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Q4 2022 AtriCure Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's Q4 2022 Earnings Conference Call. My name is Amy, and I will be your coordinator for the call today. (Operator Instructions) As a reminder, this call is being recorded for replay purposes.

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

Marissa Bych

Great. 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-mail 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 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. 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. Mike?

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

Great. Thanks, and good afternoon, and thank you for joining us today.

2022 was an outstanding year for AtriCure. We executed our plan to accelerate revenue, delivering 20% plus growth as we increased adoption across our portfolio of solutions for the treatment of atrial fibrillation, appendage management and postoperative pain management.

We also drove leverage as a result of our strong topline performance and the expanding scale of our platform while making strategic investments to drive future growth. I am incredibly proud of our team whose hard work underscores our performance and whose commitment to our mission of improving patient lives led to an impact of over 100,000 patients around the globe in 2022 alone.

We ended the year with another strong quarter, achieving \$88 million in revenue, reflecting 20% year-over-year and 6% sequential growth. Our fourth quarter performance once again demonstrated the depth of many recent catalysts across our markets, led by remarkable adoption of the EnCompass Clamp, continued expansion of our pain management franchise, and enduring strength across

the AtriClip platform.

As we progress into 2023, we are reaffirming our commitment to revenue growth above historic rates as shown through our guidance of \$380 million to \$387 million in full year revenue. We are also reaffirming our expectation to achieve breakeven adjusted EBITDA in 2023 with improvements annually thereafter as we build sustained profitability of our business.

I will now turn to a more detailed review of our business in the fourth quarter and full year 2022. Beginning with our open ablation franchise. Our 2022 performance highlighted the power of innovation at AtriCure with the commercial launch of the EnCompass Clamp in the U.S. driving an acceleration in revenue. 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. Momentum from the launch built throughout the year as we rapidly expanded to new and existing physicians.

Overall, EnCompass contributed approximately 20% of open ablation revenue in the U.S. during 2022, reflecting tailwinds from new adoption and additional revenue per procedure upon conversion to the EnCompass Clamp. Feedback from our customers has been exceptional, and we are excited for the continued impact of this technology in 2023 and beyond. Globally, our open ablation franchise saw 18% growth in 2022 as procedure volumes around the world stabilized and we advanced patient treatment. While this part of our business has been a steady driver of growth for more than a decade, the market remains vastly underpenetrated, and our opportunity is significant. We are confident in our ability to further penetrate the cardiac surgery market for many years to come.

Innovation is also central to our success in appendage management. We first entered the LAA market with clearance of the AtriClip system in 2010. Today, with multiple enhancements to our technology and unrivaled patient outcomes, AtriClip system products are the most widely used LAA management devices worldwide with more than 400,000 sold to date. We are pleased with the consistent strength of our AtriClip franchise, realizing 20% growth worldwide in 2022 and continued to advance our technology focusing on less invasive and easier to use devices.

In 2022, we initiated new activities to expand the benefit of appendage management with AtriClip through our LeAAPS clinical trial. We received FDA approval last April to begin this landmark clinical trial, one of the largest cardiac device trials in history with over 6,500 patients. The LeAAPS trial will study the prophylactic use of AtriClip devices in cardiac surgery patients who do not have Afib preoperatively, which represents over 2/3 of the 1 million cardiac surgery patients worldwide. The primary endpoint is a demonstrated reduction in ischemic stroke and systemic arterial embolism, laying the groundwork for a new frontier in stroke prevention.

We recently announced the enrollment of the first patient in the trial and are now focused on a major expansion of both trial sites and patient enrollment in 2023. The LeAAPS trial will take many years to complete. However, we expect awareness for appendage management in all cardiac procedures to increase in the interim. Further, we believe this trial will provide a meaningful extension of our addressable market over the long term.

Turning now to our hybrid AF therapy, where we made progress over the course of 2022, increasing our number of accounts by more than 50% since the initial approval. We are now ramping adoption in 14 of the 25 top cardiac centers in the United States and interest in developing hybrid Afib therapy programs remains high. We are encouraged by the feedback from clinicians and the positive impact of this procedure for patients with long-standing persistent atrial fibrillation.

Despite the progress we have made in market development, sticky and acceleration adoption is slower than we anticipated. Cultivating a therapy that requires significant coordination of resources has presented challenges, particularly in an environment where staffing constraints are impacting hospital systems around the world. But these challenges are not insurmountable, and we continue to believe that hybrid AF therapy will deliver accelerated growth in the long term as a differentiated solution for millions of patients. We have spent substantial time working directly with surgeons and EPs to understand the nuances with logistics required for case growth and to scale those takeaways, fostering deeper partnership between care teams along with tactics to implement greater efficiencies across sites. We will continue to focus on providing comprehensive support for the many programs we have in the early stages of adoption and expect 2023 to build the foundation for future growth.

Finally, our pain management franchise. Cryo Nerve Block continues to be an outstanding contributor to our business, delivering 77% growth worldwide in 2022. We dramatically enlarged our reach in the U.S. with nearly 600 sites purchasing in 2022 and saw early traction as we launched Cryo Nerve Block therapy in Europe and Australia. Most importantly, we have helped over 16,000 patients achieve temporary pain relief after thoracic surgery.

Like our other markets, a significant opportunity remains in front of us. We continue to expand our pain management business with the addition of commercial resources, enhanced technology, economic studies, and clinical data and remain focused on developing Cryo Nerve Block as a part of the standard of care for management of postoperative pain. As we have indicated in the past, Cryo Nerve Block also shows promise beyond thoracic surgery. We are actively investigating applications in sternotomy with our existing cryoSPHERE device, and we look forward to updating you on our future progress.

In summary, I would like to reiterate that 2022 was an outstanding year for AtriCure. Our results show that our growth catalysts are diverse, and our products offer differentiated and proven solutions in markets with substantial unmet needs.

As we look forward into 2023, we are cultivating both adjacent and new markets by building upon our technology and leveraging the unique physician relationships we have developed.

My earlier comments touched on the ground-breaking clinical trial, LeAAPS, which is intended to inform and better define clinical practice and treatment guidelines for stroke prevention in patients undergoing planned cardiac surgery with an elevated risk for stroke. This trial, if successful, unlocks the entire cardiac surgery market to AtriCure, which is well over \$2 billion globally. We see substantial opportunity to leverage the strength of our relationships in cardiac surgery and the AtriClip platform for better long-term patient outcomes.

I also mentioned expansion of our pain management business into sternotomy procedures, but we are elevating the use of our existing cryoSPHERE device to enhance current solutions and provide temporary pain relief. The natural synergy between our pain management and cardiac surgery business makes this an exciting opportunity along with the potential to more than double our existing market for pain management.

Additionally, in 2022, we announced that the first patient was treated in the HEAL-IST clinical trial. HEAL-IST is studying 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 effective or approved treatments for this debilitating condition. We are focused on driving additional sites and patient enrollment in 2023, along with the development of a dedicated device for the therapy in parallel to the clinical trial. We 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.

Treating patients in unaddressed and underpenetrated markets is at the core of AtriCure, and we have proven our ability to realize meaningful growth from our diversified platform. We will continue to innovate and research solutions to solve these unmet needs and believe our persistence will yield long-term growth in addition to benefiting patients every day.

I will now turn the call over to Angie Wirick, our Chief Financial Officer, for more details regarding our financial performance.

Angela L. Wirick AtriCure, Inc. - CFO

Thanks, Mike.

Our fourth quarter 2022 worldwide revenue of \$88 million increased 20.2% on a reported basis and 21.5% on a constant currency basis when compared to the fourth quarter of 2021. U.S. revenue was \$73.9 million, a 20.7% increase from the fourth quarter of 2021, reflecting healthy activity across product lines, enhanced by the continued strength from our launch of the EnCompass Clamp, pain management and appendage management products.

FEBRUARY 21, 2023 / 9:30PM GMT, Q4 2022 AtriCure Inc Earnings Call

International revenue totaled \$14.1 million, up 17.8% on a reported basis and up 25.4% on a constant currency basis as compared to the fourth quarter of 2021. Activity in key international markets highlighted by robust growth in appendage management products drove a strong fourth quarter. Sequentially, worldwide sales grew \$4.8 million or 5.7% over Q3 2022. Gross margin for the fourth quarter 2022 was 74%, down 110 basis points from the fourth quarter of 2021. The decline was driven primarily by sales of lower-margin products and supply chain and inflationary pressures.

Turning to the bottom line. We are very pleased with our fourth quarter result. We had positive adjusted EBITDA of \$6 million for the fourth quarter of 2022 compared to negative adjusted EBITDA of \$2.1 million for the fourth quarter 2021. The improvement in adjusted EBITDA is a result of strong topline growth and moderated operating costs with notable leverage in our selling and administrative spend, partially offset by pressure to gross margin. Our loss per share and adjusted loss per share was \$0.09 for the fourth quarter 2022 compared to a loss per share and adjusted loss per share of \$0.30 for the fourth quarter of 2021.

Now to review full year 2022 result. Worldwide revenue was \$330.4 million, an increase of 20.4% on a reported basis and 21.8% on a constant currency basis. U.S. sales increased 21% to \$277.2 million, while international sales increased 17.7% or 25.7% on a constant currency basis to \$53.2 million. The impact from COVID and other macroeconomic environment factors created headwinds early in 2022, but as the year progressed, we saw stabilization in our markets globally.

The commercial launch of the EnCompass Clamp drove U.S. open ablation sales to \$86.1 million or 19% growth over 2021. As we have noted in previous calls, we estimate that the pricing benefit from EnCompass accounts for roughly half of the annual growth with the remaining from continued penetration of the cardiac surgery market.

In 2022, our U.S. pain management franchise grew 75.4% to \$40 million from increasing activity in existing accounts along with new account adoption. U.S. MIS revenue was \$38.6 million, reflecting a decline in legacy procedures, offset by approximately 6% growth in Epi-Sense sales where we continued to lay the groundwork for accelerated adoption of hybrid AF therapy. Finally, in 2022, we saw strong attachment rates as U.S. appendage management sales reached \$112.6 million or 19% increase over 2021, driven largely by our AtriClip FLEX V device.

Similar to U.S. trends and activity in 2022, our international revenue growth was propelled by open ablation, pain management and appendage management products. Gross margin for the year ended at 74.4%, a decrease of 60 basis points from 2021. The decline was primarily the impact of inflationary costs and sales mix where we saw a shift to lower gross margin products. We continued to explore measures to reduce costs and improve gross margin.

Moving forward to operating expenses. In 2021, we recorded an adjustment to the fair value of contingent consideration and the impairment of the IPR&D asset associated with the aMAZE PMA. After removing the impact of these special items for comparability, full year operating expenses were \$288.6 million compared to \$253.2 million, an increase of 14%. The increase in operating costs in 2022 resulted from investments to expand our headcount across the organization, strategic clinical and product development project spend as well as impacts from inflationary costs. We are pleased with the leverage in our operating costs in 2022 and remain focused on driving efficiency and SG&A while maintaining investments in R&D.

Full year 2022 adjusted EBITDA loss was \$2.2 million compared to \$8.8 million in 2021. Our loss per share was \$1.02 in 2022 compared to earnings per share of \$1.11 in 2021. Adjusted loss per share was \$1.02 and \$1.16, respectively. We ended 2022 with \$173 million of cash and investments on hand, a strong working capital position and the flexibility to fund future opportunities and investments.

Now finally, turning to our outlook for 2023. Consistent with our announcement in early January, we expect to achieve between \$380 million and \$387 million in revenue for the year, reflecting growth of 15% to 17% over full year 2022 results. As Mike outlined earlier in the call, we have multiple growth drivers in our business globally and anticipate similar drivers leading our 2023 performance, exceptional contribution from pain management and continued strong activity in both open ablation and appendage management with very modest contribution from MIS ablation as we strengthen the foundation for long-term success.

This last point is important to our outlook for 2023. While we focus on program development for hybrid AF therapy, we believe it is

prudent to reset short-term growth expectations for this area of our business. Our long-term expectations are unchanged, and ultimately, we are confident that our focus and efforts will lead to accelerated growth in MIS ablation in the years to come. We also believe general seasonality trends, aligning with those we saw prior to the COVID pandemic, will inform revenue cadence in 2023 with first quarter revenue likely to be flat to our fourth quarter of 2022.

From a margin perspective, we anticipate 2023 gross margin to be in line with our recent results with variability caused by geographic and product mix. We continue to make meaningful investments to support further label and market expansion, enhanced reimbursement, and innovative product development within R&D expenses, maintaining our R&D spend as a percentage of 2023 revenue at approximately 18% to 19%. This level of investment contemplates heavy enrollment within our clinical trials as more sites activate in 2023 along with many technology advances across our platforms. We are moderating SG&A investments in 2023 as we continue to leverage spend and target efficiencies in scale as we grow.

With strong revenue growth and key strategic investments in mind, we expect full year 2023 adjusted EBITDA to be breakeven. Our investment priorities in 2023 are clear. We are balancing the support of our many growth catalysts with overall preservation of capital. Our focus in 2023 is to advance clinical trials with robust site expansion and patient enrollment, enhance our platforms with new technology while focusing on improving leverage and profitability. We continue to maintain a solid balance sheet which enables these investments in our future growth.

For quarterly cadence, consistent with our historical results, first quarter 2023 will be a heavier adjusted EBITDA loss that is expected to decrease each quarter as the year progresses, and we achieve our guidance of breakeven adjusted EBITDA for the year. Further, cash burn in the first quarter is normally heavier driven by the timing of variable compensation payments, share vesting and other operational needs to start the year. Our adjusted EBITDA guide translates to an adjusted loss per share for 2023 of approximately \$1.14 to \$1.19. We enter 2023 with determination to expand our patient impact and are thoughtfully managing our business for long-term success.

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

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

Thank you, Angie.

2022 was a strong year across the company and in many ways, began the next phase of AtriCure's course as we continue executing against the significant market opportunities in front of us, while also thoughtfully investing to expand our markets and impact to adjacent patient populations over time.

We are building upon the foundation we have created together over the last decade by continuing to innovate with a long-term growth mindset. The totality of our business today and in the future will ensure success in 2023 and over the coming decades, and we will continue delivering on our commitment to revenue growth above historical rates. We are just as excited to showcase the benefits of our expanding scale and operational planning as we strike to calculate a balance between investing for the future and our profitability.

And with that, I will turn it over to questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Robbie Marcus with JPMorgan.

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

Congrats on a nice quarter. Maybe to start, the MIS commentary was new and a little bit disappointing to hear in the short term. I was wondering if you could spend a bit more time on it. Why has it fallen below your expectations for growth? And how long do you think it will take to start to resume back on track with where you thought it could be?

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

Yes, really fair question. And we feel the same way overall about the kind of MIS business in terms of kind of where we are. Obviously, the data from -- that came out from the CONVERGE trial has been exceptional. More and more data continues to come out clinically to show that when you add epicardial ablation to the endocardial ablation, it actually benefits a lot more. And endocardial by itself just does not work on the long-standing persistent patients.

So, in the face of this great data that's out there and continues, why is it taking us a little bit longer to get up and running? I think it's a very fair question for us, and really, it comes down to some of the comments that I made, Robbie on there, which is that the logistics have proven to be a little bit longer to kind of get that stickiness going. There isn't pushback on whether or not this is going to benefit patients and whether or not this is going to be something that long term, we're going to have a lot of patients that are going to come through this funnel. It has more to do with really getting surgery and electrophysiology and their groups working very closely together and getting that patient flow in and having that confidence. And then that's just kind of, I'd say, a global kind of thing that we're kind of facing relative to that.

On top of that, I think we underestimated the impact of coming out of COVID and the staffing effect of when you're trying to coordinate 2 different groups like that, getting people to kind of get their attention and get the staffing to work where you get their attention upfront because we had a lot of activity even during COVID to get sites up and running and training, but then to get them to do the hard work of actually working through the logistics and working through how we're going to move that patient through the process, that's the part that's taken us longer than expected. I do feel like we've got a really good handle on it now, but it's going to take us a little bit longer. And I think ramp-up on each individual site is taking us a little bit longer on that side, which is why we've set guidance this year above our historical numbers at that 15% to 17% and feel really good about that, and that includes a weak hybrid number.

And so obviously, we would love to see that come back faster. I can't give you an exact quarter [date], but hopefully, it does and that we have some upside to those numbers at some point and additional upside that you might get relative to the other really fast-growing parts of our business. But even with a weak hybrid aspect of it in 2023 from a revenue side, we're going to make a ton of progress in these sites, and I feel like it really is going to accelerate our growth long term on that side.

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

Great. I appreciate that. And maybe to dovetail with that now with lower MIS expectations. Maybe you could speak to the different business line items and how we should be thinking about reallocating that revenue within the guidance range through the year?

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

Yes. So -- yes, I'll go through each individual franchise. So, when you think about the open ablation franchise, I think the beginning part of this year, we're going to continue to see really good strength off the open as we kind of lap that one year from rolling out EnCompass. We are seeing great traction in that part of our business. It has exceeded all expectations that we had internally. We feel really good about adoption. We're saving time, and we're making it a lot easier for surgeons that otherwise were not performing cardiac surgery ablations on their patients and those patients getting benefit. And so it's kind of met that mark and beyond, and we think that there's a lot of room for growth, both in 2023 and beyond on that particular side. So that's going to be definitely 1 major growth driver.

Number 2 is, Cryo Nerve Block continues to be a very robust growth driver for us. We're going to continue to add a lot of new people into the business in that part of our business because we need help on case coverage. It's really expanding. As I mentioned, we're in over 600 sites today, and we -- and we're just beginning to penetrate that market, not just in terms of number of sites, but to physicians and all the different procedures. So we think that, that's going to be another robust growth year for us overall. Maybe not the same percentage growth, but we do think that it's going to be a really nice strong growth year for us.

We're not including really much into our guidance relative to sternotomy. As I mentioned on the call, we're really excited about sternotomy, but we're really doing -- we're laying the groundwork this year so that next year and beyond, it's going to be sticky revenue for a really long period of time. And we know that market incredibly well because as I mentioned in my script, we have relationships with pretty much every single cardiac surgeon in the country. So it's a really -- it marries very well with our cardiac surgery team also, and they're really working very collaboratively in the field. And then Clip continues to be a very strong driver for us of kind of overall growth

for the business and feel like that's going to be a solid performer for us. So kind of in that order, I'd say, are some of the big growth drivers for us this year.

And then internationally, we've definitely seen, as you kind of saw this quarter, we're starting to see that become a more meaningful part of our business, and we feel like that's going to continue into 2023. We put new leadership there a couple of years ago, kind of right before COVID, and we're starting to see the real tangible benefits of that both in Europe and in Asia.

Operator

And our next question comes from Matt O'Brien with Piper Sandler.

Unidentified Analyst

This is [Sam] on for Matt. I guess, starting off, could you give us a little bit more information on pain management? Obviously, it was a good growth driver last year, coming in about 75%. What could we expect moving forward? And how could this play out throughout the year?

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

Well, we expect definitely continued growth in that market. We are at about 60 people or so now. If you look back about 4 years ago, we were sitting -- that was -- we were just kind of getting that therapy started. So we've kind of gone from 4 people to 60 people over the last 4 years. We're going to add more people to that group because case volumes continue to grow every week as we open up new accounts and get deeper and deeper into those accounts. As I mentioned, we're not going to see the same percentage growth. I think that the numbers are just getting larger from that standpoint, but we do anticipate that we'll still see robust growth within each of those individual accounts as we scale that business. I don't know if that's what you're looking for. If you're looking for more detail than that, I'm not sure where to go with it.

Unidentified Analyst

That's good. I guess 1 more from us on MIS, and I think a lot of it was covered previously, but would you be able to just give us a little bit more information on what [CONVERGE] did this past quarter? And when do you -- could you estimate when we could see the sort of inflection point in the future?

Angela L. Wirick AtriCure, Inc. - CFO

Yes. [Sam], I'll start with what CONVERGE did in the fourth quarter. We were down slightly year-over-year, but if you recall, the fourth quarter of 2021 was 1 of our strongest on record. So we're down sequentially and then down year-over-year in the fourth quarter. We saw good activity within the overall number of accounts, but I think the challenge that we're seeing within accounts of -- look, being able to do procedures repeatedly on a kind of a mass scale, meaning reaching a bigger number of patients throughout the quarter and the year has definitely been a challenge, and that's the logistics and the workflow within program development that Mike referred to earlier.

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

And as we look at inflection points, we're not -- I'm not ready to give you a date. What I can tell you is this -- is that from the feedback we've gotten from both electrophysiologists, cardiologists and surgeons, they want to build programs. They want to put in the time and effort, but it does take more time than we had expected. So I can't predict the exact date.

What I can share with you is that I absolutely believe this is going to be a growth driver for us from now to the end of the decade. This year is going to be a little bit tight as we get these sites up and running, but there are millions of patients that have long-standing persistent atrial fibrillation. And study after study, paper after paper shows that if you add epicardial ablation to endocardial ablation, these patients do at least twice as well and are much more durable from -- in terms of the liaison set than just the endocardial by itself.

So the combination is really powerful. And more and more data is coming out to prove that. And so from our standpoint, we really think this is going to be sticking long term, even though this year is going to be a building year for us.

Operator

And our next question comes from Bill Plovanic with Canaccord.

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

Great. Can you hear me okay?

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

Yes. Perfect.

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

Great. So just to piggyback on the MIS question, the commentary of a foundational year, you're building it. I think expectations have been probably in the 20% -- 30% to 40% year-over-year growth rate. If you're building it, does that mean it's a flat year? Does that mean it's up 10%, 20%? How do we think about the growth in the year you're building? And what specifically are you focused on with the accounts? Because I think one of the other words that keeps popping up is stickiness. So it seems like you're getting accounts started and then they might trail off. So just kind of curious what that expectation is and then how you get to it?

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

Yes, really fair question. So there's the -- when we build our guidance for the year, and I think that's the most important thing to really think about is that we (inaudible) that 15% to 17%, we're assuming that our hybrid business is well below that. That's kind of the way to think about it, and that the other businesses are driving the growth for the business. And so our hope is obviously that there's some upside to that at some point and that these sites get sticky, and they kind of really begin to drive that logistics and get the patient flow through and get those case volumes to be kind of more consistent across the board.

But in absent of having the consistency yet, I'm not ready to kind of commit to being near that corporate growth rate at this point. So it's going to be below -- significantly below that corporate growth rate in terms of how we built our guidance up, and then obviously, that tells you that the Cryo Nerve Block and the Clip are likely above that and that the open ablation is going to be having a solid year. We have historically said on the open ablation side that you're sitting in the tune of kind of the high single digits. Obviously, we've exceeded that quite a bit this year, and from an overall standpoint, it's going to be above that overall, but maybe not quite as growthy as you'd see on the Cryo Nerve Block side.

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

Okay. And then a follow-up on expenses. Your SG&A, I mean that's a pretty interesting to see it drop nominally from Q2 and Q3 in the highest revenue quarter. And I'm just curious if there's any onetime benefit that you received in the fourth quarter? Or is this more of the baseline we should be thinking of for the future?

Angela L. Wirick AtriCure, Inc. - CFO

Bill, there was 1 onetime item, 1 benefit of a collection of a receivable that had been reserved several years ago to the tune of roughly, let's say, \$1 million that benefited the quarter. We also saw, in some cases, better kind of leverage of our spend in some of the areas that have cut against us on the expense side. Travel is one that comes to mind, just a little bit favorable in the fourth quarter. I think as you look back historically, the pattern on SG&A spend, would say look at a higher percentage to start the year and then moderate as the year goes. And part of that is, we feel like we're entering the year with really good investments kind of globally within the sales team, but we'll be selective about adding -- Mike touched on a couple of areas within our Cryo Nerve Block team and then our international teams will continue to add and then a little bit more on the case support within cardiac as well. We feel like we're entering the year with a really good and solid team that can drive robust growth for the year.

Operator

And our next question comes from Marie Thibault with BTIG.

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

I wanted to ask 1 here on open ablation. I want to understand how far that growth can be sustained. I know in the past, you've given us some details like it making up 20% of revenue in 2022, and I know that price uplift as well as volume have both contributed to that growth. So I wonder if you can help us understand where we are in terms of reach with that device. How many of your accounts, if you've gone into that with all of your accounts? And how much longer kind of some of this price uplift can continue?

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

Yes, I'll start, and then I'll let Angie kind of follow up on some of the pricing questions. When we think about this market, I think we're in the really early beginnings of it. When you think about the cardiac surgery market and the Afib treatment there, we're still, as an industry, only treating 28% of those patients in the best numbers. More and more data is coming out to say that it might even be less than 28% treatment. Yet it's still a level 1 guideline across all the societies. And one of the big pieces of feedback that we received was, how do you improve that? Well, the number one thing was you needed to make it easier to perform for surgeons that don't normally get behind the heart.

And so EnCompass, which has been in development for over 4 years and is now on the market, was really targeted towards that audience to kind of do a very robust ablation for those patients and make it much easier for them to do it and get behind the heart by going through the oblique and transverse sinus and then combine that with making it a little bit quicker, and we've seen all of those benefits. And so we think that our goal is to take that 28%, and hopefully, we're going to get to over 80% some day of patients that are undergoing cardiac surgery with Afib are getting treated. And so I think we've got a huge market in front of us, significant opportunity that sits there.

And how that applies to our growth, I don't want to -- we're not getting too far ahead of ourselves when we put our guidance at 15% to 17% just because we've only had in the market for 6 to 9 months really aggressively. And so, we kind of wanted to see how that shakes out this year before we can kind of give maybe more long term what it could look like on an annualized basis. But we are feeling very confident in the sense that it's working really well. Surgeons that were not using any product to do any ablation are now doing some ablation helping these patients out, other surgeons are finding it easier to use than some of the other products and devices that we had. So we're kind of able to expand in multiple different ways, and we're learning as we're rolling it out. So it's been a great product, received very well, and I think that we've got many, many years ahead of us of strong growth with that. And hopefully, we'll get ourselves to 80% and help these patients out for a long time.

Angela L. Wirick AtriCure, Inc. - CFO

Yes. Marie, in terms of the reach, we're in just over 1/3 of accounts as we -- accounts in the U.S. as we ended the year in a pretty high conviction rate when you think about the number of accounts that started early on in the launch that have continued to order throughout the year. And then we'll lap the launch benefit really in the second half of 2023 when EnCompass is a more meaningful percentage of the open ablation revenue.

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

Okay. That's really helpful, both of you. I guess I'll ask my follow-up here on the Cryo expansion. You mentioned you're doing some exploration in sternotomy. What does that look like? And when might we start to see more meaningful revenue from the sternotomy opportunity? And can you also remind us on the sizing of that market?

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

So I'll start with the sizing. So, we've been looking at the sternotomy market for several years, and we've been studying how much pain is there. What is the difference between the sternotomy pain versus the thoracic pain? And what we're -- we got feedback from a lot of our customers that they believe there's a tremendous amount of benefit to add this to their kind of CABG procedures or their sternotomy procedures overall. There's about 255,000 CABG procedures in the United States alone. To just give you a relative comparison, there's about 140,000 to 150,000 thoracic procedures. So, it increases -- it more than doubles the size of the overall market opportunity for us, and so that's obviously vast. And we have relationships with people performing that surgery. I mean we have relationships in almost every one of those accounts in the United States and globally, and so we've got very good ability to penetrate and have access into that market.

The way that we're rolling it out is, first, over the last year or so, we've really studied how does it work, do the free spins work, where should we ablate? Like clinically making sure that before we roll it out to everybody that we understood that it could be safe and effective and really benefit patients first and foremost. So, our team has really done deep dives with KOLs around the country, tested out and learned from that.

Next step is the phase that we're in right now, which is, we're going to roll it out to a select number of sites so that we can learn from those sites about the best application for it. It is different than thoracic in terms of it's a different part of the nerve. So what do we learn from that, how long does the benefit last for that patient in terms of helping them get out of the hospital and improve their overall pain scores and things such as that. So those are things we're going to really study in these first really small number of accounts over the course of the next 6 months or so. Based on that feedback, the back half of the year will begin to roll it out a little more aggressively and then really go into a big launch early part of 2024.

Operator

Our next question comes from Mike Matson with Needham.

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

I wanted to ask one on the gross margin. So Angie, I think you said, you expect it to be flat in '23, but things like -- there's maybe still potential for some inflation and some of the mix issues that you had in '22 could carry into '23.

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

That's right, Mike. As we exited '22, I think the last 2 quarters were hit a bit more by cost increases kind of across our supply chain. And as EnCompass and cryoSPHERE became a bigger percentage of our overall revenue, we saw some really nice activity in our international markets that does come with a bit of a hit to the gross margin. So our expectation, as we think about 2023, pretty close to where we've been kind of more recently in the 74%, 75% range, but with upside as the team continues to really evaluate ways to lean production. EnCompass, for example, will be in our first full year of production here coming up in the spring and have targeted areas really to reduce cost and lean out the cost within both that and then our cryoSPHERE probe.

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

Okay. But just to be clear, you think -- you still think it could be flat even with some of those issues maybe remaining in place?

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

Yes, correct.

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

Okay. And then I want to ask one about the international business. Good to see the strength there. Maybe you could talk about, are there any more opportunities to enter new markets and just wanted to take a temperature on China and kind of what you're seeing there? And do you see any risk of the value-based purchasing effect in there?

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

So our international business, as I briefly mentioned, is really -- we put new leadership in place several years ago and that really had a positive impact on just the overall acumen and how we're going to market throughout both Europe and Asia. As it relates to Europe, I don't know if there's any new markets we can go on. We're pretty much in every market in Europe whether direct or on a distributor basis. We've got very good growth prospects there, but the biggest piece of growth prospect is that we're really at the early, early stages on the hybrid therapies and on Cryo Nerve Block just started there. And so we've seen really [strong] growth on the Clip franchises as well. And so I'd say that there's opportunity in all that, quite frankly, throughout Europe.

The penetration rate on the open side of our business is even lower in Europe than it is in the United States. So we think that there's even more opportunity there long term. We don't have EnCompass there yet. We're working on that. We think that's several years out, but there is more awareness that they need to be treating. And I think there's a lot of good growth and now that we've got really strong and

solid leadership there, I think we can make some really good inroads there.

In the Asia markets, we saw great growth in Australia this year. That was 1 of our big growing portions of our market. Japan continues to be a solid contributor. It's our #2 country in the world with many of our products in line. China has been -- surprisingly has actually been a reasonably kind of solid. It's not like decreasing, but it's also not increasing. So it's kind of been a solid market for us. We've only got our RF products there today. So we don't have an expansive portfolio. We're working on that, but we still think it's probably several years ahead before we start to see some growth coming out of -- back out of China. But at least it's in a very solid place, which 3 years ago, it was not as solid and a little bit more volatile. And today, I think we're in a very solid place and have really strong market share and a strong presence with the distributor that we have there.

Operator

And our next question comes from Suraj Kalia with Oppenheimer.

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

Mike, Angie, can you hear me all right?

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

Yes.

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

Perfect. Mike, so just picking up on some earlier questions. So the stronger outlook for open and the lukewarm outlook for hybrid in your prepared remarks somewhat counterintuitive. And I was wondering if you could just juxtapose -- you and I have talked about this offline also, but I would love for you to juxtapose how you see any potential indication creep from PFA? And if your new outlook, if CAPLA also has anything to do with the way you'll see open versus hybrid moving forward?

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

Yes. So PFA and CAPLA have absolutely 0 impact on our both short-term business. And in fact, I actually think they're going to be long term, very beneficial to us. The data that came out from CAPLA, as I know you've looked into, basically says that the endocardial catheter by itself on long-standing persistent patients does not have long-term durable effect, and the numbers were almost identical to what we saw in the CONVERGE trial in that arm of the trial. In the CONVERGE arm of the trial, we saw a significant improvement in durability with that. So we think CAPLA is incredibly supportive that for these most-difficult-to-treat patients, for these long-term Afib patients that CONVERGE and all the papers that have come out afterwards that CAPLA further supports that when you add epicardial ablation to endocardial ablation, you get a better long-term result. And endo by itself is not effective and that were complementary to it.

So I actually think that, that's actually made me even more bullish, not necessarily this year, but really more as we look long term. And as we get these logistics worked out. This year is all about logistics and workflow, not about data because the data supports that we should be growing even faster. And I believe that, that data is going to be in effect as we look at 2024, '25 and '26, once we get through all of the workflow that's out there.

As it relates to PFA, again, I think it's complementary. I think PFA is a great and really interesting technology. It is out there to improve speed and improve safety and be close to the same effectiveness as RF and cryo. And almost all of the initial devices are being tested and worked on and looked at for mostly PVI, and some of them are beginning to, obviously, as you know, look at some of the posterior wall. I think they're going to run into the same efficacious results that they're going to see with cryo and RF when you look at it on -- when you look at the posterior wall.

A study just came out from Europe called the MANIFEST study, and when you look at that data, it's very clear that in paroxysmal and even early persistent patients, the PFA works reasonably well at 1 year. Actually, very consistent on the results relative to RF and cryo. And so then physicians -- and that has nothing to do with our business. That's just -- I mean that's not the -- we're not in those markets per se today, but what it does demonstrate is that it's reasonably close on efficacious, and then people are going to have to make decisions upon the speed and the safety aspect of it as more and more data comes out. But if you actually look in the details of that

study, it shows that at 1 year, there's a significant drop-off in the long-standing persistent patient population, and those patients got a posterior wall ablation.

And so I think -- and those numbers again are very consistent with what you see in all the studies that we did with CONVERGE and other studies that have been out there for years around trying to do just endocardial ablation. So again, that to me makes it that our epicardial ablation is complementary to PFA to cryo to RF. And it really, quite frankly, emboldens me for our long-term growth prospects, again, needing to work through some of the logistics in the short term.

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

Fair enough. One other question, Mike. So Mike, maybe I'm jumping the gun here on LeAAPS and there is information you are not in a position to share, I can appreciate that. So one of the endpoints you mentioned, Mike, was, if I remember correctly, systemic embolism. And just given the idiopathic nature of thrombus formation in these patients, Mike, how do you reliably hypothesize the event rates? Any additional color there would be great. I mean you can occlude the LAA. I'm curious how do you prevent or account for everything else and systemically, which might have nothing to do with what you -- how you guys intervene.

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

Yes. No, it's a really fair and great question and one that we studied quite a bit in the design of the trial. When you look at -- when you get a sick atrium, whether it's caused by atrial fibrillation or caused by any other source like heart failure, that atrium is not operating correctly, which allows for the blood to begin to pool and the natural place for that to pool is in the appendage.

And so not only have we hypothesized, but when you looked at the ATLAS study or you look at that we did with 562 patients, and albeit it was only 1 year outlook, and it did not have a strong -- it wasn't powered for the full piece of this. You combine that with other data that's out there about kind of heart failure patients and their stroke rates relative to after cardiac surgery, we've been able to kind of come to a really good rate to basically enhance that and look at the patient population that is at a high risk of having basically a weak atrium, whether caused by atrial fibrillation because they're likely to actually get Afib or caused by heart failure. And mechanistically, we believe that, that is going to lead to a higher stroke rate in patients when they don't have that appendage because where does the blood pool?

The blood pools and -- into the appendage, and we do know that. And we do know that the appendage is sourced for that because of the trabeculation of the appendage and quite frankly, just based on the way that it is situated around the heart. So we feel very confident that this is going to be a positive result. It's obviously a long trial and trials have to be proven over a long period of time. So there's no guarantee on that front, but it's a combination of a lot of that data that I just described kind of put together and over the course of researching over the last 4 years that we feel very confident that this is going to be a successful trial.

Operator

And our final question is from Rick Wise with Stifel.

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

Just 2 quick ones for me. One, just on the macro picture. The only aspect, I think, of your comments if I heard correctly, Mike, where you talked about some of the macro headwinds we're all familiar with, (inaudible) mentioned much was staffing constraints relative to CONVERGE. I just was curious, we've heard from a lot of companies so far at the start of the year. Do you feel like macro pressures like staffing are getting better or getting worse or stable? How are you thinking about? And the same thing, maybe it's more for Angie, on the sort of cost inflation side. You're getting after some of those as you said, Angie, but are things getting worse or slowing down? Just as we start the year, I wanted to frame that.

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

Yes. As it relates to staffing, I'd say that it's not getting worse or better. I'd say it's relatively stable with most of the end of last year. My comments around staffing relative to us very specifically with it. I think we underappreciated the impact coming out of COVID that the staffing constraints would have on starting new programs and getting their time to work on the logistics and work through how they were going to hand off and care for that patient. And that was a little bit of a miss on our part relative to kind of thinking through the expectations coming out of COVID and Omicron and as we're kind of ramping back up. But overall, though, I'd say that they're relatively

consistent. They're not getting worse at this point in time by any means. For us, I just think we need more time to get through kind of on the CONVERGE side to kind of ramp that back up and get the logistics to work. And there's still some -- there are staffing constraints that are out there that do impact kind of getting their time and energy.

Angela L. Wirick AtriCure, Inc. - CFO

Yes. Rick, on the cost side, I would say, from the supply chain area, we feel like we've got good visibility at this point and can understand kind of where the costs are coming from with our key suppliers. I do think that we exited the year feeling a bit more relief in some areas such as travel where I think early in the year, I think that the pricing that we were seeing, the cost just overall relative to our [teams] travel was getting a little bit out of hand. So kind of a mix there, I'd say, feeling better from some of the areas where there's a little bit more discretionary spend and kind of have a handle on where the suppliers are coming in, in a longer-term basis.

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

Great. And just 1 small follow-up really. Mike, given the significant investment in clinical trials, LeAAPS, it seems like it's obviously a significant and important investment. How do we think about R&D expense going forward? Do we -- because of some of the spending, could we get back towards 20% of sales that we saw in -- I think it was 2020? Is -- does the dollars move higher than we saw last year? How do we think about modeling R&D?

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

Yes, before -- I'll let Angie answer the modeling question, but maybe philosophically, I think I just want to make sure I lay the land on. When we think -- I mean, I believe that one of the things that we do well and that we're going to continue to do well over the next coming decades is expand into new markets where patients are undertreated today and find therapies for them to be treated. Whether it's -- as we talked about with LeAAPS investing there; IST, I talked about; sternotomy. These are new markets.

They are market expanding with existing products that we basically have today, and clinical trials actually help kind of define what that success could look like in the market expansion opportunity. I think these are things that allow us to be a really robust and kind of big company over the course of the next decade or so and really expand that market into multiple billions.

So that's why we're making the investments, and we're uniquely positioned because we're going to be the first to market and the first into those areas, and we think the clinical -- not just differentiation, but it's also, we believe science matters in terms of actually getting the right level of adoption so that when physicians are making decisions, they're making it based on the scientific evidence that is out there. With that, I'll kind of turn it over to Angie to talk maybe more details about some of the numbers.

Angela L. Wirick AtriCure, Inc. - CFO

Yes, Rick, our prepared remarks, we said for the year, we expect about 18% to 19% R&D spend as a percentage of revenue. I think quarter-to-quarter, based on pace of enrollment, you may see a little bit of variability off that number. But we think in the near term over the next couple of years with the lens of clinical trial -- real expansion of the clinical trials and a commitment to continuing to advance our technology platform that R&D as a percentage of revenue will stay in the upper teens.

Operator

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, thank you, everybody, for joining us after an outstanding 2022. We look forward to demonstrating the sustainability and growth engine that we have here at AtriCure. Thanks for joining us and for your interest in our company. Have a great one.

Operator

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

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