

# Senseonics Announces Business Updates



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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 announced operational and financial business updates.

## Operational and Financial Updates

- Substantive review with the FDA for the PMA supplement for the next generation Eversense 180-day CGM system is nearing completion, all queries raised have been answered and a decision regarding approval is expected in the coming weeks
- Designing plans with Ascensia Diabetes Care for a smooth transition to the 180-day system in the U.S., pending FDA approval, including:
  - Marketing campaigns to highlight the availability of system upgrade programs for patients and to increase overall patient awareness
  - Payor engagement regarding reimbursement and coverage transitionsThese plans are being designed with a goal of minimizing the impact to patients, providers and sales, taking into account the expected use of existing inventory in Q1 2022 and initiating transition to the new product in Q2 2022
- Reiterating 2021 financial outlook expectation for full year 2021 global net revenue to be in the middle of the revenue guidance range of \$12.0 million to \$15.0 million

“We understand that the FDA is at full capacity managing the backlog of COVID-19 related filings creating longer than expected review timelines. We are confident a decision regarding approval of the 180-day system will be made in the coming weeks as the FDA continues to clear out the backlog,” said Tim Goodnow, PhD, President and Chief Executive Officer of Senseonics. “In 2021 we integrated operations and coordination activities with our commercial collaborator Ascensia Diabetes Care. A thoughtful go-to-market strategy is being designed to target a smooth transition to the 180-day system while providing uninterrupted service for patients, providers and

payors. We are excited to advance long-term solutions for people with diabetes as we continue to aim to make the new 180-day system available in the U.S..”

## 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® 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.

## Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for Senseonics, including statements about Senseonics' expected net revenue for the full year of 2021 and the full year of 2022, the timing and outcome of the potential decision on the 180-day Eversense system from the FDA, the timing, effectiveness and readiness for launch of the 180-day Eversense system, the ability to collaborate with Ascensia Diabetes Care, the ability to smoothly transition patients, physicians and payors, the impact of existing inventory and transition timing on financial results, the ability to manage such impact, 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 in the regulatory approval process, uncertainties inherent in the commercial launch and commercial expansion of the product, 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, Senseonics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 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.

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