron), Sensorion's clinical stage lead drug candidate, is an orally available small molecule that aims to protect and preserve inner ear tissue from damage responsible of progressive or sequelae hearing impairment. Sensorion developed SENS-401 in three Phase 2 clinical trials: (i) for the prevention of Cisplatin-Induced Ototoxicity, (ii) to prevent residual hearing loss in patients scheduled for cochlear implantation, and (iii) to treat sudden sensorineural hearing loss. SENS-401 has been granted Orphan Drug Designation by the EMA in Europe for the treatment of sudden sensorineural hearing loss, and by the FDA in the U.S. for the prevention of platinum-induced ototoxicity in pediatric population.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat, and prevent hearing loss disorders, a significant global unmet medical need. Sensorion has built a unique R&D technology platform to expand its understanding of the pathophysiology and etiology of inner ear related diseases, enabling it to select the best targets and mechanisms of action for drug candidates.

It has two gene therapy programs aimed at correcting hereditary monogenic forms of deafness, developed in the framework of its broad strategic collaboration focused on the genetics of hearing with the Institut Pasteur. SENS-501 (OTOF-GT) currently being developed in a Phase 1/2 clinical trial, targets deafness caused by mutations of the gene encoding for otoferlin and GJB2-GT targets hearing loss related to mutations in GJB2 gene to potentially address important hearing loss segments in adults and children. The Company is also working on the identification of biomarkers to improve the diagnosis of these underserved illnesses.

Sensorion's portfolio also comprises programs of a clinical-stage small molecule, SENS-401 (Arazasetron), for the treatment and prevention of hearing loss disorders. Sensorion's small molecule progressed in three Phase 2 proof of concept clinical study: firstly, in Cisplatin-Induced Ototoxicity (CIO) for the preservation of residual hearing, completed in Q1 2026. Secondly, with partner Cochlear Limited, a study of SENS-401 for the residual hearing preservation in patients scheduled for cochlear implantation, completed in 2024. Thirdly, a Phase 2 study of SENS-401 was also completed in Sudden Sensorineural Hearing Loss (SSNHL) in 2022.

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Label: **SENSORION**

ISIN: **FR0012596468**

Mnemonic: **ALSEN**

Disclaimer

This press release contains certain forward-looking statements concerning Sensorion and its business. Such forward looking statements are based on assumptions that Sensorion considers to be reasonable. However, there can be no assurance that such forward-looking statements will be verified, which statements are subject to numerous risks, including the risks set forth in the 2025 full year report published on March 18, 2026, and available on our website and to the development of economic conditions, financial markets and the markets in which Sensorion operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Sensorion or not currently considered material by Sensorion. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Sensorion to be materially different from such forward-looking statements. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Sensorion shares in any country. The communication of this press release in certain countries may constitute a violation of local laws and regulations. Any recipient of this press release must inform oneself of any such local restrictions and comply therewith.

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