

Our mission: Find solutions for hearing disorders

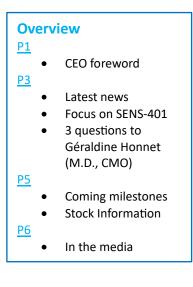
# LETTER TO SHAREHOLDERS March 2024

### **CEO foreword**

Dear Shareholders,

The start of 2024 and the last few months have been particularly exciting for our Company, thanks to a number of positive developments that have enabled us to accelerate our roadmap.

First of all, our recent fund-raising of  $\in$ 50.5 million, completed a few weeks ago, has enabled us to extend our cash horizon to the end of the 2nd quarter of 2025. This excellent financial operation comes just a few months after the refinancing of  $\in$ 35 million carried out last August. These funds will give us financial visibility for the next major milestones on our roadmap, namely the recruitment of the first two cohorts of patients in the SENS-501 (OTOF-GT) clinical trial, preparatory activities required for the application for clinical trial authorization for our second gene therapy program, GJB2-GT, and the finalization of studies on our small molecule SENS-401.



Furthermore, this capital increase was carried out at a small discount in order to preserve our longstanding shareholders. Finally, it has enabled us to strengthen our shareholder base. Alongside Sofinnova, Invus and Redmile supporting this new fundraising, Sensorion can rely, more than ever, on an international shareholder base, by welcoming new investors, including Aquilo Capital, an American investor and two other major management companies with expertise in life sciences and a long-term investment strategy.

On January 19, 2024 we received the green light from the competent authorities to start the Audiogene clinical trial, a Phase 1/2 trial designed to evaluate SENS-501 (OTOF-GT) in Europe. This drug candidate, which targets hearing loss due to otoferlin deficiency, is the most advanced asset in our pioneering gene therapy platform. Inclusion of the first patients will soon begin in the study's partner hospitals. In the field of hearing restoration in particular, gene therapy represents a breakthrough innovation and a tangible hope of cure for thousands of patients affected by various forms of genetic deafness for which there are currently no approved curative therapies. For the past five years, we have been building on the excellence of the Institut Pasteur, and in particular that of the Hearing Institute teams led by Professor Christine Petit, under an exclusive framework agreement.

This partnership, which we have just renewed for a further five years, provides us with a scientific leadership, that we convert every day into clinical development leadership. Today, we are one of a handful of biotech companies to have made the greatest strides in this emerging field of medical research, and we are the last independent company in this leading group.

Last but not least, on March 11, we announced that we met the primary endpoint with our historical asset, SENS-401, in a Phase 2 study for residual hearing preservation, conducted in partnership with the industrial group Cochlear Limited, the world leader in implantable hearing solutions. These results demonstrated the relevance of the therapeutic strategy adopted with this small molecule, whose potential is considerable.

As a result, we have gained in stability and strength in recent months, enabling us to successfully implement our roadmap and meet our commitments to our academic and industrial partners, our investors and the patients.

It is important for us today to share with you our optimism and our priorities for the months ahead. By the way, strengthening the dialogue with our investors is one of our key priorities!

I would like to thank each and every one of you for the trust you have placed in us and the loyalty you have demonstrated toward our corporate project. I hope you enjoy reading this Letter to Shareholders.

Kind regards,

Nawal Ouzren CEO of Sensorion



# LATEST NEWS / SIGNIFICANT PROGRESS SINCE SUMMER 2023

- July 19, 2023: Submission of applications for clinical trial authorization for SENS-501 (OTOF-GT) in France, Italy and Germany, following the filing with the competent UK authorities on 10 July. SENS-501 is a gene therapy program, developed with the Institut Pasteur, targeting hearing loss caused by a genetic otoferlin deficiency. Deficiency of this protein is responsible for 8% of all cases of congenital hearing loss, or around 20,000 people in Europe and the United States.
- August 3, 2023: Sensorion completes a €35 million private placement led by Redmile, an American investor specialized in healthcare, with the support of Sensorion's historical institutional shareholders, Invus and Sofinnova Partners.
- December 18, 2023: Sensorion published new data from the Phase 2a clinical trial evaluating SENS-401 in Cisplatin-Induced Ototoxicity. These data confirm the product's good safety profile and the good progress of patient recruitment in this trial.
- January 5, 2024: Sensorion announces the five-year renewal of its partnership with the Institut Pasteur, initiated in 2019 and focusing on gene therapy programs targeting hearing disorders.
- January 19, 2024: Approval for the launch of the Audiogene clinical trial, aimed at evaluating SENS-501 (OTOF-GT) in hearing loss caused by genetic otoferlin deficiency. The Audiogene trial is run by the Audinnove consortium, which brings together the Fondation Pour l'Audition, the Hearing Institute (research center of the Institut Pasteur) and the Pediatric Audiology Research Center at Necker Hospital.
- January 25, 2024: Sensorion announces the appointment by co-option of Dr Federico Mingozzi as a new member of Sensorion's Board of Directors.
- February 9, 2024: Sensorion announces a €50.5 million financing round with the participation of leading new and existing European and US healthcare investors.
- March 11, 2024 : Sensorion Announces it Has Met Primary Endpoint for SENS-401 Phase 2a Clinical Study for Residual Hearing Preservation

## FOCUS SENS-401: 3 QUESTIONS TO GERALDINE HONNET, M.D., CMO AT SENSORION



SENS-401 is a small molecule designed to treat or prevent damage to the inner ear, the cause of hearing loss. It acts by blocking the chemical mechanisms that cause the degeneration and death of hair cells in the inner ear.

SENS-401 is currently being evaluated for a number of indications, but its development is most advanced today in the preservation of residual hearing after cochlear implantation. A Phase 2a clinical trial, conducted in partnership with the Australian industrial group Cochlear Limited, world leader in cochlear implants, has produced promising initial results, which were published

# Why did you initiate development in the indication of residual hearing preservation after cochlear implantation?

The decision to implant a cochlear implant in a hearing-impaired person opens up the hope of restoring the ability to hear and communicate. Cochlear implants have amply demonstrated their effectiveness and positive impact on people's quality of life. They are currently prescribed for 80% of eligible children in developed countries.

However, the surgical act of implantation can damage the residual hearing capacity of people who are not totally deaf before the implantation. However, it has been shown that the more these residual hearing capacities are preserved, the easier the post-implant rehabilitation that enables implanted patients to acquire hearing and language skills. There is therefore a very strong medical rationale for protecting these patients' hearing.

#### What can we learn from the clinical results unveiled on July 5?

The preliminary data we have generated show that patients treated with SENS-401 lost an average of just 12 decibels of hearing capacity following the operation, compared with 33 decibels for patients in the placebo arm, not treated with SENS-401, at the end of the treatment period. This represents a statistically significant difference of 21 decibels between the two arms. We look forward to the final results of this study in Q3 2024.

#### SENS-401 is also in development against Cisplatin-Induced Ototoxicity. What's at stake in this indication?

*Cisplatin, a component of many anti-cancer chemotherapies, is toxic to hair cells. In more than half of patients exposed to it, it causes hearing loss, which can be significant. In this indication, we are evaluating in adults the extent to which SENS-401 can protect these hair cells from the damage caused by cisplatin, and ultimately preserve patients' hearing.* 



# **2024 MILESTONES**

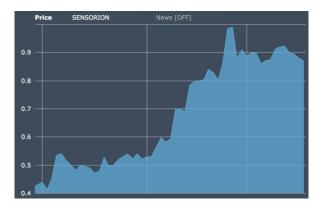
- Preliminary safety and efficacy are expected for the ongoing clinical trial of SENS-401, in the prevention of Cisplatin-Induced Ototoxicity : September 2024
- Communication on first patient in the Audiogene Phase 1/2 clinical trial of SENS-501 (OTOF-GT) for the treatment of hearing loss caused by otoferlin deficiency: 2<sup>nd</sup> half of 2024.
- Final data readout is expected in Q3 2024 for the trial of SENS-401 in the prevention of residual hearing loss following cochlear implantation : 3rd quarter of 2024

#### **STOCK INFORMATION**

Mnemonique: ALSEN Market: Euronext Growth ISIN: FR0012596468 Nb of Shares Outstanding: 275.675.531

#### Key figures (as of December 30 2023)

R&D expenses: 22,8M€ G&A expenses: 5,3M€ Net Loss: 12,3M€ Cash Position: 37M€



Share price performance over 12 months (to 03/20/2024)

#### **SENSORION IN THE PRESS**



Surdité : le test sur des bébés sourds de la thérapie génique de Sensorion démarre

Surdité chez l'enfant: la thérapie génique, un nouvel espoir





Gene Therapy Allows an 11-Year-Old Boy to Hear for the First Time « Another study by Sensorion is expected to start this month. »

« In France, meanwhile, a company called Sensorion recently <u>received a green light from regulators</u> to proceed with an otoferlin gene therapy it's developing. »



Lilly gene therapy finding puts focus on hearing loss treatment pipeline



La **thérapie génique** au secours des enfants sourds « fants âgés de 6 à 31 mois, Audiogène, sera lancé avant l'été. Il a été développé en partenariat avec des équipes de recherche de l'Institut de l'audition (Institut Pasteur), du service ORL et du centre de recherche en audiologie pédiatrique de l'hôpital Necker-Enfants malades (AP-HP) ainsi que de la Fondation pour l'audition et de Sensorion. Cette biotech française, basée à Montpellier, a développé le médicament de thérapie génique (Sens-501).

# Une thérapie génique contre la surdité





Surdité chez l'enfant : la thérapie génique, un nouvel espoir



L'audition à l'ère de la thérapie génique : quatre essais dans le monde, dont un en France, pour une surdité congénitale La thérapie génique, un « oui » pour l'ouïe



# Les Echos Audition : <u>Sensorion</u> refinance sa thérapie génique

Sensorion, la biotech française qui veut restaurer l'ouïe des bébés, lève 50 millions d'euros





Sensorion lève 50,5 millions d'euros pour soutenir ses thérapie innovantes de l'audition



La biotech montpelliéraine Sensorion lève 50 millions d'euros pour avancer ses thérapies géniques contre la surdité



Sensorion, the Montpellier-based biotech company has established itself as a leader in gene therapies for hearing loss. The most recent development is the approval to initiate a phase 1/2 clinical trial for SENS-501, a gene therapy aimed at treating hearing loss caused by mutations in the gene encoding for otoferlin. This therapy represents a significant advancement, particularly



Sensorion's hearing loss drug reaches target in comeback story after phase 2 failure

Troubles auditifs : la biotech Sensorion lève 50,5 millions d'euros





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