Senseonics Holdings, Inc. Reports Fourth Quarter and Full Year 2019 Financial Results



March 12, 2020

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE American: SENS), a medical technology company focused on the development and commercialization of a long-term, implantable continuous glucose monitoring (CGM) system for people with diabetes, today reported financial results for the fourth quarter and full year ended December 31, 2019.

Recent Highlights & Accomplishments:

- Fourth Quarter total net revenue of \$9.0 million
 - OUS net revenue of \$8.1 million
 - U.S. net revenue of \$0.8 million after accounting for gross to net reductions, primarily related to the Eversense®Bridge Program
 - U.S. gross revenue was \$2.5 million. Reconciliations of net revenue and net U.S. revenue to gross revenue and U.S. gross revenue, respectively, have been provided in the tables following the financial statements in this press release. An explanation of these measures is also included below under the heading "Non-GAAP Financial Measures"
- Exceeded the 2019 goal of 100 million covered lives through positive coverage decisions from Cigna, Humana, Health Care Service Corporation (HCSC), and BC/BS Hawaii
- Received approval to continue the PROMISE study for 365 days in an extended cohort to gather feasibility data
- Published positive longitudinal data in *Diabetes Technology and Therapeutics* demonstrating Eversense performance over four sensor cycles was stable and did not decrease over time
- Launched the Eversense CGM System with a Non-Adjunctive Claim in the U.S., enabling diabetes patients to make treatment decisions from Eversense data, including insulin dosing

"We completed several milestones in 2019 including significantly raising awareness and broadening patient access for the Eversense CGM system as well as expanding the installed base of patients in the U.S. In addressing commercial headwinds, the

Eversense Bridge Program and Certified Eversense Specialist initiatives are successfully building the foundation and proper infrastructure to seamlessly integrate Eversense in the diabetes treatment ecosystem," said Tim Goodnow, PhD, President and Chief Executive Officer of Senseonics. "In addition, professional awareness continues to grow through data publications in peer reviewed journals and podium presentations. As we enter 2020, we are confident we are positioned to drive growth and achieve long-term success with Eversense."

Fourth Quarter 2019 Results:

In the fourth quarter of 2019, total revenue, net was \$9.0 million, which includes U.S. net revenue of \$0.8 million after accounting for gross to net reductions, primarily related to the Eversense Bridge Program and OUS net revenue of \$8.1 million, compared to total revenue, net of \$7.2 million for the fourth quarter of 2018. Fourth quarter 2019 total revenue, net grew 25% compared to the prior year period. Gross revenue for the fourth quarter of 2019 was \$10.7 million, including U.S. gross revenue of \$2.5 million.

Fourth quarter 2019 gross profit decreased by \$3.3 million year-over-year, to (\$8.2) million. The decrease in gross profit was primarily due to increased cost of sales expenses including charges for obsolete inventory and product enhancements, warranties and costs to streamline the sensor supply chain.

Fourth quarter 2019 sales and marketing expenses increased by \$0.7 million year-over-year, to \$11.0 million. The increase was due primarily to commercialization efforts in the U.S.

Fourth quarter 2019 research and development expenses increased by \$1.7 million year-over-year, to \$9.7 million. The increase in research and development expenses was primarily driven by expenses associated with the 180-day PROMISE clinical study.

Fourth quarter 2019 general and administrative expenses increased by \$0.6 million year-over-year, to \$5.9 million.

Net loss was \$35.6 million, or \$0.18 per share, in the fourth quarter of 2019, compared to \$7.3 million, or \$.04 per share, in the fourth quarter of 2018.

Full Year 2019 Results:

Total revenue, net for 2019 was \$21.3 million, which includes U.S. net revenue of \$3.2 million after accounting for gross to net reductions, primarily related to the Eversense Bridge Program and OUS net revenue of \$18.1 million, compared to total revenue, net of \$18.9 million for 2018. Full year 2019 total revenue, net grew 13% compared to 2018. Gross revenue for 2019 was \$26.2 million, including U.S. gross revenue of \$8.1

million. Full year 2018 total revenue contained no material gross to net revenue adjustments.

2019 gross profit decreased by \$11.3 million year-over-year, to (\$19.4) million. The decrease in gross profit was primarily due to increased cost of sales expenses including charges for obsolete inventory and product enhancements, warranties, costs to streamline the sensor supply chain and costs for warehousing and logistics.

Sales and marketing expenses for the year ended December 31, 2019 increased \$21.8 million year-over year, to \$49.6 million, compared to \$27.7 million for 2018. The increase in sales and marketing expenses was primarily related to increases in personnel-related costs and activity to support the U.S. commercialization of Eversense.

Research and development expenses for the year ended December 31, 2019 increased \$6.6 million year-over-year, to \$38.4 million, compared to \$31.9 million for 2018. The increase in research and development expenses was primarily driven by the 180-day PROMISE clinical study costs.

General and administrative expenses for the year ended December 31, 2019 increased \$3.4 million, year-over-year, to \$23.2 million, compared to \$19.8 million for 2018. The increase in general and administrative expenses was driven primarily by an increase in personnel-related expenses, increased legal and audit expenses and other costs associated with supporting a growing operational infrastructure.

Net loss was \$115.5 million, or \$0.61 per share, for the year ended December 31, 2019, compared to \$94.0 million, or \$0.60 per share, for 2018. Net loss per share for 2019 was based on 188.8 million weighted average shares outstanding, compared to 157.4 million weighted average shares outstanding for 2018.

As of December 31, 2019, cash and cash equivalents were \$95.9 million and outstanding indebtedness was \$144.9 million.

2020 Financial Outlook

Net revenue for full year 2020 (after accounting for the gross to net reductions primarily related to the Eversense Bridge Program) is expected to be in the range of \$15 to \$20 million. The 2020 net revenue guidance range contemplates U.S. net revenue growth of approximately 100% and OUS net revenue decrease of approximately 33%. Gross revenue for full year 2020 is expected to be in the range of \$25 to \$30 million.

Going Concern

The Company intends to file its Annual Report on Form 10-K for the year ended December 31, 2019 on or before March 16, 2020, with the Securities and Exchange

Commission and the Company expects that the audited financial statements that will be included in the filing will contain a going concern emphasis of a matter paragraph in the audit opinion from its independent registered public accounting firm. This announcement is made pursuant to NYSE American Company Guide Sections 401(h) and 610(b), which require public announcement of the receipt of an audit opinion containing a going concern paragraph.

Credit Facility

Under the Company's Loan and Security Agreement with Solar Capital, the Company is required to satisfy a trailing six-month minimum product revenue covenant. The Company was in compliance with this covenant as of December 31, 2019. However, the Company expects that it will be in noncompliance with the covenant as of March 31, 2020 and that, absent a waiver or amendment to the terms of the Loan and Security Agreement, the Company would likely remain in noncompliance with the covenant for the foreseeable future thereafter. The Company has been engaged in discussions with Solar Capital to procure a waiver of this expected noncompliance. If the Company is not able to obtain a waiver, it is possible that the outstanding indebtedness under the Loan and Security Agreement and the Company's convertible notes due 2025, which contain cross-default provisions, could be accelerated and become immediately due and payable.

Conference Call and Webcast Information

Company management will host a conference call at 4:30 pm (Eastern Time) today, March 12, 2020, to discuss these financial results and recent business developments. This conference call can be accessed live by telephone or through Senseonics' website.

Live Teleconference

Information:

Dial in number: 877-883-

0383

Entry Number: 5108232
International dial in: 412-

902-6506

Live Webcast Information:

Visit http://www.senseonics.com and select the "Investor Relations" section

A replay of the call can be accessed on Senseonics' website http://www.senseonics.com under "Investor Relations."

About Senseonics

Senseonics Holdings, Inc. is a medical technology company focused on the design, development and commercialization of transformational glucose monitoring products designed to help people with diabetes confidently live their lives with ease. Senseonics' CGM systems, Eversense® and Eversense® XL, include a small sensor inserted completely under the skin that communicates with a smart transmitter worn over the sensor. The glucose data are automatically sent every 5 minutes to a mobile app on the user's smartphone.

Non-GAAP Financial Measures

In accordance with U.S. GAAP, Senseonics reports revenue in its financial statements on a net basis, which considers gross to net reductions resulting from discount programs, such as the Eversense Bridge Program. To supplement its condensed consolidated financial statements, which are prepared and presented in accordance with U.S. GAAP and present total revenue, net, Senseonics is also providing investors with gross revenue and U.S. gross revenue. These measures do not reflect the gross to net reductions from these discount programs and, accordingly, may be non-GAAP financial measures. The presentation of these non-GAAP financial measures is not intended to be considered in isolation or as a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP, and Senseonics' non-GAAP measures may be different from non-GAAP measures used by other companies.

Senseonics uses these non-GAAP financial measures for financial and operational decision-making. Senseonics' management believes that these non-GAAP financial measures provide meaningful supplemental information regarding Senseonics' performance and provide better transparency on the impact of reimbursement and the Eversense Bridge Program. Senseonics believes that both management and investors benefit from referring to these non-GAAP financial measures in assessing Senseonics' performance and when planning, forecasting, and analyzing future periods. For more information on these non-GAAP financial measures, please see the reconciliation of these non-GAAP financial measures to their nearest comparable GAAP measures at the end of this press release.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for Senseonics, including statements about Senseonics' growth and long-term success with Eversense, Senseonics' projected net revenue for full year 2020, the ongoing commercialization of Eversense and the potential life-enhancing benefits Eversense offers people with diabetes, the effect of efforts to increase market adoption, the impact of coverage decisions, and other statements containing the words "believe," "expect," "intend," "may," "projects," "will," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking

statements as a result of various important factors, including: the ability to obtain a waiver of compliance with, or amendment to, financial covenants under the Loan and Security Agreement, uncertainties in the development and regulatory approval processes, uncertainties inherent in the commercial launch and commercial expansion of the product, and such other factors as are set forth in the risk factors detailed in Senseonics' Annual Report on Form 10-K for the year ended December 31, 2018, the 10-Q for the quarter ended September 30, 2019 and Senseonics' other filings with the SEC under the heading "Risk Factors." In addition, the forward-looking statements included in this press release represent Senseonics' views as of the date hereof. Senseonics anticipates that subsequent events and developments will cause Senseonics' views to change. However, while Senseonics may elect to update these forward-looking statements at some point in the future, Senseonics specifically disclaims any obligation to do so except as required by law. These forward-looking statements should not be relied upon as representing Senseonics' views as of any date subsequent to the date hereof.

Senseonics Holdings, Inc	C.		
Selected Consolidated Balance S	heet	t Data	
(in thousands)			
		Decen	nber 31,
		2019	2018
Cash and cash equivalents	\$	95,938	\$ 136,793
Working capital ⁽¹⁾		1,050	129,220

Total assets	132,800	159,973	
Notes payable, net of discount, including current portion	90,043	14,783	
Total liabilities	141,449	88,712	
Additional paid-in capital	464,491	428,878	
Accumulated deficit	(473,343)	(357,794)	
Total stockholders' (deficit) equity	(8,649)	71,261	
(1) Working capital includes the outstanding indebtedness under the Loan and Security Agreement with Solar Capital and the convertible notes due 2025, classified as short-term liabilities due to the reasonable probability of noncompliance with the revenue covenant as of March 31, 2020 as described			

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above.

Senseonics Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except for share and per share data)

Year Ended December 31,

		2019	2018
Revenue, net	\$	4,924	\$ 2,039
Revenue, net - related parties		16,377	16,874
Total revenue		21,301	18,913
Cost of sales		40,749	27,059
Gross profit		(19,448)	(8,146)
Expenses:			
Sales and marketing expenses		49,555	27,730
Research and development expenses		38,430	31,863
General and administrative expenses		23,229	19,839
Operating loss	((130,662)	(87,578)
Other income (expense), net:			
Interest income		1,933	2,001
Interest expense		(12,197)	(8,282)
Debt issuance costs		(3,344)	_
Change in fair value of derivative liabilities		29,232	209

For the Three Months Ended <u>December 31, 2019</u>			1	Ende	e Months d 1, 2019
Reconcilia	tion of Total Revenue, (in thousand		o Gross Reve	enue	
	Senseonics Holdir	ıgs, I	nc.		
Basic and diluted weighted-average shares outstanding 188,			38,754,160	15	7,429,145
Basic and diluted net lo	oss per common share	\$	(0.61)	\$	(0.60)
Total comprehensive loss			(115,549)	\$	(93,971)
Net loss			(115,549)		(93,971)
Total other income (expense), net			15,113		(6,393)
Other (expense) income			(511)		(321)

Gross to net eductions	1,724	4,902
Gross revenue	\$ 10,677	\$ 26,203

Senseonics Holdings, Inc.

Reconciliation of U.S. Revenue, Net to U.S. Gross Revenue

(in thousands)

	For the Three Months Ended December 31, 2019		Ended		E	he Twelve Months Ended cember 31, 2019	
U.S. Revenue, net	\$	810	\$	3,247			
Gross to net reductions		1,724		4,902			
U.S. Gross revenue	\$	2,534	\$	8,149			

Senseonics Holdings, Inc.

Reconciliation of Forecasted Revenue, Net to Forecasted Gross Revenue

(in millions)

	Year Ending December 31, 2020
Revenue, net	\$ 15.0 – 20.0
Gross to net reductions	8.0 – 12.0
Gross revenue	\$ 25.0 – 30.0

View source version on businesswire.com:

https://www.businesswire.com/news/home/20200312005761/en/

Investor Contact

Lynn Lewis or Philip Taylor

Investor Relations

415-937-5406

Investors@senseonics.com

Source: Senseonics Holdings, Inc.