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Q1 2021 AtriCure Inc Earnings Call

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

## PRESENTATION

### Operator

Good afternoon, and welcome to the AtriCure's First Quarter 2021 Earnings Conference Call. My name is Mel, and I will 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 the Gilmartin Group for a few introductory comments. Ma'am?

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### 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. These statements include, but are not limited to, financial guidance, expectations regarding the timing of FDA reviews and expectations for product approvals, expectations regarding the FDA's response and whether it will approve CONVERGE, the potential CONVERGE launch timing, the potential market opportunity for CONVERGE and the adoption of the CONVERGE procedure. 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?

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

Thanks, Lynn. Good afternoon, everyone, and thank you for joining us. We hope you are safe and doing well.

We are off to a strong start in 2021 with \$59 million in total revenue for the first quarter. This represents 3% sequential revenue growth over the fourth quarter of 2020, and largely reflects improving patient flow in the United States.

At the start of the quarter, we experienced headwinds from the decreased cardiac surgery procedures following a spike in COVID-19 cases, which resulted in extended quarantines and a reallocation of resources within hospitals. However, in March, most areas in the United States began to stabilize and we saw steady growth across all of our franchises. While we believe this recovery reflects some pent-up demand, we also saw improvement in procedure volumes in March. Encouragingly, we finished the quarter with momentum, and this has continued in April.

Internationally, our performance was not as strong, especially in parts of Western Europe, due to COVID-19 resurgences and slower vaccine rollouts. Similar to the experience in the United States, we began to improve in March. However, trends in our international markets have not been as consistent, and we expect continued volatility in the coming months.

As we begin the second quarter, we expect the upward trend to continue in the United States. While we are hopeful that international markets will improve, the outlook is less clear. We believe that worldwide cardiac surgery volumes remain below pre-pandemic levels. Conditions are improving, but this health care crisis is not fully behind us yet. Therefore, we expect that we will experience some variability in the second quarter and further recovery as the year progresses.

Turning now to an update on our growth initiatives. Beginning with CONVERGE. While we are closer to completing the PMA process, we cannot provide details of either a panel meeting or approval at this time. However, we are confident that we remain on a pathway to eventual approval and look forward to providing an update on this milestone shortly. Additionally, we continue to build a dedicated sales team and develop a robust infrastructure to support the commercial steps ahead. Currently, our U.S. sales and training team consists of more than 200 individuals in the field, who are all critical to supporting our hybrid therapy growth. This includes 35 dedicated reps and clinical specialists in our EP-focused hybrid sales team and over 30 professionals supporting nationwide training and educational programs.

The opportunity ahead of us is very clear and our goal is for the hybrid Convergent therapy to become the standard of care for the millions of patients with long-standing persistent Afib. We are also making significant strides on aMAZE, our other landmark clinical trial. The aMAZE study is a 600-patient randomized controlled trial designed to show superiority of endocardial catheter plus our LARIAT suture delivery device versus endocardial catheter ablation alone.

We successfully completed patient follow-ups in early April and are now focused on analysis of the data. We remain on track for PMA submission of the aMAZE trial during the fall of this year and expect to release trial data following the submission. In our open franchise, we continue to make progress towards our 510(k) clearance of our new EnCompass Clamp in addition to the open ablation platform, where we are the market leader in cardiac surgery procedures for the treatment of Afib. We anticipate clearance later this year followed by a concentrated commercial launch at certain key centers in 2021 and a broad commercial launch thereafter.

As a reminder, the EnCompass Clamp provides a simpler and faster approach to ablating the heart in open procedures, and we expect this device to appeal to high-volume CABG surgeons. As a result, we expect this new clamp to deepen our penetration of the cardiac surgery market starting in 2022 and beyond.

The collective opportunity in addressable markets for our open and minimally invasive ablation platforms is well into the billions of dollars, representing hundreds of thousands of patients annually. This opportunity is complemented by the continued rise in left atrial appendage management procedures. We saw a record number of AtriClip LAA exclusion devices sold in the first quarter, and our left atrial appendage management franchise accounted for 40% of worldwide revenue. Our track record of delivering innovative LAAM solutions over the past several years has contributed to revenue growth, along with increasing interest in managing the left atrial appendage. We are encouraged by the growing awareness at society meetings where the LAA management is the focal point of both sessions and discussions.

Switching gears to cryoSPHERE, our dedicated device for managing postoperative pain in thoracic patients. The cryoICE cryoSPHERE probe is gaining traction in the market with sequential quarterly sales growth since launch and continuous addition of new accounts. Cryo Nerve Block, which is included in our open franchise revenue, is one of the fastest-growing parts of our business and accounted for approximately 6% of total revenue in the first quarter. Our unique technology uses a differentiated freezing method to block nerves from transmitting pain signals after cardiothoracic surgery, providing a long-standing form of pain relief for these patients. We believe this therapy will drive accelerated revenue growth in the coming years.

Looking ahead, while the pandemic is still impacting our lives, we are beginning to see some return to normalcy with the rollout of vaccines and the gradual lessening of socially restricted measures. The momentum with which we are moving forward gives us hope

we're in a pathway toward recovery. Our team continues to execute and make achievements towards our strategic initiatives, and we remain confident in our future that we are strongly positioned with multiple catalysts we have underway to accelerate our revenue growth.

In closing, I would like to take a moment to thank Scott Drake and Mark Lanning for their dedicated service and leadership on our Board of Directors. During their tenure, AtriCure has experienced tremendous growth and advancement of our mission to reduce the global Afib epidemic. We are grateful for their guidance over the years to our entire management team.

With that, I'll now turn the call over to Angie Wirick, our Chief Financial Officer, to discuss more detailed results of the quarter.

**Angela L. Wirick AtriCure, Inc. - CFO**

Thanks, Mike. Our first quarter 2021 worldwide revenue of \$59.3 million increased 11% on a GAAP basis and 10% on a constant currency basis when compared to the first quarter of 2020. On a sequential basis, we experienced growth of 3% in our worldwide revenue from the fourth to first quarter. The sequential increase results primarily from our U.S. business and improving trends in elective and nonelective procedures throughout March.

In the first quarter 2021, U.S. revenue was \$50.3 million, a 16% increase from the first quarter of 2020. We realized double-digit revenue growth in each franchise in the U.S. from the improvement in underlying procedure volume. U.S. sales of appendage management products were \$20.6 million, up 18% over the first quarter of 2020.

Open ablation product sales, which include our Cryo Nerve Block business, were \$21.1 million, up 10% over 2020.

Minimally invasive ablation sales in the U.S. were \$8.4 million, up 28% from 2020, reflecting increased elective procedures year-over-year and growth in Epi-Sense revenue.

International revenue was \$9 million, down 8% on a GAAP basis and down 13% on a constant currency basis as compared to the first quarter of 2020. As Mike mentioned earlier, we experienced more pressure in our international markets, largely related to conditions in Western Europe as a result of COVID-19.

Touching briefly on a few key metrics for the first quarter of 2021, gross margin was 75.1%, up 200 basis points from the first quarter of 2020. This improvement was driven by both geographic and product revenue mix. U.S. activity accounted for 85% of our worldwide sales compared to a range of 80% to 82% historically.

Specific products contributing to a more favorable gross margin include heavier Epi-Sense and AtriClip FLEX V and PRO V device sales.

We had an adjusted EBITDA loss of \$4.7 million compared to an adjusted EBITDA loss of \$6.1 million for the first quarter of 2020. While operating expenses increased year-over-year, the improvement to the bottom line results show revenue growth outpacing our investments.

Our loss per share was \$0.38 in the first quarter 2021 compared to a \$0.42 loss per share in the first quarter of 2020, while the adjusted loss per share each period was \$0.32 and \$0.36, respectively.

Now moving to detail on operating expenses for the quarter. For comparability, I will exclude recurring effects of noncash adjustments, the contingent consideration liability from my comments. Total operating expenses increased \$6 million or 12% from \$51.9 million in the first quarter of 2020 to \$57.9 million in the first quarter of 2021. The change results mainly from increased variable cash and stock-based compensation, offset partially by lower clinical trial expenses, reduced travel and discretionary spend for trade shows and internal meetings. Certain areas of spend where we are currently experiencing savings, such as travel and meetings, are influenced by the pandemic and we expect costs to be restored to historical levels as their top line improves and travel, training and events increase.

We ended the first quarter with \$236 million in cash and investments. As a reminder, our first quarter cash burn is typically higher than

the remainder of the year based on cash tax payments due upon stock vesting and annual variable compensation payout. We expect our quarterly cash burn to reduce significantly for the remainder of the year. And lastly, we are pleased with the recent development in the Department of Justice investigation, specifically, their decision to decline intervention in the underlying case.

And finally, turning to our outlook for 2021. We now expect to achieve approximately \$252 million to \$256 million in revenue for the year. Given the momentum we observed exiting the first quarter, we project a reduced impact from COVID in the second quarter. As Mike mentioned earlier, we continue to experience procedural volumes generally operating below normal with regional variability.

In addition, to reiterate our view for the remainder of the year, we expect cardiac surgery procedure volumes to continue to improve steadily through the year, resulting in sequential quarterly revenue growth for the remainder of 2021. While we are pleased to report 75% gross margin in the first quarter, this result was largely driven by a very favorable geographic mix, which we believe was unique to the quarter. As we scale our operations in the coming years, we do expect our business to reach and maintain a 75% gross margin consistently. And we continue to expect adjusted EBITDA to be a loss of approximately \$10 million for the full year 2021. With improvements to the top line throughout 2021, we should realize the corresponding improvement in quarterly adjusted EBITDA. We also continue to expect adjusted loss per share for 2021 to be approximately \$1.15.

At this point, I will turn the call back to Mike for closing comments.

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

Thank you, Angie. We want to end by thanking health care workers in the scientific community for helping the world overcome this pandemic. As we move towards recovery, we are excited about the path forward for AtriCure. We are also pleased with the appointment of Kris Johnson as our Board chair. Her extensive experience in medical device and growth-oriented companies will be invaluable as we deliver on many of our catalysts that we've talked about earlier today. Our outlook remains bright and with accelerated and sustainable growth over the long term.

Thank you again for joining us today. And with that, we will turn it over for questions.

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**QUESTIONS AND ANSWERS**

**Operator**

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

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**Lilia-Celine Breton Lozada JPMorgan Chase & Co, Research Division - Research Analyst**

This is actually Lili on for Robbie. So first one on CONVERGE. It sounds like you guys already know what path you'll be progressing approval or approval without a panel. So what's holding you guys back from moving forward here? What of your conversations with the FDA have been like recently? And is it still reasonable to assume some sort of update in the first half of the year? And then I just have one quick follow-up.

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

Yes. I'll start with the end. And it's very reasonable to assume that we're going to have an update very shortly as I mentioned in my comments. And you're right, we do know the answer to the question that you did ask relative to that. What's holding up is just we just need paper in hand from the FDA. Once we have that, we'll be able to announce whether or not it's going to panel or we've got the approval. As I mentioned in my comments, though, obviously, you've seen all the data. We feel very confident in our eventual chance of getting the approval there. So that's really what we can say about the CONVERGE piece at this time.

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**Lilia-Celine Breton Lozada JPMorgan Chase & Co, Research Division - Research Analyst**

Okay. Great. And then just one quick follow-up there. Any color you could provide on the exit rate coming out of March and how that's continued into April? And what sort of cadence over the rest of the year your guidance range assumes?

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

Sure. We exited strong. I don't know that I understand exactly what exit rate per se means, but we exited the month of March and March was very strong. It really picked up at the end of February and continued into March. That rate has continued into the month of April as well, as I mentioned during my remarks. We do anticipate that we'll have a -- I think -- if you think about the revenue, we will be better in the second quarter than we had initially anticipated. And the back half of the year will continue to be strong as we had anticipated. We had already put into our numbers and our guidance originally, really having a strong back half of the year. So most of that's going to probably come into the second quarter, which is where we kind of had some of the softness in our original guidance that we've now updated and increased.

**Operator**

Next question comes from the line of Rick Wise from Stifel.

**Frederick Allen Wise Stifel, Nicolaus & Company, Incorporated, Research Division - MD**

Maybe I'll focus on a couple of your major growth drivers. And just sort of -- I guess my question is sort of what's next? I mean maybe just help us appreciate given the amazing AtriClip left atrial management performance, what's next that -- separate from recovery, Mike, help sustain it? Continued new product rollout? Just if you could give us a little more granular sense and of your confidence in that area specifically?

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

Yes. I mean it's -- I appreciate the question, Rick. We're at a great point in AtriCure's history in my mind. We've got some considerable catalysts coming down the pipeline over the next several years that are going to drive the growth. You have some -- and you're seeing some of it in our numbers to some degree. First and foremost, obviously, CONVERGE, that will drive our MIS business. You saw we had a really strong MIS quarter. Part of that is because of the impact of COVID, but part of that is also because the data has been out there since May of last year. And people have seen that data at HRS and other places and lots of inbound inquiries and comments and people that are very interested in kind of adopting that. We think that's going to be a significant driver to our growth.

You add left atrial appendage on top of that, we're actually seeing an increase in the percent attachment of the AtriClip to the CONVERGE procedure specifically. And so that's also driving some of the short term growth. And we think that's going to continue. So that as the CONVERGE or the hybrid therapies grow, you're going to get the clip on top of that, and eventually, possibly even some LARIAT with the aMAZE data. So getting to the second piece, which is on left atrial appendage, we've got a rich pipeline of not just great products with the AtriClip, but obviously with aMAZE, having fully enrolled and followed up on that trial, now we're compiling the data. We are in a great position that within a couple of years to get an approval on that and then move that forward as well as another standard of care. You combine that with CONVERGE, and really, we're the only ones that will be out there with that kind of robust ability to serve this huge market, which is the long-standing persistent patient population.

On top of that, we do have other catalysts coming down the pipeline. I mentioned EnCompass getting clearance on that. The penetration rate still is ridiculously low in cardiac surgery for treating the Afib patients. We believe EnCompass will help with that for sure. And then on top of that, you've got your pain management franchise where we're really building out that team quite aggressively right now. We plan on almost doubling it probably over the next 12 or so months, 12 to 18 months. Every time we add somebody in a new area, there is great interest and it continues to drive growth. As you've seen, we've had sequential growth every single quarter since rolling out that product.

**Frederick Allen Wise Stifel, Nicolaus & Company, Incorporated, Research Division - MD**

And maybe one for Angie on gross margin. You were very clear that the first quarter. I think that must be -- might be -- must be a record gross margin for AtriCure or certainly in my memory. But how do we think about -- I guess, 2 things really, but I want to make sure I understand was it that international was so weak or the products were so strong and that won't sustain because international is going to recover. And so that will be the drag? I'm not sure I understand as clear as I'd like the dynamics there. And again, how do we think about -- for the rest of the year, are you suggesting we should be thinking about sort of 72%, 73%? And then roughly that for the year, is that the right way to think about it, Angie?

**Angela L. Wirick AtriCure, Inc. - CFO**

Yes. Rick, you have a great memory, 75% this quarter is one of our best and most recent history. The unique mix that we saw was the U.S. contributing 85% of total revenue. We typically are 80% to 82% with the U.S. contribution. And so what you'll see what we would expect for the rest of the year is international to rebound and play a bigger percentage of the overall revenue. And that's a headwind when we think about margins coming down from 75%.

Our full year outlook, I think, will show some modest improvement over where we've been historically and continue to target and progress towards 75%, but that on a consistent basis is a more long-term target in the coming years.

**Operator**

Next question comes from the line of Mike Matson from Needham.

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

Yes. This is David Saxon on for Mike. I guess, first, on the hybrid sales team, if memory serves, there weren't any new hires this quarter. So I guess, are you guys happy with the size of that team going into a potential Convergent approval? Or do you expect to make additional hires? And then other than approval, anything else that needs to be accomplished before you launch?

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

Yes. We're actually adding -- we'll be adding significantly to the hybrid team over the coming years. We feel like we are ready to the launch. We're in a great position with a number of reps. We've actually added kind of a management layer where we've converted some of the reps into area directors. So we've now got 6 areas around the country. That team is fully staffed now and then we've fully backfilled them. So we actually have been hiring, but it's more been kind of backfilling some of the people that have been promoted to take on larger management roles on that front, and we will continue to hire in that area. But we're well positioned. We've got the country covered. We feel like we're in a really, really good place on that front.

On top of that, I mentioned about the education and training team. In order to really roll this out effectively, we've got to have a robust team there. And we'll continue to add to the number of people we've got on the education and training team as well. And so yes, we will continue to add headcount over the course of the year.

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

Okay. Great. And then I guess just one on guidance. You're raising revenue, but maintaining EBITDA. So I mean, I guess, other than the new hires, any other investments that you want to call out that, I guess, is resulting in maintaining that EBITDA loss guidance?

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

Sure. I mean that's the -- go ahead, Angie. You got it.

**Angela L. Wirick AtriCure, Inc. - CFO**

We typically see a heavier loss in the first quarter and some of the project spend has shifted out. I mean you called it out, we are leaning into our catalysts for the future and adding to the team and adding training and education programs, anticipating pretty sizable launches the rest of this year. That's the kind of the thought behind the \$10 million in managing to that bottom line number.

**Operator**

Next question comes from the line of Danielle Antalffy from SVB Leerink.

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

Mike, I just wanted to follow up on a prior question as it relates to the revenue guidance. And maybe this is just The Street sort of mismodeling in Q1. But you mentioned you now are seeing potentially better momentum than previously expected heading into Q2. You beat the consensus number by a couple of million dollars. But you're only taking it up by about the beat, it looks like at the midpoint of the range. So just curious about if you could help us help bridge us there? Is this just sort of normal conservatism? I know you guys tend to be on the more conservative side. And then I have one follow-up.



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

Sure. I mean I'd look at it as -- we do anticipate that we'll have strength in the second quarter. We're just making sure that this continues. It has continued in strength in April. Obviously, just with some uncertainty as we kind of come out of the pandemic here, just making sure that Q2 is in a solid place from that standpoint overall. And then the back half shouldn't change much from what we had previously guided to.

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

Okay. That's fair. And then I guess my follow-up question is on CONVERGE, and it's sort of you mentioned fully prepared to launch. But I guess just from a strategic perspective, how should we be thinking about the early days of the launch and how quickly this can ramp? And how much upside there could potentially be to your guidance depending upon when we get news on CONVERGE and when this actually comes to market?

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

Yes, the upside of this year is going to be -- I mean, obviously, there's always the potential for upside on CONVERGE. But it's mostly really due to COVID. As COVID comes back, and I think that's what we saw, in March and has continued into the April time frame is that just as hospital beds open up and they're allowing these procedures to occur, that's what's going to drive the upside for us in 2021, both on -- both sides of our business, inclusive of our pain management side and obviously on the ablation side of our business as well. So that's really what's going to drive the upside in 2021. CONVERGE will clearly be a driver for significant growth in 2022. That's really where we see CONVERGE and then the Clip on top of that because of the attachment rate that we anticipate getting with it, that's where you'll start to see kind of some acceleration from those 2 in 2022.

**Operator**

Next question comes from the line from Matthew O'Brien from Piper Sandler.

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

Mike, just to push a little bit on CONVERGE. I think coming out of the Q4 call, a lot of us were kind of expecting, hey, it's going to be soon in terms of a decision one way or the other. So I think for investors, it might be helpful just to talk a little bit more about, I think you had said you had a sense for it back then and you felt pretty good about it back then and now fast forward a couple of months, and it's much of the same. Is there something that's a little more tangible that we can bite down on that helps us understand what the delay from how we see it might be in terms of getting that paperwork? Is it an administration change? Is it the reviewer? Slowdown at the agency? Is there something specific that's a little bit more tangible that we can look to?

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

A little bit all of the above, I'd say, when you look -- it's all administrative at this point in time. I mean I feel really good about kind of -- I wish I could tell you that I had the approval in hand or I had something to kind of announce to you on a date. But I don't. And I can't. And I think that it's an administrative thing more than anything else.

If you think back to the quarter, there were -- they did do a panel meeting. That definitely took, it was the same team that has been on top of ours. That was a part of the panel meeting that occurred this quarter. That definitely obviously was in the level of, I think, review and time that they had to spend on that was probably more than they had expected, which obviously causes some aspect of delay on our side. The interim branch chief did leave, but the person that came in has done a wonderful job. Again, we've had a really good collaborative pieces, but it's been mostly on the administrative side, to your point, in terms of any kind of delay from your perspective. Again, I wish I could say something today. Obviously, I can't. I understand why you're asking that question, but I'd say it's much more of an administrative thing than anything else. There's nothing fundamentally wrong in any way, shape or form other than that.

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

Okay. That's very helpful. Appreciate that. And then on the U.S. MIS business. I know there's some catch up, although sounds like January for pretty much everybody was pretty soft. So sure there was some slowdown there, but some catch up maybe in March. But if you look at things on a 2-year stack, you have not put up that level of growth in the MIS business over the last 2.5 years. So clearly, something is going on outside of just maybe some catch up in procedural volumes. Is there anything to point to in terms of potentially



new clinicians or going deeper in existing accounts or anything along of those lines or case. It's taken a while for people to look at the data, process it, get their programs up and running, and now they're starting to do more cases, anything along those lines?

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

Yes. You're definitely seeing a combination of 2 things. I mean one is that the first thing that got impacted by COVID was, for sure, the MIS side. So you've got a really weak end of March in 2020. But you pointed out is that we do have -- the data has been out there now. It's been presented. It's been presented at HRS in May of last year. HRS did a special session on it in November and then the long-term data came out in January. I'd say just the totality of evidence that continues to come out, get put out and published around this procedure continues to show that it is an incredibly durable procedure that works very well in these sick patients. And so you're starting to see more and more programs for sure get up and running. And those that were doing it begin to come back and say, wait a second, I really need to take a second look at that and begin to go down that path. And so I think that you're definitely starting to see the beginning of that happening for sure.

**Operator**

Next question comes from the line of Bill Plovanic from Canaccord.

**William John Plovanic Canaccord Genuity Corp., Research Division - Analyst**

Great. So on CONVERGE, just clarify, I know 3 questions have been asked, but there's no final data or any animal or any type of data you need to provide. It's truly admin, you're just waiting on at this point? And then my follow-up question is just relative to your R&D spend. And Angie spoke about the investments a bit. But I was wondering if you could provide a little more granularity on kind of what you're really working on there?

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

Sure. Yes. Just to clarify, it is admin. There's no additional work to be done on data for animals or anything else relative to this. It is purely, at this point in time, an administrative piece. I'll turn it over to Angie maybe to give some more details on the R&D spend.

**Angela L. Wirick AtriCure, Inc. - CFO**

Sure. Bill, a couple of the key areas of spend are the continued work on the aMAZE trial, patient follow-up during the quarter. We also have the continued access protocol with aMAZE that includes new patient enrollment in that particular study. A couple of other clinical trials ongoing, ICE-AFIB and DEEP. And then from a product development perspective, you're seeing pretty heavy spend with EnCompass, that's the new open clamp. And then a few other projects that are in the pipeline that you'll hear about from us in the coming years.

**William John Plovanic Canaccord Genuity Corp., Research Division - Analyst**

Okay. And if I could throw a follow-up in there. Just I think one of the questions we get is, as we talk about the aMAZE trial and LARIAT coming is -- how is that going to fit into the portfolio if you think about having the AtriClip out there, you got the CONVERGE procedure and then now you're going to have the LARIAT as well?

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

Yes. Just in -- number one is that it's our first product that's actually going to be used by the interventionalists, whether it's the electrophysiologist or in interventional cardiologists, primarily EPs at this point in time, but it really kind of gets us into that realm, has a product for them to put into their hands to serve in the same way that the AtriClip does. I mean it's got obviously very similar characteristics and that it's epicardial on the outside. It's less invasive. And so there's obviously trade-offs both ways. Our strategy is that we believe that in combination with other ablation techniques can really improve the Afib outcomes, can take the appendage out completely, does not leave anything inside, and is a superior technology overall. And so we feel like we're going to be in a really good position to be able to offer that, that you're going to be able to reduce the Afib. And we've already shown that with the clip from an electrical standpoint. We're obviously suiting to prove that out with the aMAZE trial. And that's going to position us well to have really kind of a holistic, robust solution and give them the choice to make.

**Operator**

Next question comes from the line of Suraj Kalia from Oppenheimer & Company.

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**Suraj Kalia Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst**

Mike, can you hear me all right?

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

Yes.

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**Suraj Kalia Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst**

Congrats on the quarter. My 2 questions from my side. Just piggybacking on Bill's question. So Mike, it's a foregone conclusion, aMAZE will show positive outcomes in stroke prophylaxis and AF burden reduction with the use of LARIAT. So I guess when you're looking at the complete portfolio, right, I'm more interested in AtriClip versus LARIAT. Like you said, the end user is different. The reimbursement pathway for the physician is different. Help us understand, how -- should we expect a product bifurcation within the appendage management itself? Moving forward, how should we think about -- will there be a pull-through for the AtriClip? Or is it going to be lost to LARIAT? Because LARIAT is going to be the one with tangible data, I would say, within the framework of the aMAZE trial.

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

Yes. I think it's going to be a little bit of both. It's a very good question, and I actually think it's one of our differentiators and that we're going to actually offer up for the physicians to provide to their patient choices. And what's going to work best for that particular facility in terms of how they best want to treat their patient. Some physicians are going to be very comfortable and are going to go down the LARIAT pathway, and we'll be able to support them. Some really like what they get out of the Clip, and we'll be able to support them there. Right now, the Clip is what we have that's in the market. And so that's what's becoming and getting attached. LARIAT, really, is not out there yet. Once we get the aMAZE data, we get the aMAZE approved, that will obviously change several years down the line, and then they'll probably have some questions to ask, which way do they want to go? Do they have the skill sets and do they want to go down the LARIAT? Either way you're talking about managing the appendage, and we're providing them with both options and both are really good options for them. And we're not going to dictate to them which way they go. We just want them to manage the appendage because we think it's in the best interest of the patient. And so we're going to leave that up to them. And it's interesting, depending on the EP that you talk to, some really want you to put on the Clip, and they don't ever see themselves going into the LARIAT world. Many others are like they can't wait to see the LARIAT come down, and then they'll move down that pathway. And again, we're going to be indifferent. We're going to do what's in their best interest and how they want to build their program out.

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**Suraj Kalia Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst**

Got it. Mike, on CONVERGE, if I listen to your comments, logic dictates approval is imminent, and we are going to bypass the panel. Help us understand the low-hanging fruit, let's say, for the next 3 to 4 quarters. And the reason I ask is, in the past, you guys have reported about, I believe, memory tells me 3,000 or so procedures in CONVERGE have been done? Correct me if I'm wrong there. But should we expect a step change in CONVERGE demand post-approval? Or should we expect a gradual uptick because it is being used technically off-label?

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

Yes. Well, it's actually not being used off-label. So I want to just make sure I -- we want to address that. I mean we do have a very strong label today for cardiac tissue ablation. And so that is how the product is being used today. It is absolutely an on-label use of the product today, even before the approval does happen. So now that being said, in terms of the question you asked relative to, what does this mean for an uptick, and you put it out for 3 or 4 quarters. We really view this as you'll start to see some accelerated growth in 2022. 2021, whenever the time is that we actually get there, again, whether by panel or by an official approval beforehand, what that's going to look like is getting sites up and running. We've got them segmented. Every territory has picked out key sites they're going to go into. Make sure that they've established a beachhead in every area of the country. We're being very strategic about going after them, building up those programs, learning from that and then kind of building out and accelerating. We think that we want to take the rest of this year regardless of when we get that approval to really kind of build that out. And we're starting to see some of that happen organically already even before the approval because we're getting approached by certain sites.

That being said, 2022, we do anticipate that's when you'll begin to see the ramp and maybe -- I don't know that I would call anything

low-hanging fruit, but I would say that you'll start to see the ramp in terms of having programs that are more established and able to kind of take advantage of the training and education we're providing them.

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**Operator**

(Operator Instructions) Next question comes from the line of Marie Thibault from BTIG.

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

I'll ask both of mine here right upfront. On 2 new products that we haven't really touched on too much today in the discussion. The first is on Cryo Nerve Block. I think you said in your prepared comments, 6% of total revenue, which is certainly material and impressive. Wondering what in terms of the investments you mentioned you're making, what more you can be doing there to expand use of Cryo Nerve Block and sort of where you see that product could go in terms of helping the open market grow faster? And then secondly, on EnCompass. It sounded like this could be something that's material to revenue in 2022. What are sort of your early plans to -- once that's approved, get that into the hands of cardiac surgeons and encourage use there? And I appreciate the question.

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

Great. Well, thank you, Marie. I appreciate the question. On pain management, Cryo Nerve Block, you're right. It's an exciting part of our business that we have invested and we've added significantly to the headcount on that team. We've got around 20 or so people out in the field right now. That continues to grow. So the #1 major investment is to get people to cover the United States. We need to get coverage in all major cities and areas because when we do, do that, now that we've learned the pattern for how to actually open up a city and get the right person and get them trained, the training is less than what you would see on the Afib side of it. So we can kind of have an impact a little bit more quickly. And we do anticipate that, that will continue to accelerate as this year goes on into next year. It's going to continue to be a big part of our business and a growing part of our business for years to come. The key there is, again, getting more and more people out there to getting coverage. That's where the major investment is. The second piece that we need to invest in is really continuing to get clinical data. You've heard me talk about it about all of our therapies. We really believe clinical data matters. It does change the way that people can treat. And so as a result of that, we will probably continue to invest in various different trials, not necessarily IDE trials, but we will invest in trials so that we can get data to prove out the therapy even further than what the data already suggests and shows.

The third piece really is eventually getting it into Europe. And we have applied for and are looking to try to get that into Europe over the coming years. And so that's going to be another one that we anticipate being some upside to us. They're chomping at the bit over there to use it, to hear about it at conferences from the U.S., and they definitely want access to the cryoSPHERE product.

As it relates to EnCompass, it's a great question. EnCompass is a great product. We're really excited about it. As I mentioned on the call earlier, what we see is we believe that's going to enable us to continue to grow into that kind of mid-to-high single digits in the open franchise for years to come. That really kind of helps us build upon it so that cardiac surgery isn't necessarily a growing area, but we believe through penetration and getting more people to use products, that's what EnCompass allows us. You're not going to have a hockey stick kind of growth curve that you're going to see with the Clip or the LARIAT or the Cryo Nerve Block or the EnCompass -- not the EnCompass, excuse me, the nContact product that is now EPI-Sense. And so that is really where you're going to start to see. Those are going to be big inflection points. EnCompass is going to be kind of steady as she goes.

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**Operator**

There are no further questions at this time. I would like to turn the call over to Mr. Mike Carrel for closing remarks.

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

Great. Again, thank you, everybody, for joining us today. We really appreciate you listening in and learning about all the great catalysts in the wonderful quarter we have. 2021 is going to be a banner year. Appreciate it, and have a wonderful evening. Bye now.

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**Operator**

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

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