

Sensorion reports 2020 first half results Financial position strengthened with €31m (US\$36.5m) capital raise in September 2020

- **Gene therapy agreement expands pipeline and preclinical data**
- **SENS-401 Phase II trial progressing with results expected in mid-2021**
- **Cash position of €30.7m as of June 30, 2020, further reinforced by September capital raise**
- **Cash runway now extended to H2 2022**

Montpellier, October 21, 2020 - 7:30 AM CEST - Sensorion (FR0012596468 – ALSEN), a pioneering clinical-stage and gene therapy biotech company which specializes in the development of novel therapies to treat, prevent and restore within the field of hearing loss disorders, today announces its interim annual results as of June 30, 2020 alongside its outlook for 2020.

“Sensorion’s landmark gene therapy agreement with Institut Pasteur was a major inflection point in the Company’s development. The positive preliminary preclinical data from the program targeting the OTOF gene reinforces the potential of this partnership, which expands our pipeline and supports our goal to become a leader in the field of hearing loss. The Phase 2 trial of SENS-401 in sudden sensorineural hearing loss is progressing and we expect results in mid-2021. We were delighted to successfully close an oversubscribed private placement in September, which raised €31 million. As part of this financing, we were pleased to see renewed support from existing shareholders such as Invus and Sofinnova Partners and to welcome new high-quality US and European investors. Following this financing, we estimate the cash in hand will carry us through to H2 2022” comments **Nawal Ouzren, CEO of Sensorion.**

First-half 2020 financial results

The half-year accounts as of June 30, 2020, drawn up according to IFRS standards and approved by the Board of Directors on October 20, 2020, have been duly reviewed by statutory auditors

The simplified income statement as of June 30, 2020 is as follows:

<i>In Euros – IFRS standards</i>	31.06.2020	31.06.2019
Operating income	902,203	1,042,407
Research and Development expenses	3,661,766	5,226,883
General and Administrative expenses	1,915,400	1,257,185
Total operating expenses	5,577,166	6,484,068
Operating profit/loss	-4,674,963	-5,441,662
Financial profit/loss	-44,031	-22,929
Net profit/loss	-4,718,994	-5,464,591

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On June 30, 2020, Sensorion's **operating income**, mainly the research tax credit, amounted to €0.9m, compared to €1.0m on June 30, 2019.

Operating expenses decreased by 14%, down from €6.5m on June 30, 2019 to €5.6m on June 30, 2020, mainly due to a €1.5m reduction in research costs partially offset by a €0.7m increase in G&A expenses.

The research and development expenses decreased by 30%, down from €5.2m on June 30, 2019 to €3.7m on June 30, 2020 following the halting of the SENS-111 program in December 2019 and the slowdown of expenditure on the SENS-401 clinical trial as a result of delays due to the COVID-19 pandemic.

G&A expenses are up 52%; they amounted to €1.9m on June 30, 2020, compared with €1.3m on June 30, 2019 mainly due to the increase in personnel expenses.

Operating losses on June 30, 2020 thus amounted to €4.7m, compared with a loss of €5.4m on June 30, 2019.

Net loss amounted to -€4.7m on June 30, 2020, compared with -€5.5m on June 30, 2019.

As of June 30, 2020, the company employed 24 people.

Financial structure

On February 10, 2020, Invus Public Equities LP converted all the 12,500,000 convertible bonds ("CBs") it had subscribed for in June 2019 into ordinary shares in the Company. The conversion was undertaken on a price basis of €0.76 per share. Following this operation, Invus held 20,591,259 ordinary shares and 42.29% of the share capital and voting rights in Sensorion.

On February 13, 2020, Sofinnova Crossover I SLP converted all the 7,500,000 convertible bonds ("CBs") it had subscribed for in June 2019 into ordinary shares in the Company. The conversion was undertaken on a price basis of €0.76 per share. Following this operation, Sofinnova Crossover I SLP held 11,822,258 ordinary shares and 20.19% of the share capital and voting rights in Sensorion.

Equity capital amounted to €28.7m on June 30, 2020, compared with €13.2m on June 30, 2019.

As of June 30, 2020, cash and cash equivalents amounted to €30.7m compared with €30.4m on December 31, 2019.

On September 18, 2020, Sensorion successfully raised €31m of gross proceeds before deducting underwriting commissions and estimated expenses payable by the Company.

Based on its forecasted expenses, the cash position of €30.7m at June 30, 2020 and the net proceeds from the offering, the Company believes it will be able to fund its operations until the second half of 2022.

Key developments: Science and research & development

- **Collaboration with Institut Pasteur on gene therapy programs**

In the second half of 2019, Sensorion launched two preclinical gene therapy programs targeting Usher Syndrome type 1 and Otoferlin deficiency, two monogenic forms of hereditary deafness. Under the framework agreement signed with Institut Pasteur in May 2019, other projects could also emerge in the area of genetic disorders of the inner ear. During the five years partnership agreement, Sensorion has preferred rights to the genetic disorders of the inner ear research pipeline of Institut Pasteur and the ability to implement collaborations leading to a license. These programs are conducted under the sponsorship of Professor Christine Petit, Director of the French Hearing Institute and Chair of our Scientific Advisory Board.

On June 9, 2020, Sensorion announced positive preliminary preclinical data from its gene therapy program targeting Otoferlin deficiency. *In vivo* experiments conducted in non-human primates (NHPs) show good safety and promising preliminary data on inner ear tissue tropism and the achievement of a high transduction rate efficiency.

- **Drug candidate SENS-401**

The SENS-401 Phase 2 clinical trial in the treatment of sudden sensorineural hearing loss (SSNHL) in adults is a randomized, double-blind and placebo-controlled study, aiming to recruit ~260 patients. It is being conducted in 11 countries at approximately 30 sites in Europe and Canada.

On February 17, 2020, Sensorion received Ethics Committee approval to include new military sites in the SENS-401 Phase 2 study. The new centers will recruit volunteer military personnel exposed to extreme noise during their professional activities and suffering from hearing loss.

On March 13, 2020, Sensorion provided an update on the SENS-401 SSNHL Phase 2 AUDIBLE-S trial enrollment. Patient recruitment rates from this trial now indicate the data will be available by mid-year 2021, which is later than previously announced. An important factor resulting in delayed recruitment in the trial was the reallocation of emergency room resources due to the COVID-19 situation.

The independent Data Safety Monitoring Board (DSMB) undertook a review of the safety data for the patients included in the Phase 2 clinical trial on June 5, 2020. It confirmed the absence of any concern on the safety of SENS-401 and recommended continuing the trial as scheduled.

Following the agreement signed in December 2017, Sensorion and Cochlear (world leader in cochlear implants) have continued their collaboration. Thanks to its otoprotective properties demonstrated in several preclinical models, SENS-401 could potentially preserve residual hearing in patients with cochlear implants. Since 2018, we have successfully conducted additional safety studies to assess the feasibility of long-term treatment with SENS-401 that may be required in cochlear implant indications. Preclinical data from these studies are expected by the end of 2020.

- **Technology platform**

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 in the field of small molecules and gene therapy. This platform makes it possible to carry out a panel of investigations ranging from histology and cell culture (in vitro) to behavioral and electrophysiological tests (in vivo). The Company is also working on the identification of biomarkers to improve diagnosis and treatment of these illnesses with a high unmet medical need.

- **Scientific communications**

On January 30, 2020, Sensorion presented new SENS-401 preclinical data at the ARO (Association for Research in Otolaryngology) Mid-Winter Meeting 2020. A poster and oral presentation highlighted the potential to

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significantly reduce hearing loss from chronic noise exposure in a rat model. A second poster featured the age-related hearing loss with significant early decline in functional auditory measures in Wistar rats.

Capital breakdown after the September 2020 capital increase

Sensorion's financial position strengthened further at the end of September 2020 following a €31m capital increase. The capital raise was achieved at a share price which was a 3.5% discount over the weighted average share price on the day preceding the date on which the issuance price was set (the "Reserved Offering").

The completion of this capital increase was, amongst others, supported by existing shareholders, Invus Public Equities LP, Sofinnova Partners and WuXi AppTec.

To the best of the Company's knowledge the capital structure on a non-diluted basis before and after the private placement is as follows:

Shareholders	Number of shares before the Reserved Offering ⁽¹⁾	% of the share capital before the Reserved Offering	% of voting rights before the Reserved Offering	Number of shares after the Reserved Offering ⁽¹⁾	% of share capital after the Reserved Offering	% of voting rights after the Reserved Offering	Subscription (in €)
Inserm Transfert Initiative	982,911	1.68%	1.68%	982,911	1.28%	1.28%	-
Innobio (Bpifrance)	3,499,874	5.98%	5.98%	3,499,874	4.56%	4.56%	-
Management, employees and directors	160,000	0.27%	0.27%	160,000	0.21%	0.21%	-
Cochlear	533,755	0.91%	0.91%	533,755	0.70 %	0.70%	-
Invus Public Equities LP	20,608,063	35.19%	35.19%	26,490,415	34.49%	34.49%	9,999,998
Sofinnova Partners	11,822,258	20.19%	20.19%	15,469,458	20.14%	20.14%	6,200,240
WuXi AppTec	4,055,150	6.92%	6.92%	5,249,608	6.84%	6.84%	2,030,579
3SBio	4,055,150	6.92%	6.92%	4,055,150	5.28%	5.28%	-
Free Float	12,845,891	21.94%	21.94%	20,357,881	26.51%	26.51%	-
Total	58,563,052	100%	100%	76,799,052	100%	100%	18,230,817

⁽¹⁾To the Company's knowledge and based on the last analysis from August 2020.

Strategy and prospects: 2020 and 2021

The Company intends to use the net proceeds from the Reserved Offering to develop its current gene therapy programs (OTOF and USHER), potentially broaden its gene therapy pipeline, support its pharmacology and clinical studies for the clinical development of SENS-401 and for general corporate purposes.

Expected future milestones and estimated timelines:

- Signature of a manufacturing agreement for the gene therapy program targeting otoferlin deficiency - H2 2020
- Additional NHP data for the gene therapy program targeting otoferlin deficiency - H2 2020
- Confirmatory preclinical PoC studies for the program targeting Usher syndrome type 1 - H2 2020
- Preclinical data for SENS-401 in hearing preservation after cochlear implantation - H2 2020
- Discussions with regulatory authorities on a potential OTOF clinical study - H1 2021
- Phase II readout from SENS-401 clinical study in SSNHL - mid-2021
- Potential initiation of cisplatin induced ototoxicity (CIO) clinical study with SENS-401 - H2 2021

COVID-19

Sensorion is closely monitoring the COVID-19 pandemic and is actively managing its potential impact on Company activities.

We observed a negative impact on recruitment for the SENS-401 Phase 2 trial in SSNHL during the spread of COVID-19, which started in the first quarter of 2020, due to the reallocation of emergency room resources and restrictions in the movement of populations. In order to avoid overloading healthcare facilities, ensure safety of new potential patients, prevent major protocol deviations due to missed follow-up visits and to minimize contact between patients and investigational staff, the recruitment of new patients in the study was temporarily suspended and re-started progressively following the reduction in social restrictions. It is difficult to predict the evolution of the pandemic, therefore local restrictions of populations or additional governmental measures could impact future recruitment of patients in sites participating in the ongoing Phase 2 clinical study.

Regarding patients already in the SENS-401 Phase 2 study, there is a risk that it might be impossible for some of these subjects to complete the follow-up visits as planned in the study protocol. The Company is seeking to mitigate this risk through the use of teleconferences and videoconferences.

Furthermore, the pandemic might also cause delays in the realization of preclinical gene therapy studies carried out as part of the collaboration with Institut Pasteur. This could delay the preclinical results expected for the two ongoing programs.

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

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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: SENS401 (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. In the second half of 2019, Sensorion launched two preclinical gene therapy programs aiming at correcting hereditary monogenic forms of deafness including Usher Type 1 and deafness caused by a mutation of the gene encoding for Otoferlin. The Company is 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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