

Senseonics Holdings, Inc. Reports Fourth Quarter and Full Year 2021 Financial Results



March 01, 2022

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE American: SENS), a medical technology company focused on the development and manufacturing of long-term, implantable continuous glucose monitoring (CGM) systems for people with diabetes, today reported financial results for the quarter and full year ended December 31, 2021.

Recent Highlights & Accomplishments:

- Received approval from the Food and Drug Administration (FDA) for the Eversense® E3 CGM System, offering patients:
 - Fully implantable third generation sensor, with proprietary sacrificial boronic acid (SBA) technology to enhance sensor longevity, demonstrating a mean absolute relative difference (MARD) of 8.5% in the PROMISE Study.
 - Industry leading 6-month sensor wear duration, making Eversense the longest lasting CGM system available, with essentially two sensor insertion and removal procedures per year.
 - Removable smart transmitter, held in place with a mild silicone-based adhesive, providing discreet on-body vibratory alerts and data transmission to a mobile app where glucose values, trends, and alerts are displayed.
- Initiating E3 commercial launch in the U.S. at the beginning of April, with active transition to the 6-month system and retirement of the 90-day system
- Executed consignment agreements with health care professionals to reduce acquisition barriers and expect to begin shipping product next week
- Achieved 8 million additional covered lives with positive coverage decisions from payors including Blue Cross Blue Shield of Michigan, Medical Mutual of Ohio, and CareSource
- Received CE mark for Eversense NOW Remote Monitoring App for Android users

“Following recent FDA approval, we are excited to make Eversense E3, an industry leading 6-month sensor, available to patients and health care providers in the U.S. in early April. Our partner Ascensia is establishing a newly dedicated CGM commercial organization to drive both adoption and awareness of the Eversense E3,” said Tim

Goodnow, PhD, President and Chief Executive Officer of Senseonics. “We are excited to continue advancing our long-term implantable sensor pipeline and IDE pivotal study approval for our next-generation one year sensor this year.”

Fourth Quarter 2021 Results:

Total revenue for the fourth quarter was \$4.0 million compared to \$3.9 million for the fourth quarter of 2020. This increase was due to the transition of commercial responsibility for Eversense to Ascensia and its orders for distribution in the European Union and in the United States. For the fourth quarter comparisons, U.S. revenue was \$0.7 million in 2021 compared to \$0.4 million in 2020, and revenue outside the U.S. was \$3.3 million in 2021 compared to \$3.5 million in 2020.

Fourth quarter 2021 gross loss declined by \$3.1 million year-over-year, to \$0.5 million, as compared to a gross profit of \$2.6 million for the fourth quarter 2020 due to utilization of previously written-off inventory in 2020.

Fourth quarter 2021 sales and marketing and general and administrative expenses decreased by \$2.4 million year-over-year, to \$5.8 million. The decrease was primarily the result of the transition of sales support to Ascensia for the commercialization of Eversense.

Fourth quarter 2021 research and development expenses increased by \$3.0 million year-over-year, to \$7.7 million. The increase was due to the expansion of the R&D workforce, and an increase in clinical studies, lab supplies, and contractor expenses.

Net income was \$84.4 million, or \$0.19 per share, in the fourth quarter of 2021, compared to a net loss of \$101.6 million, or (\$0.41) per share, in the fourth quarter of 2020. Net income increased by \$186.1 million due to the accounting for embedded derivatives and fair value adjustments.

Full Year 2021 Results:

Total revenue for 2021 was \$13.7 million compared to total revenue of \$4.9 million in 2020. U.S. revenue was \$2.6 million in 2021 versus \$1.1 million in 2020. Revenue outside the U.S. was \$11.1 million in 2021 versus \$3.8 million in 2020. This increase was due to the resumption of post-Covid sales and the transition of commercial responsibility for Eversense to Ascensia. Ascensia assumed commercial responsibilities for Eversense XL outside the U.S. beginning on February 1, 2021 and for the 90-day Eversense product in the U.S. during the second quarter of 2021.

Gross loss for 2021 improved by \$16.6 million year-over-year, to \$0.8 million. The 2020 gross loss of \$17.4 million was largely the result of inventory impairment charges.

Sales and marketing and general and administrative expenses for 2021 decreased by \$12.2 million year-over-year, to \$29.2 million. The decrease was primarily the result of the reduction in sales support due to the transition of Eversense commercialization responsibility to Ascensia.

Research and development expenses for 2021 increased by \$6.8 million year-over-year, to \$27.2 million. The increase was due to the expansion of our R&D workforce and various R&D efforts to improve our sensor & transmitter technology in 2021, including the FDA approval of our Eversense E3 system.

Net loss was \$302.5 million, or (\$.72) per share, in 2021, compared to \$175.2 million, or (\$0.77) per share, in 2020. Net loss decreased by \$127.3 million due to a \$149.3 million decrease to other expenses primarily related to the accounting for embedded derivatives and fair value adjustments, partially offset by an increase in expense for the extinguishment and issuance debt.

As of December 31, 2021, cash, cash equivalents, short and long-term investments were \$181.8 million and outstanding indebtedness was \$107.0 million.

2022 Financial Outlook

Global net revenue to Senseonics for the full year 2022 is expected to be in the range of \$14.0 million to \$18.0 million.

Conference Call and Webcast Information:

Company management will host a conference call at 4:30 pm (Eastern Time) today, March 1, 2022, 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: 888-317-6003
Entry Number: 2775821
International dial in: 412-317-6061

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 development and manufacturing of glucose monitoring products designed to transform lives in the global diabetes community with differentiated, long-term implantable glucose management technology. Senseonics' CGM systems, Eversense®, Eversense® XL and Eversense® E3 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.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for Senseonics, including the revenue projections under “2022 Financial Outlook,” statements about the potential benefits of the Ascensia commercialization and collaboration agreement, including the ability of Ascensia to grow the market for Eversense, the future increase in patient and provider awareness of Eversense, reductions in patient costs and expansion of access to Eversense, and other statements containing the words “believe,” “expect,” “intend,” “may,” “projects,” “will,” “planned,” 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: uncertainties inherent in the commercial launch of Eversense E3 CGM system and commercial expansion of the Eversense product, uncertainties inherent in the transition of commercialization responsibilities to Ascensia and its commercial initiatives, uncertainties in insurer, regulatory and administrative processes and decisions, uncertainties in the duration and severity of the COVID-19 pandemic, 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, 2020 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.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

December 31,
2021

December 31,
2020

Assets

Current assets:

Cash and cash equivalents	\$ 33,461	\$ 18,005
Restricted cash	—	200
Short term investments, net	96,445	—
Accounts receivable, net	205	565
Accounts receivable - related parties	1,768	2,421
Inventory, net	6,316	5,281
Prepaid expenses and other current assets	6,218	3,774
Total current assets	144,413	30,246
Option	239	1,886
Deposits and other assets	1,086	2,229

Long term investments, net	51,882	—
Property and equipment, net	1,308	1,557
Total assets	\$ 198,928	\$ 35,918

Liabilities and Stockholders' Deficit

Current liabilities:

Accounts payable	\$ 1,204	\$ 1,762
Accrued expenses and other current liabilities	14,264	11,674
Term Loans, net	2,926	3,202
Total current liabilities	18,394	16,638

Long-term debt and notes payables, net	59,798	57,216
Derivative liabilities	236,291	62,119
Option	69,401	39,734
Other liabilities	579	1,483
Total liabilities	384,743	177,190

Preferred stock and additional paid-in-capital, subject to possible redemption: \$0.001 par value per share; 0 shares issued and outstanding as of December 31, 2021 and 3,000 shares issued and outstanding as of December 31, 2020	—	2,811
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Total temporary equity	—	2,811
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Commitments and contingencies

Stockholders' deficit:

Common stock, \$0.001 par value per share; 900,000,000 shares authorized; 447,282,263 and 265,582,688 shares issued and outstanding as of December 31, 2021 and December 31, 2020	447	266
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Additional paid-in capital	765,215	504,162
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Accumulated other comprehensive income, net of tax	(212)	—
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Accumulated deficit	(950,985)	(648,511)
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Total stockholders' deficit	(185,535)	(144,083)
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Total liabilities and stockholders' deficit	\$ 198,928	\$ 35,918
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Senseonics Holdings, Inc.

**Unaudited Condensed Consolidated Statements of Operations and
Comprehensive Loss**

(in thousands, except share and per share data)

Years Ended

December 31,

2021

2020

Revenue, net	\$	1,394	\$	1,368
Revenue, net - related parties		12,281		3,581
Total revenue		13,675		4,949
Cost of sales		14,486		22,315
Gross profit (loss)		(811)		(17,366)

Expenses:

Sales and marketing expenses	7,616	20,550
Research and development expenses	27,217	20,413
General and administrative expenses	21,538	20,801
Operating loss	(57,182)	(79,130)
Other income (expense), net:		
Interest income	243	175
Loss on fair value adjustment of option	(53,152)	(30,721)
Gain (Loss) on extinguishment of debt and option	330	(21,112)
Loss on issuance of debt & other issuance costs	—	(12,706)
Interest expense	(16,720)	(16,167)
Debt issuance costs	—	(1,216)
Gain (Loss) on change in fair value of derivatives	(174,173)	(11,641)
Impairment cost	(1,647)	(2,339)
Other expense	(174)	(311)
Total other income (expense), net	(245,292)	(96,038)

Net Loss	(302,474)	(175,168)
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Other comprehensive loss, net of tax

Unrealized loss on marketable securities	(212)	—
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Total other comprehensive loss, net of tax	(212)	—
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Total comprehensive loss, net of tax	\$ (302,686)	\$ (175,168)
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Basic net loss per common share	\$ (0.72)	\$ (0.77)
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Basic weighted-average shares outstanding	422,321,023	(227,912,358)
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Diluted net loss per common share	\$ (0.72)	\$ (0.77)
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Diluted weighted-average shares outstanding	422,321,023	227,912,358
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<https://www.businesswire.com/news/home/20220301006126/en/>

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