# Senseonics Holdings, Inc.

# Investor Call

## Thursday June 21, 2018, 4:30 PM Eastern

**CORPORATE PARTICIPANTS**

**Tim Goodnow** - *President and Chief Executive Officer*

**Don Elsey** - *Chief Financial Officer*

**Mike Gill** - *Vice President and General Manager, US Region*

**PRESENTATION**

**Operator**
Good day, and welcome to the Senseonics Investor Call. All participants will be in a listen-only mode. Should you need assistance, please signal a conference specialist by pressing the "*" key followed by "0." After today's presentation, there will be an opportunity to ask questions. If you would like to ask a question, you may press "*" then "1" on your telephone keypad, to withdraw the question, please press "*" then "2." Please note, this event is being recorded.

I would now like to turn the conference over to Don Elsey, Chief Financial Officer. Please go ahead.

**Don Elsey**
Thank you very much, and welcome to the discussion of FDA approval for Senseonics Eversense system. Joining me on today's call are Tim Goodnow, President and Chief Executive Officer and Mike Gill, Vice President and General Manager of the US region.

Before we begin today, let me remind you that the company's remarks include forward-looking statements. These statements reflect management's expectations about future events, operating plans, regulatory matters, product enhancements, company performance and other matters and speak only as of the date hereof. These forward-looking statements involve a number of risks and uncertainties.

A list of the factors that could cause actual results to be materially different from those expressed or implied by any of these forward-looking statements is detailed under risk factors and elsewhere in our annual report on Form 10-K and our other reports filed with the SEC. These documents are available in the Investor Relations section of our website at www.senseonics.com. We undertake no obligation to update publicly or revise these forward-looking statements for any reason except as required by law.

With that, I will now turn the call over to Tim Goodnow. Tim?

**Tim Goodnow**
Thank you, Don. We are very excited to share the news that the FDA has approved the Eversense system for sale in the United States. This is one of the most important milestones for our company, and I'd like to take a moment to thank everyone involved. We appreciate the strong relationship that we've had with the agencies throughout the process of reviewing our submission and their support with the introduction of our novel technology to patients.

In addition, we'd like to provide a thank you to the diligent clinical study investigators and study participants whose efforts allowed us to be in front of the agencies, and importantly, to the entire Senseonics team. They worked incredibly hard every day. We know that this is a positive step in helping people with diabetes manage their disease, and we are very honored to be here today.

The Eversense CGM system that we are now bringing to the people with diabetes in the United States has unique features addressing many barriers to CGM use and providing new levels of freedom and flexibility compared to traditional CGM systems such as sensors that last up to three months and eliminate the need for weekly self insertions. The system includes a light, comfortable to wear smart transmitter that provides discrete-on vibratory alerts that can be

removed and replaced without wasting a sensor. We are thrilled to bring these options providing powerful, positive differentiating features to patients.

Specifically with regard to the label, we are very pleased that we have been approved by the FDA. The details are as expected and are fully consistent with our PMA submission and as supported by the independent panel members. The Eversense system that will be available for commercial distribution in the United States is indicated for use by people with diabetes aged 18 and older for up to 90 days. It includes the latest updates to the system, including a Gen 2 smart transmitter and a new algorithm for calculation of glucose level, which demonstrated excellent accuracy of 8.5% MARD as shown from our PRECISE II study.

We are highly committed to incorporating calibration reduction and non-adjunctive labeling to the Eversense system and these will be the first of a few supplements that we will file with the agency in the next few weeks, now that we have the primary approval completed.

At this point, our confidence in Eversense is at an all-time high after reviewing the label and post-approval study details. As we have described, we've been preparing for commercial launch in the US for some time, and for more specific details on Eversense, I would like to turn the call over to Mike Gill.

**Mike Gill**
Thank you, Tim. This is a very exciting day for Senseonics, and I too would like to thank everyone involved. That said, we are now in execution mode. Our extensive preparation up to this point will allow us to hit the ground running. Our immediate call is to have strong presence at the ADA meeting this weekend, followed by a nationwide launch, with an intense focus on outcomes starting early in the third quarter.

Our first step has been completed, in that our field organization has their early adopter target list, which are subset of the top 300 CGM prescribing doctors. Initial contacts will be made with their officers or at the ADA meeting this weekend in Orlando. If these clinicians will attending the ADA, we will be hosting them in our booth and our new Eversense mobile clinic, this is a state-of-the-art mobile clinic and product training suite that will be on the ADA exhibit floor, and then travel across the US.

In the Eversense mobile clinic, we will be training physicians and patients on the technology and procedure with didactic and hands on [indiscernible]. If you are attending the ADA, please start by and learn about the first long term implantable CGM and see a training experience like never before at the ADA.

We will be simultaneously launching our social and digital campaigns as we make Eversense a known brand across the diabetes and healthcare community. Meanwhile, our next step is to ship product to our strategic fulfillment agents in the coming week. We will also be immediately providing the payers with our clinical dossier and our market access team will be following up with medical directors whom we have already met prior to approval to start the coverage policy review.

In parallel, we will continue to meet with new payers and we are confident they will be equally enthusiastic with the novel long term capabilities of the Eversense sensor. As previously mentioned, we feel confident we will have policy coverage by the end of the year in a number of plans.

Our customer care #844-SENSE4U is active and the customer care team is ready to receive calls. Additionally the portal system is set for ATPs to place orders for patients who want to start to be the first on Eversense in the US. Our anticipation is to celebrate the first placements in late July, and in fact, we've already had many requests from physicians to be the first in their state to place Eversense.

With that said, we're off to the ADA, where we will be a major headline. Don't forget to attend the product theater on Saturday morning or come to our presentation at our booth number 1323 or, as I mentioned earlier, the Eversense mobile clinic number is 230. We look forward to seeing you there. Thank you Tim, and I will hand it back to you.

**Tim Goodnow**
Thank you. And with that, I would like to again congratulate all the Senseonics employees that have worked so hard over the years to bring this product to people with diabetes. I very much appreciate all that you have done.

And to finish, we now like to open the call up to any questions that you may have and we look forward to seeing many of you at the ADA. Thank you.

**QUESTION AND ANSWER**

**Operator**
We will now begin the question and answer session. If you would like to ask a question, you may press "*" then "1" on your touchtone phone. We do ask if you are using a speakerphone to please pickup the handset before pressing the keys, to withdraw the question, please press "*" then "2." Once again, if you would like to ask a question today, please press"*" and then "1."

And our first question is from Alex Nowak with Craig-Hallum Capital Group. Please go ahead.

**Alex Nowak**
Great. Good afternoon everyone and congrats on the approval. Just wanted to check in on the manufacturing readiness here. You sound pretty confident of launching, or starting to ship at the end of July. So just curious, what's the manufacturing readiness here for sensors and transmitters to support the launch of the remainder of 2018 as well as the ramp into 2019?

**Tim Goodnow**
Well, thanks Alex and thanks for coming on board with Senseonics. As you are aware, we have been commercializing the product in Europe for coming up on 24 months here pretty soon, so we've got some pretty good experience with the manufacturing. What I am going to do is ask Mukul Jain, our Chief Operating Officer, who spends the majority of the time that he is not thinking about regulatory issues thinking about manufacturing, to talk about what we are doing to be ready to support the early launch here, within the next few weeks, of the US product.

**Mukul Jain**
Thanks Tim. Can you hear me okay?

**Tim Goodnow**
Sounds good.

**Alex Nowak**

Yes, okay. Thank you.

**Mukul Jain**
Alright. Yes, so we have been waiting for this time, and we have been investing heavily in manufacturing readiness, so both to support the European expansion over there and also for the exciting US launch and the growth that we will see later this year and next year. So that has been an active focus for us. We have a dedicated team working with manufacturers both on current process and expansion and all the investment that we have planned, the spend has been baked into the investments that we have been working on. So we're very confident in our readiness for the launch and future growth.

**Alex Nowak**
That's great. And then it sounds like you've been talking with payers here ahead of the FDA approval. Just curious, what are you specifically hearing from the payers right now that give you the confidence and reimbursement by most of them by the end of 2018, and are the pricing discussions, are those in line with your current expectations?

**Tim Goodnow**
Sure. Mike, I'm going to ask you to go ahead. Mike has a full team that's focused, fully staffed, fully in place, and fully at work when speaking to the payers. I'll let him give you a brief update as to what we've said and what we've heard from them.

**Mike Gill**
Alex, I'll start with the last point. I think you meant we'd be finished with the payer coverage in 2018. That's a journey, as I'm sure you can appreciate. We will have some coverage within 2018 and the majority over the next two years. In terms of the feedback from the payers, it's been very positive. As you know, CGM is emerging as a standard-of-care, so they're very familiar with CGM and the great work that the previous CGM companies have done. What they specifically said about Eversense is that they are really intrigued at two levels. One is the concept around adherence and the wear time in terms of the patients that we have had experienced with outside the United States.

In addition to that, the CPT code; we have a Category III code currently. We'll be talking a lot about that at the ADA. I think you are well aware there aren't many procedure codes within endocrinology. And they are very interested in the concept of having a wrap around code that you can put all of the supply costs as well as the physician time into that and that those are two things that they have been specifically very interested in.

**Alex Nowak**
Mike, that's helpful. Then real quick on those III CPT codes, is the expectation those will get priced along with the Eversense transmitter and sensor?

**Mike Gill**
Yes, good. Sorry I missed that point. Yes, so I'd say it would, in fact they were in par with what the other CGM companies are in the United States.

**Alex Nowak**
Great, thanks. Again, congrats on the approval. Nice job.

**Mike Gill**

Thank you.

**Operator**
Your next question comes from Kyle Rose with Canaccord. Please go ahead.

**Kyle Rose**
Great, thank you for the question. And I offer the sentiment, congrats on approval, particularly heading into ADA tomorrow. I just wanted, drilling a little bit more on the reimbursement, I know that you've talked about the some coverage by the end of this year and then some more over the course for the next two years. I was just wondering, maybe you can characterize the discussions you've had to date. Do you expect any large payers by the end of the year, maybe a couple in the top 10? I'm just trying to understand how we should think about coverage as it relates to, you are also talking about initial units placed in patients in July and then continuing on through the year. So how do you think about coverage relative to commercial uptake through year end?

**Tim Goodnow**
Thanks, Kyle. We are going to defer any conservation around placements and numbers until we have our next quarterly call. As you can imagine, we are just completely focused on the launch at this point, but I will ask Mike to elaborate a little bit more. Obviously, full focus on the reimbursement and the access [indiscernible]. So, Mike you want probably to provide a little bit more detail about the key that we are going to target and what we think we can do short and medium term.

**Mike Gill**
Sure. Just to round it out, there's about 100 payers in the United States that really complement most of the CGM spend in the private pay. That is what I'm speaking about, is the private specifically. When you look at their coverage policy dates, there are set times, many of them have a June, and oftentimes they're at the end of the year. So we will have a timing effect in terms of when they actually put us into their coverage policy, when they are ready. So that would be a limiting factor, but there are certainly many that will come out of that timing based on technology that they feel are very important for their members.

When we've spoken to major payers, both at national level and local level and regional level, they feel this is a technology that they want to take a full look into. As I mentioned, we've sent out the dossier which includes the PRECISE II information that Tim mentioned earlier. And then of course, we have a complement of people who are working with the payers every day and we will be talking to them at the ADA as well as afterwards. So I can't put an exact number on that Kyle, but like I said, there is a timing piece to this and then, in addition to that, the interest level. We think the interest level is very high.

**Kyle Rose**
And then just one more question, just the state of the commercial team now. I think in the last call you talked about, you already built out the direct sales reps and then had reps going through training. Maybe just talk about what the size of the sales force stands now and an expectations for hiring through year end.

**Tim Goodnow**
Okay. Yes, we have 35 total working with HCP and patients that's inclusive of reps, clinical and then our customer care organization. On the rep side, we have stated that we will scale to, by

30 at the end of the year, and probably a similar compliment in terms of the clinical and the customer care team.

**Kyle Rose**
Great, thank you for taking the question.

**Operator**
Next question today comes from Danielle Antalffy with Leerink Partners. Please go ahead.

**Danielle Antalffy**
Hi, good afternoon, guys. And I will echo everyone's sentiments on the call. Congratulations, could not be more perfect timing as we head into ADA this week, and I am very excited to see you guys there and see Eversense highlighted. Question I had was, as you noted, the label was really in line with what you were thinking, I think you said you will file the PMA supplement here for a dosing claim in the coming weeks. How do you anticipate marketing this ahead of getting that dosing claim, given the fact that we do now have two other devices, albeit quite different and not implantable devices, that you have a dosing claim? Do you see that as a barrier and if so how do you plan to get around it? Is it something you can sell like, “Hey, we will have a dosing claim at your next implant,” or whatever. How can you address that?

**Tim Goodnow**
Thanks, Danielle. A couple of points. Obviously, we have been approved for the label as an adjunctive device and we will certainly be doing everything as we should to commercialize it as an adjunctive. From a point of differentiation, it is a conversation for sure at the marketing level, but frankly at the patient level it is of little concern. We think the great attributes that a long term implantable product had are very positive, folks. We have a very similar situation in Europe and we have frankly not seen any noticeable commentary on the presence or absence of dosing from iCGM versus another one. We will certainly work very hard on it. It is one more from a marketing perspective than it is, really, from a patient acceptance perspective.

**Danielle Antalffy**
Got it, and you don’t see that as an obstacle to getting these payers on board?

**Tim Goodnow**
No, we don’t from a private pay perspective. Obviously, there is the Medicare dynamic, which it is important for, and we will be working towards that, but I am pretty excited about our opportunity for dosing. You have all seen the analytical performance of the product. The feedback that we heard from the panel and the quality of that data, and frankly as we have talked and I told many folks, the iCGM is really an opportunity for Eversense. The data is very strong and we feel really excited about that opportunity and we think we could be one of the few devices to be able to go get that [indiscernible] pretty quickly.

**Danielle Antalffy**
Yes, got it. Then, just now that you have this approval and you do have very strong data and you could follow that iCGM pathway, do you expect to make a lot of progress over the next, call it 12 to 18 months on an integrated system? I know you guys signed a deal a few weeks ago with Beta Bionics for example. Do you think this is going to accelerate those efforts now that you guys do have a US approval?

**Tim Goodnow**

Yes, I think a couple. We have the Roche partnership with IDCL in Europe, and we are actually going to begin testing patients here in the third quarter. The Beta Bionics as you saw, has been announced, but we have actually been working with that team for quite a little time period. So we are excited about the potential there, and then as we mentioned, the next big chapter for us is the openness of an iCGM label. So those are really the opportunities for us to be a participant in the space, two very direct and the FDA's decision to have an open architecture is very attractive and we think we can be one of the early teams that utilizes that.

**Danielle Antalffy**
Perfect. Thank you very much and congrats again.

**Operator**
Next question today comes from Jason Bedford with Raymond James. Please go ahead.

**Jason Bedford**
Good afternoon. Thanks for taking the call and obviously congratulations, big event for the company here. So few questions, just to be clear, there is no change to the guidance you have out there for 2018 correct?

**Tim Goodnow**
No, a great question, Jason. We had anticipated, and I think I had foreshadowed it as best as I could, that this is almost exactly the timing that we had anticipated, so we continue to forecast $18 [million] to $20 million for this year. As we had indicated, this is still predominately in Europe but as Mike pointed out, we have got a lot of work to do in the reimbursement and we certainly expect that to be ramping. But at this point, we think we've given the guidance that we see and we feel that we got the plans in place to deliver it. Anything more than that I think would be little too aggressive from where we sit today and we certainly don't expect to do anything less than that.

**Jason Bedford**
Okay. Fair enough, that's helpful. Maybe for Mike or Tim, you mention that you target a sub-segment of the 30 high volume prescribing physicians. How big is this sub-segment?

**Tim Goodnow**
Mike, go ahead and…

**Mike Gill**
Jason, I mentioned that at the beginning, first we are going to really to talk to those physicians that are part of the 300 which we call the advocates of CGM and also the early adopters. When you think about that group entirely, if we have ten reps that's 30 customers that we can get to right in there. That's about a range for what a normal CGM rep has in terms of the number of their high prescribing physicians. When I said a subset, I mean early within the next couple of weeks, first-off.

**Jason Bedford**
Okay, but you also mentioned strategic fulfillment agents. Is that distributors, and just to be clear, are physicians going to be buying the device directly from you or do they go through distributors or strategic fulfillment agents?

**Tim Goodnow**

Yes, a good question, Jason. We are going to use, because as you are familiar, the product does have a small amount of dexamethasone, so we have made the decision that there will be fulfillment agents. Not distributors because they will do nothing more than fulfill the products to the orders from the doctors, but that is the best approach for us to get it. As we have discussed, the doctors are not likely going to be holding a lot of inventory on that and this is a great mechanism for them to be able to do that and for us to get to 50 state distribution.

**Jason Bedford**
Okay. And those relationships are already established?

**Tim Goodnow**
Yes, Mike you want just touch on it? It's going to be part of the rest of the team's effort.

**Mike Gill**
Yes, we have a number of strategic fulfillment agents. I won't name them yet, just because we are so early in. They are agents that in fact are in the CGM business, very capable, some that do DME and others that will do buy and bill, as you mentioned, Jason, earlier. To answer your question in terms of the distribution itself, I think that's one of the other advantages that we have. We have options, whether it's a DME category or if it's a procedure code using the full wrap, or bundle if you will, payment that goes through the physicians. We have distributors that are capable of doing both.

**Jason Bedford**
Okay. And then, my last question is, you mentioned the mobile clinic, is the marketing effort largely focused on physicians or will it be a consumer element to it as well?

**Mike Gill**
So, we will have both factors…well go ahead, Tim.

**Tim Goodnow**
Marisol, why don't you speak to that? That falls in the area that you just kicked off here in the last couple of hours, why don't we talk a little bit about our marketing plan for professional and consumer?

**Marisol**
Yes, absolutely. But to answer the mobile clinic, we are very excited about the opportunity to launch this at the ADA meeting and that's definitely geared towards training the physicians and other healthcare professionals on the procedure, but at the same time utilize it to training patients and educating patients. Yes, we just kicked off, now that we have PMA approval, and Mike keeps saying that we are the best-kept secret in diabetes. I think, as of today, probably no longer because we are just going to start with our full awareness campaign that is going to be geared first and foremost to the healthcare professional community to ensure that they are aware of the technology via the long term aspect of it and all the other features associated with the system. And so, we are going to be present in both social and print advertising to healthcare professionals.

At the same time, we know that patient engagement and advocacy is going to be very important, so we are going full blast with our social media campaign. Tonight, we are going to turn on our Youtube channel for example, as well as our Twitter feed. We are going to have our own US Facebook account that is different from OUS. So all of this is now possible, because if

we have the PMA approval, it's really a two-pronged approach, the healthcare professional community and then followed by the large diabetes patient community.

**Jason Bedford**
Okay, that's very helpful. Thank you.

**Operator**
And next question comes from Chris Pasquale with Guggenheim. Please go ahead.

**Chris Hart**
Hi, this is Chris Hart [ph] filling in for Chris Pasquale here. Thanks for taking my question. Again, congratulations on the approval. [Indiscernible] minus your GM goals and how quickly that can ramp?

**Tim Goodnow**
Don, you want to speak to that? He may be on mute. Yes, I apologize, Don is actually flying to Orlando, I believe.

Chris, as we have said, we expect to be able to launch at the 50% level in the US, a little bit different because of the distribution model. Pretty excited about the ability to ramp that as the volume comes up in the coming years. Right now our production volumes are still on the smaller side as we start the US ramp, but that will ramp quickly over next couple of years and with that can be improvement in the contributory margins.

**Chris Hart**
Okay, thank you. And just to back to manufacturing, I believe you said this, but just to confirm, the capacity is there to meet all initial demand out of the gate, and you do expect to be shipping this product sometime in early July. Did I hear that correctly? Thank you.

**Tim Goodnow**
Yes, that is correct. The manufacturing was risk-built, and in fact it is ready to go and we will absolutely be entering our first patients here in the next few weeks.

**Chris Hart**
Thank you, I'll see you at ADA.

**Tim Goodnow**
Great.

**CONCLUSION**

**Operator**
At this time, this will conclude today's question and answer session as well as today's conference. We do want to thank you very much for attending today's presentation. You may now disconnect your lines.