

Sensorion Reports Pipeline Update and First-Half-Year 2018 Results Re-design of SENS-111 Study

- *Three active Phase 2 programs now for inner ear diseases extend the scope of the clinical pipeline*
- *Strategic research partnerships with world-leading research institutes and industry leaders (Cochlear) strengthen domain leadership*
- *Filing for re-design of SENS-111 study which addresses slower than expected patient recruitment*
- *Successful completion of €8.65 million in capital raise supports the strategy*
- *Cash position of €8.8 million as of June 30, 2018*

Montpellier, October 18, 2018 – 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, 2018, as well as its recent developments.

Sensorion obtained regulatory approval from international authorities (Europe and Canada)¹ to advance SENS-401 in Phase 2 for hearing disorders. SENS-401 has demonstrated otoprotective (hearing loss prevention) properties in various preclinical models. This has a significant commercial potential in an area of high unmet medical needs. The otoprotective effects may also benefit patients in the context of cochlear implants which is currently being investigated in collaboration with Cochlear, the global leader of implantable hearing solutions.

SENS-111 is still in Phase 2 clinical development for Acute Unilateral Vestibulopathy (AUV). AUV as the lead indication for SENS-111 was mainly driven by the need for a robust clinical pathway to demonstrate general proof of concept. Commercially the value of SENS-111 goes far beyond this AUV indication and resides in the opportunity to get the full label for vertigo.

Recruitment of suitable patients for the ongoing clinical trial in AUV has been more challenging than expected. Completion under the current protocol would potentially lead to a significant delay. Therefore, Sensorion decided to request a redesign of the current clinical protocol in order to reduce the sample size from 207 to around 100 while still generating efficacy signal. The expected data read out will now be in 2H 2019. This in addition to the ongoing Phase 2a safety trial comparing SENS-111 with Meclizine² for which data are expected by year-end will provide a robust data package showing the medical and commercial value of SENS-111.

“It is an exciting time for Sensorion and its patients as we advance our clinical stage pipeline into Phase 2 for inner ear disorders,” said Nawal Ouzren, CEO of Sensorion. “Despite the necessary adjustments of SENS-111 phase 2 AUV trial into a Proof-of-Concept study, I am pleased by the progress achieved over the last 12 months. Three active phase 2 programs, an additional investment of 8,65 Mio € by investors, the close partnerships with Professor Christine Petit as well as Cochlear, are testimony of our position and progress. With the adjustments we made today, we will be able to continue to focus our resources on areas of previously unmet medical needs while creating value for our investors.”

In May, the Company successfully completed a capital raise³ in a reflection of growing investor confidence in Sensorion’s expertise in inner ear diseases. As a result, the cash position at end June was €8.8 million, which allows Sensorion to conduct these Phase 2 trials and prepare for another Phase 2 study, for the prevention of ototoxicity induced by cisplatin in a pediatric population, to be potentially launched in 2019.

¹ Press release dated August 20, 2018

² Press release dated July 24, 2018

³ Press release dated May 18, 2018

Press release

Financial results for the first half of 2018

The Company's accounts for the first six months, until June 30, 2018, prepared under IFRS, have been the subject of a limited review by statutory auditors and were approved by the Board of Directors on October 17, 2018.

They are characterized by an increase in Research & Development expenses in line with the objective to initiate a phase 2 clinical trial with SENS-401 in the second half of 2018.

The simplified income statement at June 30, 2018 is as follows:

| <i>In Euros – IFRS</i> | 30.06.2018 | 30.06.2017 |
|-------------------------------------|-------------------|-------------------|
| Operating income | 1 299 199 | 1 092 946 |
| Research & Development expenses | 5 849 636 | 3 941 363 |
| General and Administrative expenses | 1 542 860 | 1 571 117 |
| Total operating expenses | 7 392 496 | 5 512 480 |
| Operating profit / loss | -6 093 297 | -4 419 534 |
| Financial profit / loss | -45 186 | -130 495 |
| Net profit / loss | -6 138 483 | -4 550 029 |

At June 30, 2018, Sensorion's **operating income**, essentially comprising Research Tax Credit, totaled €1.3 million, (+18,9%) compared with June 30, 2017.

Operating expenses increased from €5.5 million at June 30, 2017 to approximately €7.4 million at June 30, 2018, principally as a result of preparing the initiation of a phase 2 clinical trial with SENS-401

General and Administrative expenses are stable, having reached approximately €1.5 million at June 30, 2018 compared to approximately €1.6 million at June 30, 2017.

The **operating loss** at June 30, 2018 was € -6.1 million, compared with € -4.4 million at June 30, 2017.

Net loss amounts to € -6,1 million at June 30, 2018, compared with a net loss of € -4.6 million at June 30, 2017.

The Company had a staff of 20, as of June 30, 2018.

Balance Sheet Highlights

At June 30, 2018, Sensorion had cash and cash equivalents of €8.8 million, versus €7.6 million at December 31, 2017. Cash used by operating and investment activities was €6.5 million.

Cash generated by financing activities was €7.7 million principally thanks to a capital increase with institutional investors effective on May 18, 2018.

Key developments during the first half 2018

Capital Raise

Sensorion successfully completed a capital increase without preferential subscription rights for an amount of €8.65 million via an accelerated book-build offering. The success of the capital raise will allow implementation of the current Sensorion strategy.

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SENS-111 drug candidate

The study protocol of the ongoing Phase 2 clinical trial in acute unilateral vestibulopathy (AUV) will be amended to shorten it while also reducing the scope. Subject to the regulatory approval (which we believe we could obtain by the end of 2018), patient enrollment will be reduced from 207 to around 100 patients, which is still sufficient to achieve clinical proof of concept. The data from the study, now expected in H2 2019, will allow the Company to prepare a strong data package covering the scientific, clinical and commercial strengths of SENS-111 and support potential out-licensing. The clinical and commercial potential of SENS-111 go far beyond AUV, and may extend to many other neurological disorders, such as migrainous vertigo or Menière's syndrome, which represent substantial commercial opportunities.

SENS-401 drug candidate

Sensorion initiated a Phase 2 clinical trial for SENS-401 in the treatment of sudden sensorineural hearing loss (SSNHL) in adults. The randomized, double-blind, placebo-controlled Phase 2 study will be conducted across 50 sites in Europe, Canada, Israel, and Turkey and enroll approximately 260 patients. Interim topline data is expected in Q4 2019.

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, which further support the development of its drug candidates.

SENS-401 data presented at the ARO MidWinter Meeting provided critical information on treatment regimen and dose translation to the clinical setting for this promising drug candidate.

Data presented in an oral presentation, at the 53rd American Neurotology Society (ANS) Annual Spring Meeting, suggested that SENS-401 can be effective for SSNHL and even if used several days after acoustic trauma. In a separate presentation at the same event, new preclinical study findings revealed the first potential biomarker for noise-induced hearing loss.

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).

Innovative Company certification

The Company renewed its Innovative Company certification from Bpifrance. This certification recognizes the innovative characteristics of products, processes and techniques developed by Sensorion and authorizes French Mutual Funds for Innovation (Fonds Communs de Placement pour l'Innovation) to invest into Sensorion

Scientific Advisory Board

Professor Christine Petit, M.D., Ph.D. was appointed as the Chair of Sensorion's Scientific Advisory Board. Professor Christine Petit presently serves concurrently as Professor at College de France, Chair of Genetics and Cellular Physiology, Professor at Pasteur Institute (Paris) and as Head of the Laboratory of Genetics and Physiology of Hearing of the Pasteur Institute, affiliated to INSERM (UMRS 1120) and Sorbonne University (Paris). Professor Christine Petit will lead the future French Hearing Institute which will open in 2019.

Strategy and outlook

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

Press release

Upcoming events

- **Assay Development for Drug Discovery and Characterization (EMBL course), October 23-25 (Heidelberg)**
- **Neuroscience (SFN), November 3-7, 2018 (San Diego)**
- **Actionaria, November 22-23, 2018 (Paris)**

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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: Seliforant (SENS-111), in phase 2 in acute unilateral vestibulopathy, and arazasetron (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.

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