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Senseonics Projects Slow Growth In 2022 Despite FDA Approval Of Eversense E3 CGM

by [Reed Miller](#)

Senseonics announced the long-awaited FDA approval of its Eversense E3 implantable CGM, featuring a sensor that lasts up to six months. The company is also developing a one-year version of Eversense and a transmitter-less version, but the stock market is disappointed with its sales projections.

[Senseonics'](#) modest revenue projections for 2022 disappointed investors, even as the company is touting the long-awaited US Food and Drug Administration approval of its next-generation Eversense E3 implantable continuous glucose monitor (CGM).

[The new premarket supplement](#) labels Eversense E3 for up to 180 days of continuous use. It [supplement to Senseonics' 2018 PMA](#) for the original version of the Eversense CGM system that indicated Eversense CGM to continually measure glucose levels in adults with diabetes for up to 90 days. In 2019, [the FDA approved Eversense](#) as a replacement for fingerstick testing. (Also see "[Continuous Glucose Monitor From Senseonics Earns FDA Approval For 'Non-Adjunctive' Claim](#)" - Medtech Insight, 10 Jun, 2019.)

Eversense E3's fully-implantable sacrificial boronic acid sensor is the longest lasting CGM sensor available and offers exceptional accuracy, according to the company. [Results](#) from the 181-patient [PROMISE](#) study of Eversense E3 confirmed its "sustained accuracy and safety" for up to 180 days.

"Further extending the duration of the longest lasting CGM system to six months represents a massive leap forward for patients," Senseonics CEO Tim Goodnow said.

Eversense E3 has a removable smart transmitter that sticks to the user with a mild silicone-based adhesive. The transmitter powers the glucose sensor wirelessly through near-field technology, provides discreet vibration alerts to the user, and transmits data to a mobile app where the user

can see their glucose values, trends, and alerts.

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Senseonics originally hoped to launch Eversense E3 last year. The company submitted the application for the PMA supplement in September 2020, but the approval was delayed for a year due the FDA’s shift to “COVID-19 priorities,” according to Goodnow. (Also see "[US FDA Device Center Hopes For ‘Normal Operations’ In 2022](#)" - Medtech Insight, 22 Dec, 2021.)

Beginning in the second quarter of 2022, Eversense E3 will be distributed in the US by New Jersey-based Ascensia Diabetes Care, which also markets the Contour line of blood glucose monitoring systems and recently created a dedicated CGM commercial team.

“We look forward to initiating Eversense E3 sales and believe that, with Ascensia’s newly dedicated CGM commercial organization, the launch of the new six-month product will establish the foundation for growth in our installed base later in 2022 and beyond,” Goodnow said.

Elaine Anderson, the head of Ascensia’s Eversense CGM business unit said, “[Eversense E3’s] unique features and benefits offer people with diabetes unparalleled flexibility, convenience, and accuracy.”

Senseonics is developing Eversense 365, a version of Eversense with next-generation Rome sensors that can last a full year.

During Senseonics’ presentation at the Jefferies London Healthcare Conference in November 2021, Goodnow explained, “The 365-day [version] is not only an improvement and further improvement in the chemistry for long-term viability in the body, but it’s also a new architecture.” This version has two embedded sensors with multiple arrays and will only need to be calibrated by the user with a fingerstick once per week, he said.

The company is also working on the Freedom system, a CGM implant with its own battery and data-processing capacity that obviates the need for a separate transmitter.

Other than longer duration between sensor changes, what CGM users ask for most often is a

system that does not require them to wear something on their skin, Goodnow said during the Stifel Healthcare Conference in November 2021.

Wall Street Is Disappointed With Sales Projections

Following the announcement of Eversense E3's approval, Senseonics announced a preliminary report on its 2021 full-year sales along with financial guidance for 2022.

The company's full-year 2021 revenue was approximately \$13.7m, including \$4m in the fourth quarter, and it expects its revenue in 2022 to reach between \$14m and \$18m.

Most of Senseonics' expenses in 2022 will go into research and development, including clinical trials of the one-year version of Eversense, according to the company. As of the end of 2021, the company had \$182m in cash, cash equivalents and marketable securities.

The company will announce its complete 2021 sales and earnings on 1 March.

"The valuation ... is unsustainable." – Jayson Bedford

Despite the announcement of Eversense E3's long-awaited FDA approval, investors were disappointed with Senseonics' projections for 2022. The company's stock price on the New York Stock Exchange dropped from \$3.64 on 10 February to below \$2.15 on 14 February.

In an 11 February note, Raymond James analyst Jayson Bedford wrote, "US approval of Eversense E3 [with the] 180-Day sensor was well-anticipated and is an important milestone for Senseonics."

However, Bedford pointed out that Senseonics' current market cap is more than \$2bn – about 40 times its estimated 2023 earnings – while its "peer companies'" market caps are around eight times their annual earnings. "Senseonics [is] one of the most dislocated stocks in our universe, as estimates are trending lower, and the valuation, in our view, is unsustainable."

According to Bedford, the CGM market is worth around \$10bn and growing 17% annually, but only about 60% of type 1 diabetics – Senseonics' main target – are currently using a CGM device, so the company is addressing a large, underpenetrated market opportunity.

However, the analyst believes Senseonics may struggle to take customers away from established

players [Abbott](#), [DexCom](#), and [Insulet](#). (Also see "[Exec Chat: Dexcom's CEO Bullish On Year Ahead With G7 CGM Launch, Dexcom One CGM Expansion](#)" - Medtech Insight, 20 Jan, 2022.)