Senseonics Holdings Inc.

Second Quarter 2016 Earnings Conference Call

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CORPORATE PARTICIPANTS

Tim Goodnow - *President and Chief Executive Officer*

Don Elsey - *Chief Financial Officer*

Mirasol Panlilio – *Global Head of Commercial Activities*

PRESENTATION

Operator
Good afternoon and welcome to the Senseonics Holding's Second Quarter 2016 Earnings Conference Call. All participants will be in listen-only mode. Should you need assistance, please signal a conference specialist by pressing "*" key followed by "0." After today's presentation, there will be an opportunity to ask questions. To ask a question you may press "*" and 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, Chief Financial Officer of Senseonics. Please go ahead.

Don Elsey
Thank you very much and welcome to the second quarter 2016 Senseonics earnings call. 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 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. Good afternoon and thank you for joining us on our quarterly call. The second quarter has been a busy and productive quarter for the company. We signed a distribution agreement with Roche, presented our 180-day trial data at the ADA, launched The Eversense System in Sweden, expanded our debt facility and increased our cash runway, we filed a CE Mark amendment for our labeling up to 180 days and we completed the US clinical trial with excellent results.

On today's call, I will start out by discussing the top-line results of our US pivotal trial that were announced earlier today, which show that our system provides state of the market accuracy for our CGM System. Then I will recap the European full 180-day trial data, as well as well as provide an update on our launch in Sweden. I will conclude by addressing anticipated market launches and providing a summary of key regulatory development initiatives. Don will provide intel on our financial results and then I will wrap up with a review of our upcoming expected milestones.

This afternoon, we were very excited to release top-line results from our US pivotal trial. The primary effectiveness objective of this study showed a compelling accuracy of 8.8% MARD over the 90-day sensor life.

As you may recall, we began the US PRECISE II trial in early January at eight clinical sites across the country. The purpose of this study was to evaluate the safety and effectiveness of the Eversense System over a 90-day period in adults with diabetes. It was an open-label, non-randomized, single arm, multicenter, pivotal study with very positive patient support and product acceptance. We were able to enroll the full 90-patient population by the end of March. And the last enrolled patient completed all testing and safety follow-up by mid-July.

As previously described, study participants visited the clinical centers at one 30, 60 and 90 days post insertion for in-clinic accuracy characterization. The centers included in the study are well versed in participating in FDA accuracy studies with most having direct experience in product approval trials from Medtronic, DexCom and Abbott CGM Systems, between the clinic visits, participants wore the device at home and followed labeling instructions that included two finger stick calibrations per day using a standard home blood glucose meter.

The PRECISE II trial design was very similar to the protocol used in European PRECISE pivotal trial. The device has prospectively calculated glucose levels, however, the devices were blinded to not show real-time glucose results nor provide any glucose related alarms to the participants. Importantly, we were able to use clinical results and data previously obtained from the European PRECISE study to update and improve the calibration and glucose results algorithm, and we implemented this improved algorithm in the product configuration used in the US PRECISE II study.

Compared to all prior primary CGM PMA application studies, PRECISE II was the largest ever in number of study participants in data collected and in length of trial. Over 16,000 comparative data points with over 2 million glucose readings were collected on 90 participants over the full 90-day investigation. Our full clinical data analysis from this study and the generation of the clinical evaluation report is underway, and will of course to be one of the key elements of our PMA submission later this year.

At this point, we have completed the CGM accuracy portion of the assessment. And as I highlighted, we reported a Mean Absolute Relative Difference or MARD of 8.8%, against the standard YSI Lab reference analyzer. The 8.8% MARD was achieved over the 90-day continuous wear across the systems overall glucose range of 40 to 400 milligrams per deciliter.

The system's safety performance was also very positive, which along with additional results will be published shortly. Needless to say, we are excited that our first generation glucose sensor with an improved the algorithm has demonstrated strong performance that is equal to or superior to that of other CGM Systems in the market.

Let me now turn to the recent FDA panel meeting. As many are familiar, the clinical chemistry and clinical toxicology devices office, OIVD, had a panel meeting with clinical experts on July 21st to solicit feedback regarding the benefits of expanding to a non-adjunctive label for the DexCom Gen5 CGM System. In a very positive move for people with diabetes, the panel supported the labeling change on a vote of 8 to 2.

As we have seen in our interactions, the FDA demonstrated a positive bias towards accepting new technology and advancing the utility of the very accurate CGM devices for people with diabetes. Although, the full approval of the labeling change is not yet granted from the agency, it is our expectation that the dosing claim will be allowed for these very accurate CGM Systems with adequate training, labeling, product attributes and robust post market surveillance to support the safe use of the devices.

With the completion of our pivotal trial, it is our objective to show in our PMA submission that with a highly accurate clinical data obtained in our pivotal trial, our Eversense CGM System is safe and effective. We will naturally be working with the FDA during submission process to provide all the information required to work towards the PMA approval. We also plan to work collaboratively with the agency during the review process to determine the right approach to pursue a dosing claim for the Eversense CGM System as quickly as possible.

And turning onto clinical front; we presented a full 180-day PRECISE study data at the recent American Diabetes Association Conference in New Orleans. As you recall, the European PRECISE study data was the basis of our 90-day CE Mark product. The 180-day study showed that the MARD observed in the 90-day results was maintained for the entire 180-day period. A key finding in this study was that the median sensor life was 149 days. The study results confirmed long-term accuracy of this sensor and demonstrated that sensors retained their high accuracy performance throughout their entire life.

On the basis of this data, we submitted a CE Mark amendment to extend the labeling claim for those sensors lasting longer than 90 days. We anticipate that by the time we receive approval of the amendment, the majority of the sensors will perform through 180 days. It is also our expectation that within the next 12 to 15 months, with additional sensor improvements under development, we will demonstrate a full 180-day sensor life for all sensors.

Switching now to the commercial side; we completed our first commercial sale on patient insertion in Sweden in June. We trained a number of physicians on the insertion procedure, all were positive experiences and they successfully completed the procedure in less than five minutes. All patients were up and running and using their systems at home. We continue to work closely with Rubin Medical on patient and healthcare provider training, as well as the marketing programs to execute our controlled launch in Sweden. Through this collaborative process, we have gained valuable insight into the clinic workflow and new patient startup procedures.

With that, we have modified our training with a focus on user startup and Smartphone connection to ensure the most positive experience possible for our users. In May, we announced a partnership with Roche for exclusive distribution of the Eversense System in Germany, Italy, and the Netherlands. The local commercial teams are now in the midst of completing or initiating the end market controlled rollout.

Similar to our controlled launch in Sweden with Rubin Medical, we are working closely with Roche to prepare the market and setting appropriate commercial infrastructure to support our initial clinic and users. We have planned to initiate a controlled launch in Germany in September followed by Italy and the Netherlands in early Q4.

In June, it was announced that in Germany continuous glucose monitoring is now reimbursement [under a broad program that applies to both type 1 and type 2, insulin using patients and include CGM Systems providing alarms to the patients. This of course, is great news for many patients and clinicians in Germany, who have been eagerly awaiting reimbursement.

The Eversense CGM System with real-time continues glucose readings and both predictive and threshold glucose alarms meets the federal agencies definition of CGM Systems that are included. Consequently, we are covered under the newly approved CGM reimbursement

category. We are now completing the application in partnership with Roche for product specific reimbursement registration codes as statutory health insurance companies were required to get the product reimbursed. This is part of a standard practice for products to gain reimbursement in Germany and we anticipate that the code will be available in Q4. We also expect that pricing under the reimbursement program will be negotiated with each payer. We are working hand-in-hand with Roche to establish the appropriate pricing for the Eversense System.

In summary, we are very pleased with our commercial progress beginning with our launch in Sweden. We are incorporating feedbacks during this controlled launch phase to the Eversense System to strengthen our broader European rollout in Germany, Italy, The Netherlands, Norway, Denmark and the rest of Europe.

Now, I would like to turn the call back over to Don to review our second quarter and first half financials and our expectations for the balance of 2016.

Don Elsey
Thank you, Tim. For the three months ended June 30, 2016, total net loss was $11.9 million or $0.13 per share, compared to $7.2 million, or $3.68 per share in the second quarter of 2015. Second quarter 2016 net loss per share is based on 92.7 million weighted average shares outstanding, compared to the 1.9 million weighted average shares outstanding in the second quarter of 2015. We currently have just over 93 million shares outstanding and expect that number to remain relatively stable for the balance of 2016.

For the six months ended June 30, 2016; total net loss was $23 million or $0.27 per share, compared to $12.9 million or $6.63 per share in the first half of 2015. First half 2016 net loss per share is based on 85 million weighted average shares outstanding, compared to 1.9 million weighted average shares outstanding in the first half of 2015.

The largest driver of the increase in net loss was higher operating expenses compared to last year. Specifically, our total operating expenses for the first half increased $10.2 million to $22.5 million, driven primarily by $5.1 million increase in R&D spending and a $4.3 million increase in G&A spending. When compared on a sequential quarterly basis, total operating expenses increased by $600,000 or 5%. Increases primarily in clinical trial expenses and other R&D expenses of $1.1 million offset by a decrease of $500,000 in non-cash compensation accounted for the majority of the growth.

I'd like to now turn to our balance sheet at quarter-end. As we recently announced, we have established a new debt facility arrangement with Oxford Finance and Silicon Valley Bank. This facility provides for loans up to a total of $30 million. This credit facility has an initial funding of $15 million, followed by three [indiscernible] of $5 million each which the company may draw on based on achievement of specific milestones. With this new debt facility the previous facility was repaid and closed. At the end of the second quarter our cash and cash equivalents were $36.2 million. This included the net proceeds from our recently expanded debt facility. Our current outstanding debt balance is $15 million.

As we stated last quarter, we remain focused on ensuring that we perform with a highest level of excellence, while at the same time, managing their spending closely with a goal of ensuring our cash runway is as long as possible. With that in mind, let me turn to our guidance.
We continue to project that 2016 revenues will be less than $1 million. With respect to spending for this year, we estimate total OPEX for 2016 to be between $37 million and $41 million of

which $3 million to $5 million will be non-cash items. This is consistent with the guidance we gave in the first quarter.

Lastly, we continue to project that our current cash plus our debt facility will be sufficient for operating needs through the third quarter of 2017.

I will now turn the call back over to Tim.

Tim Goodnow
Thank you. Now that we have given you a summary of the last quarter, I want to give an update with respect to our product developments and upcoming milestones. First, on the back of the US trial we just completed, we are working hard to complete our PMA submission material. This is a primary focus for the entire organization and we continue to expect to submit the PMA in the next few months.

Secondly, we continue to make progress on the development of our next generation smart transmitter. This new transmitter has all the current features, it is removable and rechargeable, provides on body vibration alerts and with a one-year life. On top of that, it will be 55% smaller and more ergonomically attractive. We plan to file a CE Mark amendment application for this next generation component later this quarter.

Additionally, we are also committed to expanding the indication to the pediatric population. I'm excited to announce the approval of the Health Canada pilot pediatric study at a leading diabetes center in Toronto. There we will be enrolling 30 pediatric subjects for a 180-day study. The trial design will be very similar to the PRECISE and PRECISE II trials where the subjects will continue to come to the clinic at regular intervals for accuracy measurements, while using the device at home at all times. We plan to use the safety and accuracy data generated in this study to support an IDE [ph] application for a pediatric trial in the United States.

In summary, we are of course pleased with the strong accuracy, patient acceptance as well as clinician acceptance that we observed in the US PMA clinical study. Our first generation product continues to show very strong analytical performance, extremely long sensor life and compelling user acceptance. We look forward to bringing a highly differentiated CGM product to people with diabetes.

Lastly, we continue working on a number of fronts to improve the Eversense System by enhancing accuracy even more and further expanding its longevity. We have multiple internal projects that we believe will accomplish both of these goals in the next 12 to 18 months. Our objective is to provide an Eversense System that maintains a single digit MARD, is calibrated only once per day and has a full 180-day life.

As we reflect on our accomplishments in the first half of this year, we look forward with excitement to the additional milestones on top for the balance of 2016. As noted, near-term focus includes our PMA submission, the full publication of the PRECISE II data at the Diabetes Technology Society Meeting in November, our first pediatric experience in October, launch in Germany, Italy and the Netherlands, further expansion of our distribution partnerships and market launch of our next generation transmitter. 2016 continues to be a very transformative year for Senseonics.

This concludes our prepared remarks. Joining us for questions are Mukul Jain, our Head of Operations including Regulatory Sciences; Mirasol Panlilio, our Global Head of Commercial

Activities; and Lynne Kelley, our Chief Medical Officer. Operator, let's open the call for questions.

QUESTION AND ANSWER

Operator
Certainly, 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 pickup your handset before pressing the keys. To withdraw your question, please "*" and then "2." At this time, we will pause momentarily to assemble our roster.

And our first question comes from Danielle Antalffy from Leerink Partners. Please go ahead.

Danielle Antalffy
Thank you so much. Good afternoon, guys and congrats. That is such an impressive MARD. And Tim, given where it is, it's well below where it was in the CE Mark trial, it's the lowest now on the…or soon to be on the market. So just wondering if you could provide some context or commentary around how this might change your view and speed of adoption of the product, if at all, because certainly we were kind of thinking about it more along that if it was a 10% MARD that would be great, but this is pretty phenomenal. So just wondering if you could give any color or perspective on the potential ramp now with an MARD like this?

Tim Goodnow
Well, we are certainly excited to get the level of performance. We have some very strong indications as we are going in. We wanted to be a little bit conservative with what we projected, but we have been very excited based on what we learned in the European trial. So it really is a testament to the quality of the technology and frankly the number of great people that are in the organization that makes this happen.

As you point out, the accuracy has been one of the key differentiators and as we've seen the technology and the market really advanced for CGM it is directly correlatable to the accuracy. And now that there are a couple of different alternatives that are below the 10% range, I'd expect that's going to continue to grow and accelerate quite rapidly, frankly.

And I think we are well beyond the tipping point of recognition for the use of CGM with the active insulin users is of course very high and we hear a lot of conversations about our moving into the Type 2. So it is the center of the bull's-eye. It is the most important element. And we recognize that we are going to need to stay there as we go to the one calibration a day, one calibration a week and even out to no calibration. There's no going back at this point.

Danielle Antalffy
And any early feedback or I guess it's tough to say because you guys just started the launch in Europe. I think you said June you guys did plan at the first or got the first patients on the system, but anecdotally any feedback on how the physician procedure went, it sounds like you said it was done under five minutes. And just early experience in the real world on the device, are you seeing this level of accuracy in the real world as well? Thanks so much.

Tim Goodnow

Yes. Now, we've been very happy with initial response. I let Mirasol speak to the clinicians. We worked very closely with them on the training. And obviously, we've been staying in touch with the early patients. So, I'll have Mirasol to fill in some more detail on it.

Mirasol Panlilio
I am happy to report that everything went well with our first clinic and patient use, I think we were very excited, I don't know who is more excited, us, the distributor, the clinic staff or the patient themselves. But as Tim reported, all the patients are up and running, in fact, the doctors and the nurses that we trained to the person they thought it was very easy, it was probably the easiest part of the whole training for the first insertion. Things went just very smoothly. And so, we are continuing to evaluate other ways that we can improve not just additional training for the physicians and nurses but also for the patients but things went very well for the first launch experience.

Danielle Antalffy
Okay, thanks so much.

Operator
Our next question comes from Kyle Rose of Canaccord. Please go ahead.

Kyle Rose
Great, thank you very much for taking the question. And I echo the sentiments of Danielle there with regards to the strong accuracy in the trial. I just wanted to see you know, I think that came well ahead of our expectations, and I think candidly in some of the conversations we have had in the past, probably ahead of your expectations as well. Just anything that you learned from this trial, as far as, what you take away from the technology, I mean, I think, we were looking for upper single-digits, do you think about maybe the second gen, even some of the later generation technologies there. Just wanted to see, how you think about this and how it may change your plans both in the US and OUS with this data?

Tim Goodnow
Well, certainly we are very happy as I said to give this level of data. I would say that we were a little bit more optimistic than maybe we had foreshadowed. I think I had said that we would be less than 10.5 in what I have communicated previously, but I certainly had higher expectations than that. Obviously, the key thing from our perspective is the biggest news and most recent movement in the space has to do with the dosing claim, and I know that many of the folks on the phone participated in it or at least watched the entire process. So we are at a significant point of change for not only acceptance and utilization, but the recognition by the regulators of the value of CGM. So now that we have very high confidence that we have a very accurate CGM, it is our expectation that we will be working very aggressively with the FDA to understand what is the best way for us to put our product out as quickly as we can for people in the United States to be able to use the product. So I would say that's probably the biggest recognition with a significant single-digit MARD product.

Kyle Rose
And then another data point…do you have the amount of sensors that lasted out to the 90 days, as far as those 90 patients, I mean how many of them got to the full 90 days and just what the sensor durability was? And then what expectations are for getting…and starting a longer-term trial in the US as well?

Tim Goodnow

So we do have that data, but we are not going to release that as of yet Kyle, it'll be at the diabetes technology conference. Overall, I would say that on many elements of the clinical trial we were very, very pleased with the outcome. So we will ask you to stay tuned for that specific information.

As I alluded to in my comments, our confidence is very high on our ability to pretty quickly deliver the 180 day version of the product. As you know, about half of the sensors from the earlier version lasted to 180 days. We expect that's going to continue increase. And as I said in my comments, you know, in 12, 15 so months, I would expect it will have all sensors at 180 days and we will of course be expanding our labeling with additional clinical studies to support that.

Kyle Rose
I appreciate that and then last question I will hop back in queue is, you know, when you think about the German reimbursement approval and the current commercialization OUS, I understand you haven't given longer-term guidance after '16, but I think consensus stands to somewhere in the $8 million to $10 million range. Does the reimbursement approval change your expectations as far as broader commercialization in '17, and do you think that you feel confident with respect to how the street is modeling your '17 numbers?

Tim Goodnow
Yes, I think we are comfortable with where we are right now. I don't think I would be as bold as early in the process to say that we should take a little bit bigger…a little bit bigger bite at. We certainly will do our best to deliver this product to as many people as we can. But at this point, it's just too early. Obviously, pricing needs to be negotiated, there were a lot of dynamics that go on around that. So let's continue to do our best, we work with our partner Roche which is an excellent organization, and obviously an extremely excellent organization in Germany to help us work our way through it. So at this point, let's stay tuned and continue to work hard.

Kyle Rose
Great, thank you very much for taking the questions.

Operator
Our next question comes from Jayson Bedford of Raymond James. Please go ahead.

Jayson Bedford
Good afternoon and congrats on the results, certainly a nice number. I guess, with respect to the dosing claim, Tim you were at the meeting with the data you've gathered from the PRECISE II trial here. Do you think you can replicate most of the analysis that was presented by the sponsor at the panel or do you think you will need to generate additional data?

Tim Goodnow
No, I think you are going to have generate additional modeling data, right. I think even though that wasn't well accepted by the panel members, the FDA does very much want to see what happens under your particular performance distribution. What is the risk that you may incur with an accuracy that's higher than strips and meters? If you believe the strips and meters are in that 5% to 7% MARD range, maybe some are a little bit higher of the poorer quality strips and meters, we are very much approaching it. But I do think we are going to have to demonstrate that, would be my guess with the modeling work that needs to be done. So we have not yet talked to the FDA, obviously we haven't submitted this data to them. We are of course,

planning on it, doing it very quickly. We will have those conversations, but my guess is, we will need to provide that modeling data.

Jayson Bedford
But the PRECISE II trial has enough data that you can do that analysis. It's not like you would have to generate additional human data for the label.

Tim Goodnow
I believe that to be true. As I said, this is the largest primary CGM study that has been done to-date. So from that perspective we certainly do.

Jayson Bedford
Okay. On the CE Mark amendment for the 180 day label or up to 180 days. What's the timing on when you think you can get that label?

Tim Goodnow
We are not going to forecast that right now, Jason. We are in active conversation with the notified body, to be very frank, we have got a little bit in front of ourselves in regards to the original CE Mark. So I think we want to learn from that, but we are working very hard on it, and we will continue to do the best we can to stay in good conversation with them, but we are not going to yet give a date.

Jayson Bedford
Okay. And just maybe on the commercial side, and I apologize if I missed this, but have you started selling in Norway and Denmark or is it still just Sweden right now?

Tim Goodnow
Right now, it is just Sweden, we are launching, well, I will let Mirasol fill in with, what the short-term plan is.

Mirasol Panlilio
I think for Norway and Denmark, we have got them scheduled for Q4. And then I think, the next up for us would be in September with Germany.

Jayson Bedford
Helpful, and then is…has the post market study been a deterrent to adoption at all?

Tim Goodnow
No, not at all, as I said…as we said on the last call, it was fully expected with having an implantable device that we would have to do a post market surveillance program. We do anticipate that we will have to do that in the US, but it has been no deterrent at all to the commercial activities.

Jayson Bedford
Alright, thank you. I will let someone else to jump in queue.

Operator
This concludes our question and answer session. I would like to turn the conference back over to Tim Goodnow for any closing remarks.

CONCLUSION

Tim Goodnow
Well, we are very, very encouraged with the results that we have been able to obtain not only in the last quarter but also in the first half of this year. We want to continue to thank the participants. This was a fairly lengthy much longer than any other clinical trials that have been done, and the requirement that it would be blinded to the user really requires that they have an extra level of interest in doing the study, if they are going to basically wear a black box for 90 days, but they were able to do it and we thank them very much for their participation. It is certainly the testament to their interest in finding new solutions for people with diabetes. And we want to continue to work very hard to make sure that we can be one of those solutions. So with that, we will end the call and thank you all for your participation.

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