Senseonics

First Quarter 2017 Earnings Conference Call

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CORPORATE PARTICIPANTS

Tim Goodnow - *Chief Executive Officer*

Don Elsey - *Chief Financial Officer*

PRESENTATION

Operator
Good day and welcome to the Senseonics First Quarter 2017 Earnings Conference Call. All participants 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 telephone keypad, 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. Please go ahead.

Don Elsey
Thank you very much, and welcome to the first quarter 2017 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 call today. 2017 is off to a strong start and we have made meaningful progress on a number of initiatives. We are moving forward the clinical and regulatory milestones, building and expanding our commercial presence in Europe, and we have begun preparations for our US commercial launch. Also, we are reiterating our expectation for revenue of $6 million to $7 million in 2017. Don will go into more detail on our financial statements in the section.

In the first quarter, we generated $550,000 in revenue in Europe, in line with our expectations. As we continue to gain valuable feedback from the field and on the heels of our CE mark approval for our Gen-2 smart transmitter, we have now initiated full launches in Sweden and Germany and are starting to roll out controlled launches in additional countries. In Germany our controlled launch with Roche has been very successful.

We are continuing to work collaboratively to generate positive patient and clinician experiences in the field, with this, coupled with positive reception to our Gen-2 smart transmitter, we are expanding our presence to a national launch whereby Roche will be increasing its footprints from 4 reps to their entire IDS or Intensive Diabetes sales reps to cover all of Germany.

The addition of these experienced reps that repeatedly sell high technology diabetes devices increases our feet on the ground by manyfold and strengthens the nationwide rollout of the product. We are also in the process of initiating peer-to-peer educational activities spearheaded by clinicians that have been involved with our initial controlled launch to leverage their experiences. We expect these will be particularly valuable in ensuring smooth site ramp ups, clinician comforts with the training and insertion and in streamlining workflows.

In Sweden, we are also broadening our launch with activities around our Live Fully, Rest Assured marketing campaign. This campaign supports our promise of helping users confidently live their lives with ease. Both print and online advertising features actual users discussing their experience with the product highlighting the freedom they enjoy, ease of use, and most importantly their confidence in their glucose readings.

We have just come back from the Swedish Diabetes Forum, which is their Annual Diabetes Conference where feedback on our product and testimonies from our patient base was received enthusiastically. We have initiated limited commercial rollouts in the Netherlands and Italy and are preparing to enter other European markets with similar controlled launches as deployed in our earlier countries. By mid 2017, we expect to be in a total of eight European countries, with significant expansion efforts both in Italy and Sweden.

In product news, recall that we have submitted a CE mark amendment to extend our centralized labeling for up to 180-day use. We expect to receive our clearance in the coming months for this version of the sensor that we are branding Eversense XL. We anticipate that Eversense XL will begin to rollout later in the third quarter.

As you can imagine, the combination of an even longer term sensor that can provide continuous readings for up to 180 days will show rapid evolution of the product. And having this coupled with the slim Gen-2 transmitter will create yet another level of convenience for our users.

In the United States, we have submitted our pre-marketing approval application to the FDA that is under active review. Through the interactive review with the agency, we have generated the customary list of questions that will be resolved in order to complete the substantive review.

We have already responded or in the process of responding to the FDA and are moving the review forward. We would characterize our discussing as collaborative and productive. In parallel, the FDA has being performing inspections at our facility and our manufacturing clinical sites.

The agency has completed successful BIMO inspections at Senseonics in our clinical sites with no findings. Similarly, the agency has completed quality assistance inspections of Senseonics in all of our manufacturing facilities except two foreign sites where the inspections have been scheduled. These have been collectively successful with no actions indicated.

As would be customary for a PMA for a novel device such as our Eversense, the first of a kind long-term implantable sensor and with the history of this review group using panel meetings, we expect that we will have a panel meeting as part of this review process. So we are preparing accordingly.

Given the strong safety and efficacy data that we have generated in our submitted pivotal trial, we are happy to be providing greater visibility to the medical and patient communities. Our

planning for a panel process is underway and has been included in our timeline with functions and the potential approval in the fourth quarter is intact.

In preparation for our US approval, we recently hired industry veteran Mike Gill as our VP of Sales. Mike will be leading our sales group in related support functions and will establish our direct sales force in the United States to launch Eversense.

For those of who that may not know Mike, he has spent the last 17 years in Medtronic in various leadership positions, most recently as BPO sales for the Americas region for the diabetes group. He built and managed the commercial efforts of this business that generated annual sales north of $1 billion in pumps, CGM sensors, and sensor-augmented systems.

We are thrilled to have Mike on board with his proven track record of success and commercial expertise in the diabetes sector particularly with CGM sensors. He will be instrumental in developing our commercial organization as we enter our next phase of growth.

In our pediatric trial in Canada is underway as well and we anticipate completing enrollment next week. Recall that this study involves participants aged 12 to 18 and is 180 days in duration. The first three participants have now completed the trial and feedback on the product has been extremely upbeat.

Positive commentary on the freedom from weekly sensor changes, no longer dealing with adhesive reactions and the use of the Apple Watch Displayer were all highly regarded. Each of these pediatric participants wore the sensor for 180 days and remarked how much they enjoyed the system and that they can't wait to use it again.

To provide a little color with some examples, we have heard about the experiences of a 15-year old boy who traveled more than an hour for his site visits. A 13-year old who has asked if she could keep this sensor after the sensor was removed.

A college student was pleased with her level of control and a teenage boy who is an avid hockey player and was thrilled that he could easily remove the transmitter before a game and replace it afterwards. We continue to believe that the results of this study will provide informative clinical data that will be instrumental in defining our US pediatric trial and our strategy for a label expansion in Europe.

On the product development front, we are making progress in R&D on our second generation sensor that will incorporate a completely redundant glucose-sensing capability. We expect this to further improve the accuracy, longevity, and functionality of the system with the ultimate goal of eliminating the need for a finger-stick calibration. The current version of this sensor is in human feasibility trials that we are using to define a glucose algorithm for the two parallel sensing elements.

Now, I would like to turn the call back over to Don to review our first quarter financials and then I'll finish up with some perspectives on the remainder of 2017.

Don Elsey

Thank you, Tim. For the three months ended March 31st, 2017, we generated just over $550,000 in revenue. There was no revenue in the comparable period of 2016. All revenue for the quarter was attributable to sales of the Eversense system in Europe. For the three months ended March 31st, 2017, total net loss was $13.1 million or $0.14 per share compared to a loss

of 11.2 million or $0.15 per share in the first quarter of 2016. First quarter 2017 net loss per share is based on 93.9 million, weighted average shares outstanding compared to 77.3 million weighted average shares outstanding in the first quarter of 2016.

The largest driver of the increase in net loss was higher operating expenses compared to last year. Specifically, our total net loss for the three months increased $1.9 million to $13.1 million driven primarily by a $600,000 increase in research and development, expenses for next generation sensor and transmitters, and a $500,000 increase in sales and marketing expense, which includes efforts to support our commercial rollout.

I would like to now turn to our balance sheet. At the end of the first quarter, our cash, cash equivalents, and marketable securities were 13.8 million. In the first quarter, we drew down an additional tranche of $5 million from our Oxford and Silicon Valley Bank line talking our total outstanding debt to $25 million. We continue to project that our cash balance along with the remaining facility with Oxford and Silicon Valley Bank will take us into the third quarter of this year.

We are working diligently to secure additional financing in the very near future with a target of insuring sufficient resources to support PMA approval in US launch. Let me turn to guidance for the year. As we announced in early January, our revenue guidance for 2017 is between $6 million and $7 million. This revenue is driven by sales in Europe and is anticipated primarily in the second half of the year as we transition from our controlled launch stage to full marketing in selected countries.

We want to be sure that we are transparent with expectations in the early stages of our launch. With that, for Q2, we expect a sequential increase in revenue from Q1 in between 600,000 and 1 million for the quarter. As we shared in our February call, we will not be routinely providing quarterly guidance as we go forward. I will now turn the call back to Tim.

Tim Goodnow
Thank you, as we enter 2017, we are excited about the developments we anticipate on many fronts. We are continuing to work closely with the FDA to ensure the approval our PMA for EverSense, which we anticipate late this year. We are now beginning the initial stages of launch preparation in the US.

As we have discussed in the past, we are simultaneously putting in place plans to prepare for the necessary reimbursement and are in discussion with the private payers and with clinician practitioners. On the European commercial front, we are making tangible progress with Rubin Medical and Rose Diabetes Care to meaningfully expand sales in Germany and Sweden, as well as to ramp up and initiate launches in several additional territories.

As we have said before, our mission is to deliver transformative glucose monitoring products that enable people with diabetes to confidently live their lives with ease and all of our energies are devoted to accomplishing this mission. 2017 is off to a strong start. As we strengthen our platform and expand availability of the EverSense System to an increasing number of people with diabetes, we are excited to be part of this change.

This concludes our prepared remarks. Joining us for questions are Mukul Jain, our Chief Operating Officer; Mirasol Panlilio, our Global Head of Commercial Activities; Mike Gill, our VP of Sales. Operator, let's open up the call for questions.

QUESTION AND ANSWER

Operator
We will now begin the question-and-answer session. To ask a question, you may press "*", then "1" on you touchtone phone. If you are using a speakerphone, please pick up your handset before pressing the keys. To withdraw you question, please press "*", then "2." At this time, we will pause momentarily to assemble our roster.

The first question comes from Danielle Antalffy of Leerink Partners. Please go ahead.

Danielle Antalffy
Hi, good afternoon guys. Thanks so much for taking the question.

Company Representative
Great Danielle, nice to hear from you.

Danielle Antalffy
Sitting so, Tim, I know this is still very anecdotal. It is still pretty much a limited launch at least the past quarter in both Sweden and Germany but again just wondering if you can give us any anecdotal feedback on things like reinsertion rates amongst the patients that have been implanted and feedback thus far from both patients and physicians.

Tim Goodnow
Yes, I will be happy to ask Mirasol to talk about it; she is obviously in daily contact with our partners over there. We are not prepared at this point to talk about reinsertion rates, as frankly as I have said in the past, that information is….we know when a sensor goes out, but we don't necessarily when it goes into an individual patient. But, just in regards to how its going we are pretty comfortable and excited with the process but I'll let Mirasol add a little bit more color.

Mirasol Panlilio
It's similar to what we have experienced now for the past three quarters where very positive user experience during the controlled launched we really pressured, tested our commercial program, gotten really good feedback in terms of how people are using it, who is using it, and improving the usability as well as the clinic workflow. Time and time again, I think the feedback that we are getting from users is how comfortable the wear time is for them and that every time that they finish a session, the 90-day period that they are surprised at how quickly it goes as well as the need to be inserted again. So, I think from that standpoint it's gone really well to the point that we are ready to do the national launch.

Danielle Antalffy
Okay, great. That's very helpful. And then, I just wanted to make sure we knew what was coming at ADA for you guys if anything and really over the next 12 months from a data perspective, what should we be looking for from Senseonics. Thanks for much.

Mirasol Panlilio
We do have a number of presentations that we will doing at the ADA based on mining the precise one and precise two study results. And I think I will start there with other things that are we are working on, but haven't made any announcements yet.

Tim Goodnow
And from a data perspective specifically as you have heard, we will likely be later in the year having some conversations about the performance in the pediatric patients, the populations that we have tested there as well. We are very much working with the agency, the FDA for us to prepare and submit an IDE for us to begin the 180-day testing in the United States.

We certainly won't have any data in 2017 but we certainly do want to get the trial started as quickly as we can to do the label extension in the United States. So, there are a number of different clinical testing activities that are underway in our pilot work for next generation, but the next big step for us in the US is the 180-day trial.

Mirasol Panlilio
That's helpful. Thanks so much guys.

Operator
The next question comes from the Kyle Rose of Canaccord Genuity. Please go ahead.

Kyle Rose
Great, thank you very much. Can you hear me all right?

Tim Goodnow
Kyle, how are you?

Kyle Rose
I am doing well, thank you for taking the questions. So just quickly on the regulatory pathway in the US. Obviously it seems like that's moving forward quickly, just wanted to see if you can comment on the 100-day meeting, did you have it, did it go well? And then also just your thoughts on the panel and then just from a timing perspective it sounds like you reiterated expectation for approval before year end, but just how does the timing of a panel potentially play into your thoughts in the year end?

Tim Goodnow
Let me just talk about the strategy, what we thought we have been planning on a panel frankly since the beginning. This is a review group that has used it almost exclusively with new top technologies except for frankly the 670G. So, it has always been our expectation, it's been in our timeline when we started and the review process we actually feel, has gone extremely well. The fact that the reviews have been done internally is not only an indication that one, we've been successful and we have all of our quick quality systems in a row as we should, but it also is an indication that they continue to move the program through its process.

But, when we started getting questions with regards [indiscernible] it seems to be going well, could we get an early approval, we certainly would love to do that, but we thought it would make sense to make sure that we pointed out to everybody that there is very much a potential that a…the first of a kind implantable product could be called to be discussed at a panel meeting.

So that's the thinking about it. We are in an active preparation process. I will let Mukul who runs the regulatory program for us talk a little bit about how we think about the timing.

Mukul Jain

Thanks Tim. So talking about one of the things you raised Kyle was the 100-day meeting. No, we did not even get to the 100-day meeting because we got a round of questions from FDA prior to the 100-day meeting. As a result, we have been responding to them and we do have few different multiple meetings coming up in the next couple of weeks where we are doing submission issue resolution meeting or a pre-sub on some of the questions that they've asked. From the timing perspective, we plan on getting back to them in the next few months, and if there is a panel we expect it to be in early fall, which will still put us in the fourth quarter approval timeline.

Kyle Rose
Okay. Great. I appreciate the color there. And then, in Germany, and I understand that it's still early, but just wanted to see if you had any insight as far as reimbursement status, where is Roche as far as securing reimbursement for EverSense and what was it like in their control launch where patients cash pay, were they reimbursed and then what are your expectations through the rest of this year?

Mirasol Panlilio
Yes, on the reimbursement front going forward, we are getting of course the prescriptions now and while we have reimbursement, it's the process of getting paid out by the payers is…it's not as routine and it's not standardized for CGM. They have….each of the payers still have different processes on their own and so we are finding that there is a little bit more hand holding then what we would probably like. And that goes with the entire category actually.

So we expect though that once there is many more players in the marketplace that it would smooth things out. But right now it's just not as routine as what we would like. And so what we are doing with the prescription is doing it on a case-by-case basis with each payer versus having a central payment method.

Tim Goodnow
And Kyle, just for clarification, the first group of patients that Roche put through was a program that they funded. So they've expanded beyond that now and will go full board here now with the national launch but the first 100 or so patients they funded that, we didn't go through the reimbursement process with them.

Kyle Rose
Okay. Thank you very much.

Operator
The next question comes from Jason Bedford of Raymond James. Please go ahead.

Jason Bedford
Hi, good afternoon. Thanks for taking the questions. Just to maybe cleanup the last line of discussion there, obviously Roche is moving forward with a more expansive launch in Germany. I'm guessing that does coincide with the anticipation of more favorable reimbursement going forward here in '17, correct?

Tim Goodnow
Yes, that's absolutely right. There is expectation. I just think they are still a few startup issues that they are working through. We facilitated some of that with some of the technical questions. But obviously, in the relationship this is their program to drive, so…

Jason Bedford
Okay. Fair enough. And I think it's been asked in the prior call, but just in terms of the experiences so far in Sweden and Germany, what have you learnt from the launch maybe in terms of who is getting the device? Who is attracted to it?

Mirasol Panlilio
Let me take that one. I wish I could be a lot more definitive, but it's been mix. So we've had both new to CGM as well as folks who have tried sensors in the past. It's probably 50-50 at this point. Mostly Type I, so I'm actually not sure anecdotally if we've had any Type IIs. Age wise, tend to be younger. I show my age because younger is less than 50 I would say on average. And I think the remarkable thing that we are seeing is these tend to be very active individuals, active lifestyles, people on-the-go and want that just convenience of an implantable. I don't know if that helps in terms of just feeding additional insights.

Tim Goodnow
Sorry, Jason. We have been encouraged that about half are switchers frankly that are coming from one of the other technologies but the other half are new people that are now interested and willing to give a CGM a try. So we've actually taken that as a good indication because we've opened up the opportunities to some new folks.

Jason Bedford
Okay. And when did the broader advertizing, the campaign start in Sweden?

Mirasol Panlilio
It starts this month to coincide with our Dan 2 transmitter launch as well.

Tim Goodnow
Yes, we targeted everything for this month with the release of the new transmitter.

Jason Bedford
Okay and just for clarification. The new transmitter I know was approved a couple of months ago, but that gets fully launched this month?

Tim Goodnow
Yes, it's all in tandem with essentially here on May 1st.

Jason Bedford
Okay. I think that's it from me. Thanks for taking the questions.

Tim Goodnow
Okay.

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

CONCLUSION

Tim Goodnow

Once again, I would like to thank everybody for their time in joining us on the quarter call. I know it's especially busy for those of you that are covering so many companies. We appreciate you taking the time with us. We look forward to giving you further updates in the future as I indicated 2017 is a very important year and we anticipate that each quarter is going to be a significant successive growth for us with each step. So with that we appreciate the time and have a very good evening. Thank you.

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