

Sensorion reports its 2018 annual results 75% of patients enrolled in the Sens-111 clinical trial

- *SENS-111 phase 2 AUV trial: major progress with 75% of patients enrolled in the clinical trial assessing the efficacy of SENS-111 on vertigo intensity*
- *SENS-111 phase 2a trial: the phase 2a trial has achieved its tolerance primary end point; SENS-111 affects neither the vigilance nor the cognitive performance of patients during a motion stimulus*
- *SENS 401: entry in phase 2 strengthens the pipeline with the treatment of sudden sensorineural hearing loss*
- *€2.7m in cash at 31 December 2018 and a bond issue offering the company gross income of €4.7m on 11 March 2019*

Montpellier, 27 March 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 annual results at 31 December 2018 and its outlook for 2019.

‘The repositioning of our AUV phase 2 clinical trial for SENS-111 has borne fruit, we have obtained the necessary regulatory approval and are now proud to announce that we have enrolled 75% of the patients. We confirm that the results of the proof of concept trial will be announced in the second half. Following the bond issue in March 2019, we believe that cash in hand will carry us through until the middle of the second half. 2019 will be a turnaround year for Sensorion. We expect two major clinical phase 2 results in the second half for our two drugs SENS-111 and SENS-401. Sensorion now has a promising pipeline enabling it to offer therapeutic solutions to Prevent and Treat inner ear disorders’, states Nawal Ouzren, Sensorion CEO.

2018 financial results

The annual accounts at 31 December 2018, drawn up according to IFRS standards and approved by the Board of Directors on 26 March 2019, have been duly reviewed by statutory auditors and the certification report is being issued.

They show an increase in Research & Development spending, linked to the launch of a phase 2 clinical trial for SENS-401 in the second half of 2018.

The simplified income statement at 31 December 2018 is as follows:

<i>In Euros – IFRS standards</i>	31.12.2018	31.12.2017
Operating income	2,309,859	2,025,413
Research & Development expenses	11,907,943	7,872,735
General & Administrative expenses	2,627,684	3,668,464
Total operating expenses	14,535,677	11,541,199
Operating profit/loss	-12,225,767	-9,515,785
Financial profit/loss	-124,254	-170,379
Net profit/loss	-12,350,021	-9,686,164

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At 31 December 2018, Sensorion **operating income**, mainly the research tax credit, amounted to €2.2m, i.e. +18.9% compared with 31 December 2017.

Operating expenses rose 26%, moving up from €11.5m at 31 December 2017 to €14.5m at 31 December 2018, mainly owing to the preparation of the launch of the phase 2 clinical trial with SENS-401 in the treatment of sudden hearing sensorineural loss and execution of the SENS-401 toxicology programme.

G&A expenses are down 28%; they amounted to some €2.6m at 31 December 2018 compared with €3.7m at 31 December 2017.

Operating loss at 31 December 2018 thus came to -€12.2m, compared with -€9.5m at 31 December 2017.

Net loss came to -€12.3m at 31 December 2018 versus a net loss of -€9.7m at 31 December 2017.

At 31 December 2018, the company employed 18 persons.

Financial structure

Total equity came to € 3.5m at 31 December 2018 versus €7.4 m at 31 December 2017 In May 2018, the company undertook a €8.65m share issue, broadening the shareholder base, notably with the entry into the capital of US investors such as Novalis LifeSciences (created by Marijn Dekkers).

Financial debt was reduced to €1.7 m versus 2.2 m at December 2017, following the conversion of the Yorkville bond (40 convertible bonds were converted in Q1 2018). The contract signed with Yorkville for financing via convertible bonds with share warrants ('OCABSA') was done on 18 November 2018.

At 31 December 2018, Sensorion cash and cash equivalents amounted to €2.7m versus €8.8m at 30 June 2018. Cash flow linked to operating activities and investment amounted to €12.5m.

At 31 December 2018, the company lacked sufficient net working capital to meet its cash requirements for the coming 12 months. Following the bond issue generating €4.7m in gross income, and as of today, the company has requisite cash to ensure coverage of its day-to-day expenses and its development out till the middle of the second half of 2019. Hence the company has led and continue to lead the search for financing solutions mainly industrial partnership contracts or licence agreements on one or several of its product candidates but also the search for non-dilutive financing (grants and/or repayable advances) specifically to fund the company's research programs. Those financing solutions could comprise

- the search for financing via debt, simple or bond debt, convertible or not;
- further cash call with historic shareholders;
- the search for investors as part of fund raising that may take the form of an immediate share issue (reserved or not).

In addition, the company may re-dimension its operational plans by postponing or limiting the extent of its research and development programmes.

Press release

Capital breakdown

The company's capital breakdown at 31 December 2018 is as follows. The two last columns include the impact of any conversion of the entirety of the convertible bonds issued in March 2019 (the 'CBs').

Shareholders	Number of shares	% capital and voting rights	Number of shares (after conversion of the CBs)	% capital and voting rights (after conversion of the CBs)
Bpifrance Investissements (Innobio)	3,499,874	26.79%	3,499,874	20.83%
Inserm Transfert Initiative	982,911	7.52%	982,911	5.85%
Cochlear	533,755	4.09%	533,755	3.18%
Free float	7,878,886	60.3%	7,878,886	46.90%
Management	170,506	1.30%	170,506	1.02%
CB holders	-	-	3,733,574	22.22%
Total	13,065,932	100.00%	16,799,506	100.00%

Convertible bonds converted on the basis of the Sensorion share price at the close of March 5, 2019 (€1,024)

Key developments in 2018

Research and development

- **SENS-111 drug candidate: enrolment of 75% of the patients in the phase 2 proof of concept**

Sensorion has undertaken clinical phase 2 tests with SENS-111 in acute unilateral vestibulopathy (AUV). AUV has been chosen as the first indication to initiate the SENS-111 clinical programme as it is a pure disease for which the patient phenotype is quite homogenous. Two phase 2s were conducted in 2018, the positive results of the first were published in December, the second is ongoing.

The results of the phase 2a trial reported in December 2018 were aimed at comparing the tolerance of SENS-111 versus meclizine. Meclizine was chosen as it belongs to the histamine receptor antagonist class H1 and constitutes the first line treatment of vertigo in the US.

The results of the SENS-111 phase 2a trial met the main tolerance primary end point to a statistically significant degree. The trial confirms the initial postulate whereby the SENS-111 drug candidate impacts neither the vigilance nor the cognitive performance of patients during a motion stimulus.

The trial has shown that SENS-111, in contrast to meclizine, has no negative CNS side effects such as sedation, impairment of memory and of cognitive performance.

The study protocol of the ongoing Phase 2 clinical trial in acute unilateral vestibulopathy (AUV) has been amended as announced in 2018. Sensorion has received the necessary regulatory approvals for the continuation of the modified trial. Some 100 patients are now expected in centers opened in the United-States, Europe, Israel, and South Korea. The trial has proceeded with success as we have enrolled 75% of the forecast patients. Sensorion is progressing well in this trial and we confirm that the trial results will be released in the second half of 2019, to assess efficacy of the drug candidate.

Press release

These items will allow the company to build a strong data package covering the scientific, clinical and commercial strengths of SENS-111, thereby to crystallize a SENS-111 licence partnership.

- **SENS-401 drug candidate: start of the phase 2 trial in the treatment of sudden sensorineural hearing loss (SSNHL) and ongoing collaboration with Cochlear**

Sensorion launched a phase 2 clinical trial for SENS-401 in the treatment of SSNHL in adults. This randomised, double-blind and placebo-controlled phase 2 trial will unfold in 12 countries to enrol some 260 patients and has already started in fifteen or so sites in Europe and Canada. Interim results are expected in the second half of 2019.

Following the agreement initiated in December 2017, Sensorion and Cochlear (world leader in cochlear implants) pursued their collaboration. Based on the otoprotective properties demonstrated in several preclinical models, SENS-401 could potentially save the residual hearing of patients receiving cochlear implants. In 2018 we successfully performed additional safety studies to assess the feasibility of long duration treatment with SENS-401, which may be required in the cochlear implant indication. Supported by these results, studies were carried out to assess the different potential treatment modalities for cochlear implantation and to validate the local exposure levels of SENS-401 in the inner ear in preclinical models appropriate for cochlear implants (results jointly presented jointly with Cochlear at the 2018 ARO MidWinter Meeting).

- **Technological platform**

The company is accelerating the development and utilisation of its screening platform in all inner ear pathologies. We have increased throughput of the High Content Screening platform.

Collaboration has been initiated with internationally renowned 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

At various scientific congresses in 2018, Sensorion presented major preclinical results underpinning the development of its drug candidates, and in particular:

- The results presented to the ARO MidWinter Meeting concerning SENS-401 supplied key information on the treatment mode and the dosage to use in a clinical context for this drug candidate. Indeed, the comparison of administration of a dose of SENS-401 once per day and twice per day over a period of 28 days reveals an impact of the administration duration of the treatment, leading to a reduction in severe hearing loss caused by acoustic trauma in mouse models
- Moreover, the data presented in an oral presentation, at the 53rd American Neurotology Society (ANS) Annual Spring Meeting, confirm the potential efficacy of SENS-401 in a preclinical in vivo model in the treatment of SSNHL, even if the treatment starts several days after acoustic trauma (up to 96 hours). In a separate presentation at the same event, new preclinical study findings revealed the first potential biomarker for noise-induced hearing loss (prestin).
- SENS-401 demonstrated protective effects in two preclinical models of hearing loss, in studies that were presented at the 15th International Conference on Cochlear Implants and Other Implantable Auditory Technologies (Ci2018).
- The results presented to the Annual Congress of the Society for Neuroscience in San Diego in November suggest that the otoprotective efficacy of the treatment with SENS-401 is not affected by simultaneous administration of a corticoid following dosages equivalent to the doses recommended for the treatment of patients.

Ongoing negotiation for an exclusive collaboration with the Institut Pasteur on Gene Therapy programmes targeting hearing loss

On 23 November 2018, Sensorion announced the signature of a letter of intent with the Institut Pasteur (Paris, France) in order to collaborate exclusively on several research programs to co-develop and commercialize gene therapy product candidates for restoration, treatment and prevention of hearing loss disorders

The Pasteur Institute Unit of Genetics and Physiology of Hearing, headed by Professor Christine Petit, has developed world-class expertise over the last 25 years in hearing development, molecular physiology and physiopathology leading to gene therapy programmes for inner ear disorders. Sensorion and the Institut Pasteur should collaborate in the future on several programs to correct monogenic forms of hereditary hearing loss including, amongst others, the Usher Syndrome type1 and otoferlin-deficiency. The negotiations are ongoing.

Strategy and outlook: 2019 a turnaround year

Sensorion announced on March 11 a €4.7 million nominal bond issue, consisting of one (i) convertible bond issue¹ for a nominal amount of €3.4 million subscribed by several new European investors as well as (ii) a bond issue² for a nominal amount of €1.3 million subscribed by these same European investors for an amount of €1 million and the balance by the Company's management, Mr. Patrick Langlois, Chairman of the Board of Directors and Ms. Nawal Ouzren, Chief Executive Officer³.

At the same time, in order to promote the company's development, Bpifrance has included Sensorion in the "Hub Health Tech", a highly selective growth accelerator program designed for only five technology leaders in BPI's portfolio for the current promotion. This program also provides preparation for internationalization. Bpifrance thus confirms its interest and willingness to continue to actively support Sensorion in its development

Sensorion will continue to actively develop its drug candidates which are in clinical trials, while undertaking research work in its technological screening platform. As mentioned above, the results of the phase 2 trial on the efficacy of SENS-111 in acute unilateral vestibulopathy are expected during the second half of 2019 and the phase 2 of the SENS-401, in sudden hearing loss (SSNHL), is commencing with intermediary results expected at the end of the year.

Next publication

- **2019 interim results:** 17 October 2019

¹ i.e. 3,440,862 convertible bonds with a nominal value of €1 each

² i.e. 1,290,325 bonds with a nominal value of €1 each

³ Mr. Patrick Langlois, Chairman of the Company's Board of Directors, has subscribed, through his family holding company, for bonds, up to €50,000. Ms. Nawal Ouzren, Chief Executive Officer, has subscribed for bonds, up to €200,000

Press release



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. Our clinical-stage portfolio includes two phase 2 products: Seliforant (SENS-111) in acute unilateral vestibulopathy and Arazasetron (SENS-401) for sudden sensorineural hearing loss (SSNHL). We have built a unique R&D technology platform to expand our understanding of the pathophysiology and etiology of inner ear diseases enabling us to select the best targets and modalities for drug candidates. We also identify biomarkers to improve diagnosis and treatment of these underserved illnesses.

We are uniquely placed through our 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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