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Q3 2019 AtriCure Inc Earnings Call

EVENT DATE/TIME: OCTOBER 30, 2019 / 8:30PM GMT

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's Third Quarter 2019 Earnings Conference Call. (Operator Instructions) As a reminder, this call is being recorded for replay purposes. I would now like to turn the call over to Ms. Lynn Lewis from the Gilmartin Group for a few introductory comments.

Lynn Pieper Lewis ***Gilmartin Group LLC - Founder & CEO***

Thank you. By now you should have received a copy of the earnings press release. If you've not received a copy, please call (513) 755-4136 to have one e-mailed to you. Before we begin today, let me remind you that the company's remarks include forward-looking statements. Forward-looking statements are subject to numerous risks and uncertainties, many of which are beyond AtriCure's control, including risks and uncertainties described, from time to time, in AtriCure's SEC filings.

AtriCure's results may differ materially from those projected. AtriCure undertakes no obligation to publicly update any forward-looking statements. Additionally, we refer to non-GAAP financial measures, specifically revenue reported on a constant-currency basis, adjusted EBITDA and adjusted loss per share. A reconciliation of these non-GAAP financial measures with the most directly comparable GAAP measures is included in our press release, which is available on our website.

With that, I'd like to turn the call over to Mike Carrel, President and Chief Executive Officer. Mike?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Thanks, Lynn. Good afternoon, and thank you for joining us today. We are continuing our strong momentum from the first half of 2019, with total revenue in the third quarter of approximately $57 million, our 28th consecutive quarter of double-digit revenue growth.

Our top line performance was again driven by strength across our U.S. franchises. With this strong momentum, we are raising our revenue outlook for 2019, which we now expect to be in the range of $227 million to $229 million. This range corresponds to growth of 13% to 14% for the year.

The third quarter was a very exciting quarter and transformative quarter for us here at AtriCure. It was highlighted by the strategic acquisition of SentreHEART paving the way for our direct entry into the electrophysiology market.

As we discussed in our August call announcing the transaction, SentreHEART developed the LARIAT device, which is a percutaneous suture-based approach to close the left atrial appendage. This is particularly important given the ground floor support and acceptance of managing the left atrial appendage in the treatment of Afib and the growth potential within the EP market. The LARIAT device is currently being studied in the aMAZE clinical trial. The LARIAT product is on the market today in the U.S. under a 510(k) and in Europe. However, we expect very few devices to be sold outside of the aMAZE trial. Our top priority is to complete enrollment in this trial, and we have made meaningful progress since the acquisition in August.

As of today, we have enrolled 579 patients and are on track to reach full enrollment of 600 patients in the first quarter of 2020.

With the CONVERGE, DEEP AF and aMAZE trials, we are the only 3 clinical trials addressing the most complex and advanced forms of Afib. Strategically, we expect the LARIAT technology to advance our position in the EP space as it is complementary to the endocardial catheter ablation procedures and multidisciplinary approaches such as CONVERGE and DEEP. Each of these therapies offers a valuable treatment option for Afib patients and the total addressable market for Convergent, DEEP and aMAZE procedures is well into the billions using conservative estimates.

Turning now to our quarterly results. We continue to execute and are seeing the benefit of our broad portfolio and robust pipeline. Specifically, in our U.S. business in the third quarter, we saw continued strength in our appendage management franchise, driven by our open and minimally invasive AtriClip products.

We again had meaningful contribution from our minimally invasive AtriClip PRO2 and PRO V devices as well as from our open chest AtriClip FLEX V device.

Within our open ablation platform, we remain focused on innovation, education and training to address this large still underpenetrated market. We are progressing with our plan to launch a new open clamp in 2020, which we believe will be attractive to physicians who are seeking a simpler and faster approach to ablating the heart in open procedures.

While we anticipate broad market appeal, we expect it to be particularly resonate with the CABG surgeons in the open concomitant space and to be accretive to our open ablation revenue.

In addition, in the third quarter, we received FDA clearance for expanded labeling claims for AtriClip's family devices. We were able to demonstrate through clinical evidence that AtriClip devices, both exclude and electrically isolate the left atrial appendage. This expansion of the AtriClip labeling is important because epicardial exclusion of the appendage has multiple benefits. Over the past several years, we have invested in our AtriClip portfolio with innovative new products and evidence to support increasing adoption. Physicians continue to recognize the benefits of the left atrial appendage management and how the AtriClip line of left atrial appendage management devices can serve their needs in a variety of different ways.

The cryoSPHERE probe, our dedicated device for managing postoperative pain in cardiothoracic surgical patients also contributed to our strong U.S. results in the third quarter. While it is still early, and overall revenue contribution is still relatively low, we are seeing this therapy perform well, and our account base continues to build. We are seeing -- we are steadily bolstering our small, dedicated thoracic team with clinical resources to support cases in select markets. Our approach is focused on depth rather than breadth as we first identify accounts that we believe in a comprehensive and innovative pain management program for the patients, and then we go deep, adding resources to support case volume as the business builds. We are encouraged by our results and expect the thoracic pain management market to offer significant opportunity over the long term.

Transitioning to our MIS ablation business, U.S. revenues were up 14% in the quarter, rebounding from year-to-date growth of approximately 1%. This is consistent with quarterly fluctuations we have been experiencing in this franchise and the variability that we expect to continue until we see -- receive FDA approval of our EPi-Sense system using a Convergent approach in treating symptomatic persistent Afib patients.

As it relates to the CONVERGE trial, I want to take a step back and review our time line and expectations, again. The last patient in the study was treated in August 2018 and 1 year follow-up was completed recently. Our clinical team is working through the data and are on track to submit the final PMA model, including training protocols and other details by the end of this year.

The Convergent procedure is a novel therapy for patient group for whom there is no product group label for stand-alone treatment of persistent and long-standing persistent Afib. With that in mind, we are expecting the FDA to convene a panel.

We anticipate that we will release the data in 2020, along with our submission and preparation for the panel. Based on this time line, we're optimistic that we could receive FDA approval toward the end of 2020, although this is clearly dependent on the process within the

FDA.

Internationally, third quarter results were up modestly with strength driven by our open and appendage management businesses. We recently received CE mark for AtriClip's FLEX V and PRO V devices and look forward to their contribution in the Europe and the European market in the future.

Broadly speaking, we continue to see steady growth prospects in the end user markets in which we operate outside the U.S.

In summary, we are excited about our broadening portfolio and channels this quarter and are extremely pleased with our track record of sustained double-digit top line growth.

I'll now turn the call over to Andy Wade, our Chief Financial Officer, to review our financials and the outlook, and we'll return for closing comments.

M. Andrew Wade ***AtriCure, Inc. - Senior VP & CFO***

Thanks, Mike. For the third quarter of 2019, worldwide revenue was $56.6 million, representing growth of 13.4% on a GAAP basis and 14% on a constant-currency basis. Revenue from U.S. product sales was $46.1 million, an increase of 16% from the third quarter of 2018. U.S. open ablation revenue increased 10.1% to $19.8 million. The addition of the cryoSPHERE probe in early 2019 is creating continued momentum in our open ablation franchise, along with steady contribution from open clamps.

U.S. sales of products used in minimally invasive procedures increased 14.3% to $9 million in the third quarter of 2019. The improvement from the prior year is due to comparison with relatively soft third quarter minimally invasive sales in 2018. As we have discussed on past calls, we anticipate quarterly volatility from this business.

U.S. sales of appendage management products, which now includes the LARIAT system were $16.9 million during the third quarter of 2019, an increase of 25.4%, driven primarily by AtriClip products.

We, again, realized very strong growth from the AtriClip FLEX V device, along with volume increases in the minimally invasive LAA exclusion system devices. We remain confident in sustaining growth rates for our appendage management products.

International revenue was $10.5 million, up 3.1% on a GAAP basis and 6% on a constant-currency basis as compared to the third quarter of 2018.

Open ablation and appendage management products are driving our international business this quarter, offsetting a decline in revenue for minimally invasive ablation products.

Turning to specific markets, we continue to see growth throughout Asia and had solid performance in several key areas in Europe, notably the U.K., Turkey and France, with some weakness in Germany and the Netherlands.

Gross margin for the third quarter of 2019 was 73.8% as compared with 72% for the third quarter of 2018. This improvement is due primarily to a decrease in share-based compensation from a onetime charge of approximately $500,000 in the third quarter of 2018, driven by the retirement of an operations leader.

In addition, mix was slanted to the U.S. business, which carries a higher gross margin. We continue to see improvements to operations and lower costs making strong progress toward our long-term goal of a consistent 75% gross margin.

In the third quarter of 2019, we had an adjusted EBITDA loss of $2.2 million compared to a loss of approximately $500,000 for the third quarter of 2018.

During the third quarter of 2019, we modified our definition of adjusted EBITDA to exclude acquisition costs due to their nonrecurring

nature. Approximately $3.6 million of acquisition costs were recorded for the SentreHEART acquisition in 2019.

Our operating loss for the third quarter of 2019 was $8.6 million compared to an operating loss of $6 million for the third quarter of 2018. Our net loss per share was $0.25 for the third quarter of 2019 compared to a net loss per share of $0.22 for the third quarter of 2018.

Note that a $3.1 million noncash credit to operating expenses was recorded this quarter related to the change in contingent consideration liability. Without this noncash credit to operating expenses, our adjusted loss per share for the third quarter of 2019 was $0.33 and our operating loss would have been $11.7 million.

Similarly, a $780,000 noncash credit to operating expenses was recorded in the third quarter of 2018 for the change in contingent consideration liability. Adjusted loss per share for the third quarter of 2018 was $0.24, and our operating loss would have been $6.8 million. Adjusted EBITDA results for all periods exclude noncash adjustments related to the contingent consideration liability. Excluding the impact of the noncash adjustment to the contingent consideration liability, operating expenses increased approximately $10.7 million from $42.8 million in the third quarter of 2018 to $53.5 million in the third quarter of 2019.

Research and development expenses, which include clinical and regulatory activities were $10.2 million for the third quarter of 2018 or 18% of sales. Increases in personnel costs, clinical and consulting expenses and amortization contributed to the $1.6 million total increase in research and development expenses. SG&A expenses, excluding the noncash adjustments previously described, increased approximately $9.1 million from the third quarter of 2018 to a total of $43.3 million or 77% of sales. The increase results from the SentreHEART acquisition cost and higher personnel costs from our continued investment in the commercial organization worldwide as well as incremental trade show and training activities and increases in share-based compensation expense and other operating costs.

We ended the quarter with approximately $100 million in cash, cash equivalents and investments, down approximately $3.6 million from the second quarter.

Lastly, we are updating our guidance for 2019. We now anticipate top line revenue growth of approximately 13% to 14% year-over-year or approximately $227 million to $229 million on a GAAP basis. We continue to anticipate gross margin will be approximately 73% to 74% for the year. The absorption of SentreHEART operating costs put some pressure on gross margin. However, we believe this is a small tailwind against the improvements to gross margin that we have made throughout 2019.

As a result, we are maintaining our guidance range for 2019. As we have stated many times, we are still marching toward our goal of 75% gross margins and continue to make progress on this front.

We expect R&D expenses to be 18% to 20% of sales for the year, investments in this area include the aMAZE, ICE-AFIB and DEEP AF IDE trials, growing clinical science activity and R&D pipeline development. We expect SG&A expenses to be approximately 69% to 72% of sales in 2019, which includes noncash adjustments to the contingent consideration liability recorded this year. The increase in SG&A expenses is driven by thoughtful expansion of our worldwide sales team, investments in training and education, absorption of SentreHEART operating costs, along with heavier legal and acquisition costs. We continue to expect an adjusted EBITDA loss for the full year 2019 to be in the range of $7 million to $9 million after absorbing the operating costs of SentreHEART since the acquisition.

This adjusted EBITDA range for 2019 translates to an adjusted loss per share between $1.07 and $1.14. At this point, I'd like to turn the call back to Mike for closing comments.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Thank you, Andy. Before we open for questions, I want to take a moment to acknowledge that September marks national Afib awareness month. This is a critically important time in which we work to raise awareness for this life-threatening arrhythmia by helping the public become more familiar with the symptoms, warning signs and available treatment options.

More than 33 million people are affected by Afib worldwide and the majority of those are not addressed by standard of care. Through our social media channels, we showcased our white street campaign and provided educational information about Afib and AtriCure's role in

uniting patients with physicians.

In closing, our continued performance reflects our commitment to clinically differentiated products, the diversity of our business and the overall strength of our organization. We believe that the addition of SentreHEART will serve to accelerate our strategy and will allow us to treat more patients with Afib, thus expanding our total addressable markets in a meaningful way.

We are looking forward to a bright future shaped by growth prospects created by our many business catalysts, such as CONVERGE, aMAZE, Cryo Nerve Block and several more over the next several years. We'll now open it up to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of Robbie Marcus from JPMorgan.

Robert Justin Marcus ***JP Morgan Chase & Co, Research Division - Analyst***

Congrats on a really nice quarter.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Thank you.

M. Andrew Wade ***AtriCure, Inc. - Senior VP & CFO***

Thanks, Robbie.

Robert Justin Marcus ***JP Morgan Chase & Co, Research Division - Analyst***

I was hoping you could start out with sort of the early feedback after the LARIAT acquisition or SentreHEART acquisition. What's been the discussion? Are you starting to see -- moving in with the EPs, is that relationship starting to build ahead of CONVERGE next year? Any feedback you can give early on would be great.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. I mean it's, obviously, early, but the innovation has gone smoothly on many different fronts. I mean first, more and more excited about the strategic nature of it. We have built great relationships with EPs on our side, but also they are introducing us into new EPs that we didn't have. They're doing a great job with their trial. We were a little bit nervous when we bought them with the enrollment slowdown and instead, it's actually accelerated and actually, increased and done very well on that front. I personally made visits to pretty much all of the KOLs that they were working very closely with and got very positive reception. Again, they are very excited about the aMAZE trial. The focus is on that trial. They want to make sure we're committed to it clinically and then bringing that product to market through, obviously, great education and training that will kind of bolster the team with.

I have also been really impressed with the team at SentreHEART, just top-notch professionals across the board, both in the field team that is supporting the cases, to the clinical team, to the back office. They're just wonderful people with a great culture focused on the patient. They fit really well. I mean you go through these and you're not 100% sure because you don't meet everybody when you're going through an acquisition, and the people there have just been fantastic, and they fit in really well and blend in. And great conversations are going on already in the field. I'll say that, but at the same time, we are very focused on the aMAZE trial.

We're making sure that our teams are focused on that, that we are not diluting their attention from that and getting it kind of integrated out in the field quite yet. It's more than introductions and beginning to kind of create awareness, but we really want to make sure we get that trial done. We get it enrolled, and we really kind of hit the ground running next year as well. So it's going great. I couldn't be happier with the acquisition and I'm more excited today than I was 2 months ago.

Robert Justin Marcus ***JP Morgan Chase & Co, Research Division - Analyst***

Great. And then a follow-up here. The 2 line items that stood out to me this quarter were open heart ablation and AtriClip. I know this is not a new topic without performance in both of those segments. But I was just hoping you could give a little color, particularly in third quarter what you're seeing? Where the growth is coming from? Is there any change in fundamentals or improvements that you see that would be helpful?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

I wouldn't say that there's any change, per se, on the open side of our business. It comes down to 2 different pieces. We can -- as I mentioned near here at the end, we're really pushing hard on this Afib awareness and the treatment concomitantly. As you probably well know, we've invested heavily to improve the penetration in the open space over the last 7 to 8 years since we got ourselves the PMA in that space, and we've more than doubled the number of patients every year around the. Globe in the U.S., in particular, they're actually getting treated.

That being said, still only 25% of the patients that are on the table are getting treated. Dr. McCarthy just came out a paper on that where he actually analyzed all the CMS data, looked at it and demonstrated that there are still 75% of the patients that have Afib that are getting operating on are not getting treated. And so we've got a big underpenetrated market in front of us with that.

I think you see some of that, that we will continue to have that with our training and education and the programs that we are running. On top of that, I would -- the other part of the open side of our business is that we did get benefit from cryoSPHERE and the Cryo Nerve Block team as well. So we get a couple of points from that because that team is doing very well. It is small numbers, but it can impact that growth a little bit as well and kind of give us some good kind of behind-the-scenes numbers from there without giving specifics.

On the AtriClip franchise, it actually plays off of that open business quite extensively because a lot of the clips are the Flex V clips that are going in into those open cases. People just love that product. It's been on the market now for about a year and people are -- they are using it. It's easy, simple. It doesn't cause them any kind of fatigue when they actually place the clip. It's a smaller profile. So I'd say that, that innovation is continuing to kind of build steam and momentum in that open business, in particular. And then on the other side of our business, on the MIS side, the strength in MIS kind of helps off on that because it's concomitant typically with that.

Operator

Your next question comes from the line of David Saxon from Needham.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Associate***

I guess just a quick one. Can you let us know how much SentreHEART was in the quarter?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Very -- it was almost nothing. I mean it was a very, very, very small number was in this quarter. We got -- bought them on August 13. Obviously, the focus is -- we were really focused on the trial, so it's very little bit of revenue in this quarter.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Associate***

Okay. Great. And then just looking at the box clamp, can you talk about kind of how it's going to be priced? And maybe your thoughts on the pace of adoption once you launch it?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. I think you're talking about the new clamp that we're looking at or kind of the open part of our business. And we're looking to kind of have that sometime next year. The pricing will be above what we're charging for the price of our product today, likely. We haven't set on a specific price at this time. But we do anticipate that it will be far north of what you get with a regular clamp today. It's more sophisticated, and it's actually, obviously, attacking the heart and making a lot simpler and easier for these physicians to get better and broader ablations.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Associate***

Great. And just lastly, how are you progressing with hiring clinical support in advance of CONVERGE?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Great question. We've been actually building up that team for the last several years. And so it's -- we've got a wonderful clinical team that is trained, both on the clinical side, but also our minimally invasive team to kind of get them up to speed to understand that product line. So we're progressing very, very well. We've got, I believe, about 15 or 16 minimally invasive managers that are out there today. And we've got about 5 or so on the clinical side. We anticipate that we will continue to extend and add more to that team, and we found just wonderful people in those roles. They have been a great fit and they get up to speed very quickly.

David Joshua Saxon ***Needham & Company, LLC, Research Division - Associate***

Great. And congrats on the quarter.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Thanks.

M. Andrew Wade ***AtriCure, Inc. - Senior VP & CFO***

Thanks, David.

Operator

Your next question comes from the line of Danielle Antalffy from SVB Leerink.

Danielle Joy Antalffy ***SVB Leerink LLC, Research Division - MD of Medical Supplies & Devices and Senior Analyst***

Congrats on another really solid quarter.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Thanks.

M. Andrew Wade ***AtriCure, Inc. - Senior VP & CFO***

Thanks, Danielle.

Danielle Joy Antalffy ***SVB Leerink LLC, Research Division - MD of Medical Supplies & Devices and Senior Analyst***

Yes. No problem. Mike, I just wanted to follow-up on Robbie's question and specifically, as it relates to the open ablation outperformance. I know you guys have talked about that business as a high single-digit grower. Clearly, the last few quarters you've been tracking ahead of that, I mean does your view kind of change on what the durable growth profile is for this business? It feels like maybe it's closer to low double-digit but just curious on your view that based on the -- of that based on the recent outperformance, one? And also two, this quarter, it was a strong TAVR quarter, so curious if you can comment on what you're seeing or not seeing as it relates to the aortic side of the business?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. So I mean all really good questions. I'd say that we are excited about what's happening in the open business. We continue to feel like there's going to be strength there for a long time. I don't want to get ahead of ourselves to the numbers that you're talking about consistently on that basis. That being said, we also the Cryo Nerve Block that is a big upside opportunity for us really as we enter into 2020 and 2021. As those -- that team becomes more mature, we get more coverage around the country. That definitely will help bolster and help out there quite a bit. And we do feel like there's a huge opportunity in open. But I don't know that I would get too far ahead of myself at this point relative to just to those growth rates on that front. And then you asked another question. So just remind me the question, all this.

Danielle Joy Antalffy ***SVB Leerink LLC, Research Division - MD of Medical Supplies & Devices and Senior Analyst***

Yes. The impact of TAVR low risk on the aortic valve business, it seems like there's not much if we're -- if based on the numbers you put out, but curious what you're thinking?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

I think it's consistent with what we've talked before, which is, obviously, it's having an impact on overall aortic volumes, per se, but the penetration continues to be low and patients that have Afib or are diagnosed with Afib in advance, many of those patients are not getting treated with the TAVR. They are basically saying, "You know what, we know these patients do better. There are papers that are out there showing that if you actually -- if those patients have Afib, they do, do better if you treat them surgically with the Afib than just going in and doing the TAVR." So I think there's more data that's out there. We're getting the benefit of that, and we're not necessarily seeing it in our part of the aortic business. But there is pressure on the aortic side. You're probably hearing that on probably a lot of the valve companies sides as well. But in terms of the pressure for us because the penetration is so low and the benefits of treating that Afib at the same time, we're -- it's not really affecting us at this point.

Danielle Joy Antalffy ***SVB Leerink LLC, Research Division - MD of Medical Supplies & Devices and Senior Analyst***

Got it. And then quick follow-up question for Andy just on the adjusted EBITDA, I appreciate your guidance for this year. You did come in better than we had expected in the quarter. I'm just wondering if you can comment on how you're tracking towards adjusted EBITDA positive or profitability?

M. Andrew Wade ***AtriCure, Inc. - Senior VP & CFO***

Sure. So the guidance we gave at the time of the deal back in August was that we will lose $7 million to $9 million on the EBITDA line. We still feel comfortable with that range of guidance as we said a couple months out. We're -- as Mike said, we're doing well in the integration front, but we've absorbed the cost of running the trial and the infrastructure in which to make that successful. So just feel good about the $7 million to $9 million, which is why we reiterated the guidance. So nothing else really on that front.

Operator

Your next question comes from the line of Matt O'Brien from Piper Jaffray.

Adam Carl Maeder ***Piper Jaffray Companies, Research Division - Senior Research Analyst***

It's Adam on for Matt. Congrats on the quarter. My first question is on AtriClip growth, which was strong, again, against a tough comp. Just wondering, have you seen any impact or benefit from the labeling changes that came in late August? And is this helping shape conversations that your reps are having in the field? And then I have a follow-up.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. So I'm going to kind of reverse the answer that, we're -- it's definitely shaping a lot of conversations because there is more and more activity. EPs have been talking about the benefits of doing electrical isolation. In fact, the LARIAT product that we just bought that is exactly what is doing, and that's how it's reducing the Afib in the aMAZE trial. So it does, engender a conversation, allows for that. And that's really been rich intellectual good discussion that we've been able to have as a result of that.

People are excited to have that conversation and look at what the data was that supported it. I don't know that it's driving our revenue in the short term. I mean it really -- if you know our business well, we're kind of that -- we're that player that we're here for a long haul. We have conversations and eventually, we do think that it'll kind of -- the combination of that with the 20 other things that we've done over the course of the last 4 or 5 years with new product introductions and other data that comes out is really kind of continuing to improve the adoption of the left atrial appendage product we have. But I wouldn't say this specifically drove anything in the last 6 weeks.

Adam Carl Maeder ***Piper Jaffray Companies, Research Division - Senior Research Analyst***

That's helpful. And then just wanted to ask a question on the Q3 performance. Just was hoping you could parse out the U.S. and OUS dynamics a little bit more? U.S. came in better than we were expecting while OUS came in a little bit softer. So just any additional color on those would be helpful.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes, sure. You're right. We did have a really strong U.S. business in this quarter, and we continue to see a lot of strength in the U.S. going forward. That market is one that we're incredibly strong and have great coverage. We saw a little bit of weakness in parts of Europe. We had a little bit of currency exchange impact that many people have, but a little bit of it was also in Germany and the Netherlands where we felt a little bit of pressure. While we are strong in many other countries around Europe, those 2 countries in particular were a little bit softer. There's nothing, in particular, you can look at and say, this is what caused it. We were just a little bit softer in those countries and so the percentage had an impact on us. But nothing really specific. We think that, that will come back over time. And overall, the rest of international was actually very strong.

Operator

Your next question comes from the line of Jason Mills from Canaccord.

Cecilia E. Furlong ***Canaccord Genuity Corp., Research Division - Associate***

This is actually Cecilia on for Jason. I just wanted to ask about your open business, again, specifically CABG penetration with the new clamp. How you see this going forward in 2020 and other drivers that you see that can help drive penetration higher?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. Another really good question relative to the new innovations we're coming out with. I'm really excited about the new innovation on the clamp that we just talk about because if you actually kind of go back in our history, we really haven't had a new innovation on the open side of our business for 8-plus years, even a little more since the PMA. We got the PMA in 2011. The focus then was on training and education, teaching people to do the procedure correctly, working with the different societies, helping get the guidelines kind of where they are. All that work has been done. We've created a lot of awareness, and we've moved the needle a lot.

But a lot of it, we have to make the procedure even easier to use for a broader base. And that's really what the reason that we're doing this new clamp. We think it's going to be really well received. It's easier and simpler to use. And so we're pretty excited about that. I think it will likely come out sometime next year. I don't anticipate and look at it being a catalyst to open revenue in 2020, but it really should help us sustain the kinds of open growth into 2021 and beyond. It can have -- it's really complementary to the work we've done and the training that we've done in the past relative to that.

Cecilia E. Furlong ***Canaccord Genuity Corp., Research Division - Associate***

Great. And I guess if I can just ask about your cryoSPHERE business as well? What you've seen recently in terms of just areas of strength in adoption? Any sales team dynamics, and how you see this business -- how you see building this business going forward?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Sure. I mean we've hired up to 8 therapy reps and 2 clinicals in that teams, so about 10 people and then a leader or manager that's running that group right now. They've just done a phenomenal job combined in working with our existing sales force that understands the hospitals that we're selling into. One of the things that I've been most impressed with is how well they've partnered at the hospital level in the markets that we're in. A lot of what we're seeing is in the lung resection. I'd say that's the vast majority of the cases. And we're -- but also that because that's the vast majority of cases that thoracic surgeons are doing. And so we see a lot of those cases some we played in and some others in select areas and some smaller markets, but overall, that's really where we're seeing the vast majority of the cases today. We anticipate next year adding considerably to that team as we expand other and new geographies around the country, adding a combination of both sales team members and also clinicals that can support the cases. And so we do believe in that space. We think that we can impact it and more and more data is coming out to support the therapy.

Cecilia E. Furlong ***Canaccord Genuity Corp., Research Division - Associate***

Great. And congrats on a great quarter.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Thanks.

Operator

Your next question comes from the line of Rick Wise from Stifel.

Andrew Christopher Ranieri *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

It's Drew on for Rick. And I just wanted to go back to CONVERGE for a second. But at the time of your final patient hitting 1-year follow-up, it looks like there's probably about a 100 patients that might have 2 years of follow-up. Just when it comes time to see the data at the panel and when you submit that, will you just submit 12-month follow-up for the entire patient pool or will we also be able to see longer-term durability data from the broader patient population? And just how do you think that might factor into the FDA's approval and labeling decision and translate into the -- your ultimate market opportunity?

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

Yes. It's a great question. We'll likely -- all the data, we basically have access to some of the durability data. We might be presenting some of that at the panel, so I think you're asking a really good question, Drew. On top of that as I've said before, I mean when we look at kind of all the single-center data that's out there, we are very confident and feel very good about kind of where we are as a business with this. We've got over 10,000 procedures that have been out there. We know how durable it is long term, and we think that that's also going to play a big role. We know the safety profile is both low, not only in the trial, but also incredibly low in the use in the market, and we're going to use all that data that's available to us as we move forward to get the approval next year.

Andrew Christopher Ranieri *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Got it. And then just hopping over to LARIAT. I think I heard you right saying that you're now at 579 patients enrolled. I know the aMAZE trial is a big focus for you. You're up close to 40 patients since I think you announced the SentreHEART deal. But why is first quarter 2020 the right target and not sooner? Is there anything that you're seeing in terms of enrollment slowdown? Or is it just kind of the holiday season that might kind of delay that a little bit into next year?

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

You're asking that great question, and we could absolutely close it out and get it done by the end of this year. We're on a great pace. I'm only being a little bit cautious just because we just acquired them. We're getting a sense for what the patterns look like. But right now, patient flow looks fantastic, and it could be very early in 2020 or late this year. The guidance we want to give to stick to is early part of next year in the first quarter just as what happens in the end of the year with holidays and things like that. And again, it's the first time that we've owned this, and I'm getting a sense for it.

So quite frankly, the difference between whether it gets done on December 31 or February 15 really doesn't make a large difference to us on the long-term market and what we're going after here. We're already doing the work on the back end on getting -- doing PMA readiness work getting all the models behind. So we're doing all that work behind the scenes. So I'm not -- the difference in days doesn't really matter. Yes, you're right. We've had great enrollment, and it's very possible, we could close it out by the end of the year.

Andrew Christopher Ranieri *Stifel, Nicolaus & Company, Incorporated, Research Division - Associate*

Great. And then just one last one, if you wanted to provide an update on some of your other clinical trials, like ICE-AFIB, CEASE AF and DEEP? And then separately on FROST data, I think you mentioned before that you expected in 2020, can you maybe put a little finer point on when you might expect that data either at a conference or publication?

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

All good questions. So clinical trial data, I was kind of walking through the clinical trials, you're right, we really want to focus this call on kind of explaining and reminding that we're in the process for CONVERGE and then also kind of talking a little bit about our new acquisition with aMAZE and kind of making sure everybody is up to speed on that. But you're right, on ICE-AFIB, that's our open trial. As a reminder to everybody, it's a 160-patient enrollment. We've enrolled over 20 patients to date. It's actually ahead of what our plan and schedule was. We've got 11 sites up and running. We may add a couple more sites over the course of the next several months to the early part of next year, but our focus now is to get the sites that we have up and running and going. We feel really bullish about that trail. It's created a lot of excitement. Again, another way to kind of gather more clinical evidence within that open space, which is a big part of our business as everybody knows.

On top of that, we've got the, you mentioned, FROST and the data coming off of our FROST. We do -- many submissions have been had with various different journals, so we do anticipate in one of the major shows next year that it will be accepted as an abstract and as a paper and be presented at one of those shows. It could be STS, depends on whether or not these are accepted or several others that kind of occur in the first half of the year.

When it comes to CEASE AF, that's our trial. That's kind of the DEEP trial over in Europe. And we are at 147 patients, and so we're near statistical significance on the overall trial in terms of the enrollment. We'll know more by the end of the year. And our hope is that, that will kind of conclude enrollment sometime in the early part of next year and then we -- obviously, we'll have to wait for 1 year follow-up and everything after that point in time.

And then, I think, the -- oh, and then DEEP is the other one, obviously, which is DEEP in the U.S. The DEEP AF trial, we're at 62 patients enrolled total. We're back on track. We've got -- we had -- we got about 12 sites or so enrolling now. We got a pipeline of 6 or 7 sites that we anticipate over the next 6 months will kind of get up and running and into that trial. And feeling very good about the excitement for that and the cases that have happened so far to date. So lots of good activity. Thanks for asking the questions within our other clinical pillars as well.

Operator

There are no further questions at this time. Please continue.

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

Great. Well, again, everyone, thank you for joining us today. We look forward to another strong quarter in the fourth quarter and to finishing out 2019 as we continue our commitment to treating people with Afib around the globe. Thank you, and have a wonderful day.

Operator

Ladies and gentlemen, this concludes today's conference. Thank you for participation, and have a wonderful day. You may all disconnect.