Press release

Sensorion reports full-year 2019 financial results and business update
Solid €30m cash position at year end and runway increased to beginning of Q3 2021

- ***PhII trial with SENS-401 in SSNHL started it will include patients from the French Armed Forces; SENS-401 received an IND in the US***
- ***Two preclinical Gene Therapy programs targeting Otoferlin and Usher Type 1 were initiated as part of the framework agreement signed with Institut Pasteur***
- ***Executive and scientific teams have been significantly strengthened in 2019 and early 2020 with the arrival of key renowned talents***
- ***Significant financing milestones were achieved with €38m raised with leading biotech investors and Chinese healthcare companies; €5.6m non-dilutive funding staged over five years was awarded from the French Government to Sensorion for the clinical development of SENS-401 and up to €9.7m to the "AUDINNOVE" consortium for development of Otoferlin gene therapy***
- ***Cash position was €30.4m at end of 2019 with a runway extended until beginning of Q3 2021 to adapt to the current environment***

Montpellier, April 2, 2020 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage and gene therapy biotech company which specializes in the development of novel therapies to treat, prevent and restore within the field of hearing loss disorders, announces its full-year 2019 financial results and provides an update on its business activities and outlook for 2020.

"Sensorion made significant progress in 2019 as we expanded our efforts in gene therapy development to treat monogenic forms of hearing loss. We are very proud to have established an exclusive collaboration with the world-leading experts of Institut Pasteur, led by Professor Christine Petit, in the genetics of hearing. Together we have the potential to develop treatments that could revolutionize patients' lives" **says Nawal Ouzren, CEO of Sensorion.**

"We were awarded non-dilutive funding from the French government for the clinical development of SENS-401 and the ongoing Phase 2 clinical trial will be further supported by the participation of the French military personnel. A successful capital increase, featuring leading long-term biotech investors, Invus and Sofinnova Partners, has validated our strategy, management and assets, while also reinforcing our financial position; we are well positioned to execute on our strategy. In addition, to navigate the current COVID-19 epidemic context, actions have been taken to save costs and extend our cash runway which is now until beginning of Q3 2021."

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2019 financial results

The annual accounts at December 31, 2019, drawn up according to IFRS standards and approved by the Board of Directors on April 1, 2020, have been duly reviewed by statutory auditors and the certification report is being issued.

The simplified income statement at December 31, 2019 is as follows:

In Euros – IFRS standards	**31.12.2019**	**31.12.2018**
Operating revenue	**2,522,717**	**2,309,859**
Research & Development expenses	10,208,520	11,907,943
General & Administrative expenses	3,128,236	2,627,684
Total operating expenses	**13,336,756**	**14,535,677**
Operating profit/loss	**-10,814,039**	**-12,225,767**
Financial charges	-1,282,141	-124,254
Net profit/loss	**-12,096,181**	**-12,350,021**

At December 31, 2019, Sensorion **operating revenue**, mainly the research tax credit, amounted to €2.5m, i.e. +9.2% compared with December 31, 2018.

Operating expenses declined by 8.2%, moving down from €14.5m at December 31, 2018 to €13.3m at December 31, 2019 due to costs containment measures.

G&A expenses are up 19.0%; they amounted to some €3.1m at December 31, 2019 compared with €2.6m at December 31, 2018 in relation to the corporate support costs related to the three financial operations (lawyers, issuance fees and advisors).

Operating loss at December 31, 2019 thus came to -€10.8 m, compared with -€12.2m at December 31, 2018.

The net financial charges which increased significantly to €1.3m are mainly due to the fees related to the convertible bond operations that occurred during 2019. The costs related to setting up debts recognized at fair value (convertibles bonds) are recognized as charges in the income statement.

Net loss came to -€12.1m at December 31, 2019 quite similar level compared to last year (-€12.4m at December 31, 2018).

At December 31, 2019, the company employed 20 persons.

- ## Financial structure

The simplified balance sheet at December 31, 2019 is as follows:

In Euros – IFRS standards	**31.12.2019**	**31.12.2018**
Non-current Assets	**1,724,348**	**1,165,840**
Other Current Assets	5,946,864	5,590,201
Cash & cash equivalent	30,428,319	2,711,217
Total Assets	**38,099,532**	**9,467,258**
Equity capital	**13,218,525**	**3,510,317**
Non-current Liabilities	2,036,933	1,616,803
Current Liabilities (including convertible bonds)	22,844,074	4,340,139
Total Liabilities	**38,099,532**	**9,467,258**

Total equity capital amounted to €13.2m at December 31, 2019 compared with €3.5m at December 31, 2018.

On March 2019, Sensorion undertook a bond issue of a nominal amount of €4.7m with European financial investors and management, 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. 4,516,133 bonds have been converted into 4,482,048 shares during the year.

Sensorion opened then its capital to two leading institutional biotech investors, Invus and Sofinnova Partners, which invested in Sensorion as long-term partners in June 2019 via a mandatory convertible bond issue for a nominal amount of €20 million. They have taken three seats on the board of directors (two for Invus, one for Sofinnova Partners) and are subject to a lock-up until June 30, 2020.

Sensorion completed a capital increase of €18.1 million in September 2019, with Invus and Sofinnova Partners participation as well as Wuxi AppTec and 3SBio. All investors who participated in this capital raise are subject to a lock-up until June 30, 2020.

Current liabilities at €22.8m include €20m of convertible bonds at December 31, 2019. Those bonds were fully converted by Invus and Sofinnova partners into Sensorion shares in February 2020.

At December 31, 2019, cash and cash equivalents amounted to €30.4m compared with €2.7m at December 31, 2018, thanks to the injection of funds stemming from the convertible bond issues and the subsequent capital increase.

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Capital Breakdown

The company's capital breakdown at December 31, 2019 is described in the table below. The next two columns include the impact of the conversion in February 2020 of all the convertible bonds issued in June 2019. The two last columns include the impact of the dilution of all BSPCE (stock options) attributed to employees and management.

	December 31, 2019		After conversion of Sofinnova Partners and Invus convertible bonds		On a fully diluted basis	
	Number of shares	Capital Ownership	Number of shares	Capital Ownership	Number of shares	Capital Ownership
Inserm Transfert Initiative	982,911	3.05%	982,911	1.68%	982,911	1.61%
Innobio (Bpifrance)	3,499,874	10.85%	3,499,874	5.98%	3,499,874	5.74%
Management, employees, directors[1][3][4]	221,582	0.69%	221,582	0.38%	1,817,493	2.98%
Cochlear	533,755	1.66%	533,755	0.91%	533,755	0.88%
Invus (OC 0624)[2]	4,121,599	12.78%	20,608,063	35.19%	20,608,063	33.82%
Sofinnova Partners (OC 0624)[2]	1,953,837	6.06%	11,822,258	20.19%	11,822,258	19.40%
New Investors (september 2019 capital raise)	9,489,051	29,43%	9,489,051	16.20%	9,489,051	15.57%
Free Float (including former officers)[4]	11,444,654	35.49%	11,405,558	19.48%	12,175,937	19.98%
Total	**32,247,263**	**100.00%**	**58,563,052**	**100.00%**	**60,929,342**	**100.0%**

Assumptions at December 31, 2019:
(1): Including 160,000 free shares granted on May 29, 2018
Assumptions after conversion of Sofinnova Partners and Invus convertible bonds:
(2): Based on a conversion of (OC 0624) at a price of €0.76
Assumptions on a fully diluted basis:
(3): Based on a conversion of (OC 0321) owned by an officer at a price of €1.30
(4): Including existing 2,030,109 BSPCE, BSA and free shares (including the 160,000 free shares granted on May 29,2018) issued by the company / 1 BSA = 1 share

Key developments in 2019 and beyond

R&D

- ***Launch of preclinical gene therapy programs***

After initiating the strategic collaboration with Institut Pasteur, Sensorion launched the first two preclinical programs, aiming at developing gene therapies that can correct hereditary monogenic forms of deafness, specifically deafness caused by a mutation of the gene encoding for Otoferlin (OTOF) and Usher syndrome Type 1 (USH1). Sensorion selected these projects under its exclusive agreement with the Genetics and Physiology Hearing Unit at Institut Pasteur, led by Professor Christine Petit, whose laboratory has developed world-class expertise over the last 25 years in the molecular physiology and physiopathology of the hearing system and generated data supporting the development of potential gene therapies.

In addition, the French government awarded up to €9.7 million to the "AUDINNOVE" consortium, notably including Necker Hospital, Institut Pasteur and Sensorion, to support the development of the OTOF program up to the first patient inclusion in the clinical trial.

- ***Non-dilutive funding for clinical development of SENS-401***

The French government awarded non-dilutive funding to the "PATRIOT" consortium for the clinical development of SENS-401, including work by Institut Pasteur to identify response biomarkers. The consortium includes the French Army Biomedical Research Center (IRBA), Institut Pasteur and Electronique du Mazet and the study will be the largest military trial ever conducted in France. As part of this consortium, Sensorion will receive up to €5.6 million over the duration of the project contingent on milestones completion.

- ***US IND approval for SENS-401***

Sensorion received Investigational New Drug (IND) approval from the US Food and Drug Administration (FDA) to proceed with SENS-401 based on the preclinical data and clinical development plan package.

- ***European Pediatric Investigation Plan approval for SENS-401***

The European Medicines Agency (EMA) accepted a Pediatric Investigation Plan (PIP) for development of SENS-401 in the treatment of SSNHL and for prevention of ototoxicity caused by cisplatin (CIO) in the pediatric population.

- ***Positive safety board review of ongoing SENS-401 Phase 2 trial***

An independent Data Safety Monitoring Board (DSMB) reviewed safety data for the patients who were included in the Phase 2 trial for the treatment of SSNHL and confirmed the absence of any concern as to the safety of SENS-401 and has recommended continuing the study.

- ***Results from SENS-111 Phase 2b trial in acute unilateral vestibulopathy***

SENS-111 (Seliforant) was safe and well tolerated in a Phase 2 proof-of-concept study for the treatment of acute unilateral vestibulopathy (AUV). However, it did not meet the primary endpoint of vertigo intensity and Sensorion stopped all development activities for SENS-111.

- ***Technological platform***

Our unique R&D technological platform allows us to expand our understanding of the pathophysiology and etiology of inner ear related diseases, enabling us to select the best targets and modalities for drug candidates. We have also identified a biomarker to improve diagnosis of these underserved illnesses.

Appointment of John Furey to the Board of Directors

John Furey, former COO of Spark Therapeutics, was appointed to the Board of Directors as independent board member. While at Spark Therapeutics, John led the successful launch of the first gene therapy in the US (LUXTURNA).

Scientific communication

Sensorion made presentations at a number of high-profile scientific congresses, including:

- Two posters at the ARO MidWinter Meeting, showing proof of efficacy for SENS-401 in preclinical models with a lasting SENS-401 protection of Cochlear Hair Cells in Organ Explant Cultures following Gentamicin ototoxic insult in vitro as well as data showing high nanomolar SENS-401 concentrations achieved in both perilymph and inner ear tissue after oral administration in three species, with some species differences.
- A poster presentation at the 2019 Annual Meeting of the Society for Neuroscience (SFN 2019), outlining studies that investigated the potential effects of animal model specificity on systemic and local SENS-

401 exposure using an acoustic trauma model in Wistar rats. It was found in those studies that the noise trauma did not affect the pharmacokinetics and local exposure of SENS-401.

- Three presentations at the 56th Workshop on Inner Ear Biology (IEB 2019), including a review of the development of the clinical stage oral SENS-401 with evidence supporting otoprotective efficacy in preclinical models of severe acoustic trauma and cisplatin-induced ototoxicity.

2020 announcements

- ***Conversion of Invus and Sofinnova Partners convertible bonds into ordinary shares***

On the 10th of February Invus Public Equities LP converted into ordinary shares of the company all of the 12,500,000 convertible bonds it had subscribed for in June 2019. The conversion was undertaken on a price basis of €0.76 per share resulting in Invus owning 20,591,259 ordinary shares right after conversion and 35.2% of the share capital and voting rights of Sensorion (after conversion of Sofinnova Partners convertible bonds).

On the 13th of February, Sofinnova Crossover I SLP converted into ordinary shares of the company all of the 7,500,000 convertible bonds it had subscribed for in June 2019. The conversion was undertaken on a price basis of €0.76 per share resulting in Sofinnova Crossover I SLP holding 11,822,258 ordinary shares right after conversion and 20.2% of the share capital and voting rights of Sensorion.

- ***Ethics Committee approval to include new military sites in SENS-401 Phase 2 study***

Sensorion has received approval from the Independent Ethics Committee of Strasbourg (France) to include new military sites in the ongoing Phase 2 study of SENS-401 in SSNHL. The new centers will recruit volunteer military personnel exposed to impulse noise during their professional activities and suffering from hearing loss. Inclusion of voluntary military patients on these new sites will start after final administrative steps are carried out.

- ***Appointment of new Chief Medical Officer***

Sensorion appointed gene therapy expert Géraldine Honnet MD, as Chief Medical Officer (CMO). Géraldine Honnet is a medical doctor and joins from Généthon, where she spent nine years as Chief Medical Officer, overseeing international gene therapy clinical trials in multiple rare diseases. Géraldine was responsible for the development of Généthon pipeline from pre-clinical to registration, managing Medical Affairs, Clinical Development, Clinical Operations and Regulatory affairs departments.

- ***Update on SENS-401 Phase 2 trial enrollment***

On the 13th of March, Sensorion made an update on timelines for the ongoing Phase 2 study of SENS-401 to treat Sudden Sensorineural Hearing Loss (SSNHL). Patient recruitment rates from this trial now indicate the data will be available by mid-year 2021, which is later than previously announced. The AUDIBLE-S trial is progressing but at a slower pace than our original expectations. An important factor also impacting recruitment in our trial is the repriorization of emergency room resources due to the current COVID-19 situation.

Upcoming clinical and preclinical milestones

- Interim preclinical data on SENS-401 to preserve hearing after cochlear implantation by mid-year 2020; full preclinical data package by year end 2020
- Preclinical milestones for OTOF and USH1 by mid-year 2020
- Phase 2 data for SENS-401 in Sudden Sensorineural Hearing Loss (SSNHL) by mid-year 2021

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Outlook for 2020 and COVID-19 situation update

Sensorion will keep advancing development of SENS-401 which is at clinical stage as well as pursuing research work using its R&D platform. Results from the Phase 2 of SENS-401 in Sudden Sensorineural Hearing Loss are expected by mid-year 2021. Preclinical data of SENS-401 in collaboration with Cochlear for preservation of hearing after cochlear implantation as well as preclinical milestones from the two gene therapy programs are expected this year.
Sensorion is closely monitoring the COVID-19 epidemic situation as well as its potential impact on activities of the company.
At this stage we are observing an impact on the SENS-401 phase 2 trial due to the repriorization of emergency room resources and confinement of populations. In order to avoid overload of healthcare facilities, to ensure safety of new potential patients, to prevent major protocol deviations due to non-respect of follow-up visits as planned in the protocol and to minimize contact between patients and investigational staff, the recruitment of new patients in the study has been temporarily suspended.
Regarding patients being in the study, there is a risk that it might be impossible for some of them to complete the follow-up visits as planned in the protocol of the study. Follow-up visits are being planned through teleconference or videoconference with the clinical sites with help from the clinical research organization working with Sensorion on this study. The current situation also poses a risk of delay in the opening of the new military sites that will recruit patients in the ongoing phase 2 trial of SENS-401 for sudden sensorineural hearing loss.
It's difficult to determine the evolution of the epidemic situation but there is a risk that it might cause delay in the realization of preclinical gene therapy studies carried out within the collaboration with Institut Pasteur. This would delay the preclinical results expected for the two ongoing programs.

As recommended by the French government, all the employees at Sensorion for which remote working is possible are effectively remotely working. For ethical reasons, an ongoing animal study with SENS-401 is continued with involvement of 3 employees alternating presence on site. This study is scheduled to end in April 2020 and no further animal study will be initiated before a favorable evolution of the epidemic context.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders. Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) for sudden sensorineural hearing loss (SSNHL). Sensorion has built a unique R&D technology platform to expand its understanding of the pathophysiology and etiology of inner ear related diseases enabling it to select the best targets and modalities for drug candidates. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses. Sensorion has launched in the second half of 2019 two preclinical gene therapy 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 medical need.
www.sensorion-pharma.com

Contacts

CEO
Nawal Ouzren
contact@sensorion-pharma.com
+33 4 67 20 77 30

Financial Communication
LifeSci Advisors - Sophie Baumont
sophie@lifesciadvisors.com
+33 6 27 74 74 49

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