Press release

Sensorion reports full-year 2020 financial results and provides business highlights

- ***Cash position of €62 million at year-end provides runway until the end of H2 2022***
- ***Enrolment of SENS-401 Phase 2 SSNHL clinical study progressing***
- ***Expanding internal gene therapy capabilities including AAV, analytical and process development***
- ***Reported positive preliminary non-human primate data for the OTOF program***
- ***In February 2021, extended Gene Therapy portfolio by adding a third program focused on the GJB2 mutations***

Montpellier, 18 March 2021 – 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 loss disorders, announces today its full-year 2020 financial results and provides an update on its business activities and outlook for 2021.

"We are pleased with the progress made in 2020. We raised €36 million in equity financing to help advance our otoprotective small molecule SENS-401 and our pipeline of promising preclinical gene therapies from our strategic partnership with Institut Pasteur. We expanded our unique technology platform in gene therapy by further building our internal preclinical, process development and analytical capabilities. In Q4 2021, we expect the topline data readout from the Phase 2 trial of SENS-401 to treat sudden sensorineural hearing loss (SSNHL). In H2 2021, we also expect to initiate a clinical trial of SENS-401 to treat cisplatin-induced ototoxicity, a large indication with a significant unmet medical need" **said Nawal Ouzren, CEO of Sensorion.**

Key developments in 2020: science and operational

Gene therapy collaboration with Institut Pasteur on hearing loss

On June 9, 2020, Sensorion announced positive preliminary preclinical data in non-human primates for its gene therapy program targeting Otoferlin deficiency (OTOF-GT), showing that it could deliver an intracellular marker to the inner hair cells at levels that reflect the future clinical requirements. The company plans to discuss its OTOF-GT program with regulatory authorities in H1 2021.

Additionally, Sensorion announced an agreement with Novasep on October 27, 2020, for the process development and manufacturing of adeno-associated viruses (AAV) gene therapy products for the Company's OTOF-GT program.

Technology platform expanded

Sensorion has built a unique R&D technology platform over the years to deepen the 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.

The strengthened platform includes in-vitro assays encompassing the key cochlear cell types, systems to investigate explant tissue and advanced electrophysiological methods for assessing neuronal activity.

On the in-vivo side, Sensorion is developing a suite of validated preclinical models reflecting specific pathologies and inner ear lesions, as well as advancing the use of techniques such as auditory brainstem response (ABR) and distortion product oto-acoustic emission (DPOAE) audiometry for measuring and analysing hearing parameters in those models.

The last pillar of the Company's technology platform focuses on developing biomarkers to improve diagnosis and guide treatment in the key areas of unmet medical need in hearing loss.

Drug candidate SENS-401

Our clinical program with small molecule SENS-401 continued to progress in 2020.

Sensorion is conducting a Phase 2 clinical trial of SENS-401 in the treatment of SSNHL in adults. This Phase 2, randomized, double-blinded, placebo-controlled study is being conducted in multiple countries in Europe and Canada.

On February 17, 2020, Sensorion received Ethics Committee approval to include new military sites in this study, allowing clinical investigators to recruit volunteer military personnel who have suffered from acute hearing loss.

On March 13, 2020, Sensorion provided an update on the recruitment schedule for the ongoing SENS-401 Phase 2 study for the treatment of SSNHL. Due in part to the impact of COVID-19 on patient enrolment, the availability of topline data were expected to be delayed to Q4 2021 (see below in 2021 announcements).

On June 5, 2020, the independent Data Safety Monitoring Board (DSMB) confirmed the absence of safety concerns and recommended continuation of the Phase 2 trial as scheduled.

Having demonstrated otoprotective activity in several preclinical models, SENS-401 is being studied as a potential option to preserve residual hearing in people with cochlear implants under a collaboration with Cochlear, the world leader in implantable hearing solutions. Positive preclinical data were announced on January 5, 2021 (see below in 2021 announcements). Next steps are being discussed with Cochlear.

On December 15, 2020, Sensorion and Sonova Holding AG, a leading provider of hearing solutions, announced that Sonova had acquired a 3.7% equity stake in Sensorion via an investment of €5 million. At the same time, the two companies signed a letter of intent to exclusively explore potential plans for a strategic collaboration in the field of innovative diagnostic and therapeutic solutions for certain types of hearing loss. Discussions between Sensorion and Sonova are ongoing.

Strengthened scientific and medical leadership

As part of Sensorion's strategic move into gene therapy for hearing restoration, on February 19, 2020 the Company announced the appointment of Dr. Géraldine Honnet as Chief Medical Officer. Dr. Honnet has extensive expertise both in gene therapy and small molecule clinical development across numerous disease areas.

During 2020, Sensorion also increased its R&D headcount by 30% strengthening its team with experienced scientists and researchers in gene therapy, the inner ear and neurosciences. In addition to Dr Honnet, Sensorion also appointed a preclinical head in gene therapy and a new CMC gene therapy lead with more than 20 years of experience in the field.

On July 29, 2020, Sensorion announced the appointment of five distinguished experts to its Scientific Advisory Board (SAB); Prof. Alain Fischer, Dr. Robert Dow, Prof. Paul Avan, Dr. Diane Lazard and Dr. Hernán López-Schier. The SAB is chaired by Prof. Christine Petit, Founding Director of the French Hearing Institute and a world-renowned geneticist and neurobiologist in hearing and hearing disorders.

Scientific communications

Sensorion presented at various scientific congresses and hosted two Key Opinion Leaders (KOL's) calls in 2020, including:

- New preclinical data on SENS-401 presented at the Association for Research in Otolaryngology Mid- (ARO) Winter Meeting 2020 highlighting the potential of SENS-401 to significantly prevent hearing loss due to chronic noise exposure.
- Christine Le Bec, Head of CMC Gene Therapy, gave a talk on "Challenges and Issues in Dual AAV Vectors Approach" at the Bioprocessing Summit Europe conference. She also chaired the "Advancing CMC and Analytical Strategies" track.
- During the Advanced Therapies virtual conference, Christine Le Bec, gave a presentation on "Challenges and Issues in Dual AAV Vectors Approach".
- Sensorion held a conference call with Dr. Michael Hoffer, Professor of Otolaryngology and Neurological Surgery from the University of Miami, who described the characteristics and unmet need in SSNHL (SENS-401).
- Sensorion hosted a conference call with Dr. John Greinwald, a pediatric otolaryngologist at the Children's Hospital in Cincinnati (USA), member of the American Academy of Pediatrics, and expert in genetic hearing loss. During his presentation, Dr Greinwald discussed the different forms of deafness in children due to genetic causes.

Governance: appointment of a new Chairman of the Board of Directors

On July 6, 2020, Sensorion's Board of Directors was strengthened by the appointment of Edwin Moses as Chairman of the Board of Directors. Dr. Moses has more than 25 years of executive experience as both CEO and Chairman of numerous life science companies, including Ablynx, where he led its rapid growth from a small research-focused organization to one of Europe's leading biotechnology companies, prior to its $4.8 billion acquisition by Sanofi in 2018.

2021 announcements

Since the end of the fiscal year, the key business updates are as follows:

On January 5, 2021, Sensorion provided an update on plans and progress made in the development of SENS-401 for the prevention of hearing loss. After encouraging efficacy data in preclinical models, the Company expects to begin a proof-of-concept clinical trial with SENS-401 to treat patients suffering from cisplatin-induced ototoxicity (CIO) in the second half of 2021. A natural history study of CIO in adult cancer patients is expected to start in the first half of 2021. Successful clinical findings would significantly expand Sensorion's target market for SENS-401: approximately 500,000 cancer patients are treated annually with cisplatin in the USA and EU5, a significant proportion of whom will experience severe hearing loss.

At that time, Sensorion also announced a delay in the availability of the topline results from the Phase 2 study of SENS-401 in SSNHL to Q4 2021, due to the impact of COVID-19. Additionally, Sensorion indicated that it planned to review the study design and consider opportunities to aid its successful on-time completion. Following this review, an amendment to the statistical analysis plan (SAP), which would significantly reduce the sample size without compromising on the quality and potential outcome of the trial, has been submitted to the regulatory authorities. The responses from regulators so far have been encouraging and this increases the Company's confidence in being able to generate topline data this year.

On January 19, 2021, Sensorion announced positive preclinical data demonstrating the potential of SENS-401 to preserve residual hearing after cochlear implantation, in a collaboration with Cochlear, the global leader in implantable hearing solutions. Cochlear implants are very effective in treating severe to profound hearing loss, but preserving acoustic hearing in patients with residual hearing who receive cochlear implants could provide

substantial benefit. Sensorion and Cochlear are making progress in the discussion around potential clinical study designs. Next steps are being discussed with Cochlear.

On February 15, 2021, Sensorion announced a third gene therapy collaboration with Institut Pasteur around the GJB2 gene targeting important pediatric and adult deafness markets. GJB2 mutations had already been widely recognized as the most prevalent cause of congenital deafness and now, new findings from Institut Pasteur have now demonstrated that GBJ2 mutations also underlie a wide range of other instances of severe hearing loss in the adult population. Sensorion will pursue three initial GBJ2-related indications: congenital deafness, progressive childhood hearing loss and early onset of severe presbycusis in adults.

2021 strategy and prospects

As of 31st December 2020, the Company had €62 million in cash, boosted by a successful €31 million Reserved Offering conducted in September and the December investment of €5 million by Sonova. Sensorion intends to use the new funds to develop its current gene therapy programs (OTOF-GT, GJB2-GT and USHER-GT), to support its pharmacology and clinical studies of SENS-401 and for general corporate purposes.

Nawal Ouzren, CEO of Sensorion commented: "We are working hard to secure further approvals of the protocol amendment to reduce the sample size for the SENS-401 Phase 2 SSNHL trial which will help ensure that we could complete this study on time. Sensorion will also engage with regulatory authorities in Europe and the US to discuss our potential Otorferlin gene therapy clinical trial design. We recently added a promising third program to the Sensorion gene therapy pipeline centered around the GJB2 gene, the most prevalent cause of congenital deafness. This program will focus on major new markets with an estimated patient population of 300,000 children and adults in Europe and the United States. We remain very focused on delivering on our ambitious goals this year and we will stay true to our vision to serve patients with hearing loss"**.**

Expected future milestones and estimated timelines:

- H1 2021 – Start of CIO Natural History Clinical Trial
- H1 2021 – Ongoing approvals of the protocol amendment to reduce sample size for the SENS-401 Phase 2 study in SSNHL
- H1 2021 – Discussion with regulatory authorities on potential OTOF-GT clinical study design
- H1 2021 – Generation of preclinical PoC results in older mice for USHER-GT
- H2 2021 – Initiation of SENS-401 clinical study in adults with CIO
- Q4 2021 – Communication of top line data for the SENS-401 Phase 2 clinical study in SSNHL

Press release

2020 financial results

The annual accounts at 31 December 2020, drawn up according to IFRS standards and approved by the Board of Directors on 17 March 2021, have been duly reviewed by statutory auditors.

The simplified income statement as of 31 December 2020 is as follows:

In Euros – IFRS standards	**31.12.2020**	**31.12.2019**
Operating income	**2,421,267**	**2,522,717**
Research & Development expenses	-7,679,365	-10,208,520
General & Administrative expenses	-3,631,123	-3,128,236
Total operating expenses	**-11,310,488**	**-13,336,756**
Operating profit/loss	**-8,889,220**	**-10,814,039**
Financial charges	-88,869	-1,282,141
Net profit/loss	**-8,978,089**	**-12,096,181**

For the year ended 31st December 2020, Sensorion reported **operating income** of €2.4 million, which included €1.8 million in research tax credit and €0.6 million in grants from Audinnove (RHU) and Patriot (PSPC) collaborations. The decrease of -€0.1 million compared to 2019 is explained by a decrease of -€0.7 million in research tax credit partly offset by an increase of +€0.6 million in grants.

Operating expenses declined by 15% from €13.3 million in 2019 to €11.3 million for fiscal year 2020.

R&D expenses decreased by €2.5 million mainly due to the completion of the SENS-111 clinical trial in 2019 and a slowdown of SENS-401 activities linked to the global Covid-19 pandemic situation, and partly offset by an increase in headcounts to strengthen the R&D team with Gene Therapy expertise.

G&A expenses increased by €0.5 million, mainly driven by an increase in headcount.

Operating loss at 31 December 2020 was -€8.9 million compared with -€10.8 million at 31 December 2019.

The net financial charges decreased by €1.3 million compared to 2019 which was mainly due to the costs related to the convertible bond operations.

Net loss was -€9.0 million at 31 December 2020 compared with -€12.1 million at 31 December 2019.

As of 31 December 2020, the company employed 28 persons.

Financial structure

The simplified balance sheet at 31 December 2020 is as follows:

In Euros – IFRS standards	**31.12.2020**	**31.12.2019**
Non-current Assets	**1,474,117**	**1,724,348**
Other Current Assets	4,254,909	5,946,864
Cash & cash equivalent	62,174,948	30,428,319
Total Assets	**67,903,976**	**38,099,532**
Equity	**58,379,653**	**13,218,525**
Non-current Liabilities	5,246,408	2,036,933
Current Liabilities	4,277,915	22,844,074
Total Liabilities	**67,903,976**	**38,099,532**

Total equity amounted to €58.4 million as of 31 December 2020 compared to €13.2 million at 31 December 2019; this increase of +€45 million is related to the following share capital increases partly offset by the net loss of -€9 million for the period:

- On February 10, 2020, Invus Public Equities LP converted into ordinary shares of the Company all of the 12,500,000 convertible bonds it had subscribed for in June 2019
- On February 13, 2020 Sofinnova Crossover I SLP converted into ordinary shares of the Company all of the 7,500,000 convertible bonds it had subscribed for in June 2019
- On September 18, 2020, the company announced and completed a share capital increase amounting to circa €31 million to which Invus Public Equities LP and Sofinnova Partners subscribed for a total amount of €16.2 million.
- On December 15, 2020, the Company announced and completed a share capital increase amounting to circa €5 million to the benefit of Sonova Holding AG

Cash and cash equivalents amounted to €62.2 million at 31 December 2020 compared to €30.4 million at December 31, 2019 boosted by the €29 million net proceeds of the capital increase in September and the €5 million of investment by Sonova in December.

Based on its cash position and its forecasted expenses, the Company believes it will be able to fund its operations until the end of the second half of 2022.

Non current liabilities increased by +€3.2 million after Sensorion obtained €3 million in loans including €2 million guaranteed by the French government and €1 million in a Research, Developement and Innovation loan from Bpifrance.

Current liabilities decreased by -€18.6 million, driven by the €20 million bond conversion in Q1 2020.

2020 annual accounts

The 2020 detailed accounts can be found on Sensorion's website (https://www.sensorion.com) in the investors section under the financial information tab. The annual accounts as of December 31, 2020 have been duly reviewed by statutory auditors and the certification report is being issued.

Capital Breakdown

The company's capital breakdown as of 31 December 2020 is described in the table below:

	Non-diluted basis		Fully diluted basis [2]	
	Number of shares	Equity holding	Number of shares	Equity holding
Invus Public Equities LP	26,490,415	33.22%	26,490,415	32.02%
Sofinnova Partners	15,469,458	19.40%	15,469,458	18.70%
WuXi AppTec	5,249,608	6.58%	5,249,608	6.34%
3SBio	4,055,150	5.09%	4,055,150	4.90%
Innobio	3,499,874	4.39%	3,499,874	4.23%
SONOVA AG	2,941,176	3.69%	2,941,176	3.55%
Inserm Transfert Initiative	982,911	1.23%	982,911	1.19%
Cochlear	533,755	0.67%	533,755	0.65%
Management, employees, directors [1]	160,000	0.20%	2,140,041	2.59%
Floating (including former officers and directors)	20,357,881	25.53%	21,376,612	25.84%
Total	**79,740,228**	**100.00%**	**82,739,000**	**100.00%**

(1) Including 160,000 free shares allocated on May 29, 2018

(2) Including securities giving access to the capital and stock-options described below

COVID-19

Sensorion continues to closely monitor the COVID-19 pandemic and is actively managing the potential impact on the Company's activities. We observed a negative impact in the recruitment of the SENS-401 Phase 2 trial in SSNHL driven by a reallocation of emergency room resources and restrictions in the movement of people. In order to avoid overloading healthcare facilities, to ensure the safety of new potential patients, to avoid major protocol deviations due to missed follow-up visits and to minimize contact between patients and investigational staff, new patient recruitment in the study was temporarily suspended during the past year. Recruitment re-started progressively following the reduction in sanitary restrictions. It is difficult to predict the evolution of the pandemic and how local restrictions on individuals or additional governmental measures could impact future recruitment of patients in the ongoing Phase 2 clinical study and in line with our press release of January 5, 2021, we have taken further mitigation steps including seeking approvals for a protocol amendment which will significantly reduce the number of patients required for the study.

For patients already in the SENS-401 Phase 2 study, there is a risk that some participants may not be able to attend follow-up visits as per study protocol due to government or local restrictions. The Company is seeking to mitigate this risk through the use of teleconferences and videoconferences. Furthermore, the pandemic might

cause delays in the preclinical gene therapy studies that are part of the collaboration with Institut Pasteur. The pandemic could also impact our organization more generally where restrictions impede our ability to meet and collaborate in a timely manner or interact with external parties on our various collaborations across academia, clinical centers or sub-contractors. This could delay our preclinical work for the three ongoing programs. We had previously experienced delays in March 2020 and January 2021 and in light of the evolving situation, there is a risk of another guidance change on the availability of the Phase 2 results with SENS-401 in SSNHL, though as indicated previously we are seeking to minimize this possibility. Such an eventuality could, however, have a significant adverse impact on the Company's business, results, and financial position.

As recommended by the French government, all the employees at Sensorion for which remote working was possible were working remotely until December 2020. The health and safety of the Company's employees is and continues to be a key priority for Sensorion.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders. Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) for sudden sensorineural hearing loss (SSNHL). 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. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses. Sensorion has launched three gene therapy programs, currently at preclinical stage, aimed at correcting hereditary monogenic forms of deafness including deafness caused by a mutation of the gene encoding for Otoferlin, hearing loss related to gene target GJB2 as well as Usher Syndrome Type 1 to potentially address important hearing loss segments in adults and children. The Company is potentially uniquely placed, through its platforms and pipeline of potential therapeutics, to make a lasting positive impact on hundreds of thousands of people with inner ear related disorders, a significant global unmet medical need.
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