

## Sensorion reports full year 2017 results

- Increase in operating costs consistent with advancing clinical development of SENS-111 for acute unilateral vestibulopathy (severe vertigo) and SENS-401 for sudden sensorineural hearing loss;
  - Validating deal to study combination SENS-401 with Cochlear implants to treat hearing loss;
  - Cash position of €7.6 million at December 31, 2017;
- 2018 outlook: phase II clinical data for lead drug-candidate, SENS-111; initiation of phase II clinical testing for SENS-401

**Montpellier, April 12<sup>th</sup>, 2018 (7h30 CEST) – Sensorion (FR0012596468 – ALSEN), a biotechnology company specializing in the treatment of inner ear diseases, today announces full-year financial results for the year to December 31, 2017 and its outlook for 2018**

Nawal Ouzren, CEO of Sensorion, said: «Our full-year results are aligned with the clinical development for both SENS-111 and SENS-401. In addition, we received the Orphan Drug Designation from the U.S. FDA for SENS-401 to prevent cisplatin-induced hearing loss in paediatric cancer patients, indication for which we are considering a phase II clinical trial in 2019. Finally, we signed an industrial partnership with Cochlear Ltd, the world leader in cochlear implants, for the preclinical evaluation of SENS-401 in combination with their implants.

In 2018, we will concentrate on advancing and further accelerating our important clinical-stage therapeutic-candidates for inner ear disorders with focus on two key objectives: data read-out from the phase II clinical trial with SENS-111 and the start of a phase II clinical trial with SENS-401 in patients suffering from sudden sensorineural hearing loss».

### 2017 financial results

Annual accounts to December 31, 2017, drawn up under IFRS and approved by the Board of Directors on April 10, 2018, have been reviewed by the statutory auditors, whose report is currently being prepared.

The simplified income statement at December 31, 2017 was as follows:

In euros - IFRS	31/12/2017	31/12/2016
<b>Operating income</b>	2 025 413	<b>1 769 763</b>
Research & Development costs	7 872 735	7 817 751
General costs	3 668 464	2 373 384
<b>Total operating costs</b>	<b>11 541 199</b>	<b>10 191 135</b>
<b>Operating profit/loss</b>	<b>- 9 515 785</b>	<b>- 8 421 372</b>
Financial profit/loss	- 170 379	- 412 054
<b>Net profit/loss</b>	<b>- 9 686 164</b>	<b>- 8 883 426</b>

**Press Release**

At December 31, 2017, Sensorion's **operating income** – consisting mainly of Research Tax Credit (€1.9 million) and subsidies (€0.1 million) – totalled €2.0 million, compared with €1.8 million at December 31, 2016.

**Operating costs** increased by 13% from €10.2 million at December 31, 2016 to €11.5 million at December 31, 2017, reflecting the ongoing clinical development of the Company's two lead development candidates, SENS-111 to treat acute severe vertigo and SENS-401 for treating hearing loss, as well as by non-recurring costs related to the change of CEO in April 2017. R&D costs accounted for 68% of total operating costs, compared with 77% in 2016.

The **operating loss** at December 31, 2017 was €9.5 million, versus €8.4 million at December 31, 2016.

Once the **financial loss** (€0.2 million) is taken into account, there was a **net loss** of €9.7 million over the year to December 31, 2017, compared with €8.9 million the previous year.

The Company's workforce increased from 17 staff at December 31, 2016 to 20 at December 31, 2017.

## **Financial position**

At December 31, 2017, Sensorion had cash and cash equivalents of €7.6 million, versus €8.5 million a year earlier. This decrease was the result of €8.1 million (versus €7.7 million in 2016) used for operations, the receipt of a €950 thousand interest-free "innovation loan" Bpifrance and the Occitania region of Southern France and raising €5 million via the exercise of a third tranche of OCABSA financing (convertible bonds coupled with equity warrants) from Yorkville Advisors Global, LP, a U.S. healthcare specialist investor.

Finally, our industrial partner Cochlear made a €1,6 million equity investment in Sensorion on December 21, 2017, to evaluate combining SENS-401 with their cochlear implants.

Of the 500 equity warrants issued for this third tranche, 460 were converted into ordinary shares in 2017.

All of the 40 remaining equity warrants that had not converted into ordinary shares by their holder at December 31, 2017 were converted in January 2018. Within the framework of this flexible financing line put in place in November 2015, Sensorion has the option to increase its cash position by up to approximately €9 million over the next 7 months (plus €3.75 million should all the associated equity warrants be exercised) to further support its product development activities.

During the current financial year, Sensorion expects to receive €1.9 million in Research Tax Credit reimbursement, booked at December 31, 2017.

## **2017 Highlights**

- **Research & Development:**

- **SENS-111 AUV:** Following authorization by the US regulatory authorities in 2016, the phase II clinical trial in acute unilateral vestibulopathy has been authorized in 2017 in Europe and South Korea. The first clinical centers have been opened and the first patients enrolled. The company expects results from this clinical trial around the end of 2018.

- **SENS-401 SSNHL:** Preclinical results confirmed that regular oral administration of SENS-401, even when starting administration up to 96 hours after an acoustic trauma, generates significant recovery of hearing. Results from the phase I clinical trial with SENS-401 support the start of a Phase 2 clinical trial in 2018. Additional data will be communicated at a congress in April 2018.
- **SENS-401 CIO:** In 2017, Sensorion received an Orphan Drug Designation from the FDA for SENS-401 in the prevention of platinum-induced ototoxicity in paediatric cancer patients. This may contribute to acceleration of the SENS-401 development cycle and provide for 7 years commercial exclusivity in the USA, following potential market approval.

### • Scientific Communication

In 2017, Sensorion presented or published the results of its R&D activities at leading congresses or in leading publications:

- February 15, 2017: Sensorion inner ear disease product candidates (SENS-111 and SENS-401) and its innovative technology platform were featured in three posters and during one podium presentation at the 40th Association for Research in Otolaryngology (ARO) annual meeting held in Baltimore, MD.
- May 2, 2017: Sensorion presented preclinical results of SENS-401 for prevention of Cisplatin-induced ototoxicity in an oral podium presentation at the Combined Otolaryngology Spring Meetings (COSM), which took place in San Diego, CA.
- May 11-13, 2017: Sensorion was invited as speaker in the 1<sup>st</sup> joint meeting of the European Histamine Research Society and the Japanese Histamine Research Society.
- September 12, 2017: Data published in *Otology & Neurotology* showed that oral clinical-stage SENS-401 significantly prevented Cisplatin-induced hearing loss in preclinical models.

### • Strategic Partnership

In December 2017 Sensorion and Cochlear Ltd initiated a collaboration to evaluate therapeutic combination of SENS-401 in combination with Cochlear implants in a preclinical setting, with potential mid-stage clinical testing to begin as soon as 2019. Cochlear made a €1.6 million equity investment in Sensorion. In exchange, Cochlear received a right of first negotiation for a global license to use SENS-401 in combination with certain implantable devices.

### Recent events and 2018 outlook

Since the start of 2017, Sensorion has vigorously pursued the development of all its drug candidate programs, whose progress should mark this year:

- **SENS-111:** Results from the ongoing Phase 2 clinical trial, with the planned enrolment of 207 patients, shall be available towards the end of 2018.
- **SENS-401:** Sensorion plans to initiate a phase 2 clinical trial by the end of the first half of 2018. An interim analysis of results shall be available mid-2019.

- **SENS-401 CIO:** A Phase 2 clinical trial in a paediatric population treated by chemotherapy is being planned and could start beginning of 2019.

## Upcoming Events

- **COSM (Combined Otolaryngology Spring Meetings)**, April 18-22, 2018, National Harbor, MD, USA
- **52<sup>nd</sup> Symposium of the International Society for Otoneurology**, May 24-26 2018, Toulouse, France
- **Shareholders' Meeting**, May 31, 2018 in Paris
- **Half Year results 2018**, October 19, 2018.

## About Sensorion

Sensorion is a biotech company pioneering novel treatments of inner ear diseases such as severe vertigo, tinnitus or hearing loss. Two products are currently in the clinical development stage: SENS-111, in phase 2 in acute unilateral vestibulopathy (vestibular neuritis), and SENS-401, which has completed a phase 1 trial. The company was founded by Inserm (the French Institute of Health and Medical Research) and is utilizing its pharmaceutical R&D experience and comprehensive technology platform to develop first-in-class easy-to-administer, notably orally active, drugs for treating and preventing hearing loss and the symptoms of bouts of vertigo and tinnitus.

Based in Montpellier, Southern France, Sensorion has received financial support from Bpifrance, through the InnoBio fund, and Inserm Transfert Initiative.

Sensorion has been listed on the Euronext Growth Paris exchange since April 2015. [www.sensorion-pharma.com](http://www.sensorion-pharma.com)

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