Senseonic Holdings

First Quarter 2016 Conference Call

Thursday, May 12, 2016, 4:30 PM Eastern

CORPORATE PARTICIPANTS

Tim Goodnow - President and Chief Executive Officer

Don Elsey - Chief Executive Officer

Mukul Jain - Head of Operations

Mirasol Panlilio – VP, Global Sales and Marketing

Lin Kelly - Chief Medical Officer

PRESENTATION

Keith
Hello and welcome to the Senseonics Holding's First Quarter 2016 Conference Call. All parties will be in 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. To ask a question, you may press "*" then "1" on your touchtone phone, to withdraw your question, please press "*" then "2." Please note this event is being recorded.

I would now like to turn the conference over to Don Elsey. Mr. Elsey, please go ahead.

Don Elsey
Thank you Keith. Thank you very much and welcome to the first quarter 2016 Senseonics earnings call which is our first investor call as a public company. 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, and company performance 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 employed 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.

Tim Goodnow, President and Chief Executive Officer will provide an overview of our company and strategy. I will then provide a summary of the first quarter financial results. We will then open up the call for your questions. I will now turn the call over to Tim Goodnow. Tim…

Tim Goodnow
Thank you Don, good afternoon and thank you for joining us on our first public company call. Before we begin, I would like to take this opportunity to thank our shareholders who have invested in Senseonics as a private company and to the new shareholders that have invested in us as part of our IPO in March. We appreciate the valuable contributions of growth capital to allow us to execute our strategic plans. Joining me today in addition to Don, is Mukul Jain, our Head of Operations including regulatory sciences, Mirasol Panlilio our Global Head of Commercial Activities and Lin Kelly, our Chief Medical Officer. I am fortunate to be leading such a talented team as we work together to bring our unique technology to people with diabetes. And I am happy to be sharing with you the progress that we have made.

Since this is our first earnings call, I would like to take a few minutes to review our business and provide some brief comments with respect to our strategic direction. I will also be providing a summary of our plans, and then I'll turn the call back over to Don who will provide details on our financial results.

Senseonics' mission is simple. We exist to develop and commercialize transformative glucose monitoring products that enable people with diabetes to confidently live their lives with ease. Our team strives to help remove some of the burden of diabetes by designing an accurate, safe, convenient and long-term wear continuous glucose monitoring system. Following the clinical validation of our first product entry, the Eversense CGM System, in our European pivotal trial we

endeavor to raise growth capital to execute our strategic plans. In March of this year we were successful in raising approximately $45 million in net proceeds from our initial public offering. The proceeds of this offering will be invested to complete our US pivotal clinical trial and seek regulatory approval for Eversense in the United States as well as continued R&D activities focused on new configurations of the technology and to a lesser extent to begin development of our commercial US infrastructure post PMA approval.

As you know, the Eversense CGM System is comprised of three parts, a long-term implanted sensor, a very versatile smart transmitter and our proprietary mobile application that works on both iOS and Android phones. Our system is unique in several ways. Eversense is the first and only fully implanted CGM system that eliminates the need for weekly sensor insertion. The Eversense sensor will initially be labeled for use for up to 90 days; that translates to 4 sensors per year compared to up to 40 to 60 sensors using existing CGMs. This offers both convenience and freedom for the user. Importantly, we plan to submit an amendment to our recently received CE Mark to extend the sensor term to up to 180 days which once approved will further enhance the convenience and freedom that our technology offers to patients as they will then only require two sensors per year.

Eversense is the first and only CGM System with a smart transmitter that can be taken off and put back on at any time. If you want to have a bare arm, you can remove the smart transmitter without fear of wasting the sensor and then when you are ready to get readings again you simply put the smart transmitter back on to get your real time glucose results. In our experience users really appreciate this flexibility and Eversense is the first and only CGM which provides on body vibratory alert via the smart transmitter to notify users when they have reached hypo or hyperglycemic levels. Even when their **Bol (ph)** device is not nearby. This adds discretion, safety and peace of mind for the user. There are other unique and important features of this system but these are top of mind for our users.

Let me now speak to the actual performance of the technology. Our first generation Eversense System achieved strong and sustained accuracy throughout the 90-day period. The performance was demonstrated in a precise European pivotal clinical trial that included a total of 81 participants across seven sites in Germany, the UK and the Netherlands. The study duration was for a continuous 180 days with participants being inserted with one sensor in each arm on day one and wearing the sensors up to 180 days continuously. This was the longest continuous sensor study achieved in our industry. We based our initial CE Mark application on the 90 day data from the first 44 participants in the trial. Very strong accuracy was shown as measured by mean absolute relative difference of 11.4% in the 75 milligram per deciliter and higher range throughout the 90-day period. Importantly, no device or procedure related serious adverse events were shown. The accuracy and safety performance of Eversense is compelling for a CGM technology.

As we announced earlier this week, we are excited to receive the CE Mark approval to market Eversense in Europe. The system is indicated for continually measuring interstitial fluid glucose levels in adults and is to be used as an adjunctive device, that is, to complement not replace information obtained from standard home blood glucose meters.

The CE Mark approval is a great milestone for the company and we express our appreciation to the notified body of the competent authority in Europe for their review and approval. In conjunction with our CE Mark approval we will conduct post-market surveillance activities that will include among other things gathering clinical data from long-term repeated sensor insertions. We are developing the specifics of the post-market surveillance program now. We

plan to share this surveillance program with our notified body within the next two weeks. Once the surveillance program is in place, we will begin product shipment and the controlled launch of the system, which we expect to occur before the end of this quarter.

Our PRECISE trial data is based on a one-time sensor insertion. The post market surveillance will extend the clinical experience to multiple insertion cycles and will monitor the safety and performance of the Eversense System over repeated insertions every 90 days. The data collected will be provided to our notified body as part of a continuous process to update the clinical evaluation of the product. We do not expect that the post market surveillance program will gate our controlled market launch plans or will have a material financial impact. We do believe the surveillance activity will provide valuable feedback for long term use of our product and we also expect to use this information as additional data in our PMA.

We are excited to begin the commercialization process and expect our first commercial patient sensor insertion this quarter in the first market, Sweden. Rubin Medical, a market leader in medical products for people with diabetes, is our exclusive distributor of the Scandinavian market of Sweden, Norway and Denmark. Rubin is an ideal partner for Senseonics. They are a full service sales and marketing organization who understands and is dedicated to the intensively managed diabetes community. They have a lot of market experience being the exclusive distributor of the Animas insulin pump in Scandinavia for a number of years.

During this controlled launch phase we will work hand-in-hand with Rubin Medical on patient and healthcare provider training and marketing programs to enable the adoption of the Eversense System, capture surveillance data and importantly, ensure a very positive experience amongst our users.

Let me shift it to what's next now that we have received CE Mark approval. Beyond Sweden, we are targeting other markets such as Norway, Germany and the Netherlands as the next stop markets later this year. We will deploy a similar controlled in collaborative approach with distribution partners in these markets for a successful in-country launch.

We are in active discussions with additional distributors to broaden our coverage into the other European markets. We expect to finalize at least one of these distribution agreements in the near-term. We are confident that the combination of early commercial feedback and surveillance data during this controlled launched days of the Eversense System will be important to honing our product positioning and messaging in advance of our full commercial European rollout including but not limited to Switzerland, Italy, Finland, France and the UK.

As I mentioned earlier, our PRECISE European trial was for a 180-day duration with the first 90 days used for the CE Mark submission. The results from the full PRECISE trial was safety and performance data on all patients over the course of the 180-day period will be presented in a poster at the upcoming annual American Diabetes Association meeting in June in New Orleans. Dr. Hans DeVries from the Academic Medical Center in Amsterdam and our Lead Clinical Investigator from the PRECISE trial will be presenting the results.

With the CE Mark approval of the 90-day sensor now in hand, we plan to submit an amendment to the CE Mark based on the full PRECISE study to expand our sensor label to an extended term of up to 180 days. We plan to submit the amendment to the notified body by the end of this quarter. As regulatory approval is not within our complete control we will not yet be providing guidance on the approval and launch of this extended term sensor.

Simultaneously, we have made considerable progress on the development of our next generation smart transmitter. This improved smart transmitter will continue to be removable and rechargeable, provide on-body vibration alerts and have a one-year life. Based on design input from our users, the next generation smart transmitter will offer a significantly smaller profile. The new design is 40% thinner, weighs considerably less, the same as two quarters, and is water resistant. You will have a more rounded shape to offer more discreet, wearable solution for the user. We plan to submit a CE Mark amendment application for this next generation component in the third quarter of this year.

Turning to the US, I am pleased to announce, that we have completed enrollment of our US pivotal trial at the end of March. The pivotal trial is a 90-day study with 90 participants in eight clinical locations. Some of the earlier participants have already reached the 90-day mark in the trial and we expect the trial will be complete in July leading to our PMA submission before the end of this year.

As we outlined in our public filings, we are currently anticipating a FDA review cycle of 12 months. I would like to take this opportunity to express our deepest gratitude for the people with diabetes that have participated in these studies. Their commitment to helping us to develop and characterize new products to simplify **{Indiscernible}** is greatly appreciated.

We look ahead to our sales and marketing efforts in the United States and we plan to approach the US market with a direct sales force. We intend to establish our sales infrastructure beginning in the first half of 2017. We look forward to sharing additional information on how we are approaching our commercial strategy in the United States following the PMA submission and as we get closer to launch we plan to provide both high level expectations regarding our initial launch planning as well as metrics we plan to share to help investors evaluate our commercial progress over time.

Turning to reimbursement in the United States, CGM is generally well established reimbursement. When talking to a healthcare provider about our product, their first ask is to see the accuracy and safety data and the second ask is about the reimbursement for the procedure. Time-and-time again, the healthcare providers we spoke with indicated a strong interest in the product but are desirable to have a predictable reimbursement process for the sensor procedure to account for the healthcare provider's time. Understanding this need, we have applied for a CPT category 3 codes to enable reimbursement for those procedural aspects of insertion and removal of the sensor. I am pleased to share that the AMA recently approved this application and has issued three new separate CPT codes to support these procedures. With these CPT codes now in place, healthcare providers will be able to utilize these codes when the product is launched in the United States. In addition, there are existing training and data interpretation CPT codes currently available for the CGM category which we are also able to use. These newly approved CPT codes are truly additive and enable the healthcare provider to bill and be reimbursed for performing these procedures.

Finally, it is our belief that with continued improvements in **ease of use**, enhancements to the performance and durability of CGM Systems and in conjunction with a demonstrated long-term healthcare benefit, CGM is becoming a standard of care for intensively managed paces. We believe that numerous experts would agree that this will lead to continued growth in the market. With our highly differentiated product offering a choice to users, we believe that Senseonics can play a leading role in this market.

The future objectives for CGM are to increase the length of time that a single sensor can be used to eliminate the need for strip testing for daily calibration and to have CGMs labeled as a replacement for finger stick testing. Ultimately a goal of integration with the insulin delivery devices with autonomous insulin delivery enables the artificial pancreas. We believe that Eversense takes CGM closer to these ultimate goals in diabetes management.

Our device is appealing to patients who see that changing of the sensor every week is inconvenient, cumbersome and time consuming. Patients that have used our device tell us that an implanted sensor provides for fewer decisions to make, for example, they don't have to decide every seven days whether to continue sensor wear, they can focus on managing their diabetes and not on managing the devices. Eversense also appeals to those who see the convenience of a removable smart transmitter to better fit their active lifestyle.

Based on our early feedback, our current 90-day system and our soon extended term 180-day sensor will be life-changing for users. The implantable sensor will offer the patient more discretion, ease of use and importantly improve compliance. We are excited to continue innovating our products in supporting improved solutions for people with diabetes. We look forward to updating you on our progress through many milestones in the next several months.

Now I'd like to turn the call back over to Don to review our first quarter financials and our expectations for the balance of 2016.

Don Elsey
Thank you Jim. For the three months ended March 31st, 2016, total net loss was $11.2 million, or $0.15 per share compared to $5.7 million, or $2.94 per share, in the first quarter of 2015. First quarter 2016 net loss per share is based on 77.3 million weighted average shares outstanding after giving effect to our IPO, compared to 1.9 million weighted average shares outstanding in the first quarter of 2015. We currently have just under 93 million shares outstanding and expect that this number will remain relatively stable for the balance of 2016.

The largest driver of the increase in net loss was higher operating expenses compared to last year. Specifically our total operating expenses increased $5.5 million to $10.9 million driven primarily by $2.7 million increase in R&D spending and the $2.5 million increase in G&A spending.

When compared on a sequential quarterly basis, total operating expenses increased by $2.8 million or 33% over Q4, 2015. Increases in clinical trial expenses of $1 million and a non-cash compensation of $1.4 million, primarily in the general and administrative category, accounted for the majority of the growth.

I would like to turn now to our balance sheet at quarter end. At the end of the first quarter, our cash and cash equivalents were $37.4 million. This was an advance of the exercise of the overallotment option.

Our current outstanding debt balance is $10 million. As we've indicated previously, it is our intent to arrange an expanded debt facility in the near future. 2016 is the year of milestones and the execution for the company as we establish the commercial foundation for the company. We are focused in ensuring that we perform at the highest level of excellence while at the same time managing our spending closely with the goal of ensuring our cash runway is as long as possible.

With that in mind, let me turn to our guidance. Considering that we have just received the CE Mark and we have yet to begin commercialization, there is now a lot of information upon which to give revenue guidance. We do however anticipate that 2016 revenues are likely to be less than $1 million. We will be in a position to give greater visibility to revenue projections in our next earnings call.

With respect to spending for this year we estimate total operating expenses for 2016 to be between $37 million and $41 million of which $3 to $5 million will be non-cash items.

Lastly, we expect our current cash, plus our plans for non-diluted financing will be sufficient for operating needs through the third quarter of 2017. I will now turn the call back to Tim.

Tim Goodnow
Thanks again Don. We are focused on generational product improvements and on building strong clinical evidence and developing Senseonics into a leader within the diabetes management market. We have a talented and highly motivated team and are excited about what we can accomplish over the next several years. Our goal is to initially launch the Eversense system in Europe then expand our footprint globally to the United States market and beyond.

To that end, I want to take a minute to review our upcoming milestones. As I mentioned earlier, we plan to first initiate our controlled commercial launch in Sweden this quarter. Second, submit by the end of June an amendment to the current CE Mark to extend censor labeling for up to 180 days. Third, we will expand our European footprint to additional countries with new distributor relationships in the third quarter. Fourth, we plan to submit an additional amendment to the current CE Mark for our next generation smart transmitter also in the third quarter. And fifth, we will submit our US premarket approval application to the FDA by the end of the year.

In addition to executing these milestones, we will continue to drive enhancements in our existing technology platforms through targeted R&D activities. We plan to leverage our clinical data to enhance our ability to successfully commercialize Eversense products throughout EU and eventually in the United States and we will further our clinical validation efforts to continue to build the case that our Eversense technology is easy to use, safe and effective amongst all healthcare constituents including patients, physicians and payers.

Wrapping things up, we are very excited about the progress that we've made to date. We have a truly differentiated CGM solution supported by strong clinical data and a talented and motivated organization pulling together to make a difference for patients. We look forward to updating you on our progress. This concludes our prepared remarks.

Operator, let's open the call for questions

Question and Answer

Keith
Yes, thank you. We will now begin the question and answer session. To ask a question, you may press "*" then "1" on your touchtone phone. If you are using a speakerphone, please pick

up your handset before pressing the keys. To withdraw your question, please press "*" then "2". At this time, we will just pause momentarily to assemble the roster.

And the first question comes from Danielle Antalffy with Leerink Partners.

Danielle Antalffy
Hey guys. Thank you much for taking the question and congrats on your first quarter as a public company and more congrats on the approval on what was that Tuesday night. So I have a quick question Don for you and maybe Tim as well, so thinking under a million in sales in Europe for the year, it's a little bit below what we were looking for, not trying to nitpick too much here, but I was wondering if you could provide color on what might be driving what I think could ultimately be a conservative number, is it timing of getting another distributor on board and expanding the markets beyond Scandinavia, is it market research that you've done thus far. What's driving sort of what might be a conservative number?

Don Elsey
Well Danielle thanks, we do hope it's a conservative number but at this point we do think it's the best place for us to give some level of guidance. There are a couple of dynamics as you know, the CE Mark did come in a little bit later than we had anticipated and we want to make sure that we account for that as well.

In addition, I do want to stress that we feel that it's very important that we launch this technology, it is new and it is novel. There will be a lot of questions, there will be a lot of experience, I feel that it's very important that we be successful with this launch.

We don't want to over-focus on driving to too many new markets initially to the point where we could not successfully handle it. We do not want to be the type of company that would put out a new technology as our first launch and have there be too many technical issues and have too many people spending too much time on the phone trying to deal with those. So we want to be very responsive and very gated and keep our eye on the really big prize here, which is building the market for the future.

Danielle Antalffy
Okay great. That makes total sense and I agree with you on that…in that regard. And Don, I was wondering if I could follow up on the cash situation, could you talk about cash burn currently from a quarterly perspective. I know you said that it should get us to Q3 but just wondering if you can talk about where cash burn is today. Where you expect that to go in order to get you guys out to Q3 of 2017?

Don Elsey
So thank you Danielle for that question. We are not in a position at this point in time to give quarterly guidance, I think that might be a tad precise for where we are right now. If you take a look at the first quarter, we had a net income loss of just over $11 million. We actually completed the enrolment of the US trial faster than we had anticipated and we dedicated over a million dollars to the US pivotal trial in the first quarter in addition to which you may have caught that, we had $1.4 million of non-cash comp in that first quarter. When you take those numbers out the net income loss is pretty much what consensus had for us in the first quarter.

We anticipate that generally speaking as we go through the year while there will be some ebb and flows, our quarterly expenditures and in turn, cash, is going to be relatively stable one quarter to another quarter, but I don't want to get into a lot more detail than that because as you

know, things can come up where we would choose to accelerate it by a quarter or slip it by a quarter. So hopefully that's helpful.

Danielle Antalffy
Yes, that's very helpful and just one last question for you guys here. I'm so excited to hear that the US pivotal trial has completed enrollment. What's the venue for announcing that data, will it be press released, how soon can we see that data?

Don Elsey
So Danielle, I think what we will do is we anticipate that we will have the IDE complete in early July, it will take us a little bit of time to do…to lock the database and do the analysis. So I would expect two things, one, a very top line level of conversation about how the clinical trial looks a little bit later in the summer and then I would expect a full technical presentation at the Diabetes Technology Conference in November for those that are interested in the full clinical details.

Danielle Antalffy
Okay great. Thank you so much you guys, congrats again.

Company Representative
Thank you Danielle.

Operator
Thank you. And the next question comes from Kyle Rose with Canaccord.

Kyle Rose
Thanks for taking the questions. Can you hear me all right?

Company Representative
Absolutely Kyle, thanks. Kyle, how are you?

Kyle Rose
I'm well, and I apologize, I was hopping between a few calls here. I just wanted to ask one housekeeping question. You talked about the post-market surveillance in Europe, did you give a patient number there or timeframe as far as, how long that's going to be before you are going you open it up a little wider to some of the broader countries?

Don Elsey
Yes. We are in the process of putting that together right now Kyle. We expect that we will…we are developing it right now, we will share that with our notified body in a two-week time period. The key thing and I'm not prepared, I don't have the ability to give some specific numbers at this point. But, we are highly confident today that it will not impact our launch rollout plans as we've have described them.28:21

Kyle Rose
Okay. Great, I appreciate that. Is that something that we can assume that you'll be sharing publically in a press release or something along those lines in the future, just so we get a better understand of what that's like before for the next call or how should we think about that?

Let's…we'll take that under advisement, typically a PMS program is very typical especially for a…what we would call here in the United States a Class III device. In our case there it's a AIMV, an active implantable. You typically don't publish anything along those lines, but if there's significant interest we'll look at a way to perhaps trying to get some detail around it.

Kyle Rose
Okay. Thank you. Just wanted to make sure they have everything in perspective. When you talk about the broader OUS distribution, you've got Rubin Medical in the three countries in Scandinavia there, what are your, I know you're in discussions with broader distribution partners. But, just wondered if you can characterize that for us, at what stage of those discussions would you rank them. And also do you anticipate multiple distribution agreement, is it one larger distribution agreement, how do we think about what the back half of the year will look like when we think about a distribution standpoint?

Okay, great Kyle. What I'd like to do is, I'm going to introduce Mirasol Panlilio who heads all of our commercial operations and I will ask her to speak to your question.

Mirasol Panlilio
Hey everyone. I hope you can hear me okay. I have a bit of a cold, so this is not my usual voice. But, beyond the Scandinavian market and working with Rubin Medical, we are about to announce I would say in a matter of weeks, our next distribution agreement and so that would be coming very soon. And our approach to this is to work with partners who share our commitment to the customers, those who understand the space and can increase market access for our product so to that end we are talking to a number of potential partners, we've got one in the hopper now, which we are going to announce very soon. But we're in active discussions with other distributors as well.

Kyle Rose
Great, thank you very much and look forward to seeing the data in a few weeks.

Don Elsey
And again, thank you Kyle.

Operator
Thank you. And the next question comes from Jayson Bedford with Raymond James.

Jayson Bedford
Good afternoon. Can you hear me okay?

Tim Goodnow
We can Jason. How are you?

Jayson Bedford
Doing well. Thanks Tim. Just a few questions, Just so I have the timing right. You'll submit the post-market surveillance in two weeks assuming a four to five week turnaround in order to register the first shipment by the end of June. Is that correct?

Company Representative
Yes. That's directionally very correct.

Jayson Bedford
Okay. And just on the European rollout, you mentioned Sweden, the two questions I have, does the post-market surveillance effort restrict you to Sweden. And then second I may have missed this, but when does Rubin expand to the other two Scandinavian countries?

Company Representative
So, there is no restriction in the PMS to just Sweden. I'll let Mirasol handle the second one.

Mirasol Panlilio
Let me take that on I think for Sweden we're ready to go, we are just finalizing the Swedish product kits now. But we expect that we'll be launching the product and have our first product insertion in Sweden in June. And then, the other markets Norway and Denmark would roll-in in Q3 and Q4. And then the other markets that we are working with potential distributors now would come in essentially in the second half of this year.

Jayson Bedford
Okay. That's helpful. Tim, when can you get the new algorithm included in the CE Mark, or maybe it is?

Company Representative
Yes. We do anticipate rolling that in very quickly. We obviously don't have access to the US data yet. But based on as you may recall some of the modeling we did on the European data, we are anxiously holding our breath at the result that we'll see this summer. So, we would very much like to get it to the European customers and we will be doing that as one of these CE Mark amendments that we've referred to.

Jayson Bedford
Okay. And then, the last one from me I guess, can you comment on the value of the three new CPT codes you were granted?

Company Representative
I think it's a hard to put a value on it per se other than it's truly a fishing license, right? We have the opportunity and the mechanism now with the CPT code to get payment to the prescriber. We of course, first and foremost have to get the FDA approval. So it is out a fair ways but it does, once that FDA approval comes in, it gives you the mechanism. We of course still also need to negotiate payment with the payers but we can do so under those CPT codes. But the mechanism is out of the way, the AMA was very supportive of the technology and a concept like this. So we were happy to get full support on getting those issued.

Jayson Bedford
Okay. Thank you.

Operator
Thank you. And as there are no more questions at the present time, I would like to return the call to management for any closing comments.

CONCLUSION

Company Representative
Great. Well, once again I want to thank…all of the investors whether you have been with us for some time or more recent, we are very excited and very much appreciate the opportunity to

work with you and grow this great opportunity for people with diabetes. We look forward to updating you in the coming quarters as I hope you see we have a lot to do but we have a great opportunity with this product, a lot of the excitement is building. Just in the last two days since our CE Mark, the number of email requests that we have from the European folks is truly exciting. So, we look forward to it. And we look forward to updating you very soon. Thanks again.

Operator
Thank you. The conference is now concluded. Thank you for attending today's presentation. You may now disconnect.