Press release

Sensorion Full-Year 2021 financial results and business highlights

- ***Accelerating development of the OTOF-GT and GJB2-GT gene therapy programs in collaboration with Institut Pasteur***
- ***Advancing SENS-401 joint clinical development program with Cochlear Ltd. for hearing preservation in patients scheduled for cochlear implantation with first patient enrollment expected by mid-2022***
- ***Sensorion will continue the proof-of-concept clinical study for Cisplatin-Induced Ototoxicity following a thorough analysis of the secondary endpoints of the AUDIBLE-S SENS-401 study***
- ***In line with a disciplined capital allocation approach, Sensorion will explore partnering opportunities for SENS-401 in SSNHL***
- ***Cash position of €50 million at year-end provides extended cash runway until end of Q2 2023***

Montpellier, April 28, 2022 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing disorders, announces today its full-year 2021 financial results and provides an update on its business activities and outlook for 2022.

"In 2021, Sensorion made progress across its gene therapy and small molecule programs aimed at treating hearing loss disorders," **said Nawal Ouzren, CEO of Sensorion**. "We made good progress with our gene therapy programs, notably OTOF-GT for the treatment of pediatric deafness due to otoferlin deficiency and GJB2-GT for the treatment of GJB2-driven deafness in collaboration with Institut Pasteur. In parallel, we have been expanding our gene therapy CMC platform by strengthening our development lab capabilities and reinforcing our in-house expertise.

"In our small molecule portfolio, we are advancing our existing partnership with Cochlear Limited with a clinical trial of our drug candidate SENS-401 for hearing preservation in patients scheduled for cochlear implantation. We see a compelling unmet medical need and a potential clinical development pathway for SENS-401 in Cisplatin-Induced Ototoxicity and will conduct our proof-of-concept clinical study, with a view to exploring partnership opportunities.

"During the year, we also further strengthened our Board of Directors with the appointments of Scott D. Myers as Chairman, and Dr. Aniz Girach as Independent Board Member. Both have decades of relevant, world-class scientific, medical and governance experience, and have already provided important support and guidance to Sensorion*."*

Key developments in 2021: science and operational

Gene therapy programs

- **OTOF-GT**

Sensorion received scientific advice from regulatory agencies on the preclinical and clinical development plans for OTOF-GT, the Company's dual vector AAV gene therapy program for the treatment of children born with hearing loss caused by Otoferlin deficiency.

The European Medicines Agency's advisors welcomed the ongoing Natural History Study, Audioferline (NCT04202185), a component of the AUDINNOVE project coordinated by researchers at Hôpital Necker-Enfants malades (Necker Hospital) in partnership with Sensorion. Sensorion is expanding the study across Europe to document the natural course of disease progression in otoferlin deficiency patients, define clinically meaningful endpoints suitable for market approval, and identify the patient populations that would benefit the most from Sensorion's OTOF-GT treatment. The Natural History Study will enable Sensorion to select the most relevant and clinically meaningful endpoints and clinical trial design as OTOF-GT progresses into the clinic.

At the Association for Research in Otolaryngology (ARO) 45th MidWinter Meeting in February 2022, Sensorion presented a poster on OTOF gene therapy. The data indicated potential for safe and efficient clinical translation of gene therapy for Otoferlin delivered by a dual AAV vector. The chosen capsid of AAV-OTOF in both mouse and non-human primate (NHP) models targets Inner Hair Cells (IHCs) and not Outer Hair Cells. Otof *de novo* expression in IHCs in a DFNB9 mouse model (OTOF-KO) demonstrates long-term expression of Otoferlin and hearing restoration up to one year post injection. In NHPs, the surgical procedure similar to cochlear implantation has been optimized to achieve an effective transduction rate of the targeted IHCs at levels compatible with therapeutic intervention in humans.

Sensorion goal is to start producing toxicological batches for OTOF-GT at intended clinical-scale volumes by mid-2022. The company is on track to file a Clinical Trial Application (CTA) for its OTOF-GT program in H1 2023.

- **GJB2-GT**

On February 15, 2021, Sensorion announced its largest gene therapy program to date, a collaboration with Institut Pasteur, targeting the *GJB2* gene in pediatric and adult deafness. Research by Institut Pasteur demonstrated that anomalies in *GJB2* are both the most common cause of congenital deafness as well as a wide contributor of severe age-related hearing loss in adults. Although the types of *GJB2* mutation in children and adults may differ, gene therapy could potentially provide solutions for both.

Sensorion's *GJB2* gene therapy programs have the potential to address three pathologies related to *GJB2* mutations: early onset of presbycusis in adults, progressive forms of hearing loss in children, and pediatric congenital deafness. Sensorion plans to select a candidate by mid-2022.

- **SONOVA**

In September 2021, Sensorion announced the signing of an important multi-year collaboration with Sonova, a leading international player in the hearing solutions market. The collaboration aims to create new diagnostic and therapeutic solutions for hearing loss and expands a commitment made between the two companies in December 2020, when Sonova acquired a 3.7% stake in Sensorion.

Part of the collaboration is a jointly funded study of natural history in age-related progressive hearing loss (presbycusis) in adults. It will involve the collection of disease information and samples via selected Sonova Audiological Care stores. The collaboration could lead to the introduction of genetic analysis to the routine diagnosis of progressive hearing loss in adults and subsequently open the way for improved care through a combination of advanced therapeutic interventions and traditional hearing solutions including hearing aids. Sonova and Sensorion will jointly fund the study with €7.0 million, split 70/30%, respectively, between the two companies.

- **USHER-T1-GT**

During 2021, Sensorion completed the preclinical proof-of-concept study for its gene therapy approach in Usher's syndrome type 1G (USHER-GT). This study was designed to test whether a gene therapy approach would be effective in older mice, thereby opening the possibility of extended treatment windows for clinical studies.

The results of the completed study show that there is a full restoration of the vestibular function, but that audition cannot be restored at a satisfactory level. In line with a focused approach to capital allocation, Sensorion has decided to terminate this program. The Master Research Agreement provides us the possibility to explore other opportunities with Institut Pasteur.

SENS-401

- **SENS-401 Cochlear**

At the beginning of 2021, Sensorion released positive preclinical data demonstrating that the combination of its SENS-401 molecule and a cochlear implantation helped reduce loss of residual hearing at a frequency located beyond the electrode array. Preservation of 'natural' hearing is particularly important in speech recognition.

Following this initial success, Sensorion and its partner Cochlear Limited (Cochlear) announced the initiation of a POC (Proof of Concept) clinical trial of SENS-401 (Arazasetron) in patients scheduled for cochlear implantation. The two companies are progressing with a trial of SENS-401 for hearing preservation in targeted patients. Sensorion already submitted the proposed trial design to regulatory authorities in Australia and France. The approval is anticipated in H1 2022 and the first patient enrolment is expected by mid-2022.

- **SENS-401 SSNHL**

On January 17, 2022, Sensorion provided an update on SENS-401 and released the topline data of the Phase 2 AUDIBLE-S study in Sudden Sensorineural Hearing Loss (SSNHL). SENS-401 was safe and well tolerated in the 115-patient study, however, the primary endpoint was not met.

In March 2022, a supplementary analysis of the Phase 2 AUDIBLE-S study data showed positive findings for certain trial population sub-groups within SSNHL. SENS-401 demonstrated a statistically significant effect with the high dose on pure tone audiometry (PTA) with a 10 decibels improvement vs placebo in Phase 2 AUDIBLE-S trial in SSNHL at Day 84 in per protocol idiopathic population (81 patients) treated with corticosteroids – (c. 70% of the Intent to Treat population).

In particular, it was observed that patients entering the study with profound hearing loss emerged post-treatment with mild hearing loss, meaning that they did not have difficulty hearing what is being said in quiet environments. SENS-401 induces a significative PTA change of at least 19 dB at day 28 and up to 25 dB at Day 84 allowing a reduction of the hearing loss degree from profound to mild hearing loss. A better response was observed in both treatment groups with a continuous improvement compared to control group.

However, in line with a disciplined approach to capital allocation, Sensorion has decided to explore partnership opportunities with this program and to prioritize the development of the CIO Proof-of-Concept clinical study.

- **SENS-401 Cisplatin Induced Ototoxicity (CIO)**

In a preclinical model of cisplatin-induced ototoxicity (CIO) (Petremann et al., 2017), SENS-401 demonstrated an ability to significantly reduce hearing loss. Following a supplementary analysis of the AUDIBLE-S study, Sensorion has decided to continue the POC clinical study in CIO indication as it represents a significant unmet need for patients and a very attractive market for treatment with over 500,000 patients in 2025 in G7 countries.

We filed for approval of the NOTOXIS clinical trial (CTA) at the end of 2021 and received approval earlier this year. The scientific and clinical teams have reviewed the clinical design of NOTOXIS following the AUDIBLE-S study of SENS-401. An amendment will be filed to strengthen this design based on the results obtained. Approval of this amendment is expected by H2 2022.

Expansion of technology platform

Sensorion has built a unique R&D technology platform over the years to deepen our understanding of the pathophysiology and etiology of inner ear-related diseases. The platform is being actively deployed to select targets, identify biomarkers and to optimize small molecules and gene therapy candidates.

To further strengthen its technology base, Sensorion is expanding its CMC gene therapy platform by building state of the art process development labs. Alongside Sensorion reinforced its CMC team by onboarding highly skilled Upstream (USP) and Downstream (DSP) Processing experts. Small scale bioreactors have been operating since the end of 2021 and Sensorion looks forward to the next expansion of capabilities.

Strengthening the Board of Directors

On December 20, 2021, Sensorion's Board of Directors was strengthened with the appointment of Scott D. Myers as Chairman of the Board of Directors and Independent Director. Scott D. Myers has 30 years of executive experience as both CEO and Chairman of numerous life science companies, including AMAG Pharmaceuticals, where he led its turnaround and strategic sale to Covis Pharma in November 2020. Scott succeeded Edwin Moses, who stepped down as Chairman in December 2021 to focus on his portfolio of other commitments.

On January 4, 2022, Sensorion appointed Dr. Aniz Girach as Independent Board Member. He brings over 22 years' experience in the industry. He is currently serving as Chief Medical Officer at ProQR Therapeutics NV, where he is leading the development of genetic therapies for inherited retinal diseases.

2022 Outlook

As of December 31, 2021, the Company had €50 million in cash. Sensorion intends to use these funds primarily to advance its current gene therapy programs (OTOF-GT, GJB2-GT), to progress its clinical program for SENS-401 in cochlear implantation and the CIO POC clinical study, and for general corporate purposes

In collaboration with the Hearing Institute (Institut de l'Audition), a center of Institut Pasteur, Sensorion is on track to select a gene therapy candidate to treat hearing loss due to damage to connexin 26 encoded by the *GJB2* gene by mid-year 2022 and intends to file a Clinical Trial Application (CTA) for OTOF-GT in H1 2023. In H1 2022, the Company expects to receive approval for the proposed trial design for SENS-401 in patients scheduled for cochlear implantation from regulatory authorities in Australia and France. In H2 2022, CTA for SENS-401 in CIO will be submitted.

Expected future milestones and estimated timelines:

- H1 2022 – CTA approval for SENS-401 study to preserve residual hearing post cochlear implantation
- Mid-2022 – First patient enrolled for SENS-401 study to preserve residual hearing post cochlear implementation
- Mid-2022 – GJB2-GT Candidate selection
- Mid-2022 – Delivery of toxicological batches for OTOF-GT
- H2 2022 – SENS-401 CIO (Cisplatin-Induced Ototoxicity) CTA study amendment submission
- H1 2023 – Submission of the Clinical Trial Application for the OTOF-GT program (CTA/IND)

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2021 financial results

The annual accounts at 31 December 2021, drawn up according to IFRS standards and approved by the Board of Directors on April 27, 2022, have been duly reviewed by statutory auditors.

The simplified income statement as of 31 December 2021 is as follows:

In Euros – IFRS standards	**31.12.2021**	**31.12.2020**
Operating income	**4.348.647**	**2.421.267**
Research & Development expenses	-14.623.652	-7.679.365
General & Administrative expenses	-4.749.593	-3.631.123
Total operating expenses	**-19.373.245**	**-11.310.488**
Operating profit/loss	**-15,024,597**	**-8,889,220**
Financial result	-112.192	-88.869
Net profit/loss	**-15.136.789**	**-8.978.089**

For the year ended 31st December 2021, Sensorion reported **operating income** of €4.3 million, which included €3.0 million in research tax credit, €1.1 million in grants from Audinnove (RHU) and Patriot (PSPC) collaborations and €0.25 million for the collaboration with Sonova.

Operating expenses increased by 71% from €11.3 million in 2020 to €19.4 million for fiscal year 2021.

R&D expenses increased by 90% from €7.7 million in 2020 to €14.6m in 2021. The increase was mainly driven by an expansion of preclinical and clinical studies related to SENS-401, the start of GT activities, as well as an increase of R&D headcount.

G&A expenses are up 30% from €3.6m in 2020 to €4.7 million in 2021, due mostly to an increase in consulting fees and headcount in order to support the growth of R&D activities.

Operating loss at 31 December 2021 was -€15.0 million compared with -€8.9 million at 31 December 2020.

The net financial loss increased by €0.02 million compared to 2020, mainly due to interests on our financial loans.

Net loss was -€15.1 million at 31 December 2021 compared with -€9.0 million at 31 December 2020.

As of 31 December 2021, the company employed 39 people.

Financial structure

The simplified balance sheet at 31 December 2021 is as follows:

In Euros – IFRS standards	**31.12.2021**	**31.12.2020**
Non-current Assets	**2.142.885**	**1.474.117**
Other Current Assets	6.946.055	4.254.909
Cash & cash equivalent	50.001.110	62.174.948
Total Assets	**59.090.050**	**67.903.976**
Equity	**44.055.803**	**58.379.653**
Non-current Liabilities	4.504.691	5.246.408
Current Liabilities	10.529.556	4.277.915
Total Liabilities	**59.090.550**	**67.903.976**

Other current assets increased by €2.7 million mainly due to the increase of research tax credit expected for 2021 which amounts €3.0 million.

Cash and cash equivalents amounted to €50.0 million at 31 December 2021 compared to €62.2 million at December 31, 2020.

Based on its cash position and its forecasted expenses, the Company believes it will be able to fund its operations into the end of second quarter of 2023.

Total equity amounted to €44.1 million as of 31 December 2021 compared to €58.4 million at 31 December 2020; this decrease of -€14.3 million is mainly related to the net loss of -€15.1 million for the period.

Current liabilities increased by €6.3 million mainly explained by an increase in R&D expenses and in deferred income related to the collaboration with Sonova.

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 modalities for drug candidates. Its portfolio combines both small molecule programs and a preclinical portfolio of inner ear gene therapies.
Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) progressing in a planned Phase 2 Proof of Concept study of SENS-401 clinical study in cisplatin-induced ototoxicity (CIO) and, with partner Cochlear Limited, a study of SENS-401 in patients scheduled for cochlear implantation.
Sensorion has entered into a broad strategic collaboration with Institut Pasteur focused on the genetics of hearing. It has two gene therapy programs aimed at correcting hereditary monogenic forms of deafness including deafness caused by a mutation of the gene encoding for Otoferlin, and related deafness and hearing loss related to mutation 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.
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