Senseonics Holdings

Q3 2017 Earnings Conference Call

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CORPORATE PARTICIPANTS

Tim Goodnow - *President, Chief Executive Officer*

Don Elsey - *Chief Financial Officer*

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

PRESENTATION

Operator
Good afternoon, and welcome to the Senseonics Third 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 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. Please go ahead.

Don Elsey
Thank you very much and welcome to the third 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 10K 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. Entering the final quarter of 2017, we are pleased with our accomplishments this year and are looking forward to an exciting and transformational year in 2018. In the third quarter, we had a significant new product approval, meaningful new market launches, a new milestone in quarterly revenue, and balancing improvement with the successful capital raise.

Our current commercial focus is on Europe, where we are preparing to launch Eversense XL, while expanding our presence to both deeper and broader market penetration. In the US, we are preparing for a launch into the rapidly changing diabetes' market environment. It's very clear that the pace of innovation for diabetes management is increasing. It's also evident that users and clinicians are clearly seeing its acceleration and appreciate the value of new technologies.

CGM has become the standard of care for people using insulin to manage their diabetes. Expanded CGM capabilities, including new generation prospective CGMs, as well as, flash glucose monitoring will expand utilization, expand the market, and help improve diabetes management for more people. Now more than ever, we feel favorably positioned and uniquely differentiated as the only long-term continuous glucose monitoring system within this environment.

On the call today, I will address the current state of our business, Don will provide more details on our financials, and then I will wrap-up with some comments about our strategic direction at Senseonics and our focus on the advantages of the long-term wear Eversense System.

First, we generated just over $2 million in revenue from Europe in the third quarter. This was more than the past quarters combined and in line with our expectation as we are beginning to scale. We expect a continued increase in sales throughout the fourth quarter, as we have transitioned to full launch in many of the countries, and as such, we remain comfortable with our forecast of $6 million to $7 million in revenue for 2013…2017.

During the third quarter, we also strengthened our balance sheet with an additional $26 million through an underwritten public offering. As planned, given the positive user experience and clinical acceptance of Eversense, during the third quarter, we continue with the full launch of our initial countries and move from a controlled launch to a full launch in several subsequent countries.

We are also expanding our reach internationally to six new countries, Switzerland, Denmark, Finland, Spain, Poland, and our first non-European market, South Africa. These countries have begun their pilot launch efforts, and with these, this brings the number of countries in which Eversense is available today to 13. Where Eversense has been commercially available, we are deepening our presence through an incrementally greater number of reps casting a wider net to more prescribers and diabetes' clinics.

The impact in the third quarter was significant and mirrors our revenue growth. We added more to our installed base this quarter than in all of the prior quarters combined. This increase has come largely from our three early markets of Germany, Sweden, and Italy.

Consistent with our previous comments, our installed base of patients is coming largely from those with previous sensor experience and about a quarter from new users. We continue to attract insulin-using patients who prefer to receive real-time continuous glucose readings and can be alerted when those readings begin to reach dangerously low or high glucose levels.

This is particularly true in heavy Libre markets, where we have seen a readiness to move to a 90-day continuous reading system with alerts. A recent market survey of our users, indicate a high overall satisfaction with the product and cited the top three most important features of the Eversense System to be: first, the prospective alerts for hypo and hyperglycemia; second, the long sensor life; and third, the readings on their phone.

Across the board, the Eversense features were rated very high in performance from the comfort of wear to the reliability of glucose alerts. These types of insights are helpful as they inform our messaging to attract potential users, whether new to CGM or those that are experienced. Importantly, this also validates the unmet need in the market for which Eversense is helping fulfill.

As part of the full launch mode, our distributors have also increased their consumer awareness programs. For example, an August, push campaign utilizing both, digital and direct mail in Sweden generated such interest that brand searches in Google went up nearly 700% within two weeks.

We recently came back from an ACB Symposium attended by new and established Eversense clinics in Sweden, where we learned that patients are now coming to the clinic with knowledge

of Eversense and asking for the product by name. Early market detailing focused exclusively on introductions to the medical professionals.

Now, in the more mature Eversense markets, we are successfully transitioning to add consumer awareness, and thereby creating a customer pool. We expect, this momentum will carry through the balance of the year, as our new countries add more clinics during their controlled launches, as more countries move into full launch and as our full launches continue with generating consumer and professional awareness and patient adoption.

On the new product front, our Eversense XL, or Standard Life, received CE Mark approval in mid-September, marking a major milestone in further differentiating Senseonics as the only company able to provide continuous long-term glucose readings with a single sensor. This new product provides up to twice as much sensor life as our current Eversense CGM system, extending wear up to 180 days, or 12 to 25 times more than other available sensors.

It's only a decade ago the real-time CGM was made available to the market. It started with three- and five-day sensor wear. A few years later, we incrementally improved to seven day, and recently extended to 14 days in some markets. The CGM market continues to evolve and we are excited to be part of this growth.

Last year, we significantly improved sensor duration when we introduced our milestone 90-day sensor version, this year we are doubling that sensor life. While the duration of some sensors are being counted in days, ours is counted in months. Our commitment to an improved product solution for people with diabetes goes beyond the sensor that last up to 180 days.

Importantly, Eversense XL includes the same features found on our original system: strong accuracy throughout the life of the sensor; the only transmitter that is removable and replaceable; a unique, discrete vibration alert system from the transmitter even when the phone is not nearby; as well as a gentle skin adhesive that allows for comfortable long-term wear with no irritation. Truly believe, this will change…our CGM will be used in the future, and we will work hard with the diabetes community to incorporate this into clinic practice guidelines.

We are pleased to report that we've also completed Eversense XL pre-launch activities in the UK and expect to begin clinic on-boarding this month. We are excited to work with our distributors to bring this product for those in need.

We plan to more broadly roll out Eversense XL in Europe in the first quarter of 2018, as we complete our launch activities, including training and packaging of the different language requirements for our European countries. We expect the Eversense XL to contribute meaningfully to our continued penetration and expansion in Europe.

In the United States, our PMA application continues to be evaluated by the FDA and we have an ongoing collaborative relationship with the agency. Based on the most recent discussion with the agency, we now expect to have the final requested information to them before the end of the year. As we have said previously, we expect the agency to convene an advisory panel to explore feedback on the safety elements of an implanted sensor, in addition to the training and programs designed to introduce endocrinology/diabetology professionals to the in-office procedures of sensor placement and renewal.

Given where we are in the process, we now expect that this panel meeting will most likely be held in early 2018. We are confident that the strong patient safety data and efficacy data

demonstrated in our US pivotal trial, our European pivotal trial, and our robust post-market surveillance program currently underway in Europe will support the FDA approval of Eversense. In our current planning, we are anticipating approximately two months will be required post-approval to implement all final labeling considerations from the FDA prior to our commercial launch.

In parallel, we are moving forward with preparation activities for the US launch. Our US commercial team is developing our launch plans and the architecture around those plans. Specifically, the team has begun to meet with the payer community with a goal of familiarizing payers with the technology and the concepts of long-term implantable products in the CGM space. While this will be an ongoing initiative in the process of obtaining reimbursement, we are pleased that initial feedback has been overwhelmingly positive.

Payers recognize our system has great potential in delivering better adherence, improved clinical outcomes and economic value given its novel attributes as a full-functioning CGM. In fact, payers have been consistent in sharing a desire to see disruptive technologies in the CGM category because of the known long-term adherence challenges. Therefore, as we enter the US market, we will execute a controlled launch as we work with payers to improve Eversense into the existing CGM coverage policies, after which we expect the ramp to accelerate.

Now, I will turn the call back over to Don to review our third quarter financials, and I will finish with some perspectives on the path forward. Don…

Don Elsey
Thank you, Tim. For the three months ended September 30, 2017, we generated $2.1 million in revenue compared to $37,000 in the prior year period. The increase was attributable to sales of the Eversense sensor in Europe. For the three months ended September 30, 2017, total net loss was $17.4 million or $0.13 per share, compared to $10.9 million or $0.12 per share in the third quarter of 2016.

Third Quarter 2017 net loss per share is based on $128.9 million weighted-average shares outstanding, compared to $93.4 million weighted-average shares outstanding in the third quarter of 2016.

For the nine months ended September 30th, total net loss was $42.8 million or $0.39 per share, compared to $34 million loss or $0.39 per share in the first nine months of 2016. The first nine months of 2017 net loss per share is based on $109 million weighted-average shares outstanding, compared to $87.8 million weighted-average shares outstanding in the first nine months of 2016. The largest driver of the increase in net loss for both the three- and nine-month periods was generally higher operating expense, as we grew the organization to support the broadened launch in Europe and began to prepare for the US launch.

I like to now turn to our balance sheet at quarter end. At the end of the third quarter, our cash, cash equivalents, and marketable securities were $52.7 million. This is inclusive of the equity raise of just over $26 million that we completed in August.

Let me turn to guidance for the year. As Tim mentioned earlier, 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, Don. As we push forward our product development initiatives, we are also continuing to work on an integrated automated insulin delivery system combining Eversense with the TypeZero artificial pancreas algorithm and the Roche Accu-Chek Insight pump.

The integrated AID system is in full development, whereby the TypeZero inControl algorithm is being incorporated into our Eversense path, which then controls the Insight pump. The three organizations are focused on delivering a mobile-based, long-term closed loop system to support the needs of people with diabetes.

As you may be aware, this is part of the NIH-sponsored international diabetes closed loop trial, and our efforts will be utilized in the European study arm to be conducted at the Academic Medical Center in Amsterdam; the University CHR hospital in Montpellier, France; and the University of Padova in Italy, all being coordinated by the JAEB Center for Health Research in Florida. We are also happy to announce the completion of the first clinical trial of the Eversense 180-day sensor with pediatric participants in Canada.

Feedback has been very positive with much commentary on the simplicity and seamless integration into their lives. One patient in the study was a 12-year-old boy, who played several school sports, hockey, cross-country, soccer, volleyball, and basketball, his parents described Eversense as amazing, very accurate and reliable. With the Eversense System, their son literally forgot it was there. He caught his highs and lows and treated them accordingly. The device worked when it mattered most on the ice and when he was sleeping.

Another patient was a young adult who described her numbers as previously always being out of whack. This was due to her sports and her very active lifestyle. Late night glycemic episodes were all too frequent, due to her busy physical life. Her mother described Eversense as a life-saving, sleep altering gift, pure and simple.

The final six subjects in the study will complete their 180-day sensor experience in the next few days. In total, 30 pediatric participants have participated along with six adults. We anticipate completing the safety and efficacy characterization and submitting the results for publication in early January for the ADA meeting in June.

In addition to the XL launch in Europe and our 180-day trial experience in Canada, we are accelerating plans for bringing the 180-day product to the US market. To that end, even with the primary approval still underway, we are beginning work on the 180-day trial IDE and plan to start the clinical trial in the US for the XL product in early 2018. We look forward to sharing progress in the upcoming months.

To wrap-up, we are excited about our accomplishments in the first nine months of 2017, and about our growth prospects looking ahead. We are thrilled to have XL available for our users. We are happy to have us setting revenue milestone and/or completed our equity financing. We have another busier quarter ahead of us, as we finish the year and enter 2018 well-positioned for accelerating momentum.

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. We greatly appreciate the hard work of our employees that are helping to drive these efforts forward and for the continued interest and support of our investors.

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

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 your touchtone phone. If you are using a speakerphone, please pickup your handset before pressing the keys, to withdraw your question, please press "*" then "2." At this time, we will pause momentarily to assemble our roster.

Our first question comes from Danielle Antalffy with Leerink Partners. Please go ahead.

Danielle Antalffy
Hi, good afternoon, guys and congrats on a really great quarter, great to see the adoption momentum building there. Tim, I was hoping you could comment, we obviously had a big competitive product approval here in the United States and pricing is coming into question for the CGM market broadly. I was wondering, if you could provide us with your views on how you are thinking about the pricing dynamic now with the potentially worthwhile…with a much cheaper product on the market?

Tim Goodnow
Sure, Danielle. And it's good to see you always up first with questions. We appreciate that. Obviously, bringing the Libre into the market, quite frankly, is going to be very positive for many people with diabetes. I think, what we are seeing obviously is the broad acceptance in Europe, especially with patients that have previously, of course, had been doing finger-sticks. It certainly is a different product and really designed to add incremental value to folks that are testing discretely with the finger-stick devices. But as you are obviously aware, it does not have the different functionality, thus prospective capability that the full CGMs have.

So we do anticipate that there will continue to be some pricing differential between the two technologies, the two offering solutions. With that said, I think, we have always taken the position that pricing is only going to go one direction in healthcare. There is always going to be pricing pressure to reduce the cost to society, and we've been anticipating that and planning on it from the very beginning.

The key value from a business perspective that we have always seen in these long-term sensors is the ability to utilize that length to the point where we can support any new pricing pressure that may occur and will occur in the market.

So I don't know where it's going to be, Danielle, I don't know specifically what leeway we will drive in it. It certainly will offer some alternatives for some folks. But we're seeing a lot of folks that are quite interested in actually making that transition once they are used to wearing a sensor or to a continuous sensor has been…it's been more attractive than we initially thought it would be. So we're pretty excited about that part of it.

Danielle Antalffy
Got it. Thank you.

Tim Goodnow
Hope that helps.

Danielle Antalffy
Yes. Now, that's very helpful. And actually just a follow-up on that point. So I think, you said in the prepared remarks, 75% of your patients are switchers than only a quarter are new to CGM therapy. So just wondering, I have always viewed this as potentially driving switchers, but really broadening the market. Now that you're investing in direct-to-consumer type marketing initiatives, do you expect that quarter number to grow, and do you expect to see going forward just as many new patient add to CGM therapy versus switching from other devices, or help us think about how we should think about the mix between new patients and switchers?

Tim Goodnow
Yes, I mean, we do expect that it is going to grow. Right now, you're in that phenomenon of a new product launch, where your earliest adopters are most attentive. And that, obviously, is the folks that already have some CGM experience.

So, it's not to be unexpected that they might be over indexed in the beginning. Obviously, we're interested in bringing the product to the people that can use it most and have the most interest in it. There are a number of folks that made the decision not to go to on CGM for one reason or another that we think are good candidates for a long-term sensor.

So I do think it will change over time. But at this point, I think, having the focus on early adopters, the reality of early adopters is probably what drives some of that index.

Danielle Antalffy
Alright. Thanks so much.

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

Kyle Rose
Great. Thank you very much for taking the questions. Can you guys hear me alright?

Tim Goodnow
Sure, Kyle. How are you?

Kyle Rose
I'm well. Congrats on a strong quarter. So I wanted to touch a little bit on the...just the plans for the transition from the Eversense to the Eversense XL, particularly in the international markets. And then I guess, because you talked about the trial in the US, probably you could touch on that. But again, how do you think of the pricing dynamics to change when you launch the XL into your distributors and how should we be thinking about modeling an AFP lift over time?

Tim Goodnow
I'm going to ask Mirasol, who's dealing with this on a daily basis with our distribution partners to give her perspective on.

Mirasol Panlilio
Yes, and we're still working through what the final pricing is going to be for XL. But the feedback that we've gotten, Kyle, is that, this is definitely a very non-traditional exciting new product addition to the marketplace and highly differentiated, even compared to our own Eversense 90-day sensor.

And so when you add all of the benefits of the long term, we're up 280 with the adhesive and the vibe alerts really adds up and it's really differentiated from the other CGMs that last 7 to 14 days. So I think, once we roll it out, we'll provide you with a little bit more understanding of how our pricing is.

Kyle Rose
Okay. Right now I appreciate that. And when...you gave some additional updates as far as the US market, and I just want to make sure that I'm interpreting your comments correctly, Tim. But it sounds like panel is obviously going to slip into the early part of 2018. All goes well, approval shortly thereafter maybe like that end of Q1, start of Q2, when you get approval. And then you've got two months where you need to fine tune some of the things as far as the commercial plan goes before you can enter the US markets. So I guess, is that the way to think about this from an US market entry, really more of a second half event, maybe summer around ADA next year?

Tim Goodnow
Yes, obviously, Kyle, we're highly motivated to do everything that we can to do as quickly as possible, of course. But to help give some guidance on the feeling on timing, this clearly is going to be a second half ramp just like we are seeing in Europe. But your timing, I wouldn't necessarily strongly argue with. We would like to do it a little bit earlier than that. But I do think the reality is, once we do the final conversations with the FDA, that typically is around the agreement is okay, this is exactly what your labeling will say.

And then we need to go into production and assembly of all of that. So, you know, as you are seeing with those in the space that takes about two months to do that process. So to help you guys think a little bit about the timing the way we do, we wanted to try to put that out there.

Kyle Rose
I appreciate that. And then one last question and I will get back in queue. When we think about…obviously, you have got very strong momentum in patient demand internationally, particularly when we think about the Q3, and it sounds like that momentum only continues to grow into the Q4. How should we think about the quarterly progression through 2018? Is there any reason to think that given the early stage of the commercialization that you can't continue to grow on a discrete new patient basis quarter-over-quarter for the next several quarters?

Tim Goodnow
Yes, we are certainly going to try to do that, Kyle. But I don't want to jump ahead for guidance for 2018 yet. We are certainly going to do that on the next call. We've got some more work to do. As you know, with the distribution partners, it's just one more level of complexity. So if I can hold to the next time that we formally speak on guidance that would help, but our…obviously, our intention is to continue to grow and accelerate the launch.

Kyle Rose

Terrific, thank you very much for taking the questions.

Operator
Again, if you have a question, please press "*", then "1."

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

Jayson Bedford
Hi. Can you hear me, okay?

Tim Goodnow
We can, Jason. How are you?

Jayson Bedford
Doing well, thanks. So just a few questions; first, on the top line, I realized it's a relatively small numbers here. But you showed a pretty nice sequential jump in sales. Is there any way you can give us a little flavor as to where meaning kind of in which geographies you saw the growth sequentially?

Tim Goodnow
The biggest chunk was from the earliest biggest markets as…it's pretty well understood that Germany is the second largest market in the world, we were there early. Sweden is a great market as well, and Italy is a very good market. So those are the three biggest drivers and most important markets for us right now until we get to the United States.

Jayson Bedford
And Tim, in Germany, can you comment just on reimbursement and how broad it is in that country right now?

Tim Goodnow
I will let Mirasol touch on that, it's quite attractive as, you know, but I will let Mirasol give some specifics.

Mirasol Panlilio
Yes, and similarly with the CGM being reimbursed in Germany, that bodes very well for us. We have a number of prescriptions already. And so, it's a little bit different for us, however, because we have a different reimbursement code than the other CGMs. But the prescriptions are just coming in, and so we are very pleased with how that's going.

Jayson Bedford
Okay, in terms of the 13 countries, how many are in full-launch mode right now?

Mirasol Panlilio
That's a good question. We have four that is in full-launch mode. And, of course, the six that we just started with are…probably will take some time before we move them over to the full-launch mode.

Jayson Bedford

Okay. And then just on the regulatory side, the FDA certainly seems more flexible today than they've been in the past. I am wondering, if that has kind of opened the door a little bit for you either with the opportunity to introduce the transmitter into your US submission or any new thoughts around your ability to gain the dosing claim?

Tim Goodnow
Yes, those are great questions and common conversation. Obviously, our objective is to achieve both of those in this submission. At the same time, we are in that precarious situation of obviously doing everything we can to push the primary approval and we wouldn't want to put that at any material risk. That said, this is a very open group and they are very approachable. I think we've met with them only for what four or five times…

Company Representative
Five times, yes.

Tim Goodnow
…in this approval process, so they are very open to have the conversations. It's always a matter of timing. And we love to have it to determine what the impact to the total duration might be to bring in the smaller transmitter for that ever-interesting dosing claim. I do think the world has changed potentially a little bit around dosing. We need to spend some more time with them to fully understand that as what it might mean for us.

Jason Bedford
Okay. Thank you.

Tim Goodnow
Alright, thank you

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
Great, once again, we want to thank everyone for their time during this busy season and support and we appreciate everyone's focus and questions as well. We look forward to talking with you at the next quarterly call.

With that, we will conclude. Have a great evening.

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