Press release

Sensorion reports its 2019 first half results
Signature of a framework agreement with Institut Pasteur in gene therapy
Financial position strengthened with the issuance of a €20m mandatory convertible bond

- ***Gene Therapy**: Exclusive collaboration with Institut Pasteur in gene therapy with programs targeting hearing loss. One of the two pre-clinical programs (otoferlin-deficiency) has been granted a €9.7m non-dilutive funding from RHU (hospital/university research)*
- ***SENS-401**: Paediatric plan (PIP) awarded in the treatment of sudden sensorineural hearing loss (SSNHL) and prevention of cisplatin-induced ototoxicity (CIO)*
- ***SENS-111**: Recruitment completed in the acute unilateral vestibulopathy (AUV) phase 2b proof of concept clinical trial*
- ***Cash position of €22.3m** at June 30 2019;*
- ***Sensorion opens its capital to two long term investors:** Invus Public Equities LP and Sofinnova Crossover I SLP*

Montpellier, October 31 2019 – Sensorion (FR0012596468 – ALSEN), a pioneering clinical-stage biopharmaceutical company which specializes in the development of novel therapies to restore, treat and prevent inner ear diseases such as hearing loss, tinnitus and vertigo, today announces its interim annual results at June 30 2019 and its outlook for 2019.

«The signature of a framework agreement with Institut Pasteur in gene therapy marks an inflection point in Sensorion's expansion trajectory. This partnership reinforces our pipeline, our long-term development potential and confirms the company as a leading platform in the field. We were also pleased to welcome new long term and strategic investors in the two financing operations of June and September. After the capital increase at the end of September, we estimate that cash in hand will carry us through the middle of the first quarter of 2021. We continue to build up one of the richest pipelines in the inner ear domain, with two programs in phase 2 accompanied by the new portfolio of gene therapies. We expect SENS-111 phase 2 clinical results before year end; Sensorion has a promising pipeline allowing us to develop therapeutic solutions to restore, prevent and treat inner ear disorders» , comments **Nawal Ouzren, CEO of Sensorion.**

First-half 2019 financial results

The half-year accounts at June 30 2019, drawn up according to IFRS standards and approved by the Board of Directors on October 30 2019, have been duly reviewed by statutory auditors.

The simplified income statement at June 30 2019 is as follows:

In Euros –IFRS standards	**31.06.2019**	**31.06.2018**
Operating income	**1,042,407**	**1,299,199**
Research and Development expenses	5,226,883	5,849,636
General and Administrative expenses	1,257,185	1,542,860
Total operating expenses	**6,484,068**	**7,392,496**
Operating profit/loss	**-5,441,662**	**-6,093,297**
Financial profit/loss	-22,929	-45,186
Net profit/loss	**-5,464,591**	**-6,138,483**

At June 30 2019, Sensorion **operating income**, mainly the research tax credit, amounted to €1.04m, compared to €1.29m at June 30 2018.

Operating expenses fell 12%, down from €7.4m at June 30 2018 to €6.5m at June 30 2019, mainly owing to a 20% reduction in G&A expenses and a 10% reduction in research costs. The research platform costs have been reduced while the costs of the SENS-111 clinical study have remained stable; costs for the SENS-401 clinical trial are ramping up slowly.

G&A expenses fell 20% to €1.3m at June 30 2019, compared with €1.5m at June 30 2018, reflecting the company's determination to cut costs in all areas.

Operating loss at June 30 2019 thus amounted to -€5.4m, compared with -€6.09m at June 30 2018.

Net loss amounted to -€5.5m at June 30 2019, compared with -€6.1m at June 30 2018.

At June 30 2019, the company employed 18 people.

Financial structure

On March 11th 2019, Sensorion undertook a bond issue of a nominal amount of €4.7m with European financial investors, consisting of (i) a convertible bond issue for a nominal €3.4m underwritten by several new European investors, plus (ii) a simple bond issue of a nominal €1.3m. 4,408,606 bonds have been converted into 4,398,176 shares during the first half.

Equity capital amounted to €2.3m at June 30 2019, compared with €3.5m euros at June 30 2018.

Invus and Sofinnova Crossover I SLP invested in Sensorion as long-term partners on June 12, 2019 via a mandatory convertible bond issue for a nominal amount of €20m. They have taken three seats on the board of directors (two for Invus, one for Sofinnova), and are subject to a lock-up till June 30, 2020. These bonds will undergo compulsory conversion into shares at the latest on the maturity date (June 13, 2024) and do not bear interest.

Current liabilities include €19.1m of convertible bonds at June 30 2019.

At June 30 2019, cash and cash equivalents amounted to €22.3m compared with €2.7m at December 31 2018, thanks to the injection of funds stemming from the convertible bond issues.

Key developments: Research & Development and scientific communications

- **Collaboration with Institut Pasteur in Gene Therapy programs targeting hearing loss**

On May 27 2019, Sensorion announced the signature with Institut Pasteur (Paris) of a framework agreement for a research partnership granting Sensorion an exclusive option to an exclusive license in order to develop and commercialise drug candidates in gene therapy for the restoration, treatment and prevention of hearing problems.

In the first place, Sensorion has launched two preclinical gene therapy programs targeting the Usher Syndrome type 1 and the Otoferlin-deficiency, two monogenic forms of hereditary deafness. On top of these programs, part of the framework agreement signed with Institut Pasteur, other projects could emerge in the same domain of genetic forms of deafness. During the five years of the partnership, Sensorion also has a preference right on all Institut Pasteur programs research in the domain of genetic diseases of the inner ear to implement collaborations leading to a license. These programs are conducted under the sponsorship of Professor Christine Petit, director of "L'Institut de l'Audition" and Chair of our Scientific Advisory Board.

Moreover, the specific gene therapy program aimed at correcting a hereditary monogenic form of deafness caused by a mutation of the gene encoding for Otoferlin (DNBF9) was retained on June 10 2019 in the RHU call for healthcare projects in the "Avenir" public investment program. The "AUDINNOVE" project which is conducted by the ENT department of Hospital AP-HP-NECKER, is an association that includes Institut Pasteur, "La Fondation pour l'Audition" and Sensorion as the industrial partner. This project received €9.7m as a grant, with payment in stages over the development period of the program.

- **Drug candidate SENS-111: Enrolment of the patients completed in the phase 2b proof of concept**

Sensorion has undertaken phase 2 clinical trials with SENS-111 in acute unilateral vestibulopathy (AUV). AUV was chosen as a first indication to demonstrate proof-of-concept as it is a pure disease for which the patient phenotype is quite homogeneous. Two phase 2 were conducted in 2018:

- Positive results of the first one were published in December 2018 confirming the initial hypothesis whereby the SENS-111 drug candidate impacts negatively neither the vigilance nor the cognitive performance of patients during a motion stimulus. The trial also showed that SENS-111, in contrast to meclizine, has no negative CNS (Central Nervous System) side effects such as sedation, impairment of memory and of cognitive performance
- As for the second phase 2b proof of concept, the 105 expected patients have been recruited. We announced that the last visit of the last patient took place on October 15, 2019. Efficacy data will be known by the end of the second half of 2019. This information will enable Sensorion to present a strong data package covering the scientific, clinical and commercial advantages of SENS-111 to potential partners.

- **Drug candidate SENS-401: Clinical study progressing - Paediatric Plan authorized in two indications**

The SENS-401 phase 2 clinical trial in the treatment of sudden sensorineural hearing loss in adults (SSNHL) has been launched. This randomized, double-blind and placebo-controlled phase 2 trial will unfold in 12 countries to recruit some 260 patients. It has gradually started in some fifteen sites in Europe and Canada. Interim safety data are expected at the end of the second half of 2019 and the final results of the clinical trial are expected at the end of the first half of 2020.

On June 28 2019, the European Drug Agency (EMA) accepted SENS-401 paediatric investigation plan (PIP) for both the development of the treatment of sudden hearing loss (SSNHL) and prevention of cisplatin-induced ototoxicity (CIO) in the paediatric population. This agreement is necessary for an application for a marketing authorisation in Europe.

- **Technology platform**

The company is accelerating with the development and utilisation of its specialised screening platform in all inner ear pathologies. We continue our collaboration with renowned international experts for the validation of translational, quantitative endpoint measures in tinnitus. We have also implemented robust models of chronic noise exposure and age-related hearing loss.

- **Regular scientific communication**

During the first half, Sensorion made presentations at various scientific congresses and notably:

- The results presented to the ARO MidWinter Meeting in February 2019 via two posters which showed proof of efficacy for SENS-401 in preclinical models. The first poster showed the lasting protection by SENS-401 of cochlear cilia cells for Organ of Corti explants in culture, after ototoxicity induced by gentamicin. And the second showed that a targeted local exposure to SENS 401 is not specific to a single species and the otoprotective efficacy can be generalised, the PK/PD models can thus be translated.
- The SENS-111 development program was exposed at the 'European Histamine Research Society' in Krakow in Poland. The translational development of Seliforant (i.e. SENS-111) was presented from the results of the preclinical models *in vitro* and *in vivo* up till the proof of concept (POC) validation phase.
- A presentation of the SENS-111 phase 2 trial protocol in acute unilateral vestibulopathy (AUV) was made during the symposium of the *Société Internationale d'Otoneurologie* in Venice in June.

Capital breakdown after the September 2019 capital increase

Sensorion's financial position strengthened further on end of September 2019 following a €18.1m capital increase with a 12% premium on last price, underwritten by first-tier investors. The completion of this capital increase was supported by Invus, Sofinnova Crossover I SLP and new investors including WuXi AppTec and 3SBio. The participation of Invus, Sofinnova Crossover I SLP and Marijn Dekkers in this financing round demonstrates their continued support in the Company's long-term strategy. The relationship with 3SBio will help us build a commercial strategy for the China region.

The breakdown of the company's capital at September 26th, 2019 is described in the table thereafter. The last two columns include the impact of any conversion of the entirety of the convertible bonds issued in March and June 2019.

	before the conversion of the convertible blonds		On a converted basis	
	Total number of shares	**% shareholding**	**Total number of shares**	**% shareholding**
Bpifrance Investissements (Innobio)	3 499 874	10,85%	3 499 874	7,44%
Inserm Transfert Initiative	982 911	3,05%	982 911	2,09%
Coachlear	533 755	1,66%	533 755	1,13%
Invus Public Equities LP	3 256 395	10,10%	12 405 861	26,37%
Sofinnova Partners	1 953 837	6,06%	7 443 516	15,82%
Management	221 582	0,69%	387 008	0,82%
Marijn Dekkers*	1 477 696	4,58%	1 477 696	3,14%
WuXi AppTec	4 055 150	12,58%	4 055 150	8,62%
3SBio	4 055 150	12,58%	4 055 150	8,62%
Petite Pond LLC	405 515	1,26%	405 515	0,86%
David Epstein	162 206	0,50%	162 206	0,34%
Free Float	11 643 192	36,11%	11 643 192	24,75%
Total	**32 247 263**	**100,00%**	**47 051 834**	**100,00%**

** holding the shares through its investment vehicle Novalis LifeScience Investment*

*** Assumptions:*
- the OC 0321 owned by an officer shall be converted at a price per share of €1,30
- the OC 0624 owned by Invus and Sofinova shall be converted at a price per share of €[1,3662]
- the dilution resulting from the exercise of 1,980,484 BSCPE, BSA and free shares (including 160,000 free shares granted on May 29, 2018) issued by the Company and in force does not appear in this table

Strategy and prospects: 2019 a turnaround year

The proceeds from the capital increase completed in September will mainly be used to finance the phase 2 clinical program for SENS-111 and SENS-401 as well as the preclinical gene therapy programs.

The results of the POC phase 2 study on SENS-111 efficacy in acute unilateral vestibulopathy are expected by the end of the year. SENS-401 phase 2 Interim safety results in sudden hearing loss (SSNHL), will be released by the end of the year 2019 and the top line read out is anticipated at the end of H1 2020.

The initiation of two preclinical gene therapy programs targeting Usher type 1 syndrome and Otoferlin deficiency, two monogenic forms of deafness have been launched in collaboration with Institut Pasteur.

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About Sensorion

Sensorion is a pioneering clinical-stage biopharmaceutical company, which specializes in the development of novel therapies to restore, treat and prevent inner ear diseases such as hearing loss, vertigo and tinnitus. Its clinical-stage portfolio includes two phase 2 products: Seliforant (SENS-111) under investigation for acute unilateral vestibulopathy and Arazasetron (SENS-401) for sudden sensorineural hearing loss (SSNHL).

Sensorion has built a unique R&D technology platform to deepen its understanding of the physiopathology and etiology of inner ear related diseases. This approach allows us to select the best therapeutic targets and appropriate mechanisms of action for our drug candidates. The Company has also identified biomarkers to improve diagnosis and treatment of these underserved illnesses.

In the second half of 2019, Sensorion has launched two preclinical gene 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 need in medicine today.

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