
Senseonics renews Roche distribution agreement, adding 17 countries; expects record \$8 million in 4Q18 revenue - February 6, 2019**Executive Highlights**

- **Senseonics [announced](#) preliminary 4Q18 and 2018 results, forecasting record Q4 revenue of \$8.0 million, up 54% sequentially and 176% year-over-year.** 2018 sales are expected at \$19.7 million, in line with the \$19-\$21 million guidance range and tripling 2017 sales. Full-year 2019 revenue is expected \$29-\$32 million, a softer ~55% YOY rise. International markets are estimated to contribute roughly two-thirds of expected sales.
- **As expected, Senseonics has renewed and extended its international distribution agreement with Roche.** The two-year contract adds 17 new countries, including Brazil, Russia, India, China, and other select markets in Asia Pacific and Latin America. According to CEO Dr. Tim Goodnow, the extended Roche agreement involves "pretty meaningful sensor volume with commensurate pricing considerations." The pricing reduction was not specified, but the volume tradeoff is a good move for Senseonics and in line with the CGM market's pricing dynamics.
- **Senseonics has obtained US payer coverage from Tricare and the VA, adding 18 million covered lives and bringing the total to "over 60 million people in the US."** The VA coverage even includes insulin-using type 2s! Senseonics is making "steady progress" towards its goal of covering 100 million lives by the end of 2019. The company remains on track for 10,000 US users by the end of 2019.
- **In the pipeline, Eversense [received](#) an FDA indication for MRI use,** making it the only FDA-approved MRI-safe sensor. The company is also working towards an indication for once-daily calibrations (no timing). A PMA supplement for a non-adjunctive (insulin dosing) claim was [submitted](#) in early January. The 180-day US trial is targeted to be "done" in 3Q19 - very important for expanding the product's US appeal.

On Monday, Senseonics [announced](#) preliminary 4Q18 results and a two-year extension of its international distribution agreement with Roche. The unexpected call was led by CEO Dr. Tim Goodnow.

Senseonics anticipates record revenue of \$8.0 million in 4Q18, climbing 54% sequentially from the previous record (\$5.2 million in [3Q18](#)) and up 176% YOY from just \$2.9 million in [4Q17](#). Growth was driven by increased sales in the EU and "incremental sales" in the US, which saw \$800,000 in Q4 revenue (i.e., 10% of Q4 revenue). Full-year 2018 sales are expected at \$19.7 million, on par with [guidance](#) for \$19-\$21 million. As of December 31, cash and equivalents totaled \$137 million, a ~\$26 million burn from \$163 million in [3Q18](#), likely due to investment in the US launch ([July](#)), recent [FDA submissions](#), and the [start](#) of the US 180-day PROMISE clinical trial.

Dr. Goodnow also provided 2019 guidance, anticipating full-year revenue at \$28-\$32 million. International markets are expected to generate roughly two-thirds of 2019 revenue, and 75% of US 2019 sales are expected in the second-half of the year. Dr. Goodnow anticipates a "gradual ramping" of new US patients with "more acceleration" in 2H19, aligning with previous trends from the EU launch. He expects to see an overall reinsertion rate of "upper 70%" - a 75% reinsertion rate for a user's second sensor and 90% reinsertion rates thereafter. More details below!

Table of Contents

[Extended Senseonics and Roche Distribution Agreement](#)

Extended Senseonics and Roche Distribution Agreement

Senseonics and Roche have signed a two-year extension of their international distribution agreement, which has expanded to add 17 new countries, including Brazil, Russia, India, China, and other select markets in Asia Pacific and Latin America. Under the agreement, Roche will maintain its role as exclusive distributor in Europe, the Middle East, and Africa (excluding Scandinavia and Israel) until January 31, 2021. Dr. Goodnow explained that ~17 million people with type 1 diabetes are estimated to live in the 17 additional countries, and that Senseonics is "in the very early stages of working with Roche" to expand international distribution. "Market expansion with access and volume" is a "strategic priority" for Senseonics, and Dr. Goodnow hopes the continued partnership with Roche drives increasing Eversense market share and higher demand for the CGM category. We've expected this news for a month now (the agreement expired at the end of 2018), given the clear win for both parties: Senseonics benefits from Roche's global scale and reimbursement expertise, and Eversense provides Roche with an innovative and differentiated CGM. Dr. Goodnow emphasized that both companies are "committed to the long-term investment."

- **The extended Roche agreement involves "pretty meaningful sensor volume with commensurate pricing considerations."** Details were not provided on the pricing concessions, but they were in part agreed upon to mitigate a potential "price disadvantage," as Roche had "consistent pricing expectations" across markets despite differences in reimbursement levels. Senseonics' initially proposed "tiered-pricing" approach was "pretty difficult for [Roche] to institutionalize." This is a smart move, given where FreeStyle Libre has pushed pricing and startup costs, and where Dexcom is going with G6 and G7. If Eversense can be competitive on a dollar-per-day basis, it will certainly help with global expansion.
- **Dr. Goodnow anticipates that entry into new markets will be "driven first and foremost by what reimbursement exists today."** For countries like Australia - which has existing reimbursement, Roche infrastructure, and few required product changes (e.g., translation) - Senseonics is "in a pretty good position to go very quickly." Countries like China are a different story, which will be a "couple-year process" and won't generate revenue in 2019 or even 2020. (No surprise there - Dexcom is not even in China yet.)
- **In Q&A, one investor noted that the forecasted 2019 guidance puts OUS 2019 revenue at ~\$20 million at the midpoint, which implies nearly-flat sales (from ~\$19 million) despite the expanded distribution agreement.** Dr. Goodnow acknowledged that launching into countries like China and India will "need to be done from a different economic basis," and repeated that "the Roche agreement does have significant considerations for volume improvement." The general tone throughout the call was management justifying the terms of the agreement; that said, we cannot imagine Senseonics taking on global distribution on its own.

US Eversense Launch Updates

US VP Mr. Mike Gill announced that Senseonics has obtained coverage for Eversense from Tricare and the VA, adding 18 million covered lives and bringing the total to "over 60 million people in the US." Excitingly, Mr. Gill characterized the VA policy as "very wide open," noting that Eversense eligibility extends beyond military patients with type 1 to also include insulin-dependent type 2s. Many investors were anxious to know Senseonics' progress on convincing other payers to overturn Eversense's Experimental and Investigational status, as Senseonics [did with Aetna](#). Senseonics remains actively involved in discussions with all the major payers and there has been "steady progress" towards the goal of 100 million covered lives by the end of 2019. Encouragingly, Mr. Gill noted that payers have chosen to utilize all three available channels (i.e., DME, CPPT codes, and pharmacy) with "over 15%" of coverage coming through the pharmacy channel, which has proven to be "an accelerator for adoption." Currently,

reimbursement - not patient or provider interest - is the "gating factor" on Eversense's US adoption. Dr. Goodnow believes that achieving widescale reimbursement will be a "two-year process." Some payers have asked for additional information and Senseonics is "working to provide that."

- **Dr. Goodnow touted Eversense's recently [obtained](#) FDA indication for MRI use, making Eversense the only MRI-safe sensor on the market.** Senseonics is "continuing to work on many different indications," including once-daily calibration; no timing was given, but this is important to catch up to the no-calibration FreeStyle Libre and G6 and to leapfrog Medtronic (two daily calibrations for Guardian Connect). Senseonics also [submitted](#) a PMA supplement to FDA for a non-adjunctive claim in January.
- **Dr Goodnow said the [currently-recruiting](#) US 180-day PROMISE clinical trial is targeted to be "done by Q3"** - we're not sure whether he meant a timeline for enrollment completion (the actual question asked by the investor) or the study end date. Completing the trial by late 3Q19 seems possible, as the first six-month insertion occurred [in January](#).
- **While Dr. Goodnow was unable to give a specific update on US Eversense users, he admitted to "feeling very good" about the [previous](#) goal to reach 10,000 US users by the end of 2019.** During the Q3 call [in November](#), he shared that over 600 patients in the US had already been added to the Eversense Ordering System. Dr. Goodnow expects to give an annual use base update on the upcoming 4Q18 call. He emphasized that "interest from patients are providers is very real and does not gate progress."

--by Maeve Serino, Adam Brown, and Kelly Close