Press Release

Sensorion Reports 2025 Half-Year Results, Provides Corporate Update and Announces Availability of Half-Year Report

- **Achieved expedited enrollment completion of first two Cohorts in Phase 1/2 Audiogene clinical trial evaluating SENS-501, the Company's gene therapy candidate being developed to treat a specific form of congenital deafness linked to mutations in the OTOF (otoferlin) gene**
  - **Positive initial safety profile reported in all six patients treated so far**
  - **Data from Cohort 1, at the minimally effective dose, demonstrate early signs of hearing improvement in Patient 3, using a range of standard hearing tests**
  - **Data from Cohort 2, at a higher dose, are currently being gathered; Data Monitoring Committee expected by the end of H2 2025**

- **GJB2-GT on track for first CTA filing in Q1 2026; Regulatory dossier to be supported by discussions with FDA and EMA in Q3 2025; GJB2-GT program addresses pediatric congenital deafness, progressive forms of hearing loss in children, and early onset of presbycusis in adults**

- **Completed enrollment in SENS-401's Phase 2a Proof of Concept study in Cisplatin-Induced Ototoxicity (NOTOXIS) with topline data expected to be reported by the end of H2 2025**

- **Cash and short-term deposits of €57.1m finance the Company into Q3 2026**

Montpellier, September 17, 2025, 7.30 am CET – 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 half-year 2025 results, provided a corporate update and announced the availability of the half-year report.

"I'm really pleased with our progress in H1 2025, particularly, the rapid advancement of our SENS-501 gene therapy program," **commented Nawal Ouzren, Sensorion's Chief Executive Officer**. "The expedited enrollment pace in the Audiogene trial has enabled us to test two doses in less than a year in a strictly homogeneous population of infants and toddlers between the age of 6 months up to 31 months, naive of cochlear implants. As we eagerly await the Data Monitoring Committee's recommendation and the analysis of data from Cohort 2 patients who received the higher dose, we continue to advance our development pipeline including gene therapy candidate SENS-601 (GJB2-GT) which is addressing multiple pathologies related to GJB2 mutations where preclinical activities are proceeding as planned towards a Clinical Trial Application in Q1 2026. In addition, we remain on track to report topline data results by year end 2025 from our Phase 2 clinical trial evaluating SENS-401, our small molecule program for Cisplatin-Induced Ototoxicity. This diversified approach across multiple modalities and indications positions us to capture significant value in the hearing loss market"

Pipeline Highlights and Upcoming Milestones

Gene Therapies for Hereditary Monogenic Hearing Loss

In the first half of 2025, Sensorion progressed its portfolio of gene therapies developed in collaboration with the Institut Pasteur. It advanced its first gene therapy trial Audiogene which is evaluating SENS-501 for the treatment of hearing loss caused by otoferlin deficiency, with the positive recommendation of the Data Monitoring Committee to escalate the dose into the second cohort. The Company also

advanced its GJB2-GT program toward clinical development, with regulatory Clinical Trial Application (CTA) dossier currently being prepared for a submission expected in Q1 2026.

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

SENS-501 has been developed as part of the Company's collaboration focused on the genetics of hearing with the Institut Pasteur which was initiated in 2019 and extended for an additional 5-year period on January 5, 2024. It received Orphan Drug Designation from the European Commission in 2022 and was granted Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) in 2022.

SENS-501 is currently being investigated in a Phase 1/2 clinical trial, Audiogene, in Europe and Australia. Sensorion also received approval to initiate Audiogene in Germany. 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 the brain plasticity is optimal, the chances of these young children with pre-linguistic hearing loss of acquiring normal speech and language are maximized.

The study comprises two cohorts and each are assessing different doses: 1.5E11 vg/vector/ear for the minimally effective dose in Cohort 1 and 4.5E11 vg/vector/ear for the second dose in Cohort 2, followed by an expansion cohort at the selected dose. Safety is the primary endpoint of the dose escalation study, and the efficacy endpoint of auditory brainstem response (ABR) is a secondary endpoint. As the trial progresses to the expansion cohort at the selected dose, the primary efficacy endpoint will be ABR. Audiogene also evaluates the clinical safety, performance and ease-of-use of the delivery system developed by Sensorion.

On December 27, 2024, Sensorion completed the patient enrollment of the first cohort in the Audiogene trial, with all three patients aged 6 to 31 months and naive of cochlear implant having received an injection of SENS-501 gene therapy product in one ear.

On February 21, 2025, Sensorion announced the positive recommendation from the Data Monitoring Committee (DMC) regarding the continuation of the study, following the review of the safety data of the first cohort. The Committee recommended that Audiogene proceed as planned with the assessment of the second dose, which is the escalation part of the trial.

On July 1st, 2025, the Company announced positive preliminary data from the first cohort of the study, receiving the minimally effective dose of SENS-501 (1.5E11 vg/vector/ear). The Company reported a good safety profile of all five injected patients at that time (3 patients from Cohort 1 and 2 patients from Cohort 2). Sensorion also announced the preliminary positive response observed in Patient 3 (P3) at month 3 post injection, using standard hearing tests (Auditory Brainstem Response ABR, Pure Tone Audiometry PTA, and Patient (Parents) Reported Outcomes PROs). Three-month data from the Patient 3 include:

- Positive ABR responses at two frequencies, with the best frequency reaching 70 dB
- Improvement of hearing levels across two speech frequencies with best frequency reaching 90 dB level, per PTA
- Meaningful changes in responses to sounds and voices as reported by the parents with an IT-MAIS score increase of 16 points (145% relative improvement from baseline), and met expected auditory milestones based on an age-based parent questionnaire and according to the patient's age (LittlEARS)

On July 29, 2025, Sensorion announced the completion of patient enrollment of the second cohort in Audiogene, composed of three patients aged between 6 and 31 months who received a higher dose of SENS-501 (4.5E11 vg/vector/ear) in one ear. For all patients treated in the first and second cohorts, the surgical procedure was well tolerated: the intra-cochlear administration of the gene therapy product was uneventful. No serious adverse events and no serious side effects have been reported.

Sensorion expects the Data Monitoring Committee by the end of the year 2025.

OTOCONEX, the Company's Natural History Study to document the natural course of disease progression in otoferlin deficiency patients and in children with hearing loss related to GJB2 mutations, continues to run across Europe and plays a key role in identifying eligible patients for Audiogene.

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

GJB2-GT is Sensorion's AAV-based gene therapy program initiated in 2021 and developed in collaboration with the Institut Pasteur 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 advances its GJB2-GT program toward clinical development. The regulatory Clinical Trial Application (CTA) dossier is currently being prepared for a submission expected in Q1 2026. To support the CTA submission, Sensorion has started preliminary discussions with the American and European regulatory agencies in Q3 2025.

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

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

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

The NOTOXIS Proof-of-Concept (POC) Phase 2a trial is a multicenter, randomized, controlled, open-label study designed to assess the efficacy of SENS-401 in preventing cisplatin-induced ototoxicity in adult patients with neoplastic disease, four weeks after completion of cisplatin-based chemotherapy. The trial assesses several endpoints, including the rate and severity of ototoxicity, changes in pure tone audiometry (PTA) (dB) throughout the study compared to before cisplatin treatment, and tolerability.

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 up to 90% of pediatric patients who survive cancer, representing a major unmet medical need for which there is no approved pharmaceutical treatment available.

On September 20, 2024, Professor Yann Nguyen reported preliminary safety and efficacy data during the World Congress of Audiology. The preliminary data demonstrated that a cumulative dose of cisplatin is a key factor of ototoxicity severity. A good safety profile of SENS-401 was confirmed in the long term, with the drug being administered for the first time for an average duration of up to 23 weeks. The preliminary results suggest a trend toward an otoprotective effect of SENS-401 beyond a cisplatin dose of 300 mg/m2. Despite significantly higher exposure to cisplatin in the treatment group, most participants showed only mild ototoxicity.

On March 7, 2025, Sensorion announced the completion of patient recruitment in NOTOXIS, and the trial is on track for Sensorion to report topline results by the end of H2 2025.

Strengthening the Board of Directors

On April 2, 2025, Sensorion announced the appointment of Amit Munshi as Chairman of the Board and Independent Director. Mr. Munshi brings to Sensorion approximately 35 years of experience in the healthcare industry with specific expertise in executive leadership having led multiple biotech companies

to successful transformational growth milestones and exits. He was most recently the Chief Executive Officer of Orna Therapeutics, and previously ReNAgade Therapeutics which was acquired by Orna in May 2024. Mr. Munshi's career includes serving as President and CEO of Arena Therapeutics (Nasdaq:ARNA) commencing in 2016, where he led the company's transformation from a $300M market cap company into a late clinical stage organization, before its $6.7B acquisition by Pfizer (March 2022).

Expected future milestones and estimated timelines:

- H2 2025 – SENS-501: Dose escalation Data Monitoring Committee
- H2 2025 – SENS-401 in Cisplatin-Induced Ototoxicity: Topline results
- Q1 2026 – GJB2-GT: Clinical Trial Application filing

First-Half 2025 financial highlights

- **Cash Position**

Cash & Cash Equivalents, and short-term deposits, amounted to c. €57.1m as of June 30, 2025, compared to €77.0m as of December 31, 2024.

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

R&D expenses increased by 2% from €14.7million in 2024 to €15.0 million in 2025.

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

G&A expenses were €4.1 million for 2025, compared to €3.8 million for 2024.

- **Net Loss**

Net loss was -€16.0million for 2025, compared to -€13.9 million for 2024.

- **Financial guidance**

Based on cash and cash equivalents and short-term deposit classified in other current assets of 57.1 million at 30 June 2025, the Company believes it has sufficient resources to finance its activities into the third quarter of 2026.

Financial results

The annual accounts as at June 30, 2025, were prepared according to IFRS standards and approved by the Board of Directors on September 16, 2025.

The simplified income statement as of June 30, 2025, is as follows:

In thousands of Euros – IFRS standards	**30.06.2025**	**30.06.2024**
Operating income	**2,327**	**3,332**
Research & Development expenses	-15,001	-14,660
General & Administrative expenses	-4,138	-3,791
Total operating expenses	**19,139**	**18,451**
Operating loss	**-16,812**	**-15,119**
Financial result	804	1,323
Pre-tax current income	**-16,008**	**-13,796**
Corporate Income Tax	-	-98
Net loss	**-16,008**	**-13,895**

The simplified balance sheet as of June 30, 2025, is as follows:

In thousands of Euros – IFRS standards	**30.06.2025**	**31.12.2024**
Non-current Assets	**3,448**	**3,574**
Other Current Assets	23,243	18,934
Of which short term deposit	*10,417*	*10,214*
Cash & cash equivalent	46,647	66,769
Total Assets	**73,338**	**89,277**
Equity	**56,978**	**72,138**
Non-current Liabilities	2,097	3,486
Current Liabilities	14 264	13,653
Total Liabilities	**73 338**	**89,277**

First-Half 2025 certified accounts

On September 16, 2025, the Board of Directors approved the Company's full year results as of June 30, 2025. The Half-Year Report can be found on Sensorion's website (https://www.sensorion.com/en/home/) in the investor section under financial information. The half-year accounts of 2025 have been subject to a limited review by the Company's statutory auditors, and an unqualified report has been issued on September 16, 2025.

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). The OTOF gene targeted by the Audiogene trial was discovered in 1999 at the Institut Pasteur, by Prof. Christine Petit's team (Institut reConnect, Institut de l'Audition, Pasteur Institute), who also unraveled the pathophysiology of the corresponding deafness (DFNB9).

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. The last two studies are completed. 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 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, for which the recruitment is completed, and the follow-up is ongoing. 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.
www.sensorion.com

Contacts

Investor Relations
Noémie Djokovic, Investor Relations and Communication Associate
ir.contact@sensorion-pharma.com

Press Relations
Ulysse Communication
Bruno Arabian / 00 33(0)6 87 88 47 26
barabian@ulysse-communication.com
Nicolas Entz / 00 33 (0)6 33 67 31 54
nentz@ulysse-communication.com

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 2023 full year report published on March 14, 2024, 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.