

## Sensorion Reports 2017 First-Half Results

- *Advancing clinical development for SENS-111 and SENS-401 drug candidates*
- *Cash position of €9.2 million, as of June 30, 2017*

**Montpellier, October 18, 2017 – Sensorion (FR0012596468 – ALSEN / PEA-PME eligible), a biotech company pioneering novel treatments of inner ear diseases, today announces its results for the first half of the year ending June 30, 2017, as well as its recent developments.**

“Progress in the first half of 2017 was characterized by the acceleration of our clinical development programs for both SENS-111 and SENS-401,” said Nawal Ouzren, CEO of Sensorion. “We initiated the phase 2 clinical testing of SENS-111 to treat acute unilateral vestibulopathy. We are on schedule and look forward to reporting top line data towards the end of 2018.”

“Additionally, we completed phase 1 studies of SENS-401 and began preparations for our phase 2 trials. In August we were delighted to receive a second Orphan Drug Designation for SENS-401 from the US FDA, for the prevention, in children, of hearing loss induced by chemotherapy using platin salts,” Ms Ouzren added. “We are working with US and EU regulatory authorities to initiate two phase 2 clinical trials in 2018: the first to treat *sudden deafness*; the second to prevent *cisplatin-induced ototoxicity in a pediatric population*.”

### Financial results for the first half of 2017

The Company’s accounts for the first six months, until June 30, 2017, drawn up under IFRS, have been the subject of a limited review by statutory auditors and were approved by the Board on October 17, 2017.

They are characterized by a slight increase in operating costs associated with increased clinical development activity, resulting in cash use consistent with the Company’s development objectives. The Company’s financial structure is adequately sized to finance the development of its clinical programs.

The simplified income statement at June 30, 2017 is as follows:

<i>In Euros - IFRS</i>	<b>30.06.2017</b>	<b>30.06.2016</b>
<b>Operating income</b>	<b>1 092 946</b>	<b>1 123 646</b>
Research & Development expenses	3 941 363	4 167 797
General and Administrative expenses	1 571 117	1 250 884
<b>Total operating expenses</b>	<b>5 512 480</b>	<b>5 418 681</b>
<b>Operating profit / loss</b>	<b>-4 419 534</b>	<b>-4 295 035</b>
Financial profit / loss	-130 495	1 764
<b>Net profit / loss</b>	<b>-4 550 029</b>	<b>-4 293 271</b>

At June 30, 2017, Sensorion’s **operating income**, essentially consisting of a Research Tax Credit (€1,0 million), totaled €1,1 million, a slight decrease (-2,7%) compared with June 30, 2016.

**Operating expenses** increased from €5,4 million at June 30, 2016 to approximately €5.5 million at June 30, 2017, the result of sustained clinical development of the Company’s drug candidates and non-recurring expenses related to the departure of the former CEO and the recruitment of Nawal Ouzren as CEO.

### **Press release**

General and Administrative expenses have hence increased from €1.3 million at June 30, 2016 to approximately €1.6 million at June 30, 2017.

The **operating loss** at June 30, 2017 was -€4.4 million, compared with -€4.3 million at June 30, 2016.

After **financial profit** (€0.1 million), **net loss** amounts to €4.5 million at June 30, 2017, compared with a net loss of €4,3 million at June 30, 2016.

The Company had a staff of 20, as of June 30, 2017.

### **Balance Sheet Highlights**

At June 30, 2017, Sensorion had cash and cash equivalents of €9.2 million, versus €8.5 million at December 31, 2016. Cash used by operating and investment activities was €4.9 million.

Cash generated by financing activities was €5.6 million thanks to

- The exercise, on June 30<sup>th</sup>, 2017, of the third tranche of convertible notes with warrants amounting €5 million as part of the investment protocol signed on November 19, 2015 with Yorkville Global Advisors Ltd. An amendment to this protocol was signed with the subscriber and the latter renounced the benefit of the warrants attached to the convertible notes for this tranche, as well as for an optional tranche to be subscribed before December 19, 2017. In accordance with this flexible financing agreement, Sensorion still has the ability to strengthen shareholders' equity, depending on its requirements, by up to approximately €9 million in the coming 13 months.
- The inception of a specific "innovation loan" from Bpifrance and the Occitanie Region amounting €0.9 million.

### **Key developments during the first half 2017**

#### **SENS-111 drug candidate**

Following receipt of an Investigational New Drug (IND) status from the U.S. Food and Drug Administration in late 2016, allowing the Company to initiate clinical trials in the U.S., Sensorion received a separate additional authorization from the European authorities to initiate a phase 2 clinical trial in Europe. The Company started this clinical trial during the first half of 2017, opened clinical centers to recruit patients, as planned, and expects to treat 207 patients diagnosed with AUV and report top-line data towards the end of 2018.

#### **SENS-401 drug candidate**

During the first half of 2017, the Company successfully completed a phase 1 clinical trial establishing the safety of SENS-401, its second drug candidate.

Separately SENS-401 demonstrated in preclinical testing to have a preventive effect against cisplatin-induced ototoxicity. Sensorion subsequently received Orphan Drug Designation for SENS-401 by the FDA in this indication in a pediatric population and confirmed its objective to develop SENS-401 in this indication, in addition to sudden deafness.

Subject to regulatory authorizations, Sensorion plans to initiate phase 2 clinical trials with SENS-401, to treat sudden deafness and prevention of cisplatin-induced ototoxicity in a pediatric population in the first and second half of 2018, respectively.

#### **Technological platform**

The Company is continuing development and use of its specialized screening platform in all inner ear pathologies. The results obtained so far with the technology platform have been highly translatable in humans.

#### **Scientific communication**

During the first half of this year, Sensorion presented significant preclinical results in various scientific congresses. Several key studies were presented at the 40<sup>th</sup> Annual Meeting of the Association for Research in Otolaryngology (ARO), held on February 11-15, 2017, in Baltimore, MD.

### **Press release**

Preclinical data for SENS-401, recently published in the *Journal of Otology & Neurotology*, formed the basis for the FDA granting Orphan Drug Designation for prevention of platinum salt-induced ototoxicity in a pediatric population.

### **French Tech Pass certification**

In recognition of Sensorion's innovation and internationalization potential, the Company renewed its French Tech Pass certification giving it preferential access to the services provided by Bpifrance, Business France, DGE (*Direction Générale des Entreprises*, or Directorate-General for Enterprise), Coface and Inpi, and to the French Tech Pass regional partners and French Tech community networks.

### **Strategy and outlook**

Sensorion will actively pursue development of its clinical stage drug candidates, as well as research work using its screening technology platform.

### **Upcoming events**

- **First International Inner Ear Congress, November 1-3, 2017 (Marrakech)**
- **BIO Europe conference, November 6-8, 2017 (Berlin)**
- **Neuroscience (SFN), November 10-16, 2017 (Washington, D.C.)**
- **Actionaria trade fair, November 23-24, 2017 (Paris)**
- **British Pharmacological Society, December 11-13, 2017 (London)**

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### **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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**Press release**  
**Disclaimer**

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