Atricure Inc. (Q4 2023 Earnings)
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Corporate Speakers

- Marissa Bych; Gilmartin Group; Principal
- Michael Carrel; AtriCure, Inc.; President and CEO
- Angela Wirick; AtriCure, Inc.; CFO

Participants

- Robert Marcus; J.P. Morgan; Analyst
- Unidentified Participant; UBS; Analyst
- Unidentified Participant; Canaccord; Analyst
- Matthew O'Brien; Piper Sandler; Analyst
- Sam Eiber; BITG; Analyst
- Joseph Conway; Needham; Analyst
- Daniel Stauder; Citizens JMP; Analyst
- Suraj Kalia; Oppenheimer & Company; Analyst

PRESENTATION

Operator^ Good afternoon. And welcome to AtriCure's Fourth Quarter and Full Year 2023 Earnings Conference Call. (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 introductory comments.

Marissa Bych^ Great. Thank you and good afternoon.

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 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, 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 CEO.

Michael Carrel^ Good afternoon. And thank you for joining us today. 2023 was an exceptional year at AtriCure, and I am proud to report a strong finish with fourth quarter growth of 21%, showing robust momentum throughout our entire business. Our full year revenue of $399 million represents 21% over 2022, our third consecutive year of above 20% revenue growth.

And globally, we saw increasing adoption of our broad portfolio of products for the treatment of atrial fibrillation, the left atrial appendage and postoperative pain. Our patient impact extended further than before, resulting in the achievement of our 1 millionth patient treated with AtriCure technology.

In addition, our top line performance -- in addition, our top line performance and increasing leverage drove $19 million of positive adjusted EBITDA in 2023, making significant progress towards sustained profitability throughout our business.

Before sharing operational highlights of the fourth quarter of 2023, I would like to frame the opportunity in front of AtriCure now. We identify markets where patients are underserved and create standards of care to improve these patients' lives.

We know that creating new standards of care requires sustained investment in innovation, clinical science and comprehensive education and awareness. Investing across these areas has allowed us to unlock new opportunities over the last two decades, and we are now positioned to offer solutions for millions of patients worldwide. This translates to a more than $5 billion global market opportunity today with significant potential to expand our market opportunity in the future.

AtriCure is in a unique position as a leader in each of our markets with every market still significantly underpenetrated. Therefore, we remain focused on driving adoption as well as identifying and cultivating new opportunities to drive strong growth for many years to come. As such, we are reiterating our expectations for full year 2024 revenue of $459 million to $466 million, reflecting 15% to 17% growth over 2023.

We are also reaffirming our expectations to achieve adjusted EBITDA of $26 million to $29 million for the full year, with improvements annually thereafter as we progress towards positive cash flow.

Now shifting to highlights of the quarter and 2023. Starting with the open ablation franchise, where our ablation solutions for the treatment of Afib are used concomitant to open heart surgery. In the fourth quarter, we surpassed 10,000 patients treated with our EnCompass Clamp and achieved the best quarter yet for EnCompass Clamp sales, which accounted for nearly half of our U.S. open ablation revenue for the quarter. The uptake of this product has been extraordinary since the broad commercial launch in early 2022.

At the recent Society of Thoracic Surgeons Conference, I heard from many surgeons about the impact this device is having on patients, expanding our reach throughout cardiac surgery procedures.

Globally, our open ablation franchise achieved 21% annual growth in 2023, showing a continued elevation over historical growth rates in this franchise. As we begin 2024, we are confident in the increasing adoption of the EnCompass Clamp in the United States and look forward to the European launch later in the year and other markets in the future.

Next, turning to appendage management. AtriClip products for left atrial appendage closure in both open heart and minimally invasive procedures remain a foundation of our business. In many markets around the world, AtriClip devices are leading our growth as left atrial appendage management becomes the standard of care in cardiac surgery. We are excited to have seen the STS, AHA and ACC all elevate surgical LAA exclusion to Class 1A within their guidelines recently.

And we expect this evolution in guidelines to propel strong, continued growth for our business.

Overall, our appendage management business grew 21% in 2023, and we closed out the year with an acceleration in quarterly growth at 24% for the fourth quarter. Our growth was driven primarily by sales of AtriClip FLEX V, PRO2 and PRO V devices, reflecting strong attachment to both open and minimally invasive procedures and is indicative of the immense opportunity that is still ahead. To that end, we celebrated a milestone in 2023 with more than 0.5 million AtriClip devices sold to date. This milestone stands on AtriCure's long-standing commitment and decades of innovation and research, which we are continuing in 2024 and beyond.

In late 2023, we submitted a 510(k) clearance notification to the FDA for our next-generation AtriClip device, the FLEX Mini, which builds off our proven technology to increase ease of use and significantly decrease the size of our AtriClip device, which already has the smallest profile on the market. We anticipate clearance in late 2024 with the U.S. launch following quickly thereafter.

Additionally, to extend our potential patient impact, we are actively investigating the application of AtriClip devices in patients with preoperative AFib diagnosis through our LeAAPS clinical trial. The LeAAPS trial seeks to demonstrate a clinically meaningful reduction in ischemic and systemic atrial -- or arterial embolism differentiating our AtriClip product from all other appendage management options in cardiac surgery and expanding our addressable markets globally.

Enrollment in LeAAPS began in late January 2023 and accelerated throughout the year. We ended 2023 far ahead of our internal expectations, and as of today, we have enrolled over 1,700 patients in the study. We are expanding clinical trial sites in 2024 and expect first enrollment from centers in Europe in the coming weeks.

While the trial will take several years to complete, the pace of enrollment both validates our decision to embark on this trial and underscores the excitement from clinicians and patients.

Moving now to our pain management franchise, where our cryoSPHERE probe provides temporary relief for postoperative pain.

Since the launch in 2019, the cryoSPHERE device has exhibited remarkable growth with full year 2023 revenue exceeding $50 million worldwide, reflecting growth of 26% year-over-year. The base of accounts we serve has expanded just as rapidly, and we saw more than 750 accounts purchasing globally in 2023.

That said, to capitalize on the full market potential, we have several parallel efforts underway to add growth drivers for this business. First, our next-generation technology, the cryoSPHERE Plus probe, was cleared by the FDA in the fourth quarter. The cryoSPHERE Plus device will enable faster ablations, improving efficiency of procedures. Recently, we completed the first procedures with this device with a 25% reduction in ablation time.

We expect to move to full launch in the second quarter. We are also conducting economic studies and partnering with multiple centers to expand clinical data to better illustrate the value proposition of Cryo Nerve Block therapy. We will continue to invest in commercial resources worldwide to promote awareness for this important alternative to traditional pain management practices.

Lastly, while we focus on driving adoption in thoracic and sternotomy procedures, we are carefully evaluating potential new applications and market opportunities for Cryo Nerve Block therapy and look forward to updating you on progress.

Finally, rounding out our portfolio is Hybrid AF therapy, focusing on standalone treatment of the millions of patients with long-standing persistent Afib. We ended 2023 on a high note with 27% year-over-year franchise growth in the fourth quarter. As I've said on several calls over the past year, 2023 was a building year for Hybrid AF therapy

to ensure a strong foundation for lasting success throughout our accounts and leading to accelerating growth in the future.

We were thoughtful about partnering with our customers to address workflow challenges and comprehensively understand their needs for program expansion. Our fourth quarter results confirmed that our work throughout 2023 is having an impact, and we will continue our efforts into 2024.

We expect 2024 to be an exciting year for standalone treatment of Afib as peers introduced PFA catheter technology in the U.S. market. The focus on more efficient endocardial ablation driven by PFA should provide a tailwind for everyone in the Afib market. Our hybrid approach remains complementary to PFA, just as it is complementary to other energy sources used in endocardial procedures.

Further, AF therapy remains the only proven solution for long -- Hybrid AF therapy remains the only proven solution for long-standing persistent Afib patients.

In addition to our CONVERGE trial results, there is a rapidly growing body of clinical evidence from independent studies and registries showing catheter ablation alone is not an effective treatment for patients with advanced Afib. In 2023, data from our CEASE AF study and DEEP AF clinical trial provided even more support for a hybrid approach. Moreover, recent updates to clinical guidelines published by AHA and ACC demonstrate the importance of Hybrid AF therapy. As such, we will continue to build our program development efforts with the goal of cementing efficient, scalable workflows for a broader base of customers. We have a strong conviction in the accelerating adoption of our Hybrid AF therapy for the millions of patients suffering from long-standing persistent atrial fibrillation.

In summary, 2023 was another truly exceptional year for AtriCure, defined by major milestones and patient impact and accelerating top and bottom line growth.

We are excited to carry this momentum into 2024 as we advance adoption of our therapies and invest in future growth prospects that will propel AtriCure forward for many years to come. And with that, I will turn the call over to Angie Wirick, our Chief Financial Officer. Angie?

Angela Wirick^ Thank you, Mike.

Our fourth quarter 2023 worldwide revenue of $106.5 million increased 21% on a reported basis and 20.5% on a constant currency basis when compared to the fourth quarter of 2022. U.S. revenue was $88.8 million, a 20.1% increase from the fourth quarter of 2022, reflecting robust activity across each franchise, highlighted by an uptick in adoption of our Hybrid AF therapy, representing 30.6% growth for the quarter, along with continued strength from key appendage management, open ablation and pain management products.

International revenue totaled $17.8 million, up 25.8% on a reported basis and up 22.1% on a constant currency basis as compared to the fourth quarter of 2022. We continue to see strong demand for our differentiated solutions in major international markets with significant growth in appendage management and pain management. Sequentially, worldwide sales grew $8.3 million or 8.4% over Q3 2023.

Gross margin for the fourth quarter 2023 was 74.9%, up 94 basis points from fourth quarter of 2022.

The increase was driven primarily by favorable production efficiencies, partially offset by less favorable geographic and product mix.

Fourth quarter 2023 research and development expenses increased $7 million, or 51%, and SG&A expenses increased $12.2 million, or 22%, over the fourth quarter 2022.

Turning to the bottom line, we drove positive adjusted EBITDA of $4.8 million for the fourth quarter 2023 compared to positive adjusted EBITDA of $6 million for the fourth quarter of 2022.

While we are continuing to drive improvement to gross margin and realizing operating leverage in our commercial and administrative infrastructure, we experienced a significant increase in research and development costs in the fourth quarter of 2023 due to the rapid enrollment and expansion of our LeAAPS clinical trial and multiple product development initiatives underway. Our loss per share and adjusted loss per share was $0.21 for the fourth quarter 2023 compared to a loss per share and adjusted loss per share of $0.09 for the fourth quarter of 2022.

Now to review full year 2023 results. Worldwide revenue was $399.2 million, an increase of 20.8% on a reported basis and 20.6% on a constant currency basis. U.S. sales increased 20.3% to $333.5 million. And international sales increased 23.5%, or 22.1% on a constant currency basis, to $65.7 million. The continued expansion of the EnCompass Clamp drove U.S. open ablation sales to $105.3 million or 22.3% growth over 2022.

In 2023, our U.S. pain management franchise grew 23.1% to $49.2 million from increasing activity in existing accounts, along with the new account adoption.

U.S. MIS revenue was $44.6 million, reflecting single digit growth in our legacy device sales, bolstered by approximately 18% growth in EPi-Sense sales, where we are successfully laying the groundwork for long-term growth.2023 U.S. appendage management sales reached $134.5 million, a 19.5% increase over 2022, driven largely by our AtriClip FLEX V device. And much like U.S. trends in activity in 2023, our international revenue growth was propelled by appendage management, open ablation and pain management products.

Gross margin for the year ended at 75.2%, an increase of 79 basis points from 2022.

Similar to our fourth quarter results, the increase in gross margin reflects production efficiencies realized throughout the year, partially offset by less favorable geographic and product mix.

Moving to operating expenses. Full year 2023 operating expenses increased 13.3% to $327.1 million from $288.6 million in 2022. Research and development costs expanded by $16.6 million, or 28.9%, on both clinical trial and product development project spend as we extend our pipeline with clinical evidence and innovation. SG&A expenses increased $21.9 million, or 9.5%, with leverage in our training and education programs, commercial team and infrastructure driving down operating expenses as a portion of revenue, in addition to a one-time benefit in 2023 from legal settlements. We remain focused on continued efficiencies in SG&A while maintaining investments in R&D for future expansion.

Full year 2023 adjusted EBITDA was positive $19.4 million compared to a negative $2.2 million in 2022, an improvement of $21.6 million.

Our loss per share was $0.66 in 2023 compared to a loss per share of $1.02 in 2022. Adjusted loss per share was $0.75 and $1.02, respectively. We ended 2023 with $137.3 million of cash and investments, a robust working capital position and the flexibility to fund future opportunities and investments.

Finally, turning to our outlook for 2024. Consistent with our guidance in early January, we expect to achieve between $459 million and $466 million in revenue for the year, reflecting growth of 15% to 17% over full year 2023 results. Embedded in our guidance is the assumption that product innovation and supporting clinical data will propel us to 15% growth and beyond.

Also included in our guidance are market dynamics that include increasing competition. As we look at our progress with market development and the opportunities of each franchise, we expect our franchise growth rates in the United States to align closely with our expectations of 15% to 17% annual growth.

We continue to see growth in our pain management business through deepening use in thoracic procedures and the addition of clinical data to lead to even wider acceptance of this therapy. We believe the exceptional adoption of our EnCompass Clamp will continue to drive performance in open ablation while broader progress with Hybrid AF therapy using our EPi-Sense system to lift MIS ablation growth in 2024. Complementing these drivers is our AtriClip products, which we see continuing delivery of steady growth over the large base of revenue.

Additionally, we anticipate our international growth to remain on pace with the United States in 2024 and beyond. In terms of revenue cadence for the year, we expect typical seasonality to inform 2024 with first quarter revenue likely to be flat to our fourth quarter of 2023.

From a margin perspective, we expect 2024 gross margin to be in line with our 2023 results with potential for modest improvement from cost savings initiatives later this year. We anticipate headwinds from product and geographic mix as well as increasing material costs to be offset by continued production efficiencies and leveraging scale within our operations as we grow.

And as we have said before, our primary focus with capital allocation is to incubate the next set of growth drivers for AtriCure. Therefore, we expect to maintain R&D as a percentage of revenue at roughly 19% to 20% in 2024. Our spending across SG&A will continue to moderate in proportion to revenue, providing leverage and sustained improvement to profitability. With these priorities in mind, we expect full year 2024 adjusted EBITDA to range from $26 million to $29 million, translating to an adjusted loss per share of approximately $0.74 to $0.82.

We also anticipate a moderate cash burn in 2024 against our strong cash balance and capital position. And as a reminder, our first quarter expense profile is typically highest. Variable compensation payouts, share vesting and other operational needs will drive the higher overall cash burn and modest bottom line results.

As I turn the call back to Mike for closing comments, I would like to reiterate 2023 was a stellar year at AtriCure. From expanding patient impact and revenue growth to realizing positive adjusted EBITDA, our results stem from the powerful collaboration of my AtriCure teammates. We enter 2024 with an unrelenting dedication to the patients we serve and drive to continue our financial progress.

Mike?

Michael Carrel^ Thank you, Angie.

I would like to close by congratulating our entire team on an incredible 2023. Patient outcomes are our guiding principle, and we are most proud of that at AtriCure. Your teamwork led to over 100,000 patients treated this year and over 1 million in our company's history. We are making a difference for patients with advanced forms of Afib, higher risk of stroke and pain after surgery.

As we grow and evolve in the future, patient outcomes will continue to drive our efforts as we capitalize on our leadership in these markets. And with that, I will turn it over to the operator for questions.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Please limit questions to one and one follow-up at a time and then requeue for any additional questions roster. Our first question comes from the line of Robbie Marcus with J.P. Morgan.

Robert Marcus^ Congrats on a good quarter. I wanted to start on the clip business and minimally invasive. Had good fourth quarters, beat expectations. Just, you kind of talked about it broadly, but maybe a little more specifically, how you're thinking about those two relative to open and pain as we progress into 2024.

Angela Wirick^ Yes. Robbie, thanks for the comments. I think as you heard in the scripted comments, when we look at the guidance for the year, our expectation is that in the U.S., the growth rates of each franchise are pretty tightly coupled around the corporate average. I think unlike what we were saying in 2023 based on kind of our expectations of the year of having some franchises as outperforming and some franchises kind of falling below the corporate growth rate, given the progress within each franchise and kind of development opportunities, would expect them to be more closely aligned around the corporate growth rate.

Robert Marcus^ Great. And I guess I have to ask, just given all the investor angst around your competitor Medtronic launching, an AtriClip competitor, what you're seeing so far in the field in 2024 so far. How the sales force is reacting to it and any feedback you have from physicians.

Michael Carrel^ I appreciate the second question there, Robbie. I'll handle it from a couple of different angles. I'd say first is just a reminder, we welcome competition. We think it's actually a really good thing and validates the market. And what I mean by that is that there -- as we talked about, we're still less than 5% penetrated in the overall worldwide market.

There are over 2 million patients that undergo cardiac surgery worldwide. Less than 5% or so actually have an AtriClip or their appendage managed today. We have really big opportunities in front of us as we continue to invest in innovation. We're talking about the FLEX Mini product coming out later on this year, which is our 8th generation of the AtriClip product. In addition to that, we're investing in clinical evidence with the LeAAPS trial to show a stroke reduction for patients that are undergoing cardiac surgery.

So we're making the necessary investments on those particular fronts.

We are seeing Medtronic and their clip out in the market, and we think it's great that they've actually made that kind of investment. We do see people trialing it out and using the product. But we also feel very confident that we have a superior product today in the market with our FLEX V product. And we feel like with the innovation we're coming out with the FLEX Mini and others, we're really well positioned to manage competition that comes into the market. We don't think they're going to be the first competitor in any of our franchises.

One of the things for AtriCure is that we are dedicated, as I mentioned upfront, to really establishing new standards of care in areas and putting investments in R&D on both the innovation side, so new products and continuing that. In fact, we've got seven new products coming out over the next two years. Combining that with exceptional clinical

evidence to demonstrate why our products work incredibly well. And then also putting efforts around our sales team and teams out in the field to specifically be the best in the world at understanding our products and understanding how to help patient care on that front. And we think that we're really well positioned across all of our product lines on that and welcome the competition and also welcome the validation of the markets that we're in.

Operator^ Our next question comes from the line of Danielle Antalffy with UBS.

Unidentified Participant^ Everyone, can you hear me? This is Simon on for Danielle.

Angela Wirick^ We can hear you, Simon.

Michael Carrel^ We can hear you, Simon.

Unidentified Participant^ This is [Simon Egan]. Your cryo segments really demonstrated great growth over the past several years, but it's naturally moderated just given the scale. Do you think mid-teens growth in this segment is sustainable? And what are the puts and takes to really think about moving forward here?

Michael Carrel^ Yes, appreciate the question. You stated it very well. It's obviously gotten to the size and scale, a $50 million business that grew 26% this year. We do think that those mid-teen plus growth rates are absolutely sustainable, not only in thoracic. So if you look at just the thoracic market, we're less than 20% penetrated today.

So we have a long way to go. And as I mentioned in my comments, we're investing in clinical evidence to demonstrate both the economic and clinical value around that to hopefully push those numbers up even more over the coming years. You top that off with us investing in, much like I talked about all of our product lines, we've got the cryoSPHERE Plus that just came out this year. We've got a new product coming out later on this year that is an advancement on top of that that are hopefully going to reduce the time that they need to actually do their ablation, which hopefully will also open up the sternotomy market a little more aggressively than it has because that's been the pushback in that market. So for economies alone, less than 20% penetrated.

We're coming out with new products that reduce time that will hopefully enable and actually get us into the sternotomy market a little bit more aggressively as you look in future years. And so we feel like we're in a really good position relative to the growth there.

And the final thing I'll add is when we talked about, or you heard it in my comments as well, there are other areas, extremities in particular, that could also benefit from the cryoablation that we use. And we're in the process of actually looking at that, evaluating it and studying it. We're not ready to announce anything yet. But over the next couple of years, I do believe that we'll be announcing getting into other areas outside of just thoracic and sternotomy, which have a lot of room for growth already.

So that's a good -- that's a long way of answering, yes, we feel comfortable with the kind of mid-teens growth, being in that range for a long time.

Unidentified Participant^ That's really helpful. One quick one for you. You mentioned potentially watching a product in the IST segment this year. Is that still on target? And any ideas on that would be incredibly helpful.

Michael Carrel^ Yes, so a reminder for people because we didn't really go into detail on today's call. We're running a trial called HEAL-IST for patients with inappropriate sinus tachycardia. What that represents are people that have elevated heart rates while they're resting, typically above 90. Consistently, most of these patients are in the mid-100s. And it tends to affect women in their 20s to 40s or so.

It's a very large patient population, well over 1 million patients that actually represent this market. There was an EP and a surgeon out of Belgium who invented a procedure in which you could leverage using our technology in combination with the mapping and the work done by the electrophysiologist to basically reduce that. And they showed almost 100% improvement at both a 6-month and 1-year timeframe after the procedure. The existing products that we have work incredibly well. It's under investigation for this particular disease in the United States right now, and we're making great progress on enrollment there.

And yes, we are developing a new product, because right now our product today works incredibly well, but it takes a little while to actually get access to what you need to do there. And so the new product is custom built very specifically for IST and for this specific surgery. And we do anticipate late this year, early next year to kind of have that product on the market.

Operator^ Our next question comes from the line of Bill Plovanic with Canaccord.

Unidentified Participant^ It's [John] on for Bill tonight. Congrats on a strong Q4, too. Maybe just starting on EnCompass. You said about 50% of U.S. revenue is from the clamp now.

Can you just talk about what hurdles still exist to get the remaining users to shift to the new device? Is this just contract timing or price sensitivity? And do you plan on eventually stop selling the older versions of the clamp?

Michael Carrel^ Yes. I'll start with the last. We don't anticipate stopping selling any of our old clamps. They're actually exceptional. We continue to get really good feedback on that. They work incredibly well.

They're really geared towards specific surgeons who are doing the full Cox-Maze 4. They're the ones that we studied in our PMA. For EnCompass, quite frankly, it's just

going to take time to educate people how to use the product, get people comfortable with that. We're expanding into new sites. We're in about 55% to 60% of the sites in the U.S.

So we've got a lot of room for growth relative to that. We're also planning to do a clinical trial as well, very specifically, much like we did for the ABLATE trial, which was what got us the PMA approval for our original clamps. We will anticipate doing that. We think that with that additional clinical evidence, that could also have an impact on adoption over time.

This isn't one of those ones that it's just going to grow overnight, but it's accelerated our growth rate. If you would have asked, I think, anybody if our open business could grow kind of above the low-double digits, kind of the 9%, 10%, 11% that we were growing for many, many years, this combined with reimbursement changes that have happened over the last couple of years have really accelerated adoption and more ablations that have happened.

So I think I feel really good about the progress. It's much better than we ever expected. And we'll continue to kind of talk about it out in the field from that standpoint.

Unidentified Participant^ Great. And then just on pain management, too, to kind of circle back to some of the other comments. How should we think about the timing of the economic outcome data that you had mentioned? Should -- is that going to move the needle in 2024 or beyond? And are you still considering gathering data to support an opioid reduction label?

Michael Carrel^ Yes. I don't know that I would say that it's going to be a 2024 event relative to that data. It's going to be a cumulative aspect of the data for Cryo Nerve Block and not one definitive trial. We're actually supporting many trials that are multicenter across the country and over in Europe. The purpose of that is that the totality of all that evidence we think is what's going to actually change practice. That's going to take several years to kind of do it, but I think more and more papers are coming out every year.

We had 14 trials that we were supporting or so last year. That number is going to continue into this year. Many of those are looking at opioid reduction as part of what they're looking at overall as the outcome. And so I do believe that that is something that's very important for people to track and to know. And I think more and more papers are going to be written about the fact that people that do use this product tend to have a lower use of opioids once they leave the hospital.

Operator^ Our next question comes from the line of Matthew O'Brien with Piper Sandler.

Matthew O'Brien^ So I don't know if this is for Mike or Angie, but I think Angie mentioned that you're factoring in some competitive pressure here in 2024 into your guide. You've grown 20% the last two years on the top line. You're guiding 16% at the midpoint, so about 400 basis points. That's around $16 million, I think, of potential

competition you're factoring in. Or I don't know if it's law of large numbers, whatever it may be.

Is that the right way to characterize the amount of pressure that you're anticipating? Is it only in the clip business? And then if I do the math on it, it would seem like you're kind of incorporating in around 10%, maybe a little bit north of that share loss. Is that the right way to characterize it?

Angela Wirick^ Yes, Matt. I think you know based on years here that we start the year, and we want to make sure that we're putting out a guide that we feel really good about executing against that gives us -- positions us well to kind of beat and raise as we go throughout the year. The range does consider both the growth drivers in our business as well as the potential competition in our market. But I think to that point, we are working in markets that are very, very underpenetrated and that we believe that there's still significant growth potential even with competitive pressure. So a long-winded way of saying it's not 10 points of -- or that kind of loss relative to Medtronic share.

More importantly, I think what informed our guide through 2024 is just the strength of our portfolio and the momentum that we're seeing as we exit 2023 and start a new year in 2024. But want to make sure that we guide to numbers that we can execute strongly against. That's been our philosophy for years and continues to be as we start the new year.

Matthew O'Brien^ Okay. And Angie, specifically, I know there's a lot of trialing going on. Have you seen people flipping over to Penditure and using it in a lot more cases? Or are you still seeing a dynamic where they maybe trial it and they just say, you know what, I don't like this for the most part. I'm sure there's some people that will flip.

But what are you seeing specifically there? And I do have one more follow-up.

Michael Carrel^ I mean we're definitely seeing people trial it across the country, but we feel really good about the strength of our franchise out there, Matt, and feel like people really love the AtriClip. It set a very high bar in terms of how well it works. People understand that we have a tremendous amount of clinical evidence and data behind it. On the closure in particular, showing exceptional closure and exceptional safety profile with that device. And so we feel like we're in a great position even though people are trying it at various different places throughout the country.

Matthew O'Brien^ Got it. Okay. And then on the open business, it looks like it accelerated in Q4 on a 2-year stack basis, but it was a little bit softer than I might have thought on a quarter-over-quarter basis. So just curious what you're seeing there in terms of adoption, expectations for growth there? Is it still another mid-teens?

I don't know if the guidelines can help a little bit as well. And then just any thoughts on competition? I know there's somebody that's filed to compete with you. Is that something that you're building in a little bit this year or something that essentially could impact that business as we head into 2025?

Michael Carrel^ As Angie mentioned on the guidance, pretty much all of our businesses we think being around that 15% to 17%. I mean, pun intended, they're all converging around that particular area. And so we feel like obviously there's upside potential in every one of our businesses, to your point, Matt. We're seeing great growth there. I think that to be able to continue to grow on the kind of base numbers that we've got at that kind of rate in cardiac surgery the way we are, we feel really good about it.

But we anticipate that being kind of in that 15% to 17%. Pretty much all of our franchises across that from that standpoint. And we're always looking at competition. I mean there's nothing specific to comment on at this point. And if competition does come in, I think that we will obviously address it.

But we feel really comfortable with the guidance that we've given. And that as Angie mentioned, we try to take a really conservative look at it at the beginning of the year to ensure that we can make sure that we can meet and beat it throughout the year.

Operator^ Our next question comes from the line of Marie Thibault with BITG.

Sam Eiber^ You've got Sam Eiber on for Marie. Congrats on the nice finish to the year. Maybe I can start on CONVERGE and just looking at the U.S. business growing, for the MIS business growing 16% sequentially, 30% year-over-year. It does sound like things are really starting to click there.

And I know you addressed a little bit in your prepared remarks, but any more color you can give on any specifics? And maybe does that give you the confidence now to push a little bit harder on new site activation this year?

Angela Wirick^ Yes. Sam, I think we feel really good about the activity in the fourth quarter. I think this is reflective of a year-plus of our team in the field, supported by many others in the business, really trying to hone in on where programs had a really good interest in starting a CONVERGE program, why they have not been able to accelerate and see the kind of growth that we would expect. So we feel really good that the activities are paying off and that we're making a difference in the accounts that we're focusing in on. I'd say longer term, when you think through 2024, we're looking for that to be more broadly replicated throughout the base of accounts so that we can continue these kinds of growth rates.

But I'd say the efforts in the field are really what we're seeing is starting to pay off and looking for that to have a broader impact in 2024.

Relative -- I think the second part of your question was new account activations. We did see a couple of new account activations in 2023. I'd say the focus of our team at this point in time is on existing accounts I think as they operate throughout 2024. There's still a lot of interest from customers. There's still -- we're very underpenetrated in terms of the

universe of accounts that could have CONVERGE procedures or CONVERGE programs and are still training new accounts.

And I think the work that we're doing today to help existing accounts be more efficient and think about building their programs I think long term will help us initiate new accounts and have them scale quickly.

Sam Eiber^ Really helpful, Angie. Maybe just flipping to AtriClip and maybe looking beyond maybe some of the competitive dynamics, but you also mentioned some guideline changes. And I'm just wondering if that can be maybe an additional tailwind to the underlying market and adoption for the clip business.

Michael Carrel^ Yes. Absolutely. We think that the guidelines are pretty monumental for the entire space. And it's basically saying -- a Class 1A recommendation is basically saying you should treat this appendage every single time somebody has atrial fibrillation today. And that is not just the cardiac surgeons doing it, but it's ACC and AHA to the referring cardiology community is basically saying everybody needs to treat the appendage when they're undergoing cardiac surgery. And so absolutely, we think that's a really good sign for this market overall, and obviously, AtriClip is being used to manage the appendage by many people around the globe.

So it's a great validation, just like competition is a great validation of the space and what we're doing there. And then obviously, we're expanding that market with LeAAPS, so that eventually the data we get with that changes the guidelines for every patient, not just those that have Afib. That's our goal with that. That's why we're investigating it. And you can see the excitement with 1,700 patients already enrolled out of a 6,500 person trial.

It's pretty remarkable to see that kind of growth. That's the excitement people have and the belief in managing the appendage.

Operator^ Our next question comes from the line of Joseph Conway with Needham.

Joseph Conway^ It's Joseph on for Mike. I guess maybe just touching on gross margin improvement in the quarter. I think Angie called out some production efficiencies. And looking into 2024, I think in the comments, you guys talked about just being in line for 2024, potential modest improvement. I was just wondering if you could maybe give some more color around what happened in this quarter and some of those cost saving initiatives that you expect to roll out this year, how you expect that to be phased.

Angela Wirick^ Yes. So what you saw in the fourth quarter, really strong, I'd say, production efficiencies offsetting -- we had quite a few headwinds coming from the mix of our international business. That led to an improvement off of 2022, the fourth quarter comp. And as we enter into 2024, I'd say kind of more of the same. You're going to see nice improvement.

If the only thing that we saw was improvements to kind of production efficiencies with the same kind of mix of revenue, you'd see some nice improvements in 2024, but we are expecting some headwinds, given the mix anticipation in 2024.

We've talked about in the past a couple of areas where we expect to see some improvements to margin. The first would be with the launch of the cryoSPHERE Plus probe. To the extent that the adoption of that probe takes off in comparison or replaces our existing cryoSPHERE probe, there is a nice benefit to our gross margin. Again, our launch is anticipated in the second quarter, so you would see more of that benefit in the second half of the year. And then the other thing we've talked about on other calls is the EnCompass Clamp.

Our team -- our operations team and engineering team did really nice work throughout 2023 to say, given the demand that we're seeing in this particular product line, what are some ways that we can produce this product better and more efficiently, but also have come with some cost savings that we would anticipate later in 2024. So I think the big driver in 2024 when you think about gross margin is primarily mix, but knowing that there's some fundamental production efficiencies and some nice things happening within our operations that help be a tailwind to the overall number.

Joseph Conway^ Okay. That's very helpful. And then I guess just a quick one on the new AtriClip product. You gave some commentary around timing for the launch. But just maybe if you could talk about pricing, what you guys are thinking about that.

Especially with Medtronic coming into the market, if there's anything that you're trying to hold back any price increases for that?

Michael Carrel^ Yes. So first of all, I'll comment on the product. It's called the FLEX Mini. We did file for a 510(k). And we feel like this product is going to be incredibly well received.

It's about a third of the profile and size of our product, our FLEX V product on the market today. It's incredibly easy to deploy. All the testing that we've seen so far is that it is going to be by far and away the most superior product on the market going forward. We have not determined our pricing strategy at this point, and so we'll probably hold back in terms of discussing that in any kind of detail. But we're evaluating what the best pricing strategy is right now.

Joseph Conway^ Okay. Great. Congrats on a great quarter.

Operator^ Our next question as from the line of Danny Stauder with Citizens JMP.

Daniel Stauder^ Can you hear me?

Angela Wirick^ We can hear you.

Daniel Stauder^ Great. So first off, just wanted to ask broadly about procedure volumes. So just -- we've heard from some of your peers comment on elevated volume levels and just wanted to get your color on that. And particularly as it relates to the open surgical market, have you seen any notable change in valve or CABG procedures that have led to some of the growth in open ablation in your open AtriClip procedures?

Michael Carrel^ Yes. I don't know that we've seen any kind of dramatic improvement. There's been steady improvement since COVID. But I think we're in a good, normalized period now where typically you'll see cardiac surgery growing in that kind of 1% to 2% per year. And I don't think we've seen anything different than that over the course of the last year or so. I've heard different reports that that might change and you might start to see some improved growth across the procedure in 2024 from some places.

I know HCA talked about it on one of their calls in terms of their cardiac surgery volumes. I don't know that I've heard that across every single system. So I guess I'd say right now, I'm cautiously optimistic on that one.

Daniel Stauder^ Great. And then just one follow-up. Turning to appendage management. The growth in MIS ablation was great to see. But with that, are you seeing an uptick in some of your AtriClip minimally invasive procedures?

And then could you remind us where that AtriClip mix of open to MIS sits today? And how has that changed over the past, say, year or so and where you think that could go in 2024.

Angela Wirick^ Yes. That was a nice byproduct of the strength of our MIS business in the fourth quarter. We saw an uptick in our MIS appendage management, the AtriClip Pro products realizing pretty equal growth to the open AtriClip products leading to about 22% growth for the fourth quarter in the U.S. And our attachment rates, we continue to see a steady increase in attachment. A year or so ago, we were talking about around a 75% attachment to our CONVERGE procedure. And now we're at, say, kind of mid-80s at this point in time and continue to receive really good, strong feedback from accounts that are starting CONVERGE programs or have adopted CONVERGE programs, the interest in treating the appendage surgically during the CONVERGE procedure.

As we exited the year, when you look at our U.S. appendage management business, about 25% of the revenue was from our MIS AtriClip business, and about 75% of the revenue was in our open clip business. And I think given the strength of both of those franchises, our open and MIS ablation businesses would expect for that mix to remain relatively similar with the potential for upside, I think, for the MIS product.

Operator^ Our next question comes from the line of Suraj Kalia with Oppenheimer & Company.

Suraj Kalia^ Angie, Mike, can you hear me all right?

Angela Wirick^ We can hear you.

Suraj Kalia^ Perfect. Mike, so a couple of esoteric questions was wondering if you could help us out. AtriClip in general, is it on consignment, or should we think about inventory also? And more specifically, as you'll enter FY '24, just given all the dynamics in your prepared remarks, how should we think about the pricing flow through that you'll think about for FY '24?

Michael Carrel^ Yes. On the consignment, we don't really have any consignment product. That's not -- typically it's -- we're very much on kind of a use and then replace. So we keep very, very little inventory whatsoever at sites, just enough for them to kind of plan out the procedures in the upcoming week or two. But we do not have a lot of inventory on shelf.

That's actually purposeful. We want to understand the demand. And we've got great inventory here to be able to supply that on a real-time basis. We've got 99.8% kind of delivery to make sure that no patient is not being treated from that standpoint.

Related to price, we feel like we've got a really good pricing strategy today. We've obviously got a product in the market.

Our initial one, our original AtriClip of the kind of first three generations of the products are out there today. Those are priced at a lower level. The FLEX V, which was our premium product, today is also in the market. Our highest priced products are the minimally invasive products above that. So I think we're in a really good position relative to pricing today, and we don't have any specific things to change anything on that front in the near future.

Suraj Kalia^ Got it. Mike, in terms of AtriClip Mini, is this just a desire for product stratification? And what I'm looking at is in terms of complete isolation of the LAA, you're presumably going a smaller form factor. So just kind of walk us through the rationale for introducing Mini. And Michael, to remind us, in terms of persistent AF, what percent of the cases being done by AtriCure today are persistent AF versus long-standing persistent AF?

Michael Carrel^ Sure. On the FLEX Mini, we spent a lot of time. As we mentioned in our comments, we've had 500,000 implants to date. And we do a lot of work with our customers to figure out what improvements do they want to have to the product. And so the biggest thing was really, quite frankly, they wanted a smaller product, meaning that just a smaller profile overall.

That's what the FLEX Mini does. It actually is about a third of the profile of the other products. And that's the biggest benefit that people are going to get relative to using that.

Also as many of you may know, we've got a V-shaped product, and we also have a hoop-like product, which is the original product that we had on the market. The hoop-like

product is the one that does not have as good of a deployment as the V product. And so many people wanted a hoop-like product that was smaller and had a very nice and easy and usable deployment tool with it as well.

And so that was the primary feedback that we got from people, and that's effectively what the Mini brings to market.

In addition to that and probably as important is that the Mini is also going to be used in our -- we have the PRO V product for minimally invasive, and we will have a PRO Mini product as well that will come out in late 2025, likely. And that product is going to be able to go through at least a 7-millimeter, possibly a 5-millimeter trocar to make it even less invasive as somebody actually has to do the procedure from a minimally invasive perspective. So the product, by being so -- the profile being so small, it can go through those smaller trocars, and there's a big benefit on that.

In terms of your second question, I guess, I believe you're probably talking about the CONVERGE area in terms of kind of the distinction between persistent and long-standing persistent. Our label is for long-standing persistent. That's what we talk to.

I'd say most of the patients fit within the long-standing persistent marketplace. Very few are persistent patients in terms of what we're seeing. Most of the patients that we see are patients that have had failed catheter ablations. one, two or three failed catheter ablations before they then go to a convergent or a hybrid type procedure. And so I believe that might be what you're referring to, and hopefully, I answered that question.

Suraj Kalia^ Sure. Thank you.

Operator^ Thank you. This concludes the question-and-answer session. I'd now like to hand the call back over to Mike Carrel, CEO, for closing remarks.

Michael Carrel^ Great. Again, everybody, thank you for joining us today, and we look forward to having a great 2024 together. Have a good one.

Bye now.

Operator^ This concludes today's conference call. Thank you for your participation.

You may now disconnect.