Press release

Sensorion Reports 2026 Half-Year Results, Provides Corporate Update and Announces Availability of Half-Year Report

2026-09-23

- **Clinical Trial Applications (CTAs) for SENS-601 (GJB2-GT), the Company's lead gene therapy program for GJB2-related hearing loss were filed in France and Canada, with Fast Track procedure granted in France; the Company subsequently received authorization from the French National Agency for Medicines and Health Products Safety (ANSM) to initiate the Phase I/II HearConnex clinical trial in France**
- **Investigational New Drug (IND) application in the United States and CTA in Australia expected to be submitted by year-end 2026**
- **Dosing of the first patient in HearConnex targeted by early 2027**
- **Cash, cash equivalents and short-term deposits classified in current assets amounted to €88 million as of June 30, 2026, expected to finance the Company until the end of 2027**

MONTPELLIER, France & CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Regulatory News:

Sensorion (FR001401A9Z0 – ALSEN) ("the Company") a pioneering clinical-stage biotechnology company focused on developing novel therapies to restore hearing and treat and prevent hearing loss disorders, today reported its half-year 2026 results, provided a corporate update and announced the availability of its half-year report.

"I am delighted to have joined Sensorion at such an exciting time, as SENS-601 enters the clinic" **commented Fred Chereau, Sensorion's Chief Executive Officer.**

"Having filed Clinical Trial Applications in France and Canada, with the ANSM granting Fast Track procedure for assessment of the French CTA, we subsequently received authorization from the ANSM to initiate our Phase I/II HearConnex trial in France. We are backed by high-quality investors, including Sanofi, and remain well-funded to advance the clinical development of SENS-601. We look forward to reporting further progress toward our next

milestones, including dosing the first patient in HearConnex by early 2027 and the IND submission in the United States and CTA filing in Australia, both planned by year-end 2026."

Pipeline Highlights and Upcoming Milestones

Gene Therapies for Hereditary Monogenic Hearing Loss

In the first half of 2026, Sensorion advanced SENS-601, its lead gene therapy program developed in collaboration with the Institut Pasteur, Hearing Institute / Institut reConnect, filing CTAs in France and Canada with Fast Track procedure in France. In August 2026, the Company received authorization from the ANSM to initiate its Phase I/II clinical trial, HearConnex, in France. In June 2026, Sensorion also decided to discontinue further clinical development of SENS-501, its gene therapy program for otoferlin-mediated hearing loss, in order to concentrate resources on SENS-601.

SENS-601 (GJB2-GT): Gene therapy program to restore hearing in patients with GJB2-related hearing loss

SENS-601 is Sensorion's single-vector AAV-based gene therapy candidate designed to restore hearing in patients with hearing loss related to mutations in the GJB2 gene, one of the most common genetic causes of congenital sensorineural hearing loss, accounting for approximately a quarter of autosomal recessive non-syndromic hearing loss cases according to peer-reviewed published studies. SENS-601 is designed to address three non-syndromic forms of GJB2-related hearing loss: pediatric congenital deafness, childhood-onset progressive hearing loss, and early-onset age-related presbycusis in adults, with Sensorion's initial development focus on pediatric congenital deafness.

In June 2026, Sensorion filed CTAs for SENS-601 in France, where the ANSM granted Fast Track procedure for assessment of the CTA, and in Canada. In August 2026, the Company received authorization from the ANSM to initiate its Phase I/II clinical trial, HearConnex, in France. Dosing of the first patient in HearConnex is expected by early 2027. The Company also expects to submit an IND application in the United States and a CTA in Australia by year-end 2026. SENS-601 is designed to be administered via a single intracochlear injection using Sensorion's internally developed injection system, which has already been evaluated in the Company's SENS-501 clinical program.

HearConnex is designed as a two-part, open-label study. Part 1 will assess the safety and tolerability of SENS-601, following unilateral intra-cochlear injection across two ascending-dose cohorts. Part 2 will assess the efficacy of SENS-601 in an expansion cohort following bilateral intra-cochlear injection at the optimal dose. HearConnex will also assess the safety, tolerability, performance and usability of Sensorion's injection system. HearConnex is designed as a multicenter trial, and its Coordinating Investigator is Dr. Sharon Cushing, Pediatric Otolaryngologist

and Director of the Cochlear Implant Program at The Hospital for Sick Children (SickKids) in Toronto. Dr. Cushing will also serve as Principal Investigator for the Canadian site, subject to completion of the ongoing review.

In April 2026, the Company entered into a support agreement with Bpifrance for the GJB2-GT program, as part of the 'France 2030' investment plan (ConnexGene project). The financing covers the period from January 1, 2026 to January 1, 2030 and aid is granted in the form of a repayable advance. Payments are staggered as one initial advance and four milestone-based instalments for an aggregate amount of up to €10.3 million, subject to the satisfaction of the applicable conditions precedent. In May 2026, the Company received the initial advance of €2.6 million.

OTOCONEX, the Company's ongoing Natural History Study, documents the natural course of disease progression in patients with GJB2-related hearing loss and supports patient identification and enrollment for HearConnex.

SENS-501 (OTOF-GT): Program discontinued

On June 10, 2026, Sensorion announced its decision to discontinue further clinical development of SENS-501 (OTOF-GT), its gene therapy program for otoferlin-mediated hearing loss, in light of the evolving competitive landscape in this ultra-rare indication, in order to focus its resources on SENS-601. In its Phase I/II Audiogene clinical trial, SENS-501 had shown a satisfactory safety profile, with no serious adverse events across the six infants and toddlers treated. The Company believes that the learnings from SENS-501's clinical experience can be leveraged as it advances SENS-601 into clinical development.

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

SENS-401 (Arazasetron) is an orally available small molecule that Sensorion has evaluated in three indications, for which proof-of-concept clinical studies have now been completed: (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 completed). 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 the pediatric population. Sensorion's development resources are focused on SENS-601, and the Company is exploring partnering opportunities for SENS-401.

Change in Management and the Board of Directors

On February 17, 2026, Sensorion announced that Nawal Ouzren stepped down from her roles as Chief Executive Officer and as a Director of the Company. Amit Munshi, Chairman of the Board since April 2025, assumed the role of Interim Chief Executive Officer from February 2026 to May 2026.

On May 18, 2026, the Company announced the appointment of Fred Chereau as Chief Executive Officer, effective June 1, 2026. Mr. Chereau brings over 30 years of biotech leadership experience, most recently as Senior Vice President, Strategy and Business Development at Alexion AstraZeneca Rare Disease, following his tenure as President and Chief Executive Officer of LogicBio Therapeutics, Inc. Mr. Munshi continues to serve as Chairman of the Board of Directors.

Post-Period Highlights

On July 29, 2026, the Company announced a reverse share split of its ordinary shares, exchanging every 50 existing shares with a nominal value of €0.10 each for one new share with a nominal value of €5.00 each. The reverse share split became effective on September 15, 2026, resulting in 10,312,972 ordinary shares with a nominal value of €5.00 each following the cancellation of the four treasury shares excluded from the reverse share split and had no material impact on the total value of shares held by each shareholder. Following the reverse share split, the Company's shares trade under a new ISIN code, FR001401A9Z0.

On September 3, 2026, the Company announced that it had received authorization from the ANSM to initiate HearConnex, its Phase I/II clinical trial of SENS-601 in France. On September 22, 2026, Sensorion hosted its first SENS-601 Program Day, an online scientific event featuring Prof. Christine Petit (Institut reConnect, Institut de l'Audition, Institut Pasteur, Inserm, CNRS) and Dr. Sharon Cushing (The Hospital for Sick Children, Toronto), alongside members of the Company's management team.

Subsequent to the reporting date, the Company informed its workers council of a proposed organizational restructuring to align resources with its focus on SENS-601. Consultation is ongoing, no formal plan has been approved, and the Company cannot yet estimate any financial impact.

Expected future milestones and estimated timelines:

- **By year-end 2026**: SENS-601 IND application submission in the United States
- **By year-end 2026**: SENS-601 CTA submission in Australia
- **By early 2027**: SENS-601 dosing of the first patient in HearConnex

First-Half 2026 Financial Highlights

- **Cash Position**

Cash, cash equivalents, and short-term deposits classified in current assets, amounted to €88 million as of June 30, 2026, compared to €47.5 million as of December 31, 2025

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

R&D expenses increased by 9% from €15.0 million in the first half of 2025 to €16.4 million in the first half of 2026, mainly reflecting the increase in gene therapies expenses

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

G&A expenses were €7.7 million for the first half of 2026, compared to €4.1 million for the first half of 2025, an increase primarily reflecting the impact of changes in the management team during the period.

- **Net Loss**

Net loss was €20.7 million for the first half of 2026, compared to €16.0 million for the first half of 2025.

- **Financial guidance**

Based on its cash and cash equivalents and short-term deposits classified in current assets as of June 30, 2026, the Company believes that it is in a position to finance its activities until the end of 2027.

Financial Results

The condensed half-year financial statements as of June 30, 2026, were prepared according to IFRS standards and approved by the Board of Directors on September 22, 2026.

The simplified income statement as of June 30, 2026, is as follows:

In thousands of Euros – IFRS standards	**30.06.2026**	**30.06.2025**
Operating income	**2,668**	**2,327**
Research & Development expenses	-16,400	-15,001
General & Administrative expenses	-7,690	-4,138
Total operating expenses	**-24,090**	**-19,139**
Operating loss	**-21,422**	**-16,812**
Financial result	720	804
Pre-tax current income	**-20,702**	**-16,008**
Corporate Income Tax	-2	-
Net loss	**-20,705**	**-16,008**

The simplified balance sheet as of June 30, 2026, is as follows:

In thousands of Euros – IFRS standards	**30.06.2026**	**31.12.2025**

Non-current Assets	**3,365**	**2,997**
Current assets	54,271	7,433
Cash & cash equivalent	43,133	47,457
Total Current Assets	**97,404**	**54,890**
Total Assets	**100,769**	**57,887**
Equity	**81,565**	**44,479**
Non-current Liabilities	7,036	1,441
Current Liabilities	12,169	11,966
Total Liabilities and Equity	**100,769**	**57,887**

First-Half 2026 Financial Statements

On September 22, 2026, the Board of Directors approved the Company's condensed half-year financial statements as of June 30, 2026. 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 for 2026 have been subject to a limited review by the Company's statutory auditors, and an unqualified report has been issued.

About SENS-601 (GJB2-GT)

SENS-601 (GJB2-GT) is an innovative investigational AAV-based gene therapy program developed in collaboration with Prof. Christine Petit''s team (Institut reConnect, Institut de l''Audition, Institut Pasteur, Inserm, CNRS) to treat hearing loss linked to mutations in the GJB2 gene, which plays a critical role in maintaining the ionic balance necessary for sound transduction in the inner ear. GJB2 mutations represent the most common cause of genetic congenital deafness, responsible for approximately 50% of autosomal recessive non-syndromic hearing loss. Recent research has also established that GJB2 mutations are found in early onset forms of severe presbycusis in adults, which appear to be monogenic and potentially treatable by gene therapy. SENS-601 is expected to enter clinical evaluation in the Phase I/II HearConnex trial currently being evaluated in children with congenital DFNB1A hearing loss by early 2027. With no approved gene therapies currently available for GJB2-related hearing loss, SENS-601 may have the potential to be among the first gene therapy programs addressing GJB2 mutations, if approved. This program is partially funded by the French State as part of the France 2030 investment plan (ConnexGene project, with Bpifrance).

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore hearing, and 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.

SENS-601 (GJB2-GT) is the Company's lead gene therapy program, targeting hearing loss related to mutations in the GJB2 gene to address important hearing loss segments in adults and children developed in the framework of its broad strategic collaboration focused on the genetics of hearing with the Institut Pasteur.

Sensorion's pipeline also consists of a clinical-stage small molecule program, SENS-401 (Arazasetron), for the treatment and prevention of hearing loss disorders. Sensorion's small molecule progressed in three Phase II proof of concept clinical studies: firstly, in Cisplatin-Induced Ototoxicity (CIO) for the preservation of residual hearing, with analysis 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 II study of SENS-401 was also completed in Sudden Sensorineural Hearing Loss (SSNHL) in 2022. **www.sensorion.com**

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 in the 2026 half-year report published on September 23, 2026, both 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.

Investor Relations
Sensorion
Nicolas Bogler, Investor Relations and Communication
ir.contact@sensorion-pharma.com

Press Relations
Maarc Communication
Bruno Arabian / 00 33(0)6 87 88 47 26
bruno.arabian@maarc.fr

Label: **SENSORION**

ISIN: **FR001401A9Z0**

Mnemonic: **ALSEN**

Source: Sensorion