Senseonics

Second Quarter 2017 Earnings Conference Call

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CORPORATE PARTICIPANTS

Tim Goodnow - *President, Chief Executive Officer*

Don Elsey - *Chief Financial Officer*

Mukul Jain - *Chief Operating Officer*

Mirasol Panlilio - *Vice President, General Manager of Global Commercial Operations*

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

PRESENTATION

Operator
Good afternoon, and welcome to the Senseonics Second Quarter 2017 Earnings Conference Call. All participants will be in listen-only mode only. 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 now would like to turn the conference over to Don Elsey, Chief Financial Officer. Please go ahead, sir.

Don Elsey
Thank you very much, and welcome to the second 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. As we embark on the second half of 2017, we are well positioned and are making meaningful progress on a number of fronts. We are pleased with the accomplishments we have made thus far this year. Amongst these are the scaling up of our European launch, the approval of our Gen2 transmitter, continued progress on our Canadian pediatric trial, our initial preparation work for the United States launch as well as the imminent launch of Eversense XL.

On the call today, I will address the state of each of these. Don will provide more detail on our financials. And then I'll wrap up with some comments about our longer-term direction at Senseonics.

First, we generated $800,000 in revenue in Europe in the second quarter, in line with our expectations. We expect to ramp our revenues meaningfully in the second half of the year as we have transitioned to full launch in many of the countries. As such, we are reiterating our forecast of $6 million to $7 million in revenue for 2017.

We also added roughly $40 million to our balance sheet in Q2 through an equity offering that was comprised by a group of institutional investors led by our European commercial partner, Roche.

Most recently, we have commercially launched in the countries of Belgium and Austria. This brings the number of countries in which Eversense is available to seven. By the end of the year, we expect to have doubled that number. While we are still in the early stages of our launch in Europe, we are able to share some initial metrics which provide insight as we scale and also provide visibility into our trajectory going forward.

As planned, given the positive user experience and clinical acceptance of Eversense and with the recent introduction of our Gen2 smart transmitter, during Q2 we moved from a controlled launch to a full launch in many of the countries.

As we reported previously, the distributor reps are now calling on more diabetes clinics and there are many more reps now calling on prescribers. This pivot in launch mode points to our and our partners' confidence in Eversense.

The impact is encouraging. In the last two months, we have equaled our new users from the first three quarters of the controlled launch period. We expect this momentum will carry through the balance of the year and we will convert many countries into full launch and make Eversense available in new European countries.

As our installed base grows, we're able to further analyze the type of users that are selecting our product. In our earlier experience, we are seeing that approximately 50% of our users are experienced Libre users and have upgraded to our CGM.

Anecdotally, the reason for their switching to an implantable sensor is the freedom and convenience provided by our long term sensor, the comfort in wear and the added safety of the predictive low and high glucose alerts.

Additionally, we're seeing that 20% of those selecting Eversense are new users not previously…that had not previously used either CGM or FGM in the past. These are type 1s that may have recognized that they should be on CGM to now find that the benefits of a long term sensor meet their need and are therefore making the choice to begin using a continuous monitor. The remaining 30% were previously using the Dexcom or Medtronic CGM.

Further, early analysis on patient experience has also pointed towards improved time and range as well as reduced time spent in both hyper and hypoglycemia. This is observed as a move from the first 30 days to the second 30 days and then to the final 30 days of continuous use of the first sensor. This bodes well in terms of use of the system and demonstrates the true value of being on a long term sensor.

It's too early to make any conclusion yet, but directionally, we have insights as to who we are attracting and the results they are starting to see. We can use this information to approve our product and services and ensure we are meeting the needs of our user base. Once again with a long term sensor, we can now better understand how patients are able to use their device to better manage their diabetes.

In product news, we continue to expect the CE Mark of our Eversense XL or extended life in the coming weeks. This new product provides up to twice as much sensor life as our current Eversense CGM system.

With Eversense XL, for the first time patients can extend a single sensor wear across three seasons. They can insert in the late summer, wear through the fall and finally remove it in the

winter. This is truly remarkable for our industry and a long ways from when we rejoiced when sensors lasted three days a decade ago. Now our continuous long term wear sensors offers another choice for patients with diabetes.

Best of all, the Eversense XL users will still be able to count on the same strong accuracy and with a smart transmitter that can be easily removed to replace back onto the body with a gentle adhesive. We truly believe this will change how CGM will be used in the future and we are excited to be offering to people with diabetes.

In anticipation, we are working towards finalizing product labeling for XL and expect it to have it available in the fourth quarter. We plan to initially start a rollout in the English language UK market and then expand our introduction to include the rest of Europe in the first quarter of 2018. We believe that XL will contribute meaningfully to our continued penetration and expansion in Europe once it's available.

In the United States, our PMA application continues to be evaluated by the FDA and we are in active discussions with the agency and are responding to inquiries in earnest. As we have said previously, Eversense is a novel product and is the first of a kind as a long term implantable sensor.

It is our belief that the agency will convene an advisory panel to explore the communities' feedback on the safety elements of an implantable sensor as well as the training programs designed to introduce endocrinology, diabetology professionals to the in-office procedures of sensor placement and removal. This process will allow the interested medical community to comment on an implantable product.

We are confident that the strong patient data demonstrated in our US pivotal trial, our European pivotal trial and our robust post-market surveillance program currently underway in Europe will support and confirm the efficacy and safety of the Eversense system. We continue to anticipate the advisory panel will likely be held in the late fall and that our final approval will closely follow this conclusion.

Additionally, we have begun early preparations activities in advance of our US approval and launch. As you may recall, last quarter we announced that we had hired diabetes industry veteran Mike Gill as our Vice President and General Manager of the US region. Mike has assembled a core team of leaders who are in the process of building launch plans and the architecture around those plans. Their collective focus is on building a commercial strategy, organization and approaches that span reimbursement and sales force design as well as clinical support to appropriately address our opportunity.

Specifically, they have conducted additional market diligence and research among their endocrine, nurse educator, diabetes constituents focusing on the patient population committed to multiple daily injections who could benefit from a long term accurate continuous monitoring system.

The impending launch of the Eversense XL coupled with the preparation of our launch into the US are important activities for us. We are keenly focused on setting the stage for long term success in these markets and look forward to continued progress over the coming months.

Now, I'll turn the call back over to Don to review our second quarter financials, and then I'll finish with some perspective on the balance of 2017 and our final thoughts on the path forward.

Don Elsey
Thank you, Tim. For the three months ended June 30, 2017, we generated $814,000 in revenue compared to $19,000 in the prior year period. The increase was attributable to sales of the Eversense sensor in Europe.

For the three months ended June 30, 2017, total net loss was $12.4 million or $0.12 per share compared to $11.9 million or $0.13 per share in the second quarter of 2016. Second quarter 2017 net loss per share is based on 103.7 million weighted average shares outstanding compared to 92.7 million weighted average shares outstanding in the second quarter of 2016.

The largest driver of the increase in net loss was higher interest expense compared to last year. Specifically, our total interest expense for the three months increased $500,000 to $800,000 due to our increased term loans with Oxford and Silicon Valley Bank.

For the six months ended June 30, 2017, total net loss was $25.4 million or $0.26 per share compared to $23.1 million or $0.27 per share in the first half of 2016. First half 2017 net loss per share is based on 98.8 million weighted average shares outstanding compared to 85 million weighted average shares outstanding in the first half of 2016.

The largest driver of the increase in net loss for the first six months was higher interest expense as well compared to last year. Specifically, our total interest expense for the six months increased $1 million to $1.5 million due to our increased term loans again with Oxford and the Silicon Valley Bank.

I'd like to now turn to our balance sheet at quarter end. At the end of the second quarter, our cash, cash equivalents and marketable securities were $41.4 million. In the second quarter, as Tim mentioned previously, we completed an equity raise of just over $40 million.

Turning to guidance for the year, as Tim mentioned in his opening remarks, we are reiterating our expectations for full year revenue between $6 million and $7 million with additional confidence driven by our expanding launch presence.

I will now turn the call back over to Tim.

Tim Goodnow
Thank you. I'm encouraged by the progress that we made in the first half of 2017 and I expect the second half of the year to be an active period for us as well. As I noted, we will continue to ramp sales and introduce Eversense XL in Europe, move to complete the approval process for our PMA and prepare for the US launch, all while we continue to advance our product development efforts.

To that end, we've recently announced work on an integrated automated insulin delivery system combining Eversense with the TypeZero artificial pancreas algorithm and the Roche Accu-Chek Insight pump. We're excited about this opportunity and we believe a long term, easy to use, automated insulin delivery system may help reduce some of the day-to-day burden Type 1 patient's face in their diabetes management.

This integrated AID system is now in full development and is part of the NIH-sponsored International Diabetes Closed Loop Trial. We expect to have this system in the hands of our European clinical sites early next year for the pivotal trial.

As we have illustrated, we are focused on an accurate, easy to use glucose monitoring system that continuously provides readings for up to 180 days. The automated insulin delivery system is one example of how our core long term accurate sensor can be utilized.

We have also accelerated our efforts on optimal utilization of all data captured in a long term wear sensor. The healthcare needs of today can be summarized as improved outcomes, expanded access and improved cost and efficacy. And all of these needs can be enhanced with a more real-time integrated information exchange.

Our commitment is to intersect diabetes management and lifestyle management with an eye towards ease and convenience that can able with a long term sensor. Toward this end, we are planning to have Eversense Now available in Europe in the fourth quarter of this year.

Eversense Now is designed to remotely monitor the user's CGM data in real time and provide alerts of high and low glucose events, including predictive high or lows to a caregiver, family member or friend's mobile device. We understand the added sense of security and convenience of receiving glucose predictive alerts directly on the phones can be a significant benefit for patients, their loved ones including parents.

As previously announced, we are also collaborating with TypeZero to utilize their decision support algorithm into our system to recommend optimal basal and injection doses for insulin pen users, while we soon will be announcing the pivotal clinical program to characterize the safety and efficacy of this TypeZero decision support algorithm integrated into our Eversense app.

This is the logical extension of our partner work and we are excited to address the millions of multiple daily injection patients who want to more conveniently manage their diabetes in a way that is seamlessly integrated into their lifestyles.

We believe that a CGM sensor which is inserted only a couple of times a year and then includes a reliable insulin dosing calculation based on the historical continuous data and seamlessly provided to one's Smartphone can be a significant benefit for patients. Additionally, we are continuing our product integration with Glooko-Diasend [ph], where the European Diasend system is now being used in Eversense clinics in Sweden, Norway, Italy and Germany.

Finally, we are also collaborating with Roche Diabetes Care to integrate the Eversense system into Roche's updated version of the Accu-Chek Smart Pix data management system for use by clinicians. Of note, Eversense is the first CGM to be integrated into the updated Smart Pix product allowing for better trend understanding of a patient's glycemic status.

CGM is the hub, the data source for multiple approaches to improve patient care and outcomes whether it is in the form of a component of an automated insulin delivery system or is in pairing up with a blood glucose meter or smart pen. Our strategy is to provide the best real-time, real-world data in all these settings while reducing patient overhead and improving simplicity.

In the near future, we expect to execute additional partnerships in various areas of digital health and we will continue to enhance our own applications expanding the ability of our system to provide actionable information to caregivers.

We're excited about our strategic partnerships and initiatives which will continue to drive these trends forward over the long term. Additionally, we are in parallel committed to and focused on our immediate term objectives of technology development and evolution as well as our European commercial experience and our respected entrance into the US market.

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. Our energies are devoted to accomplishing this mission. 2017 is off to a strong start and we look forward to continuing our progress.

This concludes our prepared remarks. Joining us for questions are Mukul Jain, our Chief Operating Officer, Mirasol Panlilio, our Vice President and General Manager of Global Commercial Operations and Mike Gill, our Vice President and General Manager of the US Region.

Operator, let's open up the call for questions.

QUESTION AND ANSWER

Operator
Thank you. We will now begin the question and answer session. To ask a question, you 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 pause momentarily to assemble the roster.

And the first question comes from Danielle Antalssy from Leerink Partners.

Danielle Antalssy
Hey, good afternoon, guys. Thanks so much for taking the question and congrats to all. It sounds like you guys are making really good progress. Tim, I was wondering if you could talk a little bit more about some of the metrics that you're seeing and you're appreciating that with early stages of the full launch mode. But anything you can comment on regarding re-implant rates, and I know something else we've talked about in the past. It's not just the clinicians…the physicians that are doing the quote [ph] procedure but also the nurses, maybe talk a little bit about any hesitation you are running into, as far as, doing the procedure, getting trained on the procedure? And how you think that could translate into what we should expect here in the US?

Tim Goodnow
Sure and thanks, Danielle. In regards to the further information on the metrics, as you recall, really May was the trigger point time period for us to transition. We had been doing introductory training, if you will especially for our commercial distribution partners on how to sell, how to communicate, how to follow the product through its use cycle. And it's in that time period the broad base launch in the key markets, especially Germany and Italy really occurred.

So we don't have full Q2 impact to it, but we are very encouraged with the reinsertion rates that we are seeing, especially in Italy where their launch was a little bit different than Germany. Germany, the reinsertion rates are impacted by the reality that it was about approximately 110 users that got a single sensor and were not given the opportunity to reinsert. There was some frustration with the patients who had a strong interest, but the pilot was done in a static mode such as that.

Italy on the other hand was able to see and do the reinsertion and the reinsertion rate there is appropriately high and well within the expectation at what we've modeled. So encouraged with what we are seeing. I'll let Mirasol speak to the actual insertion, training and procedure. We continue to be very active and supportive. We do have direct Senseonics employees that are onsite in Europe that work with our distributors to do the training on it. So I'll let her give a little bit of color on the, who and how of those insertions and rollout.

Mirasol Panlilio
Sure. Thanks, Tim. Danielle, just to answer your specific question about who is actually doing the procedure, most of the insertion and removal are still being done by the doctors themselves, by physicians. I don't have exact split between doctors or nurses, but the majority are still physicians and we expected that that will continue as we continue to bring on more new clinics. New clinics tend to go via doctors first and then some of them eventually turn to the nurses to do the insertion or the removal. But as Tim also mentioned, the switch or the pivot from the controlled launch to the full launch, we've now seen just many, many more new clinics come onboard, particularly in the two markets that Tim mentioned because we have more reps coming on clinics and we have many more clinics that we are calling on. For instance, we actually even had to right now looking for additional clinical trainers to tide us over during this increased demand period. So there is…we are just seeing a lot more demand now, especially given the Gen2 smart transmitter launch back in May. So hopefully that adds a little bit more color about what we are doing.

Danielle Antalssy
Yes, no that's very helpful. And if I could just follow-up, the XL, I think if I remember correctly, Tim, you've been expecting this for some time now. It feels like, maybe it is a little bit delayed. Just wondering, if you can comment on that? What might be going on there to hold that up, is it just a slowdown in the summer months with the European regulatory body or I assume you are still just as confident that it's going to get approved, there is nothing wrong. But just want to get your comment.

Tim Goodnow
No, fair question; we had based on our conversations with BSI, our notified body, anticipated that they would be wrapped up with the review in the June time period. Unfortunately it did slip. Like many of the rest of us, they really do have some capacity constraints in regards to their ability to dig in and do reviews. And the escalation process that is the normal practice for once there is a lead reviewer which we have which is in the states for us. It then gets referred to Europe for their more central analysis. That unfortunately did take a little bit longer in the summer months. BSI has certainly worked with us and recognizes that they have taken a little bit longer, but there is…there has been no issue behind it under than frankly capacity and some turnover that they have had on their team. So we do very much feel that we are at the very end, and we hope to be able to make a formal announcement on the CE Mark issuance, in the very short term.

Danielle Antalssy
Great, thanks so much for taking the questions.

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

Brandon Vazquez
Hi, everyone. Can you hear me all right?

Tim Goodnow
Yes.

Brandon Vazquez
Alright, it's actually Brandon Vazquez in for Kyle Rose. First question just on…thanks for the color on your installed base. It sounds like you guys are getting about 80% of your patients from competitors now. Do you think that's a dynamic that you will expect to continue going forward or do you think, you might start to see some more growth coming from new CGM users?

Tim Goodnow
It is a good fair question. It's still early, I would say that I would anticipate that we are certainly going to continue to have users, especially in Europe right, where the penetration of CGM is still pretty low that are going to agree to come to CGM now that they are looking at the particular benefits of any one particular system, right. Obviously, there is a good penetration of the FGM relative to CGM, because of the economics history there, but we do anticipate that a number of those are going to see the value of CGM. And as the reimbursement equity between the differences gets normalized, many folks are going to chose CGM over FGM. But I do think that the market expansion that we are seeing is going to continue. I just think it's too early to say it's going to be at the 20% level. We would obviously like it to be as large as it can, but that's what we are seeing today.

Brandon Vazquez
Okay, great. Thank you. That's very helpful. And just one other quick one to follow up, now another quarter into the launch here, any updates on attrition rates, has that been changing or anything notable there? Thank you.

Tim Goodnow
No, we are not seeing it; we still have very good retention and reinsertion rate. It's hard to comment on it directly and we don't necessarily mean to be obtuse…but recall that in Europe we are one step away. The direct customer interface, doctor interface is done, of course, with our distribution partner, and our role is to do secondary support. So we get reports, but we don't have the real-time access like we will have in the United States.

Operator
Thank you. And the next question comes from Dominick Leali with Raymond James.

Dominick Leali
Hi, this is Dominick in for Jayson. Thanks for taking the question. I was looking to start with the partnership with Roche for the artificial pancreas. I was just wondering, if we could get a sense of how big that study will be and maybe how you will that study, towards a goal of commercialization an AP [ph] product, if that's your goal.

Tim Goodnow
Yes. No, that certainly is the goal, as we partnered not only with Roche from the pump perspective, but also TypeZero; they will be bringing the algorithm. The key focus for us and requirement in the participation is that it would be more than a research project. So we are actively working with both of those partners, such that, we do, as we call it a pivotal trial to certainly support at the very least, the CE Mark for the product and to fully enable and educate us for the conversations with the FDA in regards to what their requirements will be. We've seen

a good portion of that with the work that they have done in the clinical trial that they requested for the Medtronic product, and we will certainly be focused to that. But the work is intended to commercialize a product out of the clinical program.

Dominick Leali
Okay, great. And then are there any numbers we should keep in mind, maybe for the size of the trial or when we could expect the trial to complete?

Tim Goodnow
We anticipate that we will begin enrolling in early in 2018, and then we would expect that the trial would be done in 2018. We are still negotiating the specific numbers, so we will get back to you on that as it evolves, but its material enough for regulatory consideration for product's approval.

Dominick Leali
Okay. And just a couple more here, I was wondering in Germany with Roche, if there was a specific percent of lives on the coverage that they have access to now with the full launch?

Tim Goodnow
I don't have access to that, I do know that some quarters ago that they had been in conversation with well in excess of 80% of the covered lives. I don't have an update, Mirasol; you can chime if you could do. But it's the vast majority that they've covered.

Mirasol Panlilio
Yes, I have…in terms of what we are really seeing in Germany is the reimbursement is happening, that we are getting the prescriptions and then it hasn't been much of an issue with respect to getting that reimbursed by the payers. The exact percent that we have contracts with…I can't recall at the moment.

Dominick Leali
Okay, that's helpful. And in terms of European commercialization, I think you mentioned on the last call, that you are broadening the marketing, I think Sweden in particular had a broader advertising campaign. I was wondering if that… if you saw good interest from that in the quarter and whether that was spurring interest from endocrinologists or whether it's more consumer focused.

Tim Goodnow
We have gone…I should say we are going to a more DTC approach, but investment in the summer months especially in Sweden is not a good investment. So that program is actually kicking off here as folks come back near towards September. Mirasol, I don't know if you want to add any more to it. But June, July and August are traditionally appropriately distracted months in northern Europe.

Mirasol Panlilio
Well, in general, however, the countries who are now in the controlled…in a full launch mode has increased their consumer awareness campaign and program, particularly in social media. So that's part of truly the increase in the awareness and increase in the demand is that there is just a lot more noise and buzz about the Eversense system given the campaigns by the countries. Particularly, I would say in Germany, where its consumer focused, and Italy probably a little bit more clinic focused, but eventually that would also turn into more consumer awareness campaign.

Dominick Leali
Okay and my last question was on the US regulatory dynamic. Has that…you said that you are expecting a panel but the day in the panel itself, those haven't been formally requested or have they?

Tim Goodnow
They have not. The FDA has been silent on it. But this is a group that has traditionally used the panel process for each new technology. The original transcutaneous, the original GlucoWatch, the original transcutaneous with Medtronic were all…a panel was used. In the adjacent space, the first alternate site testing of blood glucose meter, this panel called…this review group called a panel on. And as you are aware they called the panel for the dosing claim or the non-adjunctive claim for the Dexcom product. Surprisingly they did not for the 670G, but it's just my expectation and we are working towards, the fact that their history is predominately been towards calling a panel that they will do that for new generation of technology like this.

Dominick Leali
Okay. Thank you very much.

CONCLUSION

Operator
Thank you. And as that was the final question. This concludes with the question and answer session as well as the call. The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.