CLOSER LOOK

MEMORANDUM

Senseonics 2Q18 - Record sales of $3.6 million up 23% sequentially; 1st US insertions; PMA supplement for non-adjunctive, 1 cal/day to be filed "within a month" - August 8, 2018

Executive Highlights

- **Senseonics reported record revenue of $3.6 million in 2Q18, up a strong 23% sequentially from $2.9 million in 1Q18.** Sales quadrupled from 2Q17's $0.8 million. Strong EU performance (38% installed base growth) and early commercial progress in the US prompted a slight 2018 sales guidance raise by $1 million on both ends - now $19-$21 million (tripling YOY). Cash totaled $184 million at quarter's end, more than tripling sequentially thanks to $149.5 million raised from a successful public offering of common stock in June. This reflects a Q2 burn rate of ~$26 million, providing ~ seven quarters of runway at the current burn rate.
- **July 31st marked the first US Eversense insertions, and we estimate that the global installed base is just under 4,000 users (up 38% in 2Q18).** BCBS NJ is the first US payer to cover Eversense (UHC's recent Medical Policy deems it "unproven" and "not medically necessary"), and >80% of stateside users to date have come from Dexcom (though it's *one week* into the launch). Internationally, 75% of the quarter's revenue came from Italy, Germany, and Sweden, 70% of the installed base is on the 180-day XL sensor, and the Roche distribution agreement expires at the end of the year (we'd guess it will be renewed, since this is Roche's best CGM play at this stage).
- **Senseonics will submit a single PMA supplement to the FDA for non-adjunctive dosing and one-calibration per day "within a month."** IDE submission for a 180-day Eversense XL US clinical trial is expected in September, with the study anticipated to start "in the coming months" (i.e., fall) and go well into 2019. Excitingly, Dr. Goodnow also mentioned that a trial with a 365-day Eversense is expected to begin in 1H19, referencing "tremendous progress" on in-vivo stabilization over one year - that would be remarkable, though is likely a late 2020 approval at the very earliest. Plans for an iCGM indication were not mentioned, though Dr. Goodnow has noted iCGM as an opportunity for Eversense in the recent past.
- **There was no mention of the EU pivotal trial of the Roche-Senseonics-TypeZero 180-day hybrid closed loop system, nor were there updates on the Beta Bionics iLet trials.** The former was expected to start in Europe in 3Q18 (ADA), and the iLet device's home-use bridging studies will begin testing adults with Eversense (in addition to Dexcom) starting this month (FFL).

This afternoon, Senseonics reported 2Q18 financial results in a call led by CEO Dr. Tim Goodnow. While it is early days, adoption seems to be ramping gradually in Europe and the US launch is underway following FDA approval in June. Read on for the top highlights from the call!

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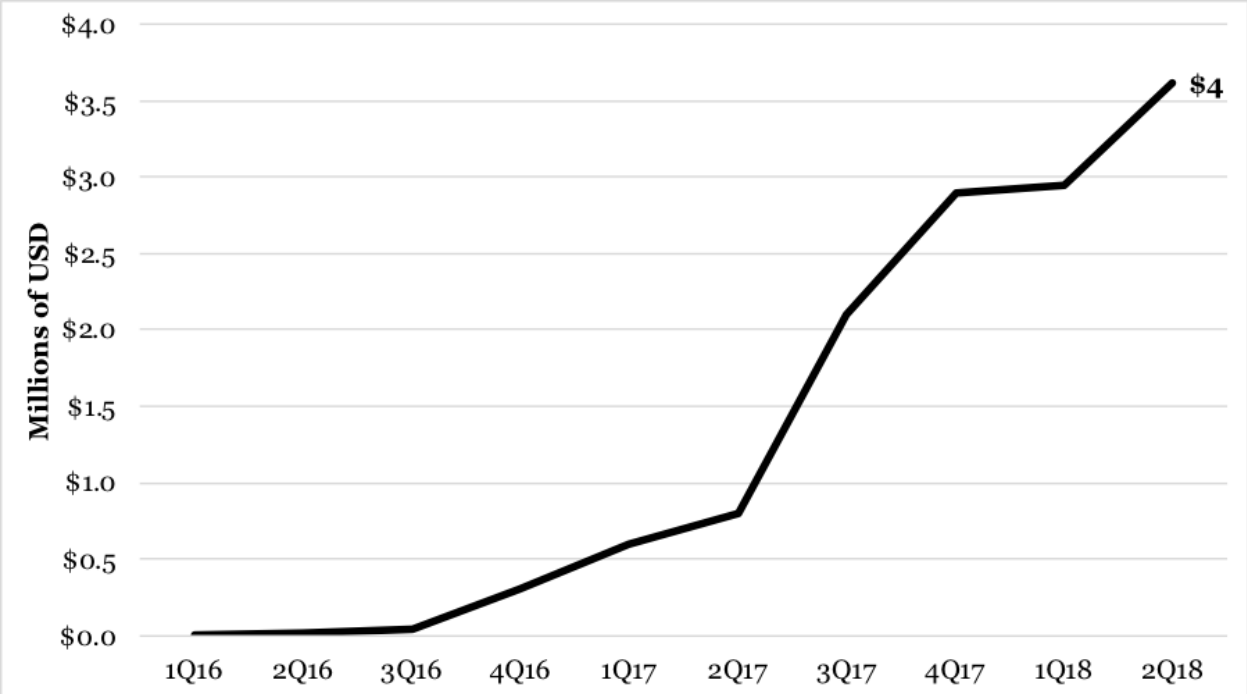
Financial Highlights

1. Record sales of $3.6 million, +23% sequentially; +$1 million raise in FY18 Guidance to $19-$21 million (tripling YOY); $184 million in cash

Senseonics reported record revenue of $3.6 million in 2Q18, up a strong 23% sequentially from $2.9 million in 1Q18. Sales quadrupled from 2Q17's $0.8 million. Due to increasing Eversense adoption in the EU and "early commercial progress" in the US, management slightly increased 2018 guidance by $1 million on both ends of the range, forecasting full-year 2018 revenue of $19-$21 million - this represents triple 2017's sales of $6 million. This also reflected a clear rise in optimism from the June call's guidance for $18-20 million in sales (following FDA approval), when Dr. Goodnow said, "Anything more than that, I think would be a little too aggressive from where we sit today..." During Q&A, management emphasized that the guidance increase is anticipated to be driven by both US and EU performance. Still, Dr. Goodnow confirmed previous expectations for "modest" contributions from 2018 US Eversense sales. As he pointed out, while US Eversense patients inserted in August could return for reinsertions in November, any patients inserted in Q4 won't be due for reinsertion until 2019. Given that Senseonics is still in the very early stages of its US launch, Dr. Goodnow explained that "it is just too early" to provide guidance for 2019.

- **At the quarter's end, cash and cash equivalents totaled $184 million, more than tripling sequentially from $61 million in 1Q18, thanks to $149.5 million raised from a public offering of common stock in June.** This reflects a Q2 burn rate of ~$26 million, providing plenty of runway for Senseonics at the current rate (~seven quarters). The extra cash on hand will be critical in the highly competitive US market, where Senseonics is marketing against two no-calibration systems (FreeStyle Libre and G6) and newly-launched standalone Guardian Connect. Sales and marketing expenses increased $2.7 million sequentially to $6.2 million, primarily driven by US launch preparations, as well as to support and expand Eversense availability in Europe. R&D expenditure was essentially flat sequentially, but increased $2.7 million YOY driven by the pre-market approval application and completion of the FDA Advisory Committee.

Figure 1. Senseonics Quarterly Sales (1Q16-2Q18)



2. Installed base up 38%, bringing global users around 3,000-4,000; Insertions up 27% Sequentially; 75% of Revenue from Italy, Germany, Sweden; 70% of Base on 180-Day sensor; Roche Agreement Expires at End of Year

We estimate that the global installed base of Eversense users is currently between ~2,800-4,000 users, obviously driven by Europe right now. This figure is based on the end-of-Q1 estimate of 2,000-2,800 users and management's comment that the installed base was up a robust 38% in the second quarter (we interpreted this as sequential growth). Insertion procedures grew 27% sequentially in the quarter, representing a slowdown from 40% sequential growth in Q1; that makes sense with more getting on the 180-day XL sensor. Indeed, the 180-day XL sensor is available in all OUS markets, and 70% of the base is already on it - the goal is to have all OUS patients converted to the longer-wear version by the end of 2018. XL has basically the same per-day pricing as the 90-day version, if not a little lower, according to management, and is still priced at parity with other real-time CGMs (estimated at $10-$12 per day, based on previous calls). Geographically, 75% of Q2 revenue came from Germany, Sweden, and Italy since they are all strong reimbursement markets (for example, 80% of lives are covered in Germany). To our surprise, distributor Roche has still yet to commercialize in France and other countries due to greater pricing pressures (per Dr. Goodnow). According to Abbott's FreeStyle Libre press release announcing national French reimbursement, there are "hundreds of thousands" of type 1s and 2s who use insulin multiple times a day in France. Presumably the reimbursement discussions are taking some time in France, especially if FreeStyle Libre is the pricing comparator.

- **The Roche OUS distribution agreement expires at the end of this year, but management is confident that both sides are interested in a renewal.** As a reminder, Roche distributes Eversense throughout all of Europe, the Middle East, and Africa, excluding Scandinavia (where Rubin Medical is the distribution partner), Finland, and Israel. A more limited version of the partnership began in May 2016. We would be surprised if the deal were not renewed, assuming the economics are currently working out for both partners. Senseonics seems to have benefitted greatly from Roche's global footprint and EU reimbursement know-how, and Roche's actions indicate that it views its relationship with Senseonics favorably ($30 million investment;

R&D agreement for AID system; Proprietary Accu-Chek Insight CGM de-prioritized in favor of Eversense; Eversense highly featured at Roche conference symposia).

- **Unlike previous calls, Dr. Goodnow didn't provide figures on the mix of patients coming from other CGM systems vs. new to CGM.** As of May, ~75% of users had switched from flash glucose monitoring (40%-50%) or traditional sensors (20%-35%). Today, Mr. Gill acknowledged growing awareness and appreciation of Dexcom and Abbott CGMs as positives for Eversense, particularly as Libre expands the market. At the same time, it will be important for all of these companies to grow the market, especially new entrants like Senseonics? A minority of intensive insulin users are on CGM worldwide, to say nothing of non-insulin users! The value proposition of Eversense will certainly change as implant duration increases - it sounds like there could be a one-year version on the market in two years, based on today's remarks (see below)- and as nonadjunctive indication and calibration reduction are achieved (in the US). Still, market expansion is still something to keep a close eye on in assessing Senseonics's health.

US Launch Highlights

1. First US Insertions on July 31st (>80% from Dexcom); Avoiding Self CGM Insertions a Major Selling Point

Senseonics met its goal to have physicians insert the first US patients with Eversense on July 31st, commencing "National Eversense Freedom Week" with a focus on freedom from frequent CGM self-insertions. Though it's one week into the launch, over 80% of these first US-based Eversense users were previously on Dexcom CGM (much higher than the ~20%-35% he's previously cited regarding the European base). We'll be watching this metric closely, as it would be a concern for Senseonics' addressable market if it's focused on former Dexcom/Libre users. US GM Mr. Mike Gill said, anecdotally, that a clinic visit for a G5 or Libre user is a branching point - providers tell them they can either upgrade to G6 (+three days of wear compared to G5) or stick with Libre (just FDA approved for 14-day wear), or switch to the 90-day Eversense - obviously this is a bit reductive on the features discussion, though we could see how the pitch might resonate with some. Earlier in the call, Mr. Gill told of a patient who "each week would be filled with anxiety knowing she would have to remove and insert another sensor." Elimination of self-insertions and fewer insertions overall is clearly a selling point that this team will continue to hammer, also as they target the ~ six million individuals "on insulin alone or insulin and orals" - implicitly including type 2s - who have said "no" to other CGMs in the past.

- **The rollout began less than six weeks following FDA approval in early June and what management referred to as a "tremendously successful" and "historic" ADA, with a standing-room-only product theater and the unveiling of the Eversense Mobile Clinic.** To date, the mobile clinic, which has been traveling around the US introducing clinicians to Eversense, has hosted ~1,200 people, the bulk of which came from the ADA and Keystone conferences. Our own Maeve Serino had the opportunity to insert a "patient" - a dummy arm, of course - at Keystone, and she was impressed by the procedure's simplicity. Dr. Goodnow estimated that, on average, the insertion takes ~2.5 minutes while removal takes ~4.5 minutes. Physicians are initially "certified" for the procedures by performing them on three patients, and it is recommended that they insert another three patients three weeks later to "build muscle memory" - from there, Mr. Gill thinks three insertions per week per provider is a reasonable estimate, particularly for the top 300 CGM-prescribing endocrinologists that Senseonics's sales team is currently calling on. Assuming Senseonics can get all 300 endocrinologists inserting three patients per week, that's 45,000 insertions per year, or enough for just over 11,000 patients on the 90-day sensor.
- **By the middle of August, the US commercial team will have 45 people on staff: 20 reps, 15 "clinical people," and 10-12 in customer care.** As previously stated, the number of reps is still expected to scale to 30 by the end of the year; where they are deployed will depend on the geographic layout of payers who begin to coverage Eversense.

2. First Payer BCBS of NJ on Board; Updated UHC Medical Policy Update Doesn't Deem Eversense Proven to Lower Glycemia or Medically Necessary

As we reported yesterday, Senseonics has secured its first payer coverage for Eversense in the form of Horizon Blue Cross Blue Shield of New Jersey (BCBSNJ), which covers ~four million lives total. Mr. Gill confirmed on the call today that, though Senseonics looking to pioneer a wraparound, category III CPT bundle that would encompass both the supply cost as well as physician time, BCBSNJ has opted for now to go through DME providers along with the new CPT codes (0446T, 0447T, 0448T) for additional provider time associated with the procedures. According to management, payers have expressed a preference for the bundle - it was framed as more efficient, since the physician is the provider, rather than the DME company - but Senseonics is willing to support either approach. To that end, the company currently contracts with three "strategic fulfillment agents," two of which fulfill DME orders and one of which is capable of providing sensors and supplies through the bundle. More strategic fulfillment agents are likely to come on board by the end of the year. How much of an *advantage* could this physician-focused reimbursement model be for Senseonics in the US CGM market? The big trend now is clearly pharmacy distribution, led by Abbott's FreeStyle Libre, and potentially with Dexcom to follow given its 2Q18 remarks.

- **Senseonics reiterated the aim to have coverage from a majority of the ~100 major private US payers in the next two years, though a questioner pointed out that the recent UnitedHealthcare Medical Policy deems implantable CGMs (i.e., Eversense) to be "unproven and/or not medically necessary for managing individuals with diabetes" (page 2).** The policy cites insufficient published clinical evidence that implantable CGM leads to improved glycemic control, specifically pointing to "small sample sized studies [that] lack adequate controls, randomization and blinding." This presumably refers to the 90-day US accuracy studies PRECISE II (n=90) and PRECISION (n=35), both of which were single-arm and focused on accuracy for FDA purposes, rather than glucose-lowering. Dr. Goodnow noted that it's standard practice for payers to not cover new technology initially, and Mr. Gill expressed confidence that the physician community will continue to submit claims for Eversense and that his team can successfully navigate through the review process (early conversations with UHC are already underway). It's unfortunate for a payer to bifurcate the CGM category in this way, since the fundamental purpose of the technology is the exact same: providing real-time, continuous glucose data and trends. To us, this is more about CGM form factor and patient preference, not much different from the form factor of using iOS or Android or wearing FreeStyle Libre vs. Dexcom. At the same time, we acknowledge that the payer review board has a job to evaluate the available evidence, and they may not consider the leap from on-body to implantable CGM as trivial. We did hear rumors of a randomized, controlled French reimbursement study (18 months; n=300) at IDF 2017, which would have the goal of demonstrating improved outcomes with implantable CGM, though the company did not verify and we have not heard an update since. There is no listing on ClinicalTrials.gov. We did notice a study underway at Padova in which 16 type 1 patients wear Eversense and Dexcom G5 each for three months, and with secondary outcomes of time-in-range and A1c. Positive results from such a study could help Senseonics make headway in the reimbursement department.
- **Will payers and pricing become a headwind for Senseonics in the US CGM market?** Senseonics could drive a different reimbursement structure, which has the advantage of differentiation but the disadvantage of having to build it from zero. One concern is more pressure on sensor pricing, as Dexcom discussed last week; we wonder if Senseonics is *all-in* more expensive in this 90-day version, given the need for four insertions per year and the HCP reimbursement to go with it. Over time, it should arguably more to a less expensive pricing model with 180-day and 365-day versions.

Pipeline Highlights

1. Single PMA Supplement for Non-Adjunctive Dosing and One Calibration Per Day to be Filed "Within a Month"; No Mention of iCGM Plans

In his prepared remarks, Dr. Goodnow announced plans to submit a single PMA supplement to the FDA "within a month" incorporating claims for non-adjunctive dosing and reduced calibration (one fingerstick/day). This timing could be viewed as a slight delay from Dr. Goodnow's comments in June following FDA approval, when he anticipated filing the supplements with the Agency in the "next few weeks"; that said, given the initial approval six weeks ago, this is fairly rapid progress. On today's call, Dr. Goodnow explained that Eversense's "accuracy and performance have proven capable of the benchmark set by the Agency" for a non-adjunctive claim. Indeed, many at the FDA Advisory Committee (Adam included) noted that Eversense's accuracy was well within the range of a non-adjunctive claim, so we don't expect Senseonics will be met with much regulatory resistance. As for reduced calibration, we've already seen one calibration per day data demonstrating a very solid MARD of 9.5% in the PRECISE II pivotal study. Previously, we had heard that a second-gen Eversense with redundant glucose-sensing capabilities was intended to be factory-calibrated. However, it's been over a year since we've received an update on this next-gen sensor, and today's comments seem to imply that (at least for now) we'll be seeing a one-cal per day version in the US first.

- **Discussion of iCGM was notably absent from today's call.** Dr. Goodnow has referenced iCGM as an opportunity for Eversense in the past, asserting in June that the sensor could get the designation "pretty quickly." Today, he mentioned his previous statements in which he described the insulin dosing claim as "one of the first supplements we planned to submit" - perhaps a hint that an iCGM claim will follow or potentially just a reference to the reduced calibration supplement. On the 1Q18 call, he did share plans to file for iCGM classification following FDA approval. Based on our read of the FDA's iCGM special controls, Eversense appears to meet the accuracy requirements, including in hypoglycemia, if the PRECISE II and PRECISION studies are pooled. Pooled data demonstrate that ~83%-92% of points are within ±15 mg/dl in hypoglycemia ranges, which should exceed the >85% bar. However, based on PRECISE II alone, Senseonics falls a bit short on hypoglycemia. The Eversense label posted by the FDA in July continues to separate out the two studies, although we'd note that the Senseonics website markets Eversense with only the three-month MARD of 8.5% found in PRECISE II (PRECISION found overall MARD of 9.6%).

2. IDE Submission for 180-Day XL US Clinical Trial Expected in September, Ahead of Trial Beginning "In the Coming Months"; 365-Day Wear US Eversense Trial to Start in 1H19

During prepared remarks, Dr. Goodnow noted plans to submit an IDE for the Eversense XL in September, expecting a 180-day US clinical trial to begin "in the coming months." This plan aligns with previous timing shared at Keystone for a US clinical trial to begin enrolling in mid-fall. Also at Keystone, we learned that the XL is expected to be approved in late 2019/early 2020, although we did not receive confirmation on today's call. Given that the trial would run well into 2019, followed by a six-month FDA approval process, late 2019/early 2020 timing seems reasonable. In his prepared remarks, Dr. Goodnow also mentioned efforts to develop a one-year sensor, referencing "tremendous progress on the in-vivo stabilization out to the one-year timeframe." He expects results "this fall" and anticipates the start of a 365-day trial in 1H19 (we assume in Europe). Dr. Goodnow expressed high confidence, claiming: "I now have every expectation that we'll be looking at a one-year life of our highly accurate sensor within 2019." We'd note, these remarks refer to a study-ready version of a sensor that we believe could be on the market in 2020 (assuming a one-year study followed by a six-month FDA review). At Keystone, a representative shared that the sensor itself will not require modifications; rather, the algorithm needs to be adjusted for extended wear. While 90-day sensor wear certainly offers substantial value-add to the seven-day, 10-day, and 14-day sensors

currently on the market, we can only imagine the degree to which a one-year sensor could be paradigm shifting, especially with reduced calibration.

3. No Updates on iDCL Pivotal Trial with Roche/Senseonics/TypeZero or on Beta Bionics iLet Home-Use Studies

There were no updates regarding the EU pivotal trial of the Roche-Senseonics-TypeZero 180-day hybrid closed loop system, nor was there mention of the Beta Bionics iLet trials. At ADA, we learned that the NIH-funded iDCL pivotal trial is slated to begin testing patients in Europe in 3Q18, in line with Senseonics' 4Q17 expectations to initiate the study in 2H18. At Friends For Life, Dr. Ed Damiano said the integrated iLet device's home-use bridging studies (running from now until October) will begin testing Eversense in adults at MGH this month, in addition to ongoing studies Dexcom. The sole mention of these collaborations came during Q&A, when Dr. Goodnow responded to a direct question and confirmed partnership with Roche and Beta Bionics.

Competitive Highlights

CEO Dr. Tim Goodnow and US VP Mr. Mike Gill on Expanding CGM, Recognizing Benefits of Competitors

We were impressed by commentary from management on expanding the CGM segment. Both Dr. Goodnow and Mr. Gill acknowledged the benefits of multiple sensors on the market, emphasizing the ultimate goal of increasing patient access. See below for some notable quotes from the call.

- **"I will say that it is honestly an advantage to us to have so much going on in the space ...** With Libre and Dexcom bringing out the G6, this is very, very, very high recognition, and the acceptance of the need of CGM, and that's been frankly attractive for us coming out. Obviously, the competitive environment is going to be important. We still are seeing the majority of our patients in Europe coming from existing products but we see a pretty good portion coming from new patients that are educated on the opportunity as well. So, our competitive dynamic will certainly be there, but so will bringing in new folks, which is the most important for all of us at the table." - Dr. Tim Goodnow
- **"I've heard one physician say if someone's coming for a three-month visit and they're on a G5, they're going to talk about Eversense because they're moving from one newer technology to the other.** And the conversation may go: "There is a new product that actually lasts for 90 days, when this new generation product (G6) will give you an additional three." It's the same thing as with a Libre patient. As Tim talked about earlier, now you have flash systems that are actually a good thing for the market, it's actually increasing CGM usage. Those patients also would be offered Eversense and the conversation would go: 'Are you interested in moving to a full featured system that actually goes from 14 days to 90 days?' So, we really believe that that long-term sensor will become a very strong conversation." - Mr. Mike Gill
- **"In terms of those patients that are not on CGM, we talk about this quite frequently because there's roughly around six million patients that are on insulin alone or insulin and orals and those patients for whatever reason haven't adopted CGM.** Oftentimes it is because of the burden of inserting a sensor every seven days to 10 days to 14 days. When physicians actually see how the patch system works with our transmitter and how easy it is to use post-procedure, patients whom they have talked to before about CGM and who have said no, those are the patients for whom they now are going to offer Eversense." - Mr. Mike Gill

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