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Q4 2019 AtriCure Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure Q4 and Full Year 2019 Earnings Conference Call. My name is Dilem, and I'll be your coordinator for the call today. (Operator Instructions) As a reminder, this call is being recorded for replay purposes.

I would now like to turn the call over to Lynn Lewis from 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 have 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. As I reflect on 2019, and as we usher in a new decade, I'm struck by the transformational development at AtriCure over the past 10 years. While concentrating our efforts on the 3 pillars of our mission: innovation, clinical science and education, we have made tremendous progress on multiple fronts and have meaningful -- have meaningfully expanded our market opportunity. Some of these highlights include: we have achieved 29 consecutive quarters of double-digit revenue growth year-over-year. We diversified and bolstered our product portfolio, launching over 12 new products and innovations beginning with the launch of the AtriClip franchise 10 years ago and strengthened more recently by the launch of cryoSPHERE for Cryo Nerve Block therapy in 2019.

We completed significant acquisitions, including nContact in 2015, and most recently, in August 2019, SentreHEART with LARIAT Suture Device. We have invested heavily in clinical trials to develop significant differentiation for the treatment of Afib over the long term.

We have trained over 3,000 physicians, nurses and other practitioners globally, through our training programs, which were recently endorsed by The Society for Thoracic Surgeons in early 2019.

And finally, we have built the infrastructure and team to support accelerated growth and ongoing expansion. We now have 725 people across the organization, including over 200 in the field globally supporting our sales. We have built a winning foundation and achieved critical milestones, setting the stage for success across our franchises in 2020 and over the next decade. To that end, and as previously announced, we expect another year of double-digit revenue growth in 2020, with revenue in the range of $254 million to $261 million.

Turning now to our landmark IDE trials we have underway, which address market expanding opportunities, both CONVERGE and aMAZE. Through these 2 clinical trials, we are the only company attempting to treat the most difficult patient population. The 70% of Afib patients that have persistent and long-standing persistent Afib, where catheter ablation alone is typically not effective. Treatment of this patient population remains vastly underpenetrated and represents well more than $1 billion of market opportunity today.

As it relates to the CONVERGE trial, we submitted our final PMA module to the FDA at the end of 2019. The results will be submitted to be released as part of late-breaking presentations at the Heart Rhythm Society meeting in early May.

To remind everyone, CONVERGE is a 153 patient superiority trial. It's a randomized controlled trial, the first of its kind, and quite frankly, the only one in the market today. We are comparing our approach, which is a hybrid procedure, combining catheter ablation with our EPi-Sense technology versus catheter ablation alone. We continue to prepare for a potential panel and are optimistic that we could receive FDA approval towards the end of 2020.

Our other market changing trial aMAZE is a 600 patient randomized controlled trial also designed to show superiority. Superiority in this case is catheter ablation plus the LARIAT technology, which excludes the appendage versus the catheter ablation alone.

Since it is known and clinically accepted that some of the Afib triggers originate from within or around the left atrial appendage, we believe this approach should effectively increase Afib treatment success rates by adding epicardial appendage management to the catheter ablation. The goal here is to show that our technology is, again, additive.

We completed enrollment in aMAZE in December 2019 and expect to have follow-up on those patients in early to mid-2021, followed by data analysis and our full PMA submission. Under this time line, we are hopeful we could receive FDA approval sometime in 2022.

I will finish my remarks on these key clinical trials by emphasizing that we are not competing against catheter companies. Both of our solutions are complementary and used in conjunction with catheters. We believe both procedures will help grow and expand the overall market and more importantly, the number of patients that can get treated more so than today.

Now moving on to our full year and fourth quarter results. Our performance remains strong. We closed out 2019 with $231 million in revenue, up 14% annually and capped off by fourth quarter revenues of $61 million and 16% growth over Q4 2018.

U.S. strength was again broad-based, driven by our appendage management franchise. In particular, our V clip line of products continue to be additive to our growth in appendage management. Both the open chest and minimally invasive version of the V clip continue to grow nicely as the benefits of the ease of placement of those devices are recognized by our customers.

We also saw strong growth internationally in our appendage management business, and we are excited about continued prospects as we have full year V clip products being available in Europe after securing CE mark in late 2019.

We continue to focus on accelerating growth within our open ablation platform. As such, we recently submitted our 510(k) to the FDA on our new open clamp EnCompass and remain on track to launch later this year.

This new clamp will provide a simpler and faster approach to ablating the heart and open procedures, and we expect it to resonate with CABG surgeons in the open concomitant space and to be accretive to our open ablation revenue in future years.

The cryoSPHERE probe, our dedicated device for managing postoperative pain in cardiothoracic surgical patients, once again contributed to our open ablation platform growth in the fourth quarter. This growth is encouraging despite the fact that the overall

revenue contribution from the cryoSPHERE probe is small.

To build the pain management account base, we are continuing to expand our thoracic team in select markets. We can see that the therapy is clearly resonating with our customers and continue to see long-term growth opportunities in this space.

Transitioning to our minimally invasive ablation business, revenues were slightly down year-over-year. In 2020, we expect volatility in this franchise will continue. Longer term, we believe FDA approval of our EPi-Sense system via the CONVERGE trial in treating symptomatic persistent and long-standing persistent Afib patients will provide meaningful growth in the minimally invasive ablation franchise.

Now looking at our other supporting clinical programs, which are focused on markets, which we are in today with the goal of obtaining additional labeling. We initiated our ICE-AFIB clinical trial in 2019, and we have a total of 9 sites actively enrolling. We expect that successful completion of this trial will generate systematic clinical evidence on the safety and effectiveness of concomitant cryosurgery for the treatment of Afib patients undergoing structural heart surgery.

We also continue to make progress in our deep AF-IDE trial with 15 sites now enrolling. As a reminder, deep AF provides another alternative for minimally invasive approaches. We believe that the successful conclusion of each of these studies, in which we are partnering with some of the best institutions globally, provides an opportunity to further support our comprehensive platform and increased awareness to promote expansion of available therapies.

Internationally, fourth quarter results were positive, primarily driven by appendage management and open franchises. Throughout 2019, we strengthened our position in Asia with growth in Japan, led by our AtriClip and cryoICE device sales and in China with our partner, Baheal and the expansion of our team.

In Europe, especially the U.K., France and Germany, we saw expanded growth of EPi-Sense and AtriClip products and steady growth in the open ablation franchise.

In summary, our future is bright with our overall performance throughout 2019, reflecting our continued product portfolio investment and expansion.

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

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

Thanks, Mike. For the fourth quarter of 2019, worldwide revenue was $61.3 million, representing growth of 15.9% on a GAAP basis and 16.4% on a constant currency basis over the fourth quarter of 2018.

Revenue from U.S. product sales increased 14.9% to $49.5 million. U.S. open ablation revenue grew 12%, driven by the addition of the cryoSPHERE probe launched in early 2019. U.S. sales of minimally invasive ablation products were down 5% to $9 million, showing continued volatility from this business.

U.S. sales of appendage management products were $19.1 million, an increase of 31.6%. The AtriClip Flex V, along with our minimally invasive LAA exclusion system devices continue to lead growth in the appendage management franchise. The fourth quarter of 2019 also includes a small impact from the LARIAT system.

International revenue totaled $11.8 million, up 20.5% on a GAAP basis and 22.8% on a constant currency basis as compared to the fourth quarter of 2018. As a reminder, the transition of the China distributor was in process during 2018, and we did not receive orders for that market in the first and fourth quarters of 2018.

In addition to the contribution from China in the fourth quarter of 2019, we saw strong growth in our Asian markets, notably Japan, as

well as our European markets driven by the U.K., Germany and the Benelux region. International growth was also led by appendage management product sales.

Gross margin was 73% for both the fourth quarter of 2019 and 2018. While we saw an increase in gross margin in the fourth quarter of 2019 as a result of operational improvements and lower production costs in our core marketing operation -- manufacturing operations, this was offset by the absorption of SentreHEART manufacturing operations as well as mix between U.S. and international sales.

In the fourth quarter of 2019, we had an adjusted EBITDA loss of $5.4 million compared to positive $0.3 million adjusted EBITDA for the fourth quarter of 2018.

The change in adjusted EBITDA was driven heavily by the absorption of the SentreHEART business predominantly within cost of revenue, aMAZE clinical trial expenses and the field team supporting the aMAZE clinical trial enrollment.

Our operating loss for the fourth quarter of 2019 was $15.3 million compared to an operating loss of $2.6 million for the fourth quarter of 2018. Our net loss per share was $0.42 for the fourth quarter of 2019 compared to a net loss per share of $0.09 for the fourth quarter of 2018. Note that in the fourth quarter, we recorded a $2 million noncash charge to operating expenses relating to a change in contingent consideration liability.

During the fourth quarter of 2018, we recorded a $4.1 million noncash credit related to this liability. The variance in the contingent consideration adjustments year-over-year is largely a result of a change in the discount rates used to measure the liability. Without these noncash adjustments to operating expenses, our adjusted loss per share was $0.37 for the fourth quarter of 2019 and $0.21 for the fourth quarter of 2018. Note that adjusted EBITDA results for all periods exclude noncash adjustments related to the contingent consideration liability.

Excluding the impact of the noncash adjustments to the contingent consideration liability, operating expenses increased approximately $12.8 million from $45.3 million in the fourth quarter of 2018 to $58.1 million in the fourth quarter of 2019.

Research and development expenses, which include clinical and regulatory activities, were $13.1 million for the fourth quarter of 2019 or 21% of sales, an increase of $4.6 million from the fourth quarter of 2018. The increase was driven primarily by additional headcount and clinical trial costs related to the aMAZE trial.

SG&A expenses, excluding the noncash adjustments previously described, increased approximately $8.1 million from the fourth quarter of 2018 to a total of $45 million or 73% of sales. The increase results from our continued investments in the commercial organization worldwide, absorption of the LARIAT field team, legal expenses and training activities.

For the full year 2019, worldwide revenue was $230.8 million, an increase of 14.5% on a GAAP basis and 15.2% on a constant currency basis.

U.S. sales grew 14.6% to $185.8 million. U.S. open ablation revenue increased 11% to $80.2 million, with growth led by the cryoSPHERE probe and supplemented by increases across all other open ablation products.

U.S. sales of ablation products used in minimally-invasive procedures, were $34.8 million, reflecting a slight decrease of 0.6% from 2018. This decrease was driven by a decline in volume of fusion products, partially offset by increases in legacy RF ablation devices.

U.S. sales of appendage management products grew 28.9% to $68.2 million, driven by strong performance of the AtriClip Flex V LAA exclusion system as well as the minimally invasive LAA exclusion system products.

International revenue grew 13.9% on a GAAP basis or 17.6% on a constant currency basis to $45 million. We continue to see increased growth in Asia and our European markets, notably the United Kingdom, Germany and France for both open ablation and appendage management product lines.

Gross margin was 73.8% for 2019 compared to 73% for 2018. The increase demonstrates continued operational improvements and lower production costs at our headquarters, a decrease in share-based compensation from a onetime charge for the retirement of an operations leader in 2018 and mix changes. These improvements were partially offset by absorption of the SentreHEART business acquired in August 2019. Loss per share for 2019 was $0.94 compared to $0.62 for 2018 and the adjusted EBITDA loss was $6.7 million for 2019 compared to $2.7 million for 2018.

Our adjusted EBITDA loss for 2019 and 2018, both exclude noncash adjustments related to the contingent consideration liability. Without these noncash adjustments, the 2019 adjusted loss per share is $1.07 and the 2018 adjusted loss per share is $0.94. We ended the year with approximately $94.5 million in cash, cash equivalents and investments.

Lastly, we are providing guidance for 2020. We anticipate top line revenue growth of approximately 10% to 13% year-over-year or approximately $254 million to $261 million on a GAAP basis.

We anticipate gross margin will be approximately 73% to 74% for the year. We expect margin improvement, driven by mix changes and cost control efforts with pressure caused by full year absorption of the SentreHEART operations. As we have noted many times, we do continue to expect our business to generate 75% gross margins within the next few years as we scale our operations.

We expect R&D expenses to be 20% to 22% of sales for the year. The increasing investment reflects a full year of aMAZE trial costs, including the continued access protocol, and continued investments in ICE-AFIB and DEEP AF IDE trials, CONVERGE PMA costs and continued access protocol, new clinical science activity along with R&D pipeline development.

We expect SG&A expenses, excluding noncash adjustments to the contingent consideration liability to be approximately 69% to 71% of sales in 2020, a slight decrease to 2019. The increase in SG&A expense dollars is driven by thoughtful expansion of the worldwide sales team, particularly in our EP-focused team and Cryo Nerve Block team.

Additionally, there are important investments in our training and marketing activities with continued leverage in the general and administrative areas. We expect adjusted EBITDA for 2020 to be a loss of approximately $10 million and adjusted loss per share between $1.14 to $1.24. Both of these metrics exclude noncash charges for the change in control -- in contingent consideration liability. We expect approximately $10 million to $12 million of noncash charges for the accretion of the contingent consideration liability in 2020.

The GAAP reported loss per share for 2020 is expected to be between $1.40 to $1.55, with the inclusion of these noncash charges.

For modeling purposes, we expect revenue growth in Q1 to be in the lower end of our guidance range and to pick up as the year progresses. Additionally, we anticipate the adjusted EBITDA loss to be highest in the first quarter as a result of heavier marketing and training costs typically incurred in the first quarter.

We expect to generate an adjusted EBITDA loss in the first quarter of 2020 of approximately $6 million to $7 million, which translates to an adjusted loss per share in the range of $0.38 and $0.41. We expect a decline in quarterly adjusted EBITDA loss throughout the rest of 2020 as revenue ramps.

At this point, I would 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 up for questions, I want to take a moment to thank our team at AtriCure. We have helped over 90,000 patients worldwide during 2019 and over 500,000 this past decade. Together, we have built a strong platform of products supported by clinical evidence and training, which provide multiple treatment alternatives for Afib patients globally. Our work truly matters, and I appreciate each and every one of your contributions toward impacting patient lives every day.

In closing, we remain confident that we are poised to significantly change the landscape of Afib treatment, and we are committed to

accomplishing our strategic initiatives to that end. We look forward to delivering a future on the foundational growth in the catalyst, including CONVERGE, aMAZE, Cryo Nerve Block, EnCompass and future AtriClip clinical data.

We'll now turn the call over to questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Jason Mills from Canaccord.

Jason Richard Mills ***Canaccord Genuity Corp., Research Division - MD of Research & Analyst***

Mike and Andy, can you hear me, okay?

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

Yes, we can hear you, Jason.

Jason Richard Mills ***Canaccord Genuity Corp., Research Division - MD of Research & Analyst***

Super. Congratulations on another great year. So I wanted to ask you a few questions that I get asked a lot from investors. And so an opportunity for you to address them head on. Probably the most often asked question is the future of the MIS business and revenue growth of MIS post CONVERGE. So perhaps you could address a few issues within that question. One would be the development of the market from a sales force perspective. So your plans on that front? Where you are now? Where you might expect to be upon FDA approval, hopefully, at the end of this year? And how that might expand in 2021? And I guess I'm guessing you're not going to give any sort of growth guidance quantitatively for 2021. But oftentimes, I get asked, should MIS, that opportunity does that portend accelerating growth potential in the overall business? Is it big enough -- is that market exciting enough to excite that kind of trend acceleration. Maybe you could address that head on too? And then I had a follow-up on the clip business.

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

Sure. Thanks for the question. And obviously, that is a question that we get a lot relative to our MIS business with CONVERGE. And the data coming out here soon and obviously, looking forward to the approval sometime in 2020. I'll address your first question or kind of the -- what you started with, which is the kind of the growth and the guidance and the acceleration of the growth rate. I mean the way we look at this is we absolutely look at this as a multibillion-dollar market. 70% of the patients that are out there have persistent or long-standing persistent Afib. Within that category, 40% of long-standing persistent Afib, it is a massive market with millions of patients globally and in the United States alone. And so it is a big market opportunity.

And today, we're only doing a couple of thousand cases on the CONVERGE side. So we see this as it's going to be a very large market opportunity. I don't see a reason that by the end of the decade, we shouldn't be doing 25,000-plus procedures at some point in time. Remember, it's complementary to the catheters. There's 150,000 catheters. They do catheter ablation today for Afib patients. That number is projected over the next 5 years to be well over 200,000. We'll be just scratching the surface on this patient population. It's a very large population from that standpoint.

So to answer your question, yes, I think it's a big enough market to generate and accelerate our growth rate. I'm not going to pick the quarter that's going to begin, but obviously, we are getting ourselves ready for it so that 2021 can begin some of that acceleration. And then as you look at 2022 and 2023, we should begin to see acceleration in the overall growth rate for the whole company as a result of the size of the market that exists there.

As it relates to the sales force, we've been building this out, as I mentioned before, prior to the acquisition of the LARIAT team, we had about 25-plus people in our MIS group. That team has been built over the last 3-plus years. They've got incredible expertise and knowledge about on the EP side, understanding mapping, what does this technology look like after you've used it. That team is made up of both direct reps and clinicals.

On top of that, we've also got a clinical education team of about 12 to 15 or so people that are really dedicated to the procedural development and training aspect of this. And then now with the LARIAT team, there's going to be cross training. Obviously, their focus is on the LARIAT technology but there will be knowledge transfer and they're out in the field. So we're going to have an EP sales force by middle of this year of over 40 people. By the end of the year, closer to 50 people that are dedicated to really calling on and serving that kind of EP space, but also understanding how that hybrid component takes place with the surgeon.

So hopefully, that gives you some context in terms of the growth this year. As we see how it picks up and as we kind of get ourselves ready for the PMA launch later this year, early part of next year, we are going to be more than ready for that and are really looking forward to it.

Jason Richard Mills ***Canaccord Genuity Corp., Research Division - MD of Research & Analyst***

Great color, Mike. On the appendage management business, I wondered if you could give us -- take a step back and give us your sense for the next couple of years in LAA management. We've seen an evolution, certainly over the last couple of years and you've both driven and benefited from that. With the acquisition of SentreHEART, clearly, you're looking to capitalize what seems to be a continued evolution in the direction of more cases, more LAAs being treated proactively. Could you talk about where you are now from a penetration standpoint in the markets in which -- in the niches of that market that you participate? What SentreHEART adds to it? And does that also sort of -- you get beyond next year, you start to see growth potentially accelerating because of that business, too, right? Could you talk a little bit about that?

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

I mean, I think you've kind of set it up really well there, Jason, which is one of the things that we have as a business is that with these acquisitions and also just the investments that we've made over the last several years to get ourselves ready for catalysts over the next 5 years. And the appendage management is a great space for that. So you're absolutely correct. I mean, if you think about -- I'll start with the LARIAT piece of it, which the market is just as big. Its additive technology to converge and to the catheter ablation. Because basically, the CONVERGE takes out the back wall, the catheter does a great job with the PVIs and then you've got the appendage management to kind of close that out. And as I mentioned in my script, a lot of the triggers, as we well know, come from around the base of the appendage and through the appendage, quite frankly. And so that's kind of the theory behind the trial. And that should be another accelerator to growth in 2023 and 2024. So you begin to kind of layer on some of these as you kind of get into the outer part of those years. And we bought SentreHEART, obviously, last year with the anticipation of that helping us accelerate our growth into the back half of the decade and be another really big multibillion-dollar market for us from that standpoint.

As it relates to clip, which you're very well aware of that's done concomitantly with other cardiac surgery, primarily today. That is pretty much how that product is being used and the penetration. We sold just over 50,000 or so in 2019, totally around the globe. So that's a lot. That's kind of industry leading. We're at over 220,000 clips sold to date. So those are some pretty big numbers. We know the product works incredibly, incredibly well. And yet, we're only scratching the surface.

If you just look at the U.S. market, we believe there are 300,000 cardiac surgeries that go on every year. Within that 300,000, about 90,000 of them have Afib, and we think about 30-or-so thousand about 30-plus -- a little bit over 30% are getting a clip concomitant with an Afib ablation, and there are some that are getting it done prophylactically as well where they're putting it on where somebody has made a decision on the end of the surgeon to do that as well. And we believe that the prophylactic is going to be something that people are going to want to do long term.

Most of these patients have a very good chance of getting Afib in their lifetime. We did a trial called ATLAS that showed positive results and they were shown last year at several different shows in terms of some abstracts and some papers that have been submitted on that. And so we're now going to look at doing a full-blown clinical trial likely to start sometime in 2021, that's going to go after a stroke label specifically for that concomitant treatment and to go after the prophylactic treatment as well.

And so we think there's a lot of room for growth over the next decade. It's kind of why I kind of started this call with. When you look at the decade, we've had an unbelievable last 10 years, and now we're building on to what we think is going to be an exciting next 10 years in the history of this company.

Operator

Our next question comes from Matthew O'Brien from Piper Sandler.

Matthew Oliver O'Brien ***Piper Sandler & Co., Research Division - MD and Senior Research Analyst***

Just a quick clarification for Andy. The 10% to 13% top line guidance, does that include any kind of impact from China, just given that submarket that you have right now? And what's going on there as far as the coronavirus goes?

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

No, the 10% to 13%, it's our best -- it's our range for the business. Don't expect, just given the size of the Asia business overall, a huge impact. But obviously, we're still evaluating as times going on, and we're working with our teams out in the field to get a better understanding of what that -- how that could potentially impact the business over time, but we're comfortable with the 10% to 13% as it stands.

Matthew Oliver O'Brien ***Piper Sandler & Co., Research Division - MD and Senior Research Analyst***

Okay. And then, Mike, you started talking about this when you were answering Jason's question about the clip business? But as I look at the guidance for 2020, it's probably going to be pretty clip heavy again. I know open, you're excited about CONVERGE, but that's more 2021, 2022 events. And then open should benefit a little bit from cryo, but it still seems like it's going to be largely a clip heavy year this year. So what gives you the confidence of that 10% to 13% with tough comps in the clip business. Doesn't sound like prophylactic is going to be a massive tailwind this year. Is the label expansion in clips going to help? Is it more sales reps, just the comfort level you have for that business, specifically this year in 2020?

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

Yes. I mean, we've -- if you recall, over the last several years, we came out with many innovations in the space. The V clip, as I mentioned, has really been a boost. And as more and more people get used to using that product, they're finding new ways to use it. And it's helping us grow the market, and we're still really, really underpenetrated in that space. Even in the treatment for Afib and there's 90,000 patients, as I mentioned before, and just over 30,000 are actually getting a clip on. So pretty much every one of those patients should be getting a clip on or having their appendage managed while they're in cardiac surgery. So we see that there's still just an underpenetration game going on within the next several years within the clip space concomitantly. And that's really what's driving most of the bullishness and the comfort on the clip. Like you said, it's going to be a big driver for our growth this year overall, and we think that the V clip has really kind of helped out quite a bit on that front.

Matthew Oliver O'Brien ***Piper Sandler & Co., Research Division - MD and Senior Research Analyst***

Okay. Can I sneak in one more real quick one? On the clinical data side, there was -- the frost abstract was posted. You hit the primary endpoint. I think you missed the secondary endpoint on the pain score. I'm just love to hear a little bit more about how significant that is? And any kind of response you're getting from the field on that data just in totality?

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

I mean, the response has been very, very good. I mean the primary endpoint, as you mentioned, was really lung function and kind of restoration of breathing. And we -- the primary endpoint was met in a big way on that particular front. So we feel very good about the results that came out with that. That was really the primary one we're looking at. The other endpoint, as you said, was more of a subjective measure around pain. They were pretty equal.

Now what's interesting about that is they were actually equally low on the pain management because they were using standard of care in some of the pain management thresholds with that. We kind of expected that within that area, but it was definitely something where we kind of saw, they were almost equivalent on the pain scores specifically, but how they recovered, how quickly they recovered was significant. And at STS this year, Dr. Liu basically presented that. And there was a very positive response from the audience when he was presenting in conversations afterwards as well.

Operator

Our next question comes from Robbie Marcus from JPMorgan.

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

I wanted to touch on CONVERGE and we're going to be getting -- hopefully, at HRS we'll get a late-breaker. But I just wanted to understand the confidence and the timing to move it into a presentation and away from a potential FDA panel pack. Was there something in the data you saw that gave you confidence to present it as a late-breaker? And do you still, at this point, expect a potential FDA panel?

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

Yes. I mean, as -- the reason that we made the decision to go for the HRS late-breaker was because we didn't want to be the first one in the Afib market specifically to go down that path. And when some other companies that were doing some trials in the Afib space decided to a different patient population for sure, but they were -- they came out of Afib Symposium, that really kind of led the way for us to be able to kind of come out at a scientific session and the closest one to when we got the data in, that we could actually submit for a late-breaker was HRS.

So it really had nothing to do with the underlying data and had everything to do with just the timing of somebody else kind of submitting for a different one that we felt comfortable not being the first one at that point in time and that it made a lot of sense to have key leading positions presented at -- as close as we possibly could from when the data came out. So that's the primary reason why we made that change to kind of get it out there.

Again, we just didn't want to be the first ones out there. And so we're kind of now following a model, much like other medical device companies have where the data comes out at the trials. And hopefully, this will be something that continues to happen within the Afib space now that several companies have done it. I think there was a second question. I can't recall what it was, though.

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

Yes, I'll just kind of wrap it into my follow-up question. It was, what's your latest thoughts on timing for maybe approval or potential FDA panel ahead of approval? And then second part, we can all dream really big numbers on what this opportunity could look like over time. So what's your latest thoughts on potential timing of approval? And then just walk us through maybe the headwinds or steps you have to walk through to drive adoption of this and help us set expectations for the ramp, should it be positive?

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

Sure. I mean, it allows me really quickly the kind of walk through the timeline. So we submitted all the FDA data back in December of 2019. There's a 100-day clock that kicks in then. We plan on having an FDA 100-day meeting sometime in the April time frame, mid- to late April is likely when we'll get feedback from the FDA on whether or not we're going to have to go to panel at that time. Obviously, I don't know at this point whether or not. I think I've talked on this call before, it really comes down to conversations with them, not really necessarily about the data per se, but about -- we had the technology out in the marketplace for a long time. It's been used for a long period of time. And so it's really that -- how does that affect it and can we get them to basically kind of move away from doing the panel? But obviously, we're at the whim of the conversations we're going to wind up having with the FDA in that April time frame or so. So I'm sure they'll have good questions for us to kind of work through. That will obviously drive a lot of the timing. If we go to panel, panels likely sometime in the July, August time frame. And then, hopefully, an approval would be shortly thereafter, 3 to 6 months. I mean it depends on kind of feedback or questions they've got on labeling. But hopefully, the sooner part of that.

So right now, we're just on a clock with the FDA and going to be having feedback. I should say, though, that while the 100-day clock starts, we have already started on many of the other operational items underlying it, not the labeling aspect of the data, but we have had audits of several different sites. We've had audits of several of our different suppliers to make sure that they all in PMA ready. The team on our end, has done a wonderful job and I feel like we are more than ready to handle all of those, and we're working collaboratively with the FDA on all fronts relative to that.

As it relates to the ramp, once we do get an approval for our products and are able to kind of move forward with the PMA from that standpoint. As, I mentioned earlier, in Jason's question, I feel like we've got the team in place. We've been training that team and getting them up and running and ready. I think that there's still work to be done this year, but it's kind of around the edges, we will absolutely be ready. You asked about what would be the headwinds upon the adoption? It's not going to be about coverage in the United States, we

will have proper coverage and well-trained team in place. It's going to be around really working through the sites for kind of logistics adoption, how do they fit it within their current program, how do they fit it with, they've got these patients and do triage at some point in time. And each site is going to have a little bit different perspective on that. So one is going to be logistics. Two is going to be how does it fit in their system. And three, I think, is going to be really making sure they've got good surgeons that can do the procedure that they can collaborate with. And getting those new surgeons up and running and trained is going to be critical. We have sites set up around the country, they're able to do that training, but it's a matter of just kind of getting throughput through some of that. That's why, as I mentioned in my comments, Jason, 2021, we should see some acceleration, but really the bigger acceleration begins in 2022 and beyond, as we've kind of gotten through some of that.

Operator

Our next question comes from Danielle Antalffy from SVB Leerink.

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

Congrats on the strong year. I wanted to ask the other side of the guidance question. And that is why only the -- I think it was 10% to 13%. I mean, if you look at what you put up in 2019, you actually saw growth acceleration? And specifically, in the back half of the year, and this is off of what we thought were tough comps in 2018. So just curious on what you are seeing that would make you expect some deceleration in 2020, number one. Number two, specifically as it relates to the open ablation business, you saw really nice growth acceleration in that business in 2019 versus 2018. So Mike, could you just remind us on what's driving that growth and how sustainable that is?

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

I mean when you look at our business, if you look at our guidance, obviously, we want to make sure that we're able to meet and exceed the guidance for the year. That's something that we've prided ourselves on overall as a business. The numbers obviously do get larger. As we look out to 2021, 2022, we've got really big catalysts that are going to change the market in general and accelerate our growth rate in really big ways. This year, really, it's another good, strong double-digit revenue growth here. If you actually look back to when we entered into 2019, our guidance was 9% to 13%. We obviously exceeded that and had a really, really good and strong year. It's the beginning part of the year, we feel really good about the year. We feel good about the team we've got in place, but we want to set it appropriately so that we can make sure that we can meet and exceed that guidance for the year. That's really what falls behind it overall. And then as you look out in the outer years, hopefully, we'll be able to accelerate based on the catalyst of these big clinical trial dates that are coming out in the future. And then also, as I mentioned, it's not just the clinical trials, we've got new products coming down the pipeline with EnCompass. And then you've also got the possibilities in other trials as well.

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

Okay, got it. And maybe I'll ask a question this way. Is there any different sort of stance on or approach that you're taking to guidance? Because you did handily beat guidance for 2019. So as you look at 2020, are you viewing things differently or approaching guidance differently to be more realistic? Or are you leaving that same sort of level of conservatism baked in?

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

We're always looking -- I mean, I wouldn't say that our philosophy or has changed in any way. We constantly look at the business from 10 different angles to make sure that we're not missing anything to make sure that we've accounted for things on all sides, both upsides and downsides relative to it. So nothing fundamentally has changed in the way that we're viewing it or looking at the year. Given that we're only 6 weeks into the year, we kind of -- nothing's fundamentally different than the way we looked at it last year.

Operator

Our next question comes from Mike Matson from Needham & Company.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Wanted to ask about this new EnCompass ablation probe. So I understand that this is something that would help maybe drive increased adoption in the CABG procedures. But is this something you may also be able to get a price and mix benefit on as well?

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

The answer is yes. I mean, it will be a higher-priced product. It's a really innovative product that basically makes it a lot easier to go around the heart and really kind of ablate in multiple different areas with having to do a lot fewer dissections for those that have more difficulty doing some of those dissections. I mentioned CABG because it tends to be in CABG or AVR patients when they're not open or they don't feel comfortable opening up the atrium for one reason or another. It really does allow you to ablate more comprehensively in various different areas in the existing clamps that we have today that are really focused on the veins only. And this really kind of gives a more complete procedure from that standpoint.

So yes, it is more comprehensive. It's a really simple and easy to use product. And our team has just done a really wonderful job on that front. And the price point will be higher than existing clamps because it's much more comprehensive in the ablations that it does.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

And then, Andy, I think you indicated that you expect the first quarter to be kind of at the lower end of the revenue guidance range, is that right? And I guess, we're more than halfway through the quarter now. So I guess what's driving that?

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

Sorry, go...

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

I'll take it. I mean, for the quarter, I mean, quite frankly, just as we entered the year, we just want to make sure that we're in a really good spot for the overall year. And that there's nothing like to read into it per se, but as we look at the year, we kind of look at the year building as we kind of get ourselves ready for CONVERGE and get ourselves ready for the launch at the end of the year. And so we wanted to make sure that we were kind of guiding appropriately.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Okay. And then finally, just on the open heart. I mean, it was good to see the double-digit growth there, but you are including the cryoprobe in there, I think. So -- and we've seen even Edwards has now seen some deterioration in their domestic cyber sales from TAVR cannibalization. So what are you seeing there? Are you seeing any impact at all from TAVR on the open heart business?

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

No, not at all. I mean, we've talked about this before. We've talked about it on this call before, the market is incredibly underpenetrated in that front. TAVR is a very, very small percentage of our overall business. We don't see really any pressure. Patients that have Afib are typically continuing to go in for surgery. And so that's not an impact. That doesn't have a real impact on our overall business. I mean it's not a material or meaningful piece to it overall.

I know we've talked about at length on this call before. And I'd say it's even less so today than it was a year ago and less so than it was the year before that. And so it becomes a smaller and smaller component of our business overall.

Operator

Our next question comes from Rick Wise from Stifel.

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

Mike and Andy, it's Drew on for Rick tonight. I just wanted to start with LARIAT for a second. So it's been about 6 months since you've had LARIAT under your belt, just how has the conversation with EP has been evolving as you kind of continue to work towards CONVERGE approval? I mean, are you seeing increased interest from LARIAT trial sites to pursue CONVERGE? Just talk about any traction that you're seeing in these early days?

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

Yes, we have -- I mean, to date, we've really focused the LARIAT team on LARIAT. There has been really not much crossover other than training and awareness and making people. But we've really had the teams separate all the way through the end of last year. We needed

to get that trial done. The trial was our #1, 2, 3, 4, 5 priority. I mean, that was really what we're doing. We're getting the team ready. Behind the scenes, we're getting the team running the field and making sure we're in the cases. The cases were being done well. That really hasn't changed. That team is incredibly clinical is really -- they're great ambassadors for us overall as a business, but we haven't leveraged them in any way towards CONVERGE in any kind of meaningful way. That will change likely as we progress towards the PMA at the end of this year. But we really haven't done much trend to kind of get them up to speed on that front.

We have moved the teams together so that they're actually working more -- they can work more collaboratively, but it's more so so that they're not bumping into each other in hospitals and things like that. Again, by the end of the year, I think that will change, but we're really kind of doing this in a very methodical way and haven't seen any kind of uptake per se on the CONVERGE side in that.

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

Got it. And then just from the AF symposium and then the left atrial appendage meeting a couple of weeks ago. I mean, CONVERGE could clearly drive adoption if it's positive, but when you're talking about the market, it seems like you're talking just more on catheter ablation and salvage procedures. And we've been hearing clinician feedback saying that they could even think of this as a front-line therapy. So just how are you kind of -- I know you can't really market this, but how are you positioning it or thinking about CONVERGE as a front-line therapy versus a redo procedure for previously failed catheter ablation?

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

I mean, we think that it can be both. I mean, I think that there's a practicality of it. So the trial itself is actually done in a front-line therapy putting all -- that randomization was done on the novel hearts that had never been ablated before. So the data is actually going to be on patients that had not been ablated before had not gone through a PVI. And so that's obviously how the -- it's going to be pushed out that way once we actually are able to get that label and the approval relative to that. So we do see that as a really big market opportunity. But we're also realistic to know that a lot of times, these patients do go through a catheter first, especially as the EP is trying to triage it and that, that's going to be kind of concomitant to that particular procedure at that time. And so I'd say that the way we're looking at it is it really applies to both. We'll wind up marketing it as the FDA gives us whatever leeway and latitude they give towards that, we'll basically leverage that, but it can be both the front-line therapy and obviously, one that can be after a catheter ablation has already been done, and they failed. I see both having an impact on this patient population.

We tend to go to the number of catheters. The reason I use that having the number of -- catheter number is because the numbers are so large, like, when I start talking about, there are 6 million patients in the United States that have Afib, 4 million of them have persistent, long-standing persistent, and we're doing 2,000 procedures today. It's just -- it's like, well, that's a pretty big market and that is completely -- that's untapped. So then I try to bring it down to, okay, well, what's the reality of who's getting ablated today? And it's through that, it's close to -- depending on what numbers you look at 120,000 to 150,000 catheter ablations that are being done every year, 50-50 or 50% are paroxysmal early stage and 50% of the later stage ones that we tend to focus on and even just attaching to some of those and being complementary to that, as I mentioned in my comments, that also is just a huge market. And that market is growing, as we all know, at north of 10%. So that's why we tend to focus on the number of catheter ablations just to kind of make it easy for people to think through it.

Operator

Our next question comes from Marie Thibault from BTIG.

Marie Yoko Thibault ***BTIG, LLC, Research Division - Director & Digital Health Analyst***

I want to start here. I want to get a few more details on the V clip launch in Europe you have this year. I know it's been a strong product in the U.S. And how should we think about that launch throughout this year? It sounds like it should be helping both on the pricing side as well as supporting kind of sustained strong future growth over there? Any more details you can give us on that launch?

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

Yes, I think it's -- the European market has been clamoring for the V clip. It is a higher-priced market. So they're more price-sensitive over in Europe. And so we don't anticipate that it's all of a sudden, just going to take off. We -- it will take a little bit of time. So this year is going to be kind of about seeding the market and beginning to grow it. But I think the biggest excitement is just the clip is the

fastest-growing part of our market overall in Europe. And then you combine that with now, we've got our most innovative and great technology that's out there that they're going to get access to, it's going to create buzz and excitement about AtriCure is bringing new products into this market and spent the time that we care about that market, and we do care deeply about it, and that you'll begin to kind of see it kind of as an additive piece to the growth overall there, but not necessarily some hockey stick is going to happen because the (inaudible) of that market because they are a little bit more price-sensitive and that we're pretty disciplined on the price on it.

Marie Yoko Thibault ***BTIG, LLC, Research Division - Director & Digital Health Analyst***

Okay, understood. And my second follow-up, it's more of a modeling question. I appreciate the uptick in R&D spend for 2020, given the multiple research priorities you have. But when we think about converged data at HRS, a possible FDA panel, the aMAZE cap, the other trials, the pipeline, can you help us how to think about the quarterly R&D spend cadence throughout the year?

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

Sure. It's -- as you think about it, there's going to be some ups and downs, kind of, I would say, throughout the year, just given cadence of the different trials and as the caps come online. But quite frankly, the easiest way to think about it is just as a starting point, the percentages we gave in the script, just to kind of keep you in line. There's going to be some movements up and down, obviously, around those on a quarterly basis. But you're right, it's a lot of moving parts. And so without giving you very specific quarter-by-quarter numbers, I would start with what we've kind of provided in the prepared remarks.

Operator

I show no further questions in the queue. At this time, I'd like to turn the call over to Mike Carrel, President and CEO, for closing remarks. Please go ahead.

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

Again, everyone, thank you for joining the call today. As you can tell, we're excited about the next decade together, and we look forward to talking to you again soon and seeing you at HRS for the late-breaker. Talk to you soon. Have a great day.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.