

## Sensorion Reports Full-Year 2024 Results, Provides Corporate Update and Announces Availability of Full-Year Report

- Enrolled first cohort into SENS-501's Phase 1/2 clinical trial, Audiogene, and received a positive DMC recommendation; enrollment of second cohort and KOL event to present new data expected during H1 2025
- Primary and secondary endpoints achieved in SENS-401's Phase 2a Proof of Concept study for the preservation of residual hearing following cochlear implantation; business development discussions ongoing
- End of enrollment in SENS-401's Phase 2a Proof of Concept study in Cisplatin-Induced Ototoxicity, NOTOXIS; topline data to be reported by end of Q4 2025
- Strengthened balance sheet and shareholder registry via capital increases raising €65.5m from top tier U.S. and European healthcare dedicated institutional investors
- Cash and short-term deposits of €77m finance the Company until end of Q1 2026

Montpellier, March 14, 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 full-year 2024 results, provided a corporate update, and announced the availability of the full-year report.

"This past year has been an exceptional period of progress on clinical and corporate development fronts," commented Nawal Ouzren, Chief Executive Officer of Sensorion. "Our portfolio of next generation treatments for hearing loss disorders achieved important development milestones highlighted by the first cohort being enrolled in Audiogene, our first gene therapy clinical trial, and with SENS-401's Phase 2a POC study meeting its primary and secondary endpoints in preserving residual hearing following cochlear implantation. On the operational side, we executed two successful financings totaling over €65 million which enabled us to maintain development pace for the entire pipeline of programs while welcoming some of the healthcare sector's leading institutional investors to the registry. We head into 2025 well positioned to execute on our clinical and corporate growth plan and on behalf of the entire team, I extend gratitude to our longstanding shareholders, to the patients and to the doctors for their continued support as we remain steadfast in bringing to market disruptive treatments for hearing loss disorders."

### Pipeline Highlights and Upcoming Milestones

#### Gene Therapies for Hereditary Monogenic Hearing Loss

In 2024, Sensorion advanced its portfolio of gene therapies developed in collaboration with the Institut Pasteur. The Company achieved several notable milestones with lead candidate 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 development product aims at restoring 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 Europe<sup>1</sup>.

On January 19, 2024, Sensorion announced the approval to initiate the Phase 1/2 gene therapy clinical trial of SENS-501, Audiogene. The study design consists of two cohorts of two doses followed by an expansion cohort at the selected dose. Safety will be the primary endpoint for the dose escalation cohort, and the auditory brainstem response (ABR) will be the primary efficacy endpoint of the dose expansion cohort. Audiogene will also assess the clinical safety, performance, and usability of the administration device system developed by Sensorion. Additionally, Sensorion received the European Medicines Agency's decision agreeing on a Pediatric Investigation Plan (PIP) for SENS-501, in September 2024.

In September 2024, Sensorion reported the injection of the first patient recruited in the Audiogene trial, and, during the symposium it held during the World Congress of Audiology, reported initial safety data of the first patient.

On December 27, 2024, Sensorion announced the patient recruitment completion of the first cohort of patients in the Audiogene study, with all first three toddlers and infants having received an injection of the gene therapy product, SENS-501.

On February 21, 2025, Sensorion received a positive recommendation from the Data Monitoring Committee of Audiogene, after reviewing the first cohort tolerability and safety data. Sensorion plans on completing the recruitment of the second cohort of patients and on hosting a KOL event to present new data in H1 2025.

### **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 provided GJB2-GT Proof-of-Concept data at the European Society of Cell & Gene Therapy (ESGCT), which took place on October 22-25, 2024, Rome, Italy. Sensorion is advancing the candidate into CTA/IND-enabling activities for anticipated submission in Q1 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 preserve residual hearing following cochlear implantation (Phase 2a completed), and (iii) to prevent 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. SENS-401 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. The Company is conducting strategic business discussions to partner its small molecule, SENS-401.

### **SENS-401 to preserve residual hearing after cochlear implantation**

Sensorion's Phase 2a Proof of Concept clinical trial of SENS-401 in patients scheduled for a cochlear implantation was a multicentric, randomized, controlled open-label trial aimed at evaluating the presence of SENS-401 in the cochlea (perilymph) after 7 days of twice-daily oral administration in adult patients prior to cochlear implantation due to moderately severe to profound hearing impairment. Patients started

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<sup>1</sup> Rodríguez-Ballesteros M, Reynoso R, Olarte M, Villamar M, Morera C, Santarelli R, Arslan E, Medá C, Curet C, Völter C, Sainz-Quevedo M, Castorina P, Ambrosetti U, Berrettini S, Frei K, Tedín S, Smith J, Cruz Tapia M, Cavallé L, Gelvez N, Primignani P, Gómez-Rosas E, Martín M, Moreno-Pelayo MA, Tamayo M, Moreno-Barral J, Moreno F, del Castillo I. A multicenter study on the prevalence and spectrum of mutations in the otoferlin gene (OTOF) in subjects with nonsyndromic hearing impairment and auditory neuropathy. Hum Mutat. 2008 Jun;29(6):823-31. doi: 10.1002/humu.20708. PMID: 18381613.

treatment with SENS-401 7 days before implantation and continued to receive SENS-401 for a further 42 days. This study was developed in collaboration with Cochlear Limited, the global leader in implantable hearing solutions.

On February 1, 2024, Sensorion announced the completion of patient inclusion in the Phase 2a POC clinical trial.

On March 11, 2024, Sensorion announced that the primary endpoint of assessing the presence of SENS-401 in the inner ear perilymph at a level sufficient to elicit a therapeutic benefit was met in 100% of the patients sampled, 7 days after the start of the treatment.

On September 20, 2024, study investigator Professor Stephen O'Leary, M.D., Ph.D., during a symposium organized by Sensorion at the World Congress of Audiology, and Professor Christophe Vincent in a dedicated session on auditory implants for adults, reported analysis of Sensorion's final data of SENS-401. After 7 weeks of treatment with SENS-401 (and 6 weeks after cochlear implantation), the reduction in residual hearing loss was systematically better at the 3 frequencies 250, 500 & 750Hz in the group treated with SENS-401. This protective effect was maintained 8 weeks after cessation of treatment (14 weeks after cochlear implantation). The results show that patients treated with SENS-401 have 'complete' hearing preservation (40% of patients) compared with the control group (0% of patients) according to the Skarzynski index. In addition, the favorable safety profile of SENS-401 has been validated, in line with previous studies on SENS-401.

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

Cisplatin and other platinum-based compounds are essential chemotherapeutic agents in the treatment of many cancers. A serious side effect of these therapies is ototoxicity, permanent and irreversible hearing loss, which occurs in 40 to 60%<sup>2</sup> of adult and pediatric patients treated. This indication represents a significant unmet medical need for patients and constitutes a potential large global market.

The Phase 2a Proof-of-Concept (POC) NOTOXIS trial is a multicenter, randomized, controlled, open-label study, designed to evaluate the efficacy of SENS-401 to prevent ototoxicity induced by cisplatin in adult patients with a neoplastic disease 4 weeks after the completion of cisplatin-based chemotherapy. The trial assesses several outcome measures, including the rate and severity of ototoxicity, the change from baseline in Pure Tone Audiometry (PTA) (dB) throughout the study and the tolerance.

On July 23, 2024, Sensorion announced a positive recommendation from the Data Safety Monitoring Board (DSMB) regarding the continuation of NOTOXIS.

On September 20, 2024, Professor Yann Nguyen reported preliminary safety and efficacy data in Sensorion's NOTOXIS trial, during the World Congress of Audiology. The preliminary data show that a cumulative dose of cisplatin is a key factor of ototoxicity severity. A good safety profile of SENS-401 is 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/m<sup>2</sup>. Despite significant exposure to cisplatin in the treatment group, most participants showed only mild ototoxicity.

On March 7, 2025, the Company announced the end of patient enrollment in NOTOXIS, its Phase 2a POC clinical trial of SENS-401 in Cisplatin-Induced Ototoxicity. Sensorion plans on reporting the topline data by the end of 2025.

### **Strengthening the Board of Directors and senior leadership**

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<sup>2</sup> JCO Oncology practice, ASCO, volume 19, Issue 5/ CIO: a concise review of the burden, prevention and interception strategies, May 2024 Chattaraj.

On January 25, 2024, Sensorion announced the nomination of Dr. Federico Mingozi as board member. Dr. Federico Mingozi has previously worked at Spark Therapeutics, where he served as Chief Science and Technology Officer. Federico brings over 25 years of experience in gene therapy, immunology, as well as biochemistry and molecular biology in academia and industry. He is well known for his significant contributions to the development of gene therapies for the treatment of various diseases. Furthermore, he has played a key role in advancing the understanding of the interactions between gene therapy vectors and the host immune system, as well as in the formulation of strategies to overcome immune responses to anti-AAV vectors.

On June 27, 2024, Sensorion appointed Laurene Danon as Chief Financial Officer. Laurene brings to Sensorion more than 15 years of experience in investment banking and international equity capital markets. A graduate of HEC, she began her career in London with the investment bank J.P. Morgan in a corporate finance advisory capacity, before specializing in equity capital markets at J.P. Morgan and later at Jefferies International. Prior to joining Sensorion, she founded the strategic advisory firm Concorde Advisory, where she supported and managed the execution of strategic corporate finance projects for her clients. In total, Laurene has led executions for 70 transactions totalling over \$35 billion raised.

#### **Expected future milestones and estimated timelines**

- H1 2025 – SENS-501: Enrollment completion of the second cohort of patients in Audiogene trial and KOL event to present new data
- H2 2025 – SENS-401 in Cisplatin-Induced Ototoxicity: Topline results
- Q1 2026 – GJB2-GT: Clinical Trial Applications filing

#### **Full Year 2024 financial highlights**

- **Cash Position**

Cash & Cash Equivalents, and short-term deposits, amounted to c. €77m as of December 31, 2024, compared to €37.0m as of December 31, 2023.

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

R&D expenses increased by 13 % from €22.8 million in 2023 to €25.7 million in 2024.

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

G&A expenses were €9.4 million for 2024, compared to €5.3 million for 2023.

- **Net Loss**

Net loss was -€26.0million for 2024, compared to -€22.1 million for 2023.

- **Financial guidance**

Based on cash and cash equivalents and short-term deposit classified in other current assets of €77.0 million at 31 December 204, the Company has sufficient net working capital to meet its cash requirements until the end of Q1 2026.

#### **Financial results**

The annual accounts as at December 31, 2024, were prepared according to IFRS standards and approved by the Board of Directors on March 13, 2025.

The simplified income statement as of December 31, 2024, is as follows:

<i>In thousands of Euros – IFRS standards</i>	<b>31.12.2024</b>	<b>31.12.2023</b>
<b>Operating income</b>	<b>6,653</b>	<b>5,698</b>
Research & Development expenses	-25,664	-22,755
General & Administrative expenses	-9,390	-5,253
<b>Total operating expenses</b>	<b>-35,054</b>	<b>-28,009</b>
<b>Operating loss</b>	<b>-28,401</b>	<b>-22,310</b>
Financial result	2,555	544
Corporate Income Tax	-126	-297
<b>Net loss</b>	<b>-25,972</b>	<b>-22,063</b>

The simplified balance sheet as of December 31, 2024, is as follows:

<i>In thousands of Euros – IFRS standards</i>	<b>31.12.2024</b>	<b>31.12.2023</b>
<b>Non-current Assets</b>	<b>3,574</b>	<b>3,236</b>
Other Current Assets	18,934	6,292
<i>Of which short term deposit</i>	<i>10 214</i>	
Cash & cash equivalent	66,769	36,974
<b>Total Assets</b>	<b>89,277</b>	<b>46,502</b>
<b>Equity</b>	<b>72,138</b>	<b>33,275</b>
Non-current Liabilities	3,486	3,646
Current Liabilities	13,653	9,581
<b>Total Liabilities</b>	<b>89,277</b>	<b>46,502</b>

## 2024 certified accounts

On March 13, 2025, the Board of Directors approved the Company's full year results as of December 31, 2024. 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 2024 have been subject to a limited review 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. 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.

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