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Q3 2022 AtriCure Inc Earnings Call

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CORPORATE PARTICIPANTS

Angela L. Wirick *AtriCure, Inc. - CFO*
Marissa Bych *Gilmartin Group*
Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

CONFERENCE CALL PARTICIPANTS

Frederick Allen Wise *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*
John Edward Young *Canaccord Genuity Corp., Research Division - Associate*
Marie Yoko Thibault *BTIG, LLC, Research Division - MD and Medical Technology and Digital Health Analyst*
Matthew Oliver O'Brien *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*
Michael Stephen Matson *Needham & Company, LLC, Research Division - Senior Analyst*
Robert Justin Marcus *JPMorgan Chase & Co, Research Division - Analyst*
Suraj Kalia *Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst*

PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's Q3 2022 Earnings Conference Call. My name is Stacy, and I'll be your coordinator for the call today. (Operator Instructions)

I would like to turn the call over to Marissa Bych from the Gilmartin Group for a few introductory comments.

Marissa Bych ***Gilmartin Group***

Thank you. By now, you should have received a copy of the earnings press release. If you have not received a copy, please call 513-644-4484 to have one e-mailed to you.

Before we begin, 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 therapy and future product approvals, clearances, reimbursement and clinical trial outcomes. 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.

And with that, I would like to turn the call over to Mike Carrel, President and Chief Executive Officer.

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

Thank you, Marissa. Good afternoon, and thank you everyone for joining us. We hope you're well. I am pleased to share another outstanding quarter for AtriCure, as we drive adoption across our therapies to improve patient lives and capture the substantial opportunities in front of us. We ended the third quarter with $83.2 million in revenue, reflecting growth of approximately 18% over a strong third quarter of 2021. Highlights for the quarter included continued expansion of our pain management franchise and rising commercial traction from our recently launched EnCompass Clamp as well as mounting adoption of AtriClip devices globally.

Turning to third quarter Epi-Sense product revenue in the U.S., which increased 12% year-over-year and 3% on a sequential basis. Hybrid AF therapy courses experienced record attendance in this quarter as we trained many cardiac teams on the overall benefits to patients and best practices for setting up a program and working through protocols and logistics. We are seeing growth in both the average number of accounts and procedure volume per account each quarter as we continue to focus on establishing Hybrid AF therapy as a standard of care for long-standing persistent atrial fibrillation patients.

Additionally, we are seeing increased adoption at top-tier sites, with 14 of the top 25 cardiac programs in the U.S. building programs. To that end, in September, we highlighted the experiences of Dr. Eric Buch and Dr. Zayd Eldadah, implementing Hybrid AF therapy in their respective practices. Both EPs emphasize the excellent clinical outcomes for their patients as well as plans to substantially increase adoption. We believe the commentary from both physicians underscores the efficacy of Hybrid AF therapy, an immense opportunity for AtriCure, to address this unmet need for millions of patients.

Shifting to our pain management franchise, Cryo Nerve Block continues to be our fastest-growing therapy. In the third quarter, we saw sequential revenue increased 3% and are gaining traction within a broad base of accounts with well over 500 accounts year-to-date. We believe strong adoption of Cryo Nerve Block therapy is due to physicians seeing immediate results from providing temporary pain relief for patients after thoracic surgery. While we are working to impact more patients in this space, we are also exploring new opportunities, including the application of Cryo Nerve Block for sternotomy. We look forward to sharing our progress on future calls.

Now on to our open ablation franchise. Earlier this year, we announced full-scale commercial launch of the EnCompass Clamp in the United States. The EnCompass Clamp leverages the proven technology of our synergy ablation system to provide a simpler and faster approach to ablation in open heart procedures. Strong momentum from our initial launch carried into the third quarter, driving nearly 21% growth in the U.S. open ablation revenue year-over-year, reflecting a mix of new adoption and additional revenue per procedure upon conversion to the EnCompass Clamp. We are pleased to share that EnCompass contributed nearly 25% of our U.S. open ablation revenue in the third quarter and we are continuing to expand accounts and surgeons. Feedback from our customers has been exceptional and we remain confident in our ability to further penetrate the cardiac surgery market for many years to come.

Finally, our AtriClip product line continues to see consistent growth worldwide with 18% year-over-year growth this quarter. We are advancing our efforts to innovate the AtriClip platform, focusing on less invasive and easier-to-use devices. We've seen many opportunities for growth in our appendage management franchise as we increased demand in both our open and minimally invasive businesses.

In addition to our existing opportunities, we are actively investigating an expanded application for the AtriClip platform through the LeAAPS clinical trial. This landmark trial examines the prophylactic use of AtriClip devices for stroke reduction in cardiac surgery patients without a pre-operative Afib diagnosis. Over 2/3 of the nearly 1 million cardiac surgery patients worldwide do not have pre-operative Afib diagnosis, yet have an increased risk in their lifetime. We believe this trial will demonstrate the benefit of excluding the LAA with the AtriClip, providing a substantial extension of our markets. Trial initiation is underway with patient enrollment expected in the coming months. While the trial will take a number of years to complete, we anticipate awareness for appendage management in all cardiac surgery procedures to increase in the interim.

In addition to our efforts at market expansion through LeAAPS clinical trial, we are cultivating new markets by building upon existing technology and leveraging the unique physician relationships we have developed. Earlier this year, we announced the first patient was treated in the HEAL-IST clinical trial. HEAL-IST will study 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. It affects millions of people around the world and currently there are no approved treatments for this debilitating condition. We continue to make progress with the trial and remain excited for the potential of this new therapy to unlock another significant market opportunity and provide a solution to the many patients with IST. In addition, we are advancing product development efforts on a dedicated device for this therapy, and we'll share more as we continue our efforts to build the market.

Across our business, we are seeing growing interest in our differentiated solutions and are proud to work with all 50 of the U.S. News & World Report's best hospitals for cardiology and heart surgery. The investments we have made in innovation, clinical science and education, position AtriCure for accelerated and durable growth for years to come.

I will now turn the call over to Angie Wirick, our Chief Financial Officer, to discuss more detail about the quarter.

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

Thank you, Mike. Our third quarter 2022 worldwide revenue of $83.2 million increased 18.1% on a reported basis and 19.8% on a constant currency basis when compared to the third quarter of 2021. Revenue was driven by solid growth across key product lines and geographies bolstered by outstanding results in pain management, appendage management and open ablation. On a sequential basis, we experienced a 1.5% decline in revenue from the second quarter attributed to normal seasonal variation in underlying procedures.

In the third quarter 2022, U.S. revenue was $69.8 million, a 21.3% increase from the third quarter of 2021. Open ablation product sales, which exclude pain management, were $21.6 million compared to $17.9 million, up 20.5% over 2021, showing building strength from the EnCompass launch with a combination of new adoption and incremental revenue per procedure. We estimate open concomitant procedure growth was roughly half of the growth for the quarter, consistent with our expectations of sustained and steady penetration of the cardiac surgery market.

Minimally invasive ablation sales were $10.1 million, up 0.9% from 2021. As Mike noted earlier, within U.S. minimally invasive ablation sales, Epi-Sense revenues increased approximately 12% year-over-year and 3% on a sequential quarter basis. However, Epi-Sense revenue growth was offset by approximately 21% decline in the legacy MIS ablation revenue year-over-year. We exited the third quarter with 75% of U.S. MIS revenues attributed to the Epi-Sense system and continue to believe in the significant long-term growth potential for Hybrid AF therapy. Rounding out U.S. revenue, pain management sales were $10.5 million compared to $6.3 million, up 68.1% over the third quarter of 2021.

Sales of appendage management products in the U.S. were $27.6 million, up 18% over the third quarter of 2021. International revenue was $13.4 million, up 4.2% on a reported basis and 13.5% on a constant currency basis as compared to the third quarter of 2021. European sales accounted for $7.3 million, driven by increased activity in the United Kingdom and broader markets, offset by unfavorable exchange rates as well as slowed activity in the Netherlands and Germany. Asia and other international markets accounted for $6.1 million in international sales on strength in most markets, but notably Australia and Japan, partially offset by prior year activity in China. Overall, international markets were fueled by growing adoption of AtriClip devices, resulting in an increase in appendage management revenue of 19.5% from the third quarter of 2021.

Now turning to another key metric for the third quarter of 2022. Gross margin was 74.1%, flat to the third quarter of 2021. While we are seeing benefits from increasing scale of our operations, more recently, they have been offset by rising costs and supply chain pressure as well as a shift to lower gross margin products.

Moving to detail on operating expenses for the quarter. As a reminder, operating expenses for the third quarter of 2021 included a $189.9 million credit to operating expenses with a change in fair value of contingent consideration, offset partially by an $82.3 million intangible asset impairment charge for the IPR&D asset associated with the aMAZE trial. Excluding these items, operating expenses increased $11.3 million or 18.4% from $61.2 million in the third quarter of 2021 to $72.4 million in the third quarter of 2022. The increase was primarily driven by research and development activities, which grew approximately 34% year-over-year, while selling, general and administrative expenses increased 15%.

Our adjusted EBITDA was negative $735,000 compared to a positive adjusted EBITDA of $691,000 for the third quarter of 2021. Our basic and diluted net loss per share was $0.27 in the third quarter of 2022 compared to a basic and diluted net income per share of $2.15 and $2.11 in the third quarter of 2021. The adjusted loss per share in the third quarter 2022 and 2021 was $0.27 and $0.23 respectively. Our balance sheet is very strong and we ended the third quarter with $174 million in cash and investments. The modest cash burn shown this quarter largely reflects capital expenditures associated with the expansion of our manufacturing operations as well as an increase in inventories.

Turning to our outlook for 2022. Given the ongoing momentum across our business, we now expect to achieve approximately $328 million to $333 million in annual revenue, reflecting full year growth of approximately 20% to 21%. As we think about fourth quarter expectations by geography and franchise, we believe the EnCompass launch will continue to positively impact U.S. open ablation revenue. Within U.S. MIS ablation, throughout this year, we have seen more pronounced impact to procedures in our legacy MIS business as we operate within a much smaller base of customers. Therefore, while fourth quarter of 2021 included $3.7 million of a contribution from legacy MIS devices, we are trending at approximately $2.5 million currently. And finally, like many other companies, we faced increasing headwinds from unfavorable exchange rates in the third quarter and expect this pressure again in the fourth quarter.

We continue to expect 2022 gross margin to be comparable to the full year 2021 with the potential for varying impacts from increasing costs and mix, largely on the strength of our pain management franchise and the EnCompass launch. We are maintaining our level of investment in research and development activities with spending in product development and clinical science initiatives across our platforms. Additionally, our plans anticipate the thoughtful investments in our commercial team, along with market development activities and training and awareness programs.

We expect the full year 2022 adjusted EBITDA to be a loss of approximately $4 million corresponding to an adjusted loss per share for 2022 of approximately $1.10 to $1.12. Therefore, fourth quarter results are expected to be approximately $4 million in positive adjusted EBITDA. As we navigate the remainder of this year, our employees across the globe remain focused on our patient-first mission. Whether that means clinical trial or product development activities, market awareness and education, administrative support or the production and fulfillment of our products, the AtriCure team has shown immense collaboration and dedication despite a tough backdrop from various uncertainties in the world and economy. Thank you all for making our company truly a special place and breathing life into our mission and values each day.

Now I will turn the call back to Mike for closing comments.

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

Thank you, Angie. In addition to being proud of our team for a great financial quarter in which we grew the business and advanced many long-term growth catalysts, I'm truly in awe of the wide-ranging talent of our employees. I'd like to highlight a program developed by our team, the Women's Cardiac Health Awareness initiative. In early October, AtriCure sponsored an All-Star Physician Panel, discussing the unique needs of women in prevention, screening and treatment of atrial fibrillation. This live online event brought together leaders in the field of cardiac surgery, electrophysiology and thoracic surgery to educate peers about the importance of improving the heart health of women. The program was a tremendous success and a huge step in our effort to encourage a heart team approach to address gaps in healthcare.

Additionally, I'm honored to share that AtriCure has been selected as one of only 20 finalists in the nation for the 2022 Diversity, Equity and Inclusion Awards by the National Association of Corporate Directors or NACD. This prestigious recognition is a testament of our intentional action around DE&I, beginning with the composition of our Board of Directors and continuing with training, practices and objectives that have a measurable impact across our employee base. The commitment to fostering a workplace that rejects discrimination, celebrates differences and promotes equality is fundamental to our organization and how we operate. At AtriCure, our future is bright, and we're thankful of support for all of you on this call today.

With that, I'll turn it over to the operator.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Robert Marcus of J.P. Morgan.

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

Congrats on a good quarter. Maybe to start off, the focus is on the MIS business, and I appreciate that it looks like CONVERGE did grow in the quarter. It was the legacy business that there was something like a $2 million headwind or so. It was really helpful to have that online event last month. How do we think about when we might start to see some more tangible improvements and sequential growth there? Now with one month under your belt, do you think it might be fourth quarter or do you think we're going to have to wait until 2023 to start to see it pick up?

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

It's a great question, a fair question, and obviously, one that we've had on this call and one that we're expecting, Robbie. So I appreciate you bringing it up right away. From our perspective, as we look at very specifically the Epi-Sense part of our business and kind of what we see as the growth, we're making good traction, as I mentioned. We're in 14 sites now out of the top 25 programs in the country. Many of those sites are just beginning their programs. So I don't think you're going to see tremendous impact in the fourth quarter, but I do think that as we look at next year and the year after, you're starting to see really some traction, the increase in the number of accounts and more depth within those accounts as well. But the hockey stick, I can't give a specific time necessarily on when that's going to hit, but we feel really good that the momentum is beginning to build in these programs and beginning to expand.

When you think about what we tried to do at that show, when we looked at Dr. Buch and Dr. Eldadah, the goal of that was to show you really two outstanding programs that were at different places. So Dr. Eldadah was one who -- they've been around for a long time. And what the data did for them is it allowed them to expand and look outside of just Dr. Eldadah doing the referrals to the other 12 to 14 EPs he have in his practice and the other hospitals that they contract with. And so that really kind of begin to explore that. And actually, today, they just announced they did their 350th case today. So they're really beginning to see that momentum build within that program as well. And we wanted to show that once the program is established, it even has more expansion opportunities within it.

Dr. Buch is a little different, because he was really about that early stage, which is they just got going right when the data came out. They really got going when we got the label, and that enabled them to kind of move on. Now the label is only year and a half ago, they're now up to almost 35, 40 cases or so this year. And we anticipate that those that were starting now will begin to really kind of contribute in a bigger way, probably the end of next year and into the year after, but even a little bit at the beginning of next year.

So you can see these programs are beginning to build. This is going to be strong, durable revenue for a long time in these accounts. And we've got lots of people coming to the training programs that we have. And so it's not about kind of if, it's really about when for us in terms of the timing of this, because I think the data is there and it's compelling and the market is really, really big.

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

Maybe as we look to 2023, I think it's important that fourth quarter is going to be the first in a while, if not the first ever. I didn't look all the way back, just EBITDA profitable quarter. Is this a trend you think you should be carrying forward into 2023 and its profitability from here on out or might the first half of the year turn back negative before turning profitable again?

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

It's a good question, Robbie. What we typically see in the first two quarters of the year is typically a higher loss and the balance for the full year typically comes down. That's if you were to look back at AtriCure's P&L for many, many years. Where we're sitting at today, it's an $8 million loss year-to-date. We are expecting positive $4 million for the fourth quarter, bringing the full year to the guide of about a $4 million loss. I think as we enter next year, without giving a specific date of achieving full year profitability, I think pretty naturally, this happens in the near-term.

Historically, we've been able to make good improvements to the bottom line at lower growth rates in the history of AtriCure and would expect despite a lot of the great investments that we're making in the big opportunities that are in front of us that we would turn to profitability in the near-term. It's definitely a focus of us and our team and I think without having to sacrifice a lot of the great initiatives, particularly when you think about our R&D spending.

Operator

Our next question comes from Rick Wise with Stifel.

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

Maybe to start with gross margin, you called out that -- I mean, obviously, it was flat year-over-year, a little surprising given the higher sales volume. Maybe you could expand on the inflationary supply chain cost pressures? And I mean, is it getting worse? Just what's happening? Where are we in AtriCure feeling those pressures? And I was a little surprised at the language about shift to product mix and lower margin products. I wasn't sure I understood that fully. And just help us think about, just at a high level, can gross margins -- should we expect gross margins to improve in '23?

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

So with regards to the cost and some of the supply pressures, I'd say, this was the first quarter where we started to see maybe a bit of an increase in some of the costs. It may be the timeline of different contracts that we're working under. But the other pressure that we saw was maybe not the optimized production volumes we would have liked to have seen during the quarter, so maybe some limitation there. That being said, exceptionally proud of the team given the backdrop that we're operating in that we haven't had any backstop in being able to fulfill orders.

So with regard to the second part of the commentary, the shift in product mix really is focused on two products. So the cryoSPHERE device is a lower gross margin product. And as that becomes a bigger component of our overall revenue, it is having an impact on the gross margin. Great growth rate. It's a phenomenal therapy, but it does come at a slightly lower gross margin than you see out of our other RF and cryo products.

The other big driver this quarter, in particular, was we had a nice uptick in the EnCompass Clamp revenue, and that is another one. This is just first year out of development and first year into production and it will take some time for us to lean the cost, but the team has identified some great areas that they're focusing on for 2023. So that being said, I feel comfortable in the balance. I think our guide in general is for the balance of the year to be around what we did in the full year 2021, which was right about 75%. The big impacts here really being product shift in mix and then geography mixes as well.

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

And just one on Cryo Nerve Block. I mean, it continues to grow sequentially, very impressive, the 500 accounts. We've done some checks recently with thoracic surgeons who are using it, their reactions have been incredibly positive. Talk about the physician reaction. You touched on it a little bit, Mike. Maybe help us understand what's next for the technology? How your thoughts are evolving about the opportunity? And can this growth continue?

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

Great question, and you're right. I think the instant response you get from physicians and not just physicians, but also people that care for the patients after they go out of surgery in the ICU floor, the nurses, the PAs and others is instant gratification because they see the patients recovering more quickly, they can breathe more easily and they can kind of get up and walk around. That's really, really important towards the recovery, especially in many of these different thoracic cases. So I think that's a common theme that we hear from people all the time, which is just a dramatic and immediate impact they sense.

As it relates to the overall market, the overall market in the U.S. is about 140,000 to 150,000 thoracic procedures every year. That number is growing. We'll do about 16,000 to 18,000 or so of those cases this year. So as you can tell, we're really not even -- we're just over 10% or so penetrated into the space. We think that number can obviously grow quite dramatically because of the impact that we can have.

And so one is, yes, we've got a lot of room for growth just within the thoracic part of our business, both going deeper into the accounts, 500 accounts. There are more accounts that we can get into. But a lot of this is getting even deeper within the accounts that we have today as well and then kind of sharing it across more thoracic surgeons that might be in an area.

Number two is, I kind of briefly mentioned it that as we think about how do we expand it, we're already thinking about new markets for the technology, in particular, sternotomy. And we anticipate that some time probably mid-to-late next year that you might be -- we'll be able to kind of maybe roll something out a little bit more aggressively into that area. That probably won't have much impact on 2023 revenue, but we do anticipate that that will expand the market quite dramatically '24 and beyond.

Think about sternotomies, it's about 250,000 or so of them in the U.S. alone, 600,000-plus on a global basis. So when you start to do the math and the benefits that could be there, it's a very large market opportunity for us. We're just at the beginning stages of kind of learning a little bit more about it. And hopefully, middle part of next year, we'll be able to roll something out more officially.

Operator

Our next question will come from Marie Thibault from BTIG.

Marie Yoko Thibault ***BTIG, LLC, Research Division - MD and Medical Technology and Digital Health Analyst***

I wanted to ask a question here first on CONVERGE. And maybe you can give us some more detailed thoughts on how you're thinking about the ramp going forward. It certainly sounds like you're feeling optimistic about the momentum you're seeing. But as we look into 2023, are there ways to sort of characterize the ramp in terms of the cadence you'd expect into the next year? And as a second part of that same question. On the legacy MIS declines, is that $2.5 million? Is that a number we should think about going forward or do you expect that to eventually rebound?

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

Yeah, I'll start with the first on the legacy MIS business. The 2.5% is kind of where we anticipate it being for the time being, and that's kind of where we are. It's obviously at a much lower number than it had been historically. I'd say that just a little bit more color into that, that was the part that went -- it got hit the most by COVID. And those programs are just more difficult to get back up and running and going and get consistent again. Find the staffing, they're in the hospital for a longer period of time. And so while we had some really good sites, it was in a much smaller base of customers. So that impact had a broader impact on that base. And it's kind of been consistent we think in that kind of $2.5 million range or so.

As it relates to the kind of cadence for next year, we do see next year obviously being better than this year. We anticipate that we're going to see momentum build into the next year and throughout as we're adding more of these accounts. I'm not ready to give like real specific cadence throughout next year yet just because I think we want to learn more as we're getting more consistency coming out of COVID and getting these sites to have more consistent streams of patients that are coming in before I'm ready to kind of give a specific cadence kind of by quarter or anything like that for next year. So I don't think we're ready to kind of give that kind of cadence. But we do anticipate growth to really pick up next year quite a bit and feel confident that that's going to happen.

Marie Yoko Thibault ***BTIG, LLC, Research Division - MD and Medical Technology and Digital Health Analyst***

And then my follow-up here on the strength you had in the open ablation market this quarter, certainly, we've heard positive commentary on cardiac surgery this quarter so far from some of your peers. Do you expect some of that to be sustainable? Are we working through a backlog? How do you sort of see the open ablation franchise moving forward here over the very near-term?

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

I think from an open ablation standpoint -- I think from a cardiac surgery standpoint, maybe I'll start with that because that's where you've started the question. We definitely see that that is a very durable base of business. I mean, it's not growing super fast in terms of at the case level. But you're definitely starting to see that come back to a more normalized place before COVID, and we feel very good about the overall kind of cardiac surgery market in general.

I think many, many years ago, people were a little bit worried about it. And now I think there's a lot of confidence that that's a robust area, especially with kind of the baby boomers getting older, people living longer, that cardiac surgery is a very good outlet and they get great results. And so as a result, I think that's going to be kind of -- it will be a solid base. The good news for us and the message we've always said is it's about penetration. It's about saying even today, we're still only in about 27% of all the cases that -- of patients that have atrial fibrillation. That's up from 10% maybe 12 years ago, but 27% is not 75%. And all the guidelines are there. And we've now eliminated things to enable us to kind of grow and to continue to grow and get that penetration up.

#1 is that we just added a new technology to make it simpler and easier for someone to ablate the heart without having to open up the heart. EnCompass does that, and that was one of the big pushbacks that basically was in kind of limiting that piece of the business. So really, we believe we can grow that penetration from 27%, and that's really what we're focused on. How do we get after those surgeons that are non-treaters today. They're not doing the ablations today.

#2 is that the recent reimbursement changes that happened in October of 2021 where they added significantly to this. It doesn't have an immediate impact, but it definitely has an impact that over time, they start realizing that, wait a second, this actually is profitable for us in addition to being really good for the patients. And so you kind of have the combination of that happening. Again, that doesn't have an overnight impact. You really #1 have to focus on the patient and what's right there. But then it's always nice when you've got the additional reimbursement. It's been recognized by CMS that treating these patients makes sense for the patient and for the system overall. And I think those two things over the course of the next many years to come are going to able us to grow that penetration of 27%, and I mean much, much north of that.

Operator

Our next question comes from William Plovanic from Canaccord Genuity.

John Edward Young ***Canaccord Genuity Corp., Research Division - Associate***

It's John on for Bill tonight. Could you start with just talking about the quarter-over-quarter trends in the U.S. appendage management business? Was the AtriClip mix -- product mix different this quarter?

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

No, John, mix was relatively similar quarter-to-quarter.

John Edward Young ***Canaccord Genuity Corp., Research Division - Associate***

And then back to cryoSPHERE, I mean, you've seen really great growth in the pain management business. Can you talk about your thoughts on label expansion and possible clinical work to show opioid [reduction] label or maybe improvements in length of stay?

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

Yeah, it's a great question, one we have a lot of conversation about internally all the time, John, around what can we do to expand or get more data out there. So we have invested in many different trials already, a lot of single center and maybe small multi-center trials to try to show different length of stay impact. You're not going to see as much length of stay in some of the robotic thoracic cases just because they're only in the hospital for a couple of days. And so really, what you have to have there is, you've just got -- they've got to see the benefit of actually seeing significant reduction in pain in that patient for not just their time in the hospital, but over the longer time.

And so we're looking at different economic studies to show that how do you actually benefit the system overall within that four to six month or four to six week period for that patient population. And those are the kinds of studies that we're looking to study. So it's not necessarily a label expansion. It's really looking at the economic analysis for being able to justify spending the money, because they see the impact for to way on a patient. Then it's about, can we get some economic analysis that's beyond just that length of stay component.

As it relates to the opioid side of it, I think it is one that we're looking at. The big thing we're looking at right now is how do you get a consistent piece there, which is not every site uses opioids in the same way and there's really no standard of care for these patients. And we've run a lot of different advisory boards to try to figure out how do we hone in on the exact right one that's going to be applicable after we do the study. So I'd say that some time probably next year or late next year, hopefully, we'll have a study in mind. It doesn't necessarily have to be a label expansion study. It could just be studies that are done on a multi-center basis, and that's kind of the work we're doing right now to look at that.

Operator

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

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

So Mike, can we talk a little bit more about Convergent in the quarter? I'm pretty sure Q3 tends to be a seasonally slower quarter, but I think you said that you were actually up 3% sequentially. First of all, is that right? Where did that growth come from? I know it's existing centers, but what did you see as far as adoption? And then again, kind of to Marie's question about next year, it feels like you're trying to guide us to be a little bit more conservative with our view on Convergent for early next year, maybe building more so towards the end of next year and then maybe more of an inflection in '24. Am I characterizing that right?

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

Matt, I'll take the first part. We did see sequential growth in Epi-Sense of 3% quarter-over-quarter and most of that was just driven by a higher number of accounts that we're ordering. So we hit kind of a high watermark in terms of number of accounts ordering in the quarter in Q3 of this year. So that was -- it was a mix. It was new accounts as well as going deeper within existing accounts.

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

And then as it relates to the cadence of kind of the trend, again, I think you're kind of characterizing it reasonably accurately around kind of what we're thinking about. But we don't want to get too far ahead of ourselves after one quarter. We've had a couple of quarters earlier, we've seen some nice sequential growth. We do feel like this is going to be a long-term durable strategy for us or business, but we don't want to get ahead and kind of give numbers specifically yet for the earlier part of next year.

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

And then as a follow-up, and I appreciate that feedback. There was a -- on the PFA side, I hear a lot like PFA is going to pick over the whole industry, and that's why Convergent is never going to take off. But there was a safety notice recently about PFA and hey, people are using it off-label, stay in your lane. So I'm just curious, I know it's early, if that warning letter or notification will really keep people to using PFAs for paroxysmal versus long-standing persistent and really keep people a little bit more driven to use the Convergent approach in the future for long-standing persistent? And then just real quick on the IST side, is that difficult to identify patient population? And could that be challenging as far as you're trying to get that indication out there and rolling going forward? I know again it's super early.

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

First, on the PFA side, our thoughts really haven't changed much. I think it's a potentially complementary product to us. I think there's a lot to learn. I think what you're seeing in some of the data that's coming out from some of the early studies is demonstrating that there's a lot for us to learn, but it's still an exciting technology and has a lot of promise. Most of the studies are being done in paroxysmal patients at this time. And I think that -- I think we'll kind of wait for that.

I think what we do is we actually add a lot of value. And if you watch the Dr. Eldadah, he actually I thought explained it very well on our call where he was talking about the fact that the epicardial portion combined with any kind of endocardial portion, whether PFA, RF or cryo is going to benefit the patient from that standpoint. You really want to have it sandwiched and get a truly durable transmitral lesion. We believe whether it's PFA, RF or cryo that there's going to be a benefit to the epicardial approach, enhancing that durability long-term.

And there's a lot to learn about what's going to happen with PFA. So when I have the conversations with a lot of EPs, I think that we're going to -- once we get through kind of the super exciting front, we really get down to brass tacks of thinking through how they're going to implement this. I think CONVERGE has a really big role to play even in PFA accounts, if and when that does take off at some point in time.

From an IST standpoint, there are a lot of patients that have IST. I think you're right that a lot of work has to be done to begin to kind of develop the care pathway for those patients, finding them that referral basis is going to happen. We saw a lot of activity in Belgium where they actually got a lot of patients once they announced they had a solution for it. I think once we have a solution, and then this is prime for kind of a direct-to-consumer type of activity at some point, because it's -- the patients that are going to be out there, they're going to come and want to get treated. They're going to want to find treatment because there is no treatment today. That's many years off. We've obviously got to get the label first, so there's a ways to go on that. But I would anticipate that's probably how they're going to reach a lot of this patient population.

Operator

Our next question is coming from Mike Matson of Needham & Company.

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

Just one on cryoSPHERE. So to expand into the sternotomy opportunity, what do you have to do from a product and regulatory standpoint? Do you have to redesign the product? Do you have to get another 510(k), et cetera?

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

Yeah, it's a really good question, Mike. Right now, we've got to go through some internal testing just to make sure that we kind of understand how it works and so on. We do have cases that are actually happening there today. So from that standpoint, the biggest thing we've got to do is just make sure that they can apply it safely, but the product itself doesn't have to change. The product actually works very well.

I'm guessing many of them are going to want maybe a little shorter shaft or maybe a little bend in it so they can kind of get a little bit different access to it as opposed to the report. But otherwise, the actual way we deliver the cryo energy to the ball at the end, how that comes delivering the exact right amount, it's the same intercostal nerve that you're ablating when you're doing the with thoracotomy. So it's very consistent from that standpoint. And so from that standpoint, we don't think we need to make much on the regulatory or the product standpoint side.

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

And then you gave us your latest penetration numbers for open heart ablation. I was wondering if you could do the same with AtriClip? I mean, continuing to see really strong growth here. But just wondering what you think the penetration is in U.S. and worldwide for AtriClip? And that's assuming you don't obviously have the stroke indication that you're running a LeAAPS trial for?

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

We believe that we're probably closer into the mid-40s or so on the overall AtriClip on open cardiac cases today. So there's still a lot of room for growth even in open cardiac cases. Obviously, we're expanding the market with the LeAAPS trial and feel very confident in moving forward on that. And so from our standpoint, we feel like we're in a good position to not only just expand penetration, but also into a new market.

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

And then it sounds like you've got some new versions of AtriClip coming. And I think part of the growth story there has been that you've gotten some nice price premiums when you've launched them in the past. So do you think you can continue to do that with new versions? In other words, price them at a premium?

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

I think to be told on the pricing side of things, but the biggest thing right now is that we're always innovating to make the product easier to use for them to be able to put on all anatomies to make it simple, leaving less behind. Those are the kinds of things that we're looking for. So it's making it smaller, making it more mobile and really continuing to innovate to show people we're making major investments in the platform long-term that they can apply it on every one of their cases.

Operator

Our next question comes from Suraj Kalia of Oppenheimer.

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

(technical difficulty)

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

Suraj, if you're speaking on this call, it's a little tough to hear you.

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

Sorry about that, Mike. So Mike, I know people have asked a lot about CONVERGE. If I could just -- Mike, when you look at the pie chart for the quarter, just the growth pie chart, if I could split it, here is the growth X percent from CONVERGE versus cryoSPHERE versus

AtriClip versus others, just give us a relative framework of how we should think about the different components of growth? And the reason I ask is, we are seeing the number -- the embedded numbers in CONVERGE, but it seems most of the growth seems to be coming from cryoSPHERE and AtriClip. Maybe you could parse it to the next layer would be great?

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

So Suraj, when you break down the U.S. business, I think the numbers go like this. The pain management business, so the cryoSPHERE probe grew a little over 68% year-over-year. That was followed then by our open ablation business, which again, my commentary included that about half of that, so half of the 20% growth or so for the quarter is really procedure growth. The other half is from an uptick in pricing that we're seeing on the EnCompass Clamp, followed by the appendage management business, which reported about 18% growth in the U.S. year-over-year, then Epi-Sense -- the Epi-Sense tool was 12% and then offset by a decline in the legacy MIS tools year-over-year.

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

And Angie, did you talk about new stores, same-store sales specifically for CONVERGE?

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

The prepared comments included that this was one of our record quarters from a number of centers that we're ordering. And we've cautioned investors to take a look at the kind of number of centers that are ordering. Some centers may be ordering, but it's a one or two buy during the quarter, which is why we've been hesitant to give kind of the total population. Until we get accounts that are really going and fully have adopted driving significant volume, I'd say, number of centers to us is an encouraging sign of an adoption, but maybe not the best sign relative to overall revenue.

Operator

And with that, I'm showing no further questions at this time. I would now like to turn the conference back to Mike Carrel for closing remarks.

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

Great. Again everyone, thank you for joining us tonight. As you can probably tell from our tone and tenor on the call tonight, we are really excited about our future, about the diverse platform we have across all of the parts of our business and momentum in each and every area that we've got there. Thanks again for supporting us, and we look forward to hearing or talking to you early next year. Have a great one.

Operator

This concludes today's conference call. Thank you for participating. You may now disconnect.