CLOSER LOOK

MEMORANDUM

Senseonics 1Q17 - $14 million in cash remains; $0.6 million in revenue doubles from Q4; FDA approval expected in 4Q17, but possible Ad Comm in Fall; 8 EU country launches expected by mid-2017 - May 5, 2017

Senseonics reported 1Q17 financial results earlier today in a call led by CEO Dr. Tim Goodnow. Revenue for the first quarter totaled $600,000 in these early days of commercializing the Eversense implantable CGM, on-body transmitter, and mobile app in Europe. There was no revenue one year ago (1Q16), but this doubles the $300,000 reported in 4Q16. Management reiterated 2017 guidance for $6-$7 million in revenue, which would require a very significant ramp from this point, but there are some key milestones this year:

- **FDA approval of Eversense is still slated for 4Q17** - the Agency has already performed a number of inspections, finding no issues, and the management team is actively preparing for an advisory committee that could take place in early fall
- **The commercial launches in Germany (with distributor Roche, who has upped sales force from four reps to its entire intensive diabetes sales team) and Sweden (with distributor Rubin Medical) are now going "full bore"**, and market presence in eight European countries is expected by mid-2017 (Sweden, Germany, Italy and Netherlands in limited fashion, plus four more).
- **The second-gen transmitter (smaller, water-resistant) will roll out this month** after receiving a CE Mark in February .
- **The 180-day indication, now called "Eversense XL" CGM system, is expected to launch later in 3Q17**. (Arguably not an ideal name for an on-body device, even if it refers to wear length and not size.)

Senseonics has also brought on VP of Sales Mr. Mike Gill, who previously guided Medtronic Americas regional sales to over $1 billion in pump and sensor sales.

As of March 31, the company had ~$14 million in cash, and outstanding indebtedness of $25 million. Based on this quarter's cash burn, we'd estimate runaway to extend another couple of quarters, though operating cost may well rise with as US commercialization efforts increase. Two quarters ago, management alluded to a "potential equity arrangement" that would take the company to the end of 2017 - to date, we haven't heard more on this.

- **Management reiterated that about 50% of customers to date are new to CGM, a good sign that the implantable approach could expand the market, perhaps dramatically.** Most of these patients are type 1 (if not all), younger than 50, and very active individuals.
- **Senseonics is already working with FDA to prepare and submit an IDE to begin 180-day testing in the US.** The 180-day indication would be the next big step in the US - no data is expected to be ready in 2017, but the company would like to get a trial started ASAP.
- **While Eversense has reimbursement in Germany, the process of getting paid sounds a little rocky at this point.** Said Global Head of Commercial Activities Ms. Mirasol Panlilio: "The process is not as routine and standardized for CGM. The payers each have different processes, so we're finding that there's a little more hand-holding than we'd probably like. That goes for the entire [CGM] category actually. We expect that once more players are in the market, it'll smooth things. We're doing prescriptions on a case-by-case basis with each payer, vs. a central payment method." We agree it's early days and the payer landscape is improving. Notably, Roche funded the first group of patients in the limited launch. Dexcom commented on Germany in its 1Q17 call earlier this week,

noting that contracts are still in the works with some of the biggest payers - currently, it has under 20% of the payers covered.

- **The first pediatric clinical trial of Eversense in Canada - patients ages 12-18 in a 180-day study - is underway, and enrollment should wrap up next week.** The first three participants have completed the trial and their feedback is "extremely upbeat" - management noted that patients loved not having to perform weekly sensor changes, avoiding adhesive troubles, and the Apple watch display. (We assume the Apple Watch reads data from the Eversense smartphone app, though if it could go straight from the transmitter to the watch without the phone, it would be a huge advantage over Dexcom.) Data from this trial will be "instrumental" in defining the US pediatric trial and the strategy for EU label expansion.
- **A second-gen sensor, with the ultimate goal of eliminating fingerstick calibrations, remains in human feasibility trials.** The sensor has redundant glucose-sensing capabilities, facilitating improved accuracy, longevity, and functionality. These trials are designed to define the glucose sensing algorithm for the parallel sensing elements.

-- by Brian Levine, Adam Brown, and Kelly Close