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Q1 2022 AtriCure Inc Earnings Call

EVENT DATE/TIME: MAY 03, 2022 / 8:30PM GMT

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## PRESENTATION

### Operator

Good afternoon, and welcome to AtriCure's First Quarter 2022 Earnings Conference Call. My name is Jeff, 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 Marissa Bych from the Gilmartin Group for a few introductory comments.

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### **Marissa Bych** *Gilmartin Group - Vice President*

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 expectations and guidance, expectations regarding the potential market opportunity for AtriCure's franchises and growth initiatives, including the adoption of the Hybrid AF procedure and future product approvals, clearances and reimbursements. 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 measures with the most directly comparable GAAP measures is included in our press release, which is available on our website.

And with that, I would 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*

Good afternoon, and thank you for joining us. We hope that you're all well. I'm pleased to share that AtriCure delivered an excellent first quarter results as growth across key product lines and geographies demonstrated the strength of our portfolio despite challenging conditions to begin the quarter.

We generated \$74.6 million in revenue, reflecting growth of approximately 26% over the first quarter of 2021. Highlights for the quarter included the growth of our cryoSPHERE probe for pain management and strength in our AtriClip product line, showing the broad appeal and continued adoption by new and existing customers.

Before providing a more detailed review of our business, I would like to comment on the operating environment today. As discussed on

our fourth quarter 2021 call, the Omicron variant brought capacity and staffing constraints to our customer base early in the year, and we experienced pressure to the cardiac procedures globally, in particular, elective procedures. However, as conditions began to improve in late February and early March, we saw a strong return in procedure volumes and demand. This stability has continued into the second quarter, and we are gaining momentum.

Based on the current backdrop and considering continued robust physician interest in our therapies, we remain confident in our ability to execute over the remainder of the year. As a result, we are increasing our 2022 revenue guidance to \$318 million to \$330 million, reflecting full year growth of approximately 16% to 20%.

Now let's focus on the initiatives driving our growth, starting with Hybrid AF therapy. Last week, we celebrated the 1-year anniversary of PMA approval for the Epi-Sense system for the treatment of patients with long-standing persistent Afib. This approval resulted from the groundbreaking CONVERGE trial, which demonstrated the superiority of Hybrid AF therapy using our Epi-Sense system with an endocardial catheter versus the endocardial catheter ablation alone. Hybrid AF therapy is additive to catheter ablation and the only FDA-approved stand-alone treatment for patients with long-standing persistent Afib, giving AtriCure a clear and differentiated position in a vastly underpenetrated market.

Key accomplishments over the last year include completion of multiple Hybrid AF therapy training courses, which have been co-sponsored by the Heart Rhythm Society, or HRS, expansion of our customer base and increasing AtriClip attachment in Hybrid AF procedures. The response to the launch and our training programs has been excellent, and we continue to see great potential and add new and grow within existing accounts. Therefore, as the year progresses, we expect sales of the Epi-Sense system to accelerate.

We also continue to make investments in our sales team, enhancing clinical support and adding therapy awareness reps to build comprehensive and effective programs for providers and their patients. With millions of diagnosed Afib patients and roughly 45% of those considered long-standing persistent, we possess the unique opportunity to establish Hybrid AF therapy as the standard of care in the coming years as it is the only proven therapy for these patients.

Turning now to our open ablation franchise. We are excited to have recently announced our full-scale commercial launch of the EnCompass Clamp in the United States following FDA 510(k) clearance last year. EnCompass provides a simpler and faster approach to ablating in open-heart procedures, leveraging the proven technology of our synergy ablation system.

While the contribution to 2022 revenue will be moderate, feedback on our initial limited launch has been exceptional, and we are already seeing growing interest from physicians. With the addition of EnCompass, we expect to sustain upper single-digit revenue growth in our open ablation franchise and deepen our penetration of the cardiac surgery market.

Complementing the opportunities for our open and minimally invasive or hybrid therapies is our appendage management franchise. The AtriClip product line has driven consistent growth over the decade as continued innovation and increasing awareness to manage the LAA has led to broad adoption globally.

In the first quarter of 2022, our appendage management franchise delivered revenue growth of approximately 30%, reflecting record sales of the AtriClip Flex V and PRO-V devices. There is ample opportunities still ahead as we grow Hybrid AF therapy, increase penetration in cardiac surgery and pursue clinical trials to extend our addressable markets, and more will be made on that point in a moment.

Next, I would like to highlight our pain management franchise. Cryo Nerve Block therapy continues to be the fastest-growing part of our business. Our unique technology, the cryoSPHERE probe uses a differentiated freezing method to block nerves from transmitting pain signals after thoracic surgery, providing a long-standing form of pain relief for patients. Pain management has an important -- was an important driver of our first quarter results with sales of the cryoSPHERE probe roughly doubling year-over-year.

We have been pleased to see consistent growth of our customer base reflected in procedure volume and account traction to date. Even with this incredible growth, the ability to impact patients undergoing thoracic surgery remains a significant opportunity for AtriCure, and

we continue to make investments in our commercial and training teams while expanding clinical evidence for the Cryo Nerve Block therapy.

Finally, I would like to discuss a few key and exciting clinical and regulatory developments that position us for sustained long-term growth. Starting with the LeAAPS clinical trial, I am thrilled to announce that last week we received FDA approval to move forward with our landmark clinical trial. LeAAPS will examine the prophylactic use of AtriClip devices in cardiac surgery patients without preoperative Afib diagnosis with the primary endpoint of the randomized controlled trial demonstrated a reduction in ischemic stroke in systemic arterial embolism.

As a reminder, over 2/3 of the nearly 1 million cardiac surgery patients worldwide do not have preoperative Afib diagnosis. With this clinical trial, we are one step closer to a meaningful expansion of the addressable market for our appendage management franchise.

The LeAAPS trial will take a number of years to complete with enrollment targeting 6,500 subjects at up to 250 sites globally. Using early interest in the study as an indication, we expect awareness of appendage management in all cardiac surgery procedures to be a topic of increasing scientific interest.

We are also cultivating markets that are highly complementary to our core competency of treating complex arrhythmias, leveraging the unique physician relationships we have developed and building upon our technology platforms. Earlier in the year, we detailed plans for HEAL-IST, a new IDE trial for the treatment of patients with inappropriate sinus tachycardia, or IST, using hybrid ablation procedures. IST is characterized by an elevated heart rate and distressing symptoms of heart palpitations contributing to the inability to sleep or exercise. Like Afib, IST has dramatic impact on a patient's quality of life. And currently, there are no approved treatments.

I am pleased to share that we received FDA approval for the HEAL-IST trial and are now beginning site initiation followed by first patient enrollment. In addition, we are making progress on the development of a dedicated device for this therapy. Our approach to the significant market -- the significant unmet need for treatment of IST patients follows the hallmark of AtriCure: innovative technology, combined with robust clinical science and advanced physician education.

In summary, we remain excited about our future. Much like the last decade, we continue to deliver on our immediate opportunities while we make investments in long-term growth drivers.

I would like to thank the AtriCure team for their dedication to our patient first mission and focus on execution as we capitalize on these opportunities and bring life-changing technology to market.

I will now turn the call over to Angie Wirick, Chief Financial Officer, to discuss more detailed results for the quarter.

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

Thanks, Mike. Leading the review of our financial performance, I would like to call out adjustments to our revenue reporting framework this quarter. We are disaggregating cryoSPHERE sales from our open ablation revenue to provide more insight to the growth of our pain management business.

Quarterly U.S. pain management sales in 2021 were approximately \$3.9 million, \$5.7 million, \$6.2 million and \$6.9 million, respectively. Additionally, we have combined valve revenue with open ablation revenue. A summary of quarterly franchise revenue is included in the investor deck filed along with our earnings release this afternoon. Retrospective and prospective analysis presented in subsequent remarks also account for these adjustments.

And now turning to our financial results for the quarter. Our first quarter 2022 worldwide revenue of \$74.6 million increased 25.8% on a reported basis and 26.7% on a constant currency basis when compared to the first quarter of 2021. As Mike noted earlier, we saw solid growth across key product lines and geographies, bolstered by outstanding results in pain management and appendage management.

On a sequential basis, we experienced growth of 1.9% in our worldwide revenue from the fourth to first quarter. Cardiac surgery

procedure volumes, in particular, elective procedures faced pressure at the beginning of the quarter, but have since rebounded and stabilized.

In the first quarter 2022, U.S. revenue was \$62.3 million, a 23.8% increase from the first quarter of 2021. Open ablation product sales, which no longer include pain management, were \$19 million compared to \$17.4 million, up 8.8% over 2021. Pain management sales were \$8 million compared to \$3.9 million, up 105.6% over the first quarter of 2021. U.S. sales of appendage management products were \$26.7 million, up 29.5% over the first quarter of 2021. And minimally invasive ablation sales were \$8.6 million, up 2.7% from 2021.

Due to the elective nature of the procedures, our MIS business was more directly impacted by Omicron-related disruptions relative to our other franchises early in the quarter. However, we saw low double-digit revenue growth from the EPI-Sense product year-over-year, which offset declines in other MIS ablation revenue. With the addition of new sites and physicians over the past year, we are confident EPI-Sense revenue will pick up significantly as the year progresses.

International revenue was \$12.3 million, up 37.2% on a reported basis and 43.1% on a constant currency basis as compared to the first quarter of 2021. European sales accounted for \$7.2 million, up 25.5% over the prior year, driven by increased volume throughout our major markets and partially offset by unfavorable exchange rates.

Asia and other international markets accounted for \$5.1 million in international sales, up 58.3% over the same period in the prior year. Much of this increase came from China with smaller boosts from Japan, Canada and Australia.

Now turning to another key metric for the first quarter of 2022. Gross margin was 74.5%, down 60 basis points from the first quarter of 2021. While we are experiencing modest cost pressures, the decline in gross margin primarily reflects geographic and product mix between years.

U.S. product sales accounted for 84% of the first quarter 2022 revenue compared to 85% of the first quarter 2021 revenue, and the shift in 2022 was largely to distributor markets, specifically Asia, with a lower gross margin. Fortunately, as a result of the ongoing diligence of our operations and quality team, we have been able to navigate the pandemic and unprecedented supply challenges without interruption to our customers.

Now moving to detail on operating expenses for the quarter. Total operating expenses increased \$9.3 million or 15% from \$60.4 million in the first quarter of 2021 to \$69.7 million in the first quarter of 2022. The change results mainly from the addition of head count over the last year, expanded physician training programs, including our mobile labs, meetings and trade shows shifting from virtual back to in-person events and travel returning to normal levels. These increases were offset slightly by the elimination of a \$2.5 million charge for the change in contingent consideration, which was included in the first quarter of 2021.

Adjusted EBITDA was negative \$4.2 million compared to a negative adjusted EBITDA of \$4.7 million for the first quarter of 2021. Our loss per share was \$0.33 in the first quarter of 2022 compared to a loss per share of \$0.38 in the first quarter of 2021, while the adjusted loss per share each period was \$0.32 -- \$0.33 and \$0.32, respectively.

Our balance sheet is strong, and we ended the first quarter with \$182 million in cash and investments. As a reminder, cash burn in the first quarter is typically higher than the remainder of the year based on cash tax payments due upon stock vesting and annual variable compensation payouts. We expect our quarterly cash burn to reduce significantly for the remainder of the year.

Finally, turning to our outlook for 2022. Given the strength in the underlying business and the results of the first quarter, we now expect to achieve approximately \$318 million to \$330 million in revenue for the year, reflecting growth of approximately 16% to 20%. These growth rates represent an acceleration of over our historical growth, driven by expansion of the Hybrid AF therapy and pain management, along with continued strength in appendage management.

With the COVID impact subsiding, we do expect pre-pandemic seasonal trends to reemerge, balanced by the building momentum from expansion of our therapies. So with that lens, we anticipate a moderated sequential increase in revenue in the second quarter of 2022.

We continue to expect 2022 gross margin to be comparable to 2021 with the potential for varying impacts from increasing costs and mix. We are maintaining our level of investment in research and development activities, ensuring a robust pipeline and growing clinical evidence across our therapies. Additionally, our plans anticipate the thoughtful expansion of our commercial team, along with training and awareness programs. Therefore, we continue to expect adjusted EBITDA to be a loss of approximately \$2 million to \$4 million for the full year 2022, corresponding to an adjusted loss per share for 2022 of approximately \$1.07 to \$1.12.

With improvements to the top line throughout 2022, we should realize a corresponding improvement in quarterly adjusted EBITDA. We are well positioned as a result of the ongoing investments in our catalyst-rich future and are making meaningful progress towards profitability.

And 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. I would like to end by recognizing the AtriCure team and the collaboration that has led to so many breakthrough achievements in our history. The CONVERGE approval for long-standing persistent patients 1 year ago was a watershed moment for the company. Additionally, we continue to be innovative in other areas with the launch of our EnCompass Clamp and therapy development for pain management.

So a huge thank you to the AtriCure team for your dedication to our shared vision to establish our therapies as the standard of care for patients around the world. Together, our work will have a lasting impact. And as our team continues to grow in preparation of the opportunities ahead of us, we are committed to maintaining a welcoming and mission-driven organization that brings meaning to our employees and drives a brighter future for patients and providers.

Thank you, everyone, for joining us tonight. And with that, we'll open it up to questions.

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**QUESTIONS AND ANSWERS**

**Operator**

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

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**Lilia-Celine Lozada J.P. Morgan - Equity Research Analyst**

It's Lilly on for Robbie. First, could you guys talk about how you're thinking about minimally invasive growth over the rest of the year? It's been about a year since the CONVERGE launch. So are there any metrics you can share on when you've seen doctors start to ramp up their procedure volumes? And what do you think that means for when we could see an inflection in adoption here?

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

Yes, we're definitely starting -- I mean, we've added a lot of net new customers over the last year, as we talked about. And we will give out a number later on in the year. We're not ready to give out an exact number of sites right now. I think when that number is more meaningful.

That therapy did have the impact of Omicron earlier in this quarter. So that was the one that got impacted the most in kind of the January and February time frame. We did see an acceleration into the March time frame, and we anticipate that accelerating as the year goes on.

We are seeing an increase per site. We're also seeing an increase in the number of sites right now. We're not ready to give that exact number out yet, again, because I think it's going to be something more meaningful later on in the year when we kind of think about how to kind of give that out to everybody. But we're already starting to see some of that momentum build.

As an example, if you actually look at our -- some of the sites and you look at like the top 5 cardiac centers in the United States, we're already in 3 of the top 5 centers in the United States today. That's really new over the last 18 or so months, and those have been

accelerated and building momentum as well.

And so we're really starting to see a lot of really nice momentum across the board with the training and the education that we're doing. And we'll get into some more specifics again later on in the year to be more helpful to you.

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**Lilia-Celine Lozada J.P. Morgan - Equity Research Analyst**

Okay. That's really helpful. And then maybe just one on the P&L. You guys are border line breakeven now. So could you give us your high level thoughts on how you're balancing between investing in the business with all the pipeline products you have versus driving profitability? And is the back half of the year a reasonable time frame to expect you guys to be sustainably profitable?

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

Sure, Lilly. And it's a fair question. I think we will naturally reach positive EBITDA for the full year in the coming years. And this year, as we discussed in the prepared remarks, we expect our adjusted EBITDA loss to be in the range of \$2 million to \$4 million, which is an improvement over our historical levels and over what you saw in 2021. But at this stage, we are really focusing on the opportunities within each of our franchise and intend to improve -- to prioritize kind of the investments and programs that we've detailed on this and other calls to help us sustain and continue to grow beyond our historical rates.

So as you would expect with the expansion of the top line, we're going to see some leverage in our operating expenses and would reach EBITDA positive for the full year pretty naturally. As you think of the rest of the year, given the guide of \$2 million to \$4 million of a loss in our results this quarter, you should expect positive EBITDA kind of for the balance of the year.

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**Operator**

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

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

Congrats on a good quarter. I guess, Mike and Angie, if I could follow up on the Epi-Sense business. And I get that it's elective and so sensitive to Omicron. But I guess this -- it's still so early in the launch. Can you talk a little bit about some of the dynamics, thinking maybe this is a procedure where it takes a little bit longer from scheduling to actually doing it? Is that one of the dynamics that maybe makes it a little bit even more elective and difficult to recover, take longer to recover? Just trying to get a sense of what's going on there because it's still early in the launch.

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

I think you actually said that really well, Danielle. In terms of -- one of the items that we talked about -- I mean, the interest in this therapy is great. I mean, the EPs, the hospitals we're actually getting surgeons. Everybody's really interested in it. The big lift we've always talked about is actually getting that collaboration and logistics to come together. We are making great progress. We've got great programs in place in which we are enabling that to happen.

But like you said, when you do have an Omicron hit and you're kind of in the middle of setting some of those up, that does get kind of delayed and it does have some impact overall on us, which is what you kind of saw a little bit in the beginning part of this year when Omicron hit kind of in the December time frame and kind of wrapping into this year.

So I think you actually articulated it very well in terms of what that impact looks like. But to be true, as this year progresses -- we saw a really strong March and we anticipate we are going to see acceleration in this as the year progresses, because many of the sites that we got up and running last year should be in that phase of beginning to really show promise and show consistency on patient flow.

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

Okay. Got it. And then I'm curious -- again, I know it's early. But just what kind of patients are you seeing being treated with Epi-Sense? Is it more in the long-standing persistent never been treated before patient population? Any color on the type of patients that you're seeing? And whether you're seeing at the centers that have adopted, are they seeing a pickup in referrals from the outside cardiologists?

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

You know, it's a really, really insightful and great question, Danielle, because that actually is -- I just came back from HRS and I was at Western Afib earlier, and this is the conversation, which is: What is the patient population that best fits relative to this therapy? And we are definitely seeing long-standing persistent patients.

That's where there's really this extreme differentiation between the results, because there really are no results in any other technology there. So it's a very easy conversation for them to have with the patients that this is the only approval that is out there. They talk to their patients about that. They're getting into those types of conversations.

That being said, I will say that it's sometimes de novo. Sometimes, I'd say more than not, it's a failed catheter ablation from before. So many of these patients, maybe they failed 1 or 2 times before our therapy had been approved. Now they're bringing them back and saying, "Hey, there is a therapy out there for you. We know the other piece didn't work." And they're kind of bringing them back to kind of help treat them from that standpoint.

I'd say that tends to be the direction that a lot of these sites are going. What we do see as sites progress, though, is they start that way, and then they quickly see what great results they're getting in these really, really difficult to treat patients. And then they start to move to de novo. So the sites that have been doing this for a longer time tend to do more de novo. The earlier sites tend to do more failed catheter ablations because they're kind of testing it out. And that's kind of been the pattern that we've seen overall.

And the other piece that's kind of important is that more and more, there's a conversation about adding the left atrial appendage and the management of the appendage with a clip. And we're at about a 75% attachment today. And that's up from really kind of 60% to 70% most of last year. So we're definitely starting to see that ramp up as well.

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**Operator**

Your next question comes from the line of Bill Plovanic from Canaccord.

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**John Young Canaccord Genuity, Inc. - Senior Associate**

It's John on for Bill tonight. I also wanted just to ask a little bit on CONVERGE. What is the size of the dedicated sales force and clinical support to date? And are any more plans to add resources beyond the additional mobile labs that you guys already added? And how do you think about upstream education of cardiologists for it?

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

Yes. I want to make sure I'm answering. So I'll hit on a couple of different numbers for you that might be helpful. So on the overall kind of clinical support and sales team out in the field and the management team that kind of supports them is really at about 58 or so. So just approaching that 60 overall number. That is up dramatically over the last year. I think we've added 23 net new people over the last 6 months or so. So we've had a really dramatic investment in that team to get greater coverage and train them up on the clinical side. And so we're actually making really good improvements on that front.

Relative to the clinical side of things and the education piece, we've got 3 mobile labs around the country right now. We did add a new one in the first quarter in February. And those labs are getting busy and doing a lot of work and training a lot of people. And that's actually one of the key pieces to kind of bring the training to the sites and has been a very important way for us to kind of get out and get the word out and get the training out from that standpoint.

In terms of the number of people in clinical education, I don't have that number off the top of my head. Angie might be able to give it.

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

Yes. I think it's close to 45 at this point, John. And it's an area that when you think about investments that we're making, we're increasing the team size throughout the year.

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

And the 45, John, is -- some of that's minimally invasive. Some of that's -- or hybrid. And some of that's also just in general cardiac surgery. But a lot of them are trained in both. So they kind of cross train, and their ability to train in kind of all areas of it as well. But that number, 45, is up quite dramatically as well over the course of last year. Big investment, as Angie said.

**John Young Canaccord Genuity, Inc. - Senior Associate**

Great. That's really helpful.

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

Did I answer all your questions?

**John Young Canaccord Genuity, Inc. - Senior Associate**

You did. Sorry, if they are multiple. And then just turning to the Cryo Nerve Block business. We saw a little bit of the OUS revenue, was a new breakout. Can you talk about the rollout in Europe, some detail on which countries you're targeting? Which commercial resources you're using? And what you're seeing from reimbursement?

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

Yes. So we actually hit our 50th case about a month ago or so. So it's -- like it's up and running. It's being used. It's being talked about. It reminds me of probably about 2 to 3 years ago when Cryo Nerve Block started to kind of gain some traction in the U.S. and started to get word of mouth out there, because they started: "The product works, and it works incredibly well at reducing that pain after surgery."

We're targeting the core markets that you would think in Western Europe. Italy, Germany, the U.K. tend to be the 3 areas that are probably having the most uptake relative to that.

Unfortunately, on the reimbursement side, there is not really good reimbursement yet. We're really establishing the therapy and hoping that the clinical evidence that we're getting out there and these results will then help lead to some the reimbursement far into the future. But at this point, they're doing it because it works and it works incredibly well.

**Operator**

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

**John McAuley Stifel, Nicolaus and Co.**

This is actually John on for Rick today. Just as a first question, you had an excellent quarter with AtriClip sales and you mentioned a little early in the call I think you were getting a concomitant clipping rate at around 75%. Is there any way to shake out how much growth CONVERGE is helping drive from the AtriClip, if you can quantify that for me? And just maybe point to a couple of other key drivers of what's moving adoption forward here?

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

I'll hit on the adoption first, and then I'll let Angie maybe talk in more specifics about any kind of breakout from that standpoint. But -- I mean, one, the product works incredibly well. It's continuing to get a lot of momentum and conversation around managing the appendage is the right thing to do. The LAAOS III trial came out middle of last year, showing the benefits of doing it, concomitant in cardiac surgery with patients that have atrial fibrillation. And so we're the benefactor of really good science and data that's come out, that obviously bleeds over into other areas.

The other piece is that when you look at the just clear results of how well the product works at closure and when you see all of the new percutaneous devices, which are wonderful devices and do a great job -- but when they have an opportunity to put a clip on, they realize that they can pretty much get 100% closure, complete closure on that appendage.

And so more and more EPs as they're doing CONVERGE are saying they really want this to be a part of the full procedure. And that's really become -- kind of driving a lot of that and a lot of that attachment. It's not being driven by the surgeons. It's really being driven by

EP demand that they believe that the clip really does a wonderful job of closing off the appendage effectively.

That's what's really kind of driving it. I'd say the combination of data science that's been out there with knowing what's there from the success rates in the clip, those are the 2 things primarily that are driving it. And I'll let Angie maybe answer the second part of the question.

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

Sure. John, when you think about the growth rate of about 30% in AtriClip or appendage management, the minimally invasive appendage management products grew less than that just given kind of the softness that we saw in the MIS ablation revenue. So more of the growth was really driven by the open concomitant, the appendage management products that grew above the 30%.

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**John McAuley Stifel, Nicolaus and Co.**

That's helpful. And then just one more from me kind of on how CONVERGE is ramping up in existing centers. I'm curious from what you've seen. It's been approved for a year now. How long it's taking for physicians to get up to more of the high end of the adoption curve? And how you think that might increase or improve over time when best practices get established?

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

Yes. We're still really in the early phases of that. I wouldn't say that we're at any kind of optimal state at almost any site in the country at this point. So it's really kind of tough to say that we're there yet with anybody. I'd say that we're seeing lots of really good momentum and movement, and we're starting to see them begin to talk more and more to the referring cardiology base. I think John also asked -- the other John asked that question earlier about more conversations happening with cardiology and the referring physicians and kind of demanding this as one of the therapies that they consider as EPs.

So I'd say we're starting to see that momentum build. But again, we're not really at that phase. I know it's been a year. But think about through that year, we've gone through Delta, staffing issues and Omicron all in the middle of while we're trying to make a major launch and get sites up and running. So they've had a lot on their minds at those sites.

And so getting back -- in some ways what Danielle said before, we've actually had a lot of net new sites and growth within this area despite the fact that we've had a tremendous headwind against us relative to kind of COVID and the impact on staffing. And I think that you'll start to see in the back half of this year a lot of those sites that we've been working are going to start to build up momentum, and then next year will be a really gangbuster year.

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**Operator**

Your next question comes from the line of Marie Thibault from BTIG.

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**Sam Eiber BTIG - Equity Research Associate**

Mike and Angie, this is Sam on for Marie. Maybe on the EnCompass Clamp here. Can you help me frame maybe what's the opportunity? How many or what percentage of surgeons maybe wanted to do these concomitant ablations, but decided to punt before the clamp came out? And maybe as a follow-up, how much training is required to -- for them to start to feel comfortable with the redesigned clamp?

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

Yes. It's a good question. So I'm going to focus more on patients than on physicians, because when you think about the number of patients, only about 25% of patients today that undergo cardiac surgery that have Afib are actually getting treated, which means 75% -- maybe some studies say it's 70% -- it's a really large number of patients that are not getting treated undergoing cardiac surgery. Yet, it is a level 1 guideline by all the societies.

And we believe that by making it easier for those surgeons that are not used to getting behind the heart to treat that large bolus of patients, and we think this can make a dramatic impact on that. And that's about -- in the U.S., you've got about 85,000 to 90,000 or so patients that fit within that category of have Afib going into cardiac surgery, about 20,000 to 25,000 of them are getting treated, which

tells you the delta is what the opportunity is. And again, the guidelines say you should treat these patients.

And so we believe the EnCompass Clamp makes it a lot easier for them to really do a great ablation on this and on those patients and make a difference in their lives. And that's really kind of the target market, quite frankly. And so we're making good progress on that.

In terms of the training element of it, it doesn't take that long. But it does have a little bit of learning curve, meaning it's like usually 1 or 2 cases to kind of get really comfortable. We tend to do a lab in advance of it. We do both -- sometimes cadaver labs. But then we've also got models that we basically bring out, and they're able to kind of test those up. All of our reps have them, where they can kind of use the product in advance. We've also got really good tutorial and videos. And then we're in those initial cases with them. And it takes about 1 or 2 times to kind of get really comfortable. And then after that, they're off and running.

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**Sam Eiber BTIG - Equity Research Associate**

Really helpful, Mike. And maybe just a big picture question on staffing. Obviously, things are starting to get better in March and throughout April. I guess, at a high level, are things starting to normalize a bit? Are we at a level where maybe staffing is -- it's not getting any worse, it's not getting any better, but more just staying level at this point?

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

And I wish I could say that staffing was not a concern, but it still remains a concern for most hospitals. You guys read the same reports that I do, where hospital CEOs and systems are talking about the fact that the staffing issue is going to be with us for many, many years. I agree with your sentiment that it's not necessarily getting worse, but it's also not getting better. And they've learned to optimize and figure out the logistics at the hospital and how to take care of those that they've got there.

But there's less noise out in the system right now relative to it, but it's still there. There's still an underlying staffing concern that happens to be out there. Again, like you said, I don't think it's getting worse. But it hasn't gotten dramatically better either.

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**Operator**

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

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

Maybe starting with a 2-parter on guidance. I mean, it looks like you've really only raised the lower end by a little less than you beat in the quarter. Your commentary sounds pretty positive, especially with EPI-Sense expected to accelerate and the overall environment improving. So I just wanted to ask if you're seeing anything in the market that's a cause for concern, if the guidance is more reflective of tougher comps in the balance of the year and some conservatism?

And then the second part of the question. Angie, I think in the script you mentioned you're expecting a moderate sequential increase in the second quarter. So is mid-single digits the right way to think about that comment?

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

Yes. I'll start, and Angie can kind of add on to any kind of comments that I might have relative to the guidance. As we looked at the year -- like you said, we did bring it up by pretty much around what we beat in the first quarter. We still feel really good about kind of the remainder of the year. So I think what we're trying to tell you is keep the remainder of the year kind of as you had it. I think -- overall, I think that's the kind of basic message on that.

You're right, we do think that things are going to accelerate. But the comp in Q2 is the toughest comp for the year. You've heard that from other companies, where last year there seemed to be a little bit more backlog than what you saw from this year. But again, we still do see nice sequential growth from Q1 to Q2 this year for sure. And I think your numbers are in and around the range of where we need to be.

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

Yes. Maybe, David, I would just add: I think that just given this is the first quarter, even though we saw a strong first quarter result, it's still early in the year and we don't want to get ahead of ourselves. We're confident in the outlook for the year and the accelerated growth.

Now relative to your question over the moderate kind of increase first to second quarter sequentially, I think consensus is just under 8%, which historical results would tell you, you should expect something slightly better than that. I think historically, we've seen 9% to 10% sequential growth. So there's some upside to that number. And we'd be pleased with a 7% or 8% increase sequentially.

And as we indicated in the prepared remarks, we expect that as the year continues as we continue to drive therapy adoption and expansion, not just of Hybrid AF therapy, but you'll also see this in pain management and in our appendage management franchise, that we'll continue to gain traction and increase as the year continues.

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

Okay. Yes, that's all super helpful. And then maybe just on cryoSPHERE. I mean, we've been waiting to break it out. So it's nice to see that in this quarter. Maybe can you give us a sense of where you're seeing the most growth? Is it increased volumes in current accounts? Or is it adoption by new accounts?

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

It's a combination of both. I'd say what's been really remarkable and what we've been pleased to see is the consistency with which our team is adding new accounts, and that they continue to do procedures, but are also still driving deeper adoption within accounts. So every quarter, we're looking at new accounts and what contribution they make to revenue.

And it's been nice to see both the number of accounts and the percentage of revenue that they're driving being pretty steady and steady over a number of quarters. This isn't just an experience over the last quarter or 2, but we've seen that really since the launch in early 2019.

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

And congrats on the quarter.

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**Operator**

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

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

Mike, I'm sorry to beat a dead horse here, but you guys had a great performance across the board. The one area that's going to get attention is the domestic MIS business. And it's understandable that it could be a little soft given coordinating schedules, et cetera. Are there other metrics you can provide?

I don't know if the low double-digit number you mentioned earlier was the exit rate in March. But is that the exit rate you guys saw out of MIS in March? Is it getting better in April? Are you adding a ton of new accounts? Is it up 20%? Or is there any kind of metrics you could provide there? And then should we think about MIS growing faster than the overall business this year? Or is that more of a 2023 event?

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

I want to first comment -- and I made a comment that might have been a little misleading before. The logistics has an impact overall, but really it wasn't just that. It's just that it's the most elective procedure we have. And if you've seen it drop throughout COVID when the spikes have come up, the first procedure that has kind of been taken off has been -- or pushed out, where cases get pushed out 4 weeks, 5 weeks, 8 weeks, has been within the CONVERGE or the EPI-Sense area. That's really what was in MIS.

That's what we've seen and that's what you saw at the beginning of this year. It wasn't -- the logistics is that we just didn't have all the sites up and running perfectly where they could kind of avoid some aspects of that. So it had a small contributing factor to it. But it's really more about the elective nature of it when you start to see that. And because we've gotten a lot of net new sites up and running and we do feel like once they're kind of up and running and going later on this year and into next year, that we should see some substantial

growth on that.

We're not ready to give specifics. I think Angie did mention in her comments that we do believe that this is going to be growing at higher than corporate rate over time. We do think that we'll have a nice strong and solid second quarter, but that will build into the back half of the year and be even stronger in the second half of the year and into next year.

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

Yes. Matt, the low double-digit growth that we saw from EPI-Sense in the first quarter was for the full quarter. And take that in balance of the TT procedure, which is the other component of our MIS revenue, was actually down pretty significantly. Both are very elective procedures and saw pressure in the first quarter, resulting in the overall blend of just under 3% growth in the U.S. for MIS ablation.

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

Got it. Very helpful. And then a follow-up. And I don't know if this is for you, Mike, or for you, Angie. But congrats on the updates for LeAAPS and then for IST. How big a spend on those studies are we looking at on an annual basis? And I guess, Angie, this is for you and I don't know if you want to comment on it, but it's something that gets a lot of attention. Is the spend on those plus all the other investments is going to be so meaningful in '23 that you can't turn EBITDA positive next year?

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

Yes, maybe I'll just comment. I think nothing significant has changed in the recent months with both of the trial approvals coming through that really impacts our 2022 spending outlook. At the beginning of a trial, it's a little more moderate spend than you would see once you've got sites up enrolled and you're enrolling patients and treating subjects.

So while we were optimistic for the developments to unfold during the year, as they have, it doesn't really impact the spending outlook that we had for the year. I think the best way without giving specifics on a target profitability date or exact dollar amount of spend on either initiative, I'd reiterate we do expect pretty naturally in the coming years to hit profitability despite the investments that we're making in these areas, really leaning into our growth opportunities and expect to see some leverage out of the P&L.

Within R&D what you've seen historically is kind of an upper teens as a percentage of revenue investment in R&D activities, which include these clinical trials. And I think with the onset of both LeAAPS and HEAL-IST starting, you'll see that sustained over the coming years.

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**Operator**

Your next question comes from the line of Suraj Kalia from Oppenheimer.

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

Mike, Angie, can you hear me all right?

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

We can.

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

Perfect. So Mike, I know CONVERGE has been beat up to death. Let me start off with a different question. Mike, looking at your perspective on the competitive demand for EP lab times -- and the reason I bring that up is specifically on all the ongoing PFA trials given -- our field checks keep picking up-- there's quite a bit of excitement. And I wonder if you all are seeing any -- from a lab time perspective, I'd love to get your perspective there?

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

Yes, it's actually -- it's the opposite of the way I think you're articulating the question, which is that we actually help lab times because CONVERGE does not take up lab times. In fact, the study showed that they actually get almost an hour of saving of lab time when they do go in with the catheter to get the results they get that are better. So we're actually an efficiency helper for many of the sites on EP lab sites.

So whether it's PFA on the trials that you're starting to see up and running or just the general nature and number of cases that are out there -- and there's a lot of catheter cases that are going on out there. But we actually save them time. So CONVERGE is actually one of the big selling points for getting something up and running because this allows them to spend a lot less time on these really complicated patients, and so they can just do touch-up work and get a better result. So it's a win-win across the board.

That's actually one of the really neat things about this and why it's so collaborative is that they win on multiple fronts. They win with a better patient outcome that they do better. They win possibly by adding a clip and managing the appendage. They win by having less time to spend in the lab with them as well. So everybody kind of gets a good win on that. And the patient wins most importantly.

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

Got it. Mike, in your prepared remarks, you mentioned about CONVERGE or Hybrid AF -- and I'm paraphrasing here -- ultimately becoming the standard of care. How do you envision Hybrid AF as standard of care? Is it going to be on a staged basis and on a same-day basis?

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

I don't know that it's -- I don't have an opinion necessarily whether it's going to be staged or same day. Both work incredibly well. Individual sites have different logistical items to them. They've got different opinions on whether it's better to wait for the edema to kind of come down from the initial procedure or not. That really comes down to the individual site and their thoughts on it.

The standard of care that I'm talking about doesn't have to do with how they're kind of operating it from that standpoint. It's that you've got long-standing persistent patients that represent 45% of all patients out there, and there is -- this is the only therapy that has an approval and it's complementary to the existing catheters and even the catheters that are undergoing trials right now. Every one of those trials are complementary to the work that we're doing today.

So from my standpoint, that's what I'm saying. For long-standing persistent patients, it's an undertreated population, a complete unmet need. And this is an opportunity for both helping those patients out long term, bringing new patients into the system that have been forgotten about and they've given up on to help them out. And we feel like we've got a solution here that has been proven with the clinical data and evidence to help that patient population out. And we believe that we can make it a standard of care over the next 5-plus years.

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

Got it. And finally, Mike, if I could, then I'll hop back in queue. How is the discussion OUS on the hybrid approach, if at all, knowing that it's early days in the U.S., not forget if -- how your OUS discussions might be going if at all? And also, is our math right that EPI-Sense was -- or CONVERGE, give or take in the quarter -- and again, rough math -- is between 500 and 600 cases in the quarter?

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

Yes. It was more cases than that. But the international side of it was we're starting to see some traction in many different countries, in particular, in Italy and Germany. We're starting to see a lot more awareness and demand in that part of the world. We don't have approvals in much of Asia. We just got approval in Australia, and so we're starting to see some sites get up and running there. So that's kind of at its infancy.

We are applying for in Japan to get shown an approval that we expect over the next 2 to 3 years. So it's a little ways out. We've submitted the clinical data from the clinical trial of CONVERGE. We're in conversations now with their equivalent of the FDA to kind of work through that. And so we're making good progress from that standpoint as well. And the Japanese market, we believe, could be a very strong and good market for us as well.

And so that kind of gives you a sense for on the international side of things in terms of the progress that we're making in those areas.

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**Operator**

There are no more questions at this time. Turning the call back over to Mr. Mike Carrel for closing remarks.

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

Great. Well, again, everybody, we really appreciate you joining the call today. Hopefully, you can tell by the tone that we're pretty excited about our future. We really have an opportunity. We've got a great platform for growth here along multiple franchises, our open ablation franchise, which has been long standing a big part and foundational piece of our business. We've got new products, new reimbursement in there that we think is going to drive growth.

Combine that with the work that's being done on the hybrid side of our business, the label we got last year and the progress we've made in adding new sites, we think that our future is incredibly bright. And if you want to add on top of that, the pain management franchise that we have, that as you saw is the fastest-growing piece of our business and really impacting a lot of patients around the world.

We're excited about our business. We're excited about it domestically. We're also excited about it globally. We thank you for your interest and look forward to future calls. Have a great day.

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**Operator**

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

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