AtriCure, Inc. (Q4 2024 Earnings)
February 12, 2025

Corporate Speakers

- Marissa Bych; Gilmartin Group; Principal
- Michael H. Carrel; AtriCure Inc.; President and Chief Executive Officer
- Angela Wirick; AtriCure Inc.; Chief Financial Officer

Participants

- Lilia-Celine Lozada; JP Morgan; Analyst
- William Plovanic; Canaccord; Analyst
- Matthew O'Brien; Piper Sandler; Managing Director and Senior Research Analyst
- Marie Thibault; BTIG; Managing Director
- Frederick Wise; Stifel; Managing Director
- Michael Matson; Needham and Company; Senior Equity Research Analyst
- Daniel Stauder; Citizens JMP; Vice President, Equity Research
- Danielle Antalffy; UBS; Analyst
- Suraj Kalia; Oppenheimer; Managing Director

PRESENTATION

Operator^ Good afternoon. And welcome to AtriCure's Fourth Quarter and Full Year 2024 Earnings Conference Call. This call is being recorded for replay purposes. (Operator Instructions) I would now like to turn the call over to Marissa Bych from the Gilmartin Group for a few introductory comments. You may begin.

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-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, competition, 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 constant currency revenue, 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 H. Carrel^ Great. Thank you, Marissa. Good afternoon. And to everyone, thank you for joining us today. 2024 was another successful year at AtriCure, demonstrated by our continued growth, improved profitability, several new product launches and progress on key clinical trial and evidence initiatives across our franchises.

For the year, we achieved revenue of $465 million or 17% growth with outstanding performance in our pain management, open appendage management and open ablation franchises. We also made significant strides in profitability, expanding our full year adjusted EBITDA from $19 million in 2023 to $31 million in 2024.

We exited 2024 with strong momentum throughout our business worldwide and remain excited about AtriCure's future. In January, we provided our financial outlook for the year, and I am pleased to reaffirm our 2025 revenue guidance of $517 million to $527 million.

Following a robust 2024 margin performance, we now expect to deliver full year 2025 adjusted EBITDA of $42 million to $44 million, an increase of nearly 40% over 2024. Additionally, we expect modest cash flow generation for the full year.

Before I turn to more details on our fourth quarter and 2024, I would like to remind everyone that we are hosting an Analyst and Investor Day at our headquarters in Mason, Ohio on March 26. We plan to review our leading product portfolio and innovative pipeline for market expansion, while showcasing our facility and team throughout the event.

We will be joined by several leading physicians including Dr. Whitlock, who is the Chief of Cardiac Surgery at McMaster University, the author of the Seminal LAAOS III -3 trial and the lead PI on our LeAAPS trial; and Dr.

Soltez, who is a leading surgeon from the Cleveland Clinic and a world-class expert in heart failure. Both are lead investigators on our landmark clinical trials and as mentioned, key opinion leaders in the field of cardiac surgery.

We will also have two electrophysiologists, Dr. Makati and Dr. Sood to share perspectives on their experience with the Convergent procedure and current market trends including PFA. Finally, we intend to provide long-term financial goals as we focus on driving both continued growth and expanding profitability.

Now turning to updates on our business and highlights from the quarter and full year, beginning with our pain management franchise, which grew 32% worldwide in 2024 and 43% in the fourth quarter.

Pain Management performance reflects strong execution by our global commercial team, bolstered by the launches of two new products in the United States, our cryoSPHERE+ and cryoSPHERE MAX probes.

These probes reduced freeze times by 25% to 50%, respectively, compared to the original cryoSPHERE probe, resulting in a meaningful overall reduction in Cryo Nerve Block therapy procedure time which can be a critical factor in adoption.

The advances in innovation with the cryoSPHERE+ and CryoSPHERE MAX have allowed us to engage with new and existing physicians as we drive deeper into accounts. In 2024, we added nearly 100 new accounts globally and saw more than 800 customers utilize Cryo Nerve Block therapy. We also increased our efforts to engage with the clinical support staff at hospitals as they are often the closest to the patient during recovery.

We received exceptional feedback on this therapy as support staff observed improved post-operative recovery in patients with a multimodal pain management strategy that includes Cryo Nerve Block and believe that our devices are a preferred solution for managing post-operative pain.

Looking forward, in 2025 we are focused on continuing the launch of our new cryoSPHERE probes as well as developing evidence that further supports the economic value demonstrated by our pain management devices.

We are also exploring additional use cases for Cryo Nerve Block therapy such as lower extremity amputations, which will expand our addressable market well beyond thoracotomy and sternotomy procedures.

We look forward to sharing more insights into this at our Analyst and Investor Day as well. Moving to our franchises for the treatment of atrial fibrillation. Our open franchise grew 16% worldwide in 2024, driven by EnCompass Clamp sales. We saw an acceleration in growth to 17% in the fourth quarter, which was also driven by more than 50% growth in EnCompass.

Our team worked methodically to reach both new and existing physicians and accounts throughout the United States and capitalized on the launch of the EnCompass Short Clamp early in 2024 to increase adoption. This product is a smaller form factor configuration and has extended the impact of the EnCompass launch in the United States.

In addition, during the fourth quarter, we launched the EnCompass Clamp in Europe. Our EnCompass Clamp is now present in over 700 accounts worldwide, representing an increase in accounts of 21% from 2023.

We will continue our commercial expansion in the United States and Europe in 2025 and look forward to progressing treatment of patients in cardiac surgery. Building on our success and 25-year history of being a pioneer in cardiac surgery, we are continuing to invest in prospective clinical science to support expanded treatment.

To that end, earlier this year, we received FDA approval for our next cardiac surgery clinical trial, BOXX-NO AF, studying prophylactic ablation for reduction of postoperative AFib. It is a widely established fact that cardiac surgery patients experience an elevated risk of developing Afib following their procedure.

This trial is expected to show the benefits of treating patients without preoperative Afib with our EnCompass Clamp and AtriClip devices, further expanding our addressable market and continuing our leadership in this space.

We will begin the study later this year by initiating clinical trial sites and enrolling our first patient in 2025. Turning to minimally invasive Afib treatment. Our Hybrid AF therapy continues to feel the pressure of PFA adoption in the United States.

For 2024, our global Hybrid franchise grew 5% with a robust 22% growth in our international markets, tempered by 3% growth in the United States. Focusing on the United States, in the fourth quarter, we saw accounts continue to prioritize the use of PFA devices to treat patients. We anticipate these trends to remain throughout 2025, resulting in downward pressure on this franchise in our minimally invasive AtriClip devices.

However, outside the United States, our minimally invasive ablation growth rates doubled in 2024 from 11% growth in 2023 to 22% growth in 2024. This acceleration in growth was driven by increased adoption of our Epi-Sense devices for Hybrid AF therapy in Europe, as more patients turn to our Hybrid convergent procedure as a lasting solution to treat patients with long-standing persistent atrial fibrillation.

In the year ahead, we anticipate sustained pressure in hybrid -- in our U.S. hybrid business, but we are seeing proof points such as our experience in Europe, which support a solid long-term growth outlook for our Hybrid AF therapy. PFA technologies are expanding the funnel of patients that receive catheter ablations. And ultimately, our Convergent procedure remains the only effective option for patients with long-standing persistent atrial fibrillation.

Now shifting to our appendage management franchise, which delivered full year worldwide revenue growth of 16%, comprised of 21% growth in our open AtriClip devices and 3% in our MIS appendage management devices.

We are incredibly pleased with the sustained momentum of our open appendage management business in the United States, where we achieved 20% growth in the fourth quarter following an acceleration of growth throughout 2024. During the fourth quarter, we also widened our launch of the AtriClip Flex-Mini in the U.S.

We have received overwhelmingly positive feedback for the Flex Mini, which increased procedure visibility with increased procedure visibility, the primary differentiator of this device. Like our Flex-V clip, we expect the Flex-Mini to be a sustained growth tailwind for many years to come.

In 2024, we also made meaningful strides in our geographical reach and indications with our AtriClip devices. We achieved approval for the sale of the AtriClip devices in China and look forward to ramping that business in 2025 and beyond. We also received an expansion of our indication for AtriClip in CE-marked countries for patients at high risk of thromboembolism and stroke.

We believe these updates reflect the quality and efficacy of our AtriClip devices, which have been demonstrated in more than 85 peer-reviewed papers covering over 11,000 patients. The breadth of clinical evidence in support of managing the appendage also led to the improvement in guidelines for clinical practice, making the left atrial appendage exclusion a Class 1A recommendation in every major global society's guidelines. And finally, I want to touch on our clinical efforts to further extend and grow the surgical appendage management market.

We continue to progress with the LeAAPS trial studying prophylactic appendage management in non-Afib patients undergoing cardiac surgery. This trial has the potential to multiply our appendage management market by showing a stroke reduction benefit for managing the left atrial appendage in millions of patients globally undergoing cardiac surgery.

Currently, we have over 4,600 patients enrolled and expect to complete full enrollment of 6,500 patients this year. Much like our other markets, AtriCure is leading in the surgical appendage management market with investments in both clinical science and new product innovation such as the Flex-Mini I talked about earlier, providing growth opportunities for our business well into the future. In closing, 2024 was another remarkable year of achievements for AtriCure.

We continued to drive double-digit top line growth, increased profitability, launched several innovative products that will drive growth for years to come, and continued to advance the clinical development required to support the efficacy and adoption of our therapies long term.

We have also championed efforts to increase reimbursement for therapies using our devices and are building evidence to show the economic value of adoption.

We have developed a diversified portfolio of products that deliver meaningfully improved outcomes for patients and physicians, positioning us for continued strength well into the future. And with that, I would like to turn the call over to Angie Wirick, our Chief Financial Officer. Angie?

Angela Wirick^ Thanks, Mike. Our fourth quarter 2024 worldwide revenue of $124.3 million increased 16.6% on a reported basis and 16.7% on a constant currency basis when compared to the fourth quarter of 2023. U.S. revenue was $101.6 million, a 14.4% increase from the fourth quarter of 2023, reflecting continued strength from pain management, open appendage management and open ablation products.

International revenue totaled $22.7 million, up 27.7% on a reported basis and up 28.1% on a constant currency basis as compared to the fourth quarter of 2023. We saw strong demand across our major international markets with significant growth in pain management, minimally invasive ablation and appendage management franchises.

Sequentially, worldwide sales grew $8.4 million, or 7.2% over Q3 2024. Gross margin for the fourth quarter 2024 was 74.5%, a decrease of 39 basis points from the fourth quarter of 2023, driven primarily by less favorable geographic and product mix.

Fourth quarter 2024 research and development expenses increased $14.2 million, or 68.1%, and SG&A expenses increased $4.5 million, or 6.6% over the fourth quarter of 2023. Much of the

increase in R&D was the result of a $12 million cash payment for our exclusive licensing and co-development agreement for PFA technology as well as continued strong enrollment of our LeAAPS clinical trial.

Turning to the bottom line. We drove positive adjusted EBITDA of $12.7 million for the fourth quarter 2024, compared to positive adjusted EBITDA of $4.8 million for the fourth quarter of 2023.

Our loss per share was $0.33 and adjusted loss per share was $0.08 for the fourth quarter of 2024, compared to a loss per share and adjusted loss per share of $0.21 for the fourth quarter of 2023. Now to review full year 2024 results. Worldwide revenue was $465.3 million, an increase of 16.5% on a reported and constant currency basis.

U.S. sales increased 14.8% to $382.8 million, and international sales increased 25.6% on both a reported and constant currency basis to $82.5 million. U.S. open ablation sales increased to $123.6 million, or 17.4% over 2023, propelled by approximately 50% growth in EnCompass Clamp sales.

Our U.S. pain management franchise grew 25.7% to $61.8 million, driven by accelerated adoption in Cryo Nerve Block therapies stemming from the release of the cryoSPHERE+, cryoSPHERE MAX probes during the year. U.S. MIS revenue was $45.7 million, reflecting low single-digit growth.

And finally, U.S. appendage management sales reached $151.6 million, a 12.7% increase over 2023 with 18% growth in open appendage management devices and a 3% decline in our MIS appendage management devices. Our AtriClip Flex-V device and the fourth quarter launch of AtriClip Flex-Mini were drivers of our open appendage management growth in 2024.

International revenue saw accelerated growth across all franchises and major geographic regions, with particularly strong growth in pain management, minimally invasive ablation, and both open and minimally invasive appendage management devices.

Gross margin for the year ended at 74.7%, a decrease of 55 basis points from 2023. The decline was driven by less favorable product and geographic mix, with our international revenue contributing 18% of worldwide revenue in 2024 compared to 16% in 2023. Moving to operating expenses.

Full year 2024 operating expenses increased 18.5% to $387.5 million, up from $327.1 million in 2023. Research and development costs expanded by $22.3 million, or 30.1%, which includes the upfront payment associated with our PFA partnership agreement.

Excluding this charge, organic growth in research and development expenses was approximately 14%, driven by clinical trial costs and product development as we make progress on our pipeline for market expansion. SG&A expenses as reported increased $38.2 million, or 15%. When excluding the net benefit from legal settlements in 2023, SG&A expenses increased approximately 13% in 2024.

We are generating operating leverage throughout our commercial and administrative infrastructure while continuing investments in R&D initiatives for sustained growth. Full year 2024 adjusted EBITDA was $31.1 million, compared to $19.4 million in 2023, an improvement of $11.7 million.

Our loss per share was $0.95 in 2024, compared to a loss per share of $0.66 in 2023. Adjusted loss per share was $0.67 and $0.75, respectively. We ended 2024 with $122.7 million in cash and investments for a full year cash burn of approximately $15 million. Note that 2024 cash burn included the upfront investment of $12 million associated with our PFA technology arrangement paid in the fourth quarter.

Overall, we continue to hold a robust working capital position and a strong balance sheet to support our future. And finally, turning to our outlook for 2025. Consistent with our guidance in early January, we expect to achieve between $517 million and $527 million in revenue for the year, reflecting growth of 11% to 13% over full year 2024 results.

As we look at the headwinds and tailwinds for our U.S. franchises, we expect pain management to lead our 2025 performance, followed by open appendage management and open ablation. And as Mike mentioned in his remarks, we expect our minimally invasive ablation and MIS appendage management to continue to experience pressure in 2025, and our guidance range assumes that revenue for both will decline year-over-year.

Finally, we expect international growth to continue outpacing U.S. growth in 2025 based on size of our markets, overall level of penetration and momentum throughout our franchises outside the U.S. In terms of revenue cadence, we expect typical seasonality to inform 2025 with first quarter revenue likely to be flat to our fourth quarter of 2024.

From a margin perspective, we expect relatively flat 2025 gross margins compared to 2024, with modest variability driven by the strength of international growth and new product launches in the United States.

In addition to mix impact, we expect increasing material costs to be offset by focused cost savings initiatives with our EnCompass Clamp lines and overall operational scale. Turning to operating expenses.

Our primary focus with capital allocation remains the identification and cultivation of the next set of growth drivers for AtriCure. Therefore, we expect R&D as a percentage of revenue to be roughly 20% in 2025, which includes up to $10 million in milestone payments related to our progress on our PFA platform during 2025.

As a reminder, milestone payments are excluded from adjusted EBITDA. Spending across SG&A will moderate in proportion to revenue as the year progresses, leading to improvements in profitability.

With these priorities in mind, we now expect full year 2025 adjusted EBITDA to range from $42 million to $44 million, translating to an adjusted loss per share of approximately $0.57 to $0.64.

We also anticipate moderate cash generation for the full year 2025, further strengthening our cash balance and overall capital position.

As a reminder, we typically see heavy cash burn during our first quarter from annual variable compensation payouts, share vesting and operational needs. We anticipate a net cash burn in the first quarter of 2025, followed by positive cash generation for the remainder of the year and full year 2025.

In closing, I'd like to reiterate Mike's earlier comments. 2024 was an outstanding year for AtriCure, with our talented team of more than 1,300 people driving increased patient treatment across our markets worldwide.

We begin 2025 excited for the continued impact of our product launches, new and ongoing research initiatives and showing operational efficiency that results in growing profitability. And with that, I'll turn the call back to Mike.

Michael H. Carrel^ Thank you, Angie. Our performance this past year would not have been possible without the AtriCure team. I would like to close by thanking them for their persistence, humility and patient-first mindset that they demonstrated throughout 2024.

I have the utmost confidence that our team will continue driving progress in each of our markets in 2025 and beyond. Additionally, we look forward to hosting our investors and analysts at our company headquarters in March.

There is no substitute for experiencing our facility, products and team in person, and I hope to see many of you at this event on March 26. And with that, we'll turn it over to questions. Operator?

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question comes from the line of Lily Lozada with JP Morgan.

Lilia-Celine Lozada^ Maybe I'll start with the open business. EnCompass has put up really impressive growth considering we're pretty well into the launch at this point. So where would you say we stand in the conversion from your legacy products to EnCompass? And how long can this sort of growth in the open business continue?

Michael H. Carrel^ Yes. I mean I think we're pretty much through all of the conversion from the legacy products into EnCompass. Every -- pretty much everybody that is now -- the growth coming from EnCompass is from net new users or using them on additional cases. The target, as many of you know has been to go after the coronary bypass market where patients or physicians had not treated before. Patients had Afib going into cardiac surgery.

They felt like it was too difficult to utilize some of the technology that was out there to get behind the veins, et cetera. EnCompass was built for that physician population. And so pretty much all of

the growth coming out of EnCompass is coming from, again, net new users or an expansion of use within that base but not cannibalizing or any kind of conversion at this point.

Lilia-Celine Lozada^ And then maybe on the MIS side of things, you had talked about PFA dynamics sort of stabilizing in Europe after it had been on the market for a while. So how would you characterize those dynamics now? Is PFA a non-issue there at this point? And are you assuming that the U.S. follows a similar trajectory at some point?

Michael H. Carrel^ I think you said it well. Yes. We are pretty much through most of the PFA piece there. You're now starting to see physicians there and programs wanting to get involved that we're holding on and not doing anything, now adding net new areas to their treatment algorithm with using our technology and the convergent approach.

So, we're definitely seeing that in Europe. That's why you saw the growth. You saw the expansion in the growth to over 20% this year in the Convergent area, and a lot of that was net new sites and expansion within existing sites, pretty much all around that Convergent platform. And we do anticipate that, that dynamic is going to happen in the United States.

We think 2025 is going to feel the pressure of that. But remember that Europe is around 2.5 years, three years ahead of the United States in this area. So, we started to see that benefit last year. We anticipate, hopefully, maybe the end of this year, early part of 2026 that we could start to see some of it.

But as I mentioned, we are starting to see some proof points. There are sites today that are actually starting to -- that were -- went down to almost no usage that are now coming back and beginning to actually do referrals as well. So, we do see a lot of bright points out there, and we do think that it's going to follow the same pathway as Europe.

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

William Plovanic^ First is just product related. In terms of EnCompass OUS and the Cryo+ and MAX in the U.S., where exactly are you in the rollout in terms of kind of account penetration and what have you? And then secondly, on EBITDA, you increased your EBITDA guidance by a couple of million on the low end. Just what changed?

Michael H. Carrel^ I'll address the first, and I'll let Angie address the second. For EnCompass OUS, we're just starting. I mean it's going to be a little slower launch than the U.S., mostly just because structurally, it's different there relative to reimbursement. And it's approved in all the countries throughout Europe.

But it's actually getting it, making sure that we're positioning it properly, doing all the necessary training. So we anticipate that, that growth will really start to kick in the back half of the year but not much in the beginning part. So, we're at the super early stages.

We do have sites up and running and utilizing the technology, getting great feedback on it, but it's just going to take a little bit longer to kind of just get it into country and to make sure it can kind of work through the reimbursement pieces got to work through there.

As it relates to Cryo MAX and Flex-Mini, the two launches that really happened kind of at the beginning of Q4, we're at the super early innings of that. We actually saw great progress on both of those into a lot of sites, probably a lot better than we had expected.

I mean we actually looked at some analysis that showed us that from the Flex-Mini and Flex-V launches, we had almost doubled the number of new accounts in the first three months on Flex-Mini versus Flex-V. So, the progress and excitement is absolutely there, but it's still super early innings and super low numbers overall, because it's just three months into it at this point.

Angela Wirick^ Yes, Bill, on the question related to the adjusted EBITDA guidance, I'd say with the way that which we closed out 2024 kind of the strength on the bottom line better than we had anticipated.

We are seeing some nice efficiencies throughout the business and felt like when we looked at the range for 2025, given kind of where the final numbers came in for 2024, felt very confident that we could raise the floor on that range to the $42 million to $44 million for 2025.

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

Matthew O'Brien^ Angie, can I follow-up a little bit on Bill's question on EBITDA. You did a nice job expanding here in '24. The bump in '25 is still about the same or a little bit better than what you did in '24, but you still have that international headwind as far as profitability goes.

So where does you have extra leverage come from across the P&L? Because I'm just having a hard time getting the model all the way up to the midpoint of that range. And then I do have a follow-up.

Angela Wirick^ Yes. The international headwind will feel mostly on our gross margin. I think investors as well as you might know gross margin profile looks a little different for our international business.

That being said, from the global perspective, you do have the benefit of multiple new product launches in the U.S. with some very focused efforts on some of our products that we've been manufacturing. I called out the EnCompass Clamp in the scripted comments, expecting those to be a buffer against the growing international business, which we would expect to outpace U.S. growth.

I'd say further down the P&L, you're seeing both R&D and SG&A growing at a rate that's slightly below top line. R&D slightly less and then a couple of points down for SG&A, and that's because of the efficiency that we're driving and seeing throughout our business in almost every area of the business.

Matthew O'Brien^ Got it. And then, Mike, on the revenue guide for the year, I know it's early, you guys are typically conservative. The midpoint of the range is kind of in that 12.5% growth -- around 12.5% growth.

I know it's a little bit tougher comp in '24, but it's still kind of below the two-year stacks below that 15% level that you've kind of talked about historically. Is that how we should think about AtriCure going forward, maybe low teens growth in the future until some of these other opportunities really start to kick in? Or do you think it's still more of that 15% number?

Michael H. Carrel^ Yes. It's a great question. I think right now for this year, we're comfortable right now talking about the growth rate that you just talked about. I think, why don't you come on to the Analyst Day, we'll give you some more feedback on kind of what that longer-term growth rate looks like. But we're pretty confident that we've got a strong growth rate in the solid double-digit area for a long time to come.

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

Marie Thibault^ Nice quarter. For Flex-Mini, I know it's only three months in, but you talked about multi-year sustained strength. So, as we think about the guide you've given for 2025, is there a way to parse out what portion of the installed base you think will convert in 2025? It sounds like you think that will be sort of a multi-year conversion process.

Angela Wirick^ I think that is absolutely the right way to think about this. While the launch is off to a great start, we are expecting this to take a while to get to kind of all of the accounts, so to speak.

Looking back on our Flex-V product launch six or so years ago, that was a multi-year effort before it represented the majority of clip sales and in each one of our accounts and expecting the same for Flex-Mini.

Marie Thibault^ And then maybe kind of a high-level question here on the revenue outlook, kind of echoing Matt, on sort of the conservatism we typically see from you to start the year. Is there a way to kind of quantify -- you've got a lot of new products coming.

I know they typically come with pricing uplifts. Is there a way to quantify kind of the impact of volume versus pricing uplift that's being assumed in that growth number?

Angela Wirick^ Yes. The growth number would assume the majority of the growth is volume-based. So you do have the upside depending on kind of the mix between the Flex-Mini or cryoSPHERE MAX where those come in. So that is an area where we do believe that there is upside from delivering in the range that we've guided to.

Operator^ Our next question comes from the line of Rick Wise with Stifel.

Frederick Wise^ Maybe we could dive a little bit more into gross margin. I don't think -- did I miss it? I don't think you gave any specific 2025 gross margin guidance.

But just looking at the fourth quarter, and Angie, you highlighted the mix, the OUS mix and product mix, et cetera, but it was 200 basis points less than we look for, clearly, maybe our fault, my fault, but it was less than the third quarter.

I just want to make sure that as we look at our recalibrate our models, from this point of view that we're thinking about it thoughtfully, rebasing it maybe, how should we think about GM for the year ahead?

Angela Wirick^ Yes. Thanks, Rick, for the question. I think rebasing around a 75% gross margin. We didn't give a specific target within the scripted comments, said relatively flat. I think the international mix is one of the drivers behind some of the weakness that we saw in margin throughout 2024, a growing component of our overall revenue mix and at the highest percentage contribution in the fourth quarter.

That is -- we do expect to be offset somewhat by new product launches within the U.S., where we are enjoying better overall margins, along with some areas in which we're driving cost efficiency through product lines that we've been manufacturing for a couple of years now. So, I think centering around kind of the 75%, which is around where we landed for the full year of 2024 is a good outlook thinking through 2025.

Frederick Wise^ That's great. And I was hoping you could give us a little more color is a question for you both on the R&D charge.

What R&D, if you take out that and what's one of the other items I think you mentioned, Angie? What's sort of base R&D? And maybe you can update us -- I'm sure the Analyst Day as well but update us on the project status, where are we, any new thoughts, any new timeline -- any time we could expect something more concrete from this initiative?

Angela Wirick^ All right. Rick, I'm going to try and answer your question. You're breaking up a little bit on our end here. So, the R&D charge that we took in the fourth quarter was an upfront payment for the co-licensing and development arrangement for our PFA platform.

We're working with a partner for that area of product development in the fourth quarter. That was a $12 million charge and payment, which would have put our kind of organic R&D. So, take that out of the reported R&D, would put our organic R&D at around $30 million, which is about a $10 million increase over the fourth quarter in 2023.

So, you were seeing some nice growth kind of in that -- or $2 million, I should say, increase over 2023, seeing some nice growth in R&D, again, focused on our LeAAPS clinical trial and continuing to develop our platform of product development projects across our business.

In 2025, we expect to complete a couple of key milestones in this development arrangement, which will result in about $10 million total charges throughout the year. So that is factored into our forecast when we say we expect R&D as a percentage of revenue to be about 20% for the full year and would expect to give more details at our Analyst and Investor Day late in March.

Operator^ Our next question comes from the line of Mike Matson with Needham & Company.

Michael Matson^ So I just want to ask one on the PFA agreement that you announced last quarter. I don't know if you're in a position to tell us more there, but I think what I would like to know and I think other people would like to know is what's the regulatory path there? Would it be

510k data, PMA? And to what degree would you need to run trials? And are you planning on putting the PFA capability into both the open and MIS products?

Michael H. Carrel^ Yes. I think it's a great question, Mike. We're going to go into some more details at the Analyst Day for sure. But to answer kind of the high-level questions around, I mean we do anticipate that we will need to run a PMA for this.

It will go into both of our open clamps and into our other products as well in particular, the EnCompass Clamp and then also into our EPI-Sense device. Those will be some of the first products that we do wind up rolling out.

We'll roll out a kind of more granular timeline around first-in-human and some of the other clinical evidence and kind of when we would kick off those trials and when we would anticipate to kind of have clearance on those and get through the PMA process at the Analyst Day.

So, we'll kind of have a better broad kind of milestone-based piece on that front for you at the Analyst Day. But yes, we do anticipate that you're going to have to go through a PMA process for this.

Michael Matson^ And then just wanted to ask for some more detail on this BOXX-NO AF trial in terms of the design, the timing. Maybe we'll hear more about that at the Investor Day as well. I imagine we will.

But -- and then I thought it was interesting that you mentioned that it's going to include the use of ablation, but also AtriClip. So, it seems like another way you could expand the use of AtriClip as well in addition to LeAAPS?

Michael H. Carrel^ Yes. It's a great question. I'll give some high-level view, and we will go into more details at the meeting. It's actually a very similar patient population that is going to be enrolled in LeAAPS. So, it effectively kind of takes it to almost every cardiac surgery patient. The focus is on those patients that don't have pre-op Afib, and we're going to be looking at several different endpoints.

The first endpoint is going to be looking at post-operative atrial fibrillation and basically having a significant reduction. And there's lots of clinical evidence that have come out in the last three years to show that not only the reduction of that, but also the clinical benefit to the patient and also the economic benefit to the system because typically, patients can get home more quickly when they're able to have that post-op Afib managed. And again, we think that the combination of the ablation and the clip are actually going to lead to very good results within this trial.

We'll also look at those patients longer term so that we can actually reduce or bend the curve as they like to say, in terms of the amount of Afib in those patients longer term because that post-op Afib many believe is a precursor to longer-term Afib and that we can hopefully kind of stunt the progression of that Afib in that particular patient population as well and we're going to be looking at that also. And so, it's a really novel, exciting area.

It really expands our market presence quite substantially, both in terms of the number of patients and then obviously the amount that's going to be within each procedure. So, we're pretty excited about the trial. And like you said, we will go into much more detail at the meeting. Dr. Soltez and Dr. Whitlock are both PIs on that trial, and we'll be able to both present on it and then answer questions as well.

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

Daniel Stauder^ Yes. Great. So just first, on the softness expected for minimally invasive in 2025. You talked about a rebound potentially in early '26. But could you just give us an idea of what's baked in the guidance for 2025? How cautious is your outlook in terms of MIS? The sales range contemplate bear case for MIS? Or just any color there on what that includes would be great.

Angela Wirick^ Yes. Danny, consistent with the scripted comments at both points of the guide range, we are assuming that our U.S. hybrid ablation and MIS AtriClip devices see a decline, but there is no growth in either of those businesses for the full year 2025.

I think as we think through the year, first half of 2025 is when we're going to see the most pressure. and would expect just given the time and PFA devices on the market when we enter into the second half of the year, you start to see somewhat of an improvement, but the full year guide assumes for that -- those two product categories that it is a decline year-over-year.

Daniel Stauder^ Great. And just one follow-up on pain management. Just in terms of the new indications, specifically postamputation pain, what could the timing be there potentially? And what's the pathway? Do you need anything on the clinical side? Or is it really just more surgeon education and training? Anything there would be great.

Michael H. Carrel^ Yes. We already have the labeling for pain management. So, we're actually very comfortable kind of in peripheral kind of pain and nerve pain. That's something that we actually have in our labeling today and feel very good about that.

But we are developing a new device in this particular area, and we're going to go into more detail at the Analyst Day. But effectively, we'll have a new device to go after that market. We have certain physicians that are already doing the procedure. We've been looking at this for about three years now.

It's probably been about 250 patients where they've seen excellent results on it. And again, we're going to get into much more detail on kind of what we've seen, what the results of some of that data looks like and why we're excited about it in terms of the overall size of the market.

But it's another very large multi-hundred-million-dollar market to be in and to expand upon the existing pain management franchise that we have. And we are the only player in that area, and have very unique capabilities there. So, we feel like, it's an area that we can grow for many years to come and a whole brand-new area for us to go after.

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

Danielle Antalffy^ Mike, I'm just trying to get a better sense of the runway, the growth runway you guys have in your open ablation business. And EnCompass has been super successful in enabling you guys to unlock the CABG market, which you talked about.

I don't know if there's a good way to frame this, whether it's number of incremental surgeons you're adding each year and sort of how penetrated you are from a surgeon user perspective or if it's penetration of the CABG market. But any way to help frame where we are today and what runway is left ahead would be super helpful.

Michael H. Carrel^ I'm actually glad you re-asked the question because I think Lilly earlier had asked it as well and I forgot to answer it. So, it's a very fair and good question. And maybe just a quick history lesson.

If you look back about 15 years, penetration in this market was around 10%. And then we got our label in 2011. We're able to obviously change guidelines. You've also seen a dramatic change in reimbursement over the last three years. You've seen the introduction of EnCompass to make it easier to use.

So, a lot of things go into that. Guideline changes, better reimbursement and an easier-to-use product that significantly reduces procedural time. When you pull all that together, what you've seen is, as of today, we're sitting at about probably in the U.S., about 35% of patients with pre-op Afib get treated today, which is still, given the guidelines and given the recent change in reimbursement, still incredibly low.

So, there's a huge runway just within Afib patients first and foremost, still for the next 5-plus years, pretty meaningfully that we can get in the U.S. Those numbers are significantly lower OUS. Those numbers are closer to 20% when you look at an OUS basis. And we just got our EnCompass Clamp approved there.

So, we think that there's a lot of room for runway in the international market as well. And then when you add on top of that, again, we'll talk about Analyst Day. I'm not trying to punt everything to that, but it's just when you look at that post-op Afib area, that is a market that's about 3x the size of the pre-op Afib market.

And so, when you look at that, there's a huge runway relative to that part of the market as well. So, we think we've got decades worth of growth, when you look at it overall, and we're going to be excited to talk in more detail and in person with everybody when you come to Mason, Ohio on March 26.

Danielle Antalffy^ Okay. Great. That's helpful. And then on the convert side of things, I was curious if you could give a little bit -- you touched on it a bit on the call but you're seeing success for the MIS business in Europe.

I appreciate the U.S. is a few years behind, but it's not often that you see new products ramp faster in Europe than in the U.S., just given the dynamics for Europe. Is there anything that Europe is doing that's different that could be potentially translatable here in the U.S., thinking

about like the logistics between the cardiac surgeon and the EP. I don't know if there's something that can be copied here in the U.S. as to what's happening in Europe.

Michael H. Carrel^ Interesting enough, we actually have more sites in the U.S. trained and up and running and have logistics actually worked out really well. And I think until PFA, you started to see growth rates in that 30%-plus marker for us for about two to three quarters in a row before kind of the PFA onslaught hit the U.S.

What is applicable, though, is that what they're seeing in Europe is sites that were super excited about PFA, which is a great technology, and I'm not knocking it anyway, but they are seeing non-responders, a lot of them. I mean you're talking about in paroxysmal and in early persistent kind of less than one year, you see people not responding 35% of the time.

Well eventually, if they don't respond to one or two catheter ablations, they effectively come through that funnel that you talk about. And so more hitting the top of the funnel, they have to ask themselves, what are they going to do with that patient. And that's really why they've started to develop it and start to develop new programs in Europe, specifically because they have nothing else for that patient at that point in time.

So, they've been doing it for two or three years, and it's kind of the timeline to kind of get through the funnel. It has adopted, as you mentioned, super quickly in the United States, which means the top of the funnel is very high. Yes, people are doing this, and they're trying to do it in the persistent patient and maybe even some in the long-standing persistent as kind of their first-line therapy.

But if they're going to have that kind of non-responder rate at the same levels that you're seeing over in Europe, or even close to that, then the market is going to be enormous for patients that don't respond to the PFA catheters. And so even, if they go to one to 2, 3, that's why it's going to just take some time to kind of get through 2025.

The patients that were treated in 2024 might go back for a catheter or two more, and then you're going to start to see them come back. And I think that that's the dynamic that we do think is going to -- that mirrors Europe that you're going to start to see later this year and into 2026 and beyond.

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

Suraj Kalia^ Perfect. So, Mike, one of the things that you have consistently talked about for the past few calls is deeper account penetration. Maybe if you could quantify it for us as how should we think about the deeper account penetration, maybe customer concentration in the U.S., same-store new store sales? Just kind of put some guideposts around it so that we can better understand your commentary about deeper accounts.

Angela Wirick^ Suraj, So Suraj, I think if you look to some of the scripted comments, if you think about EnCompass and our open ablation franchise, we talked about a 20% account growth that was worldwide. The majority of that growth was from U.S., yet EnCompass as a product grew more than 50%.

So, we do think that we're seeing increased penetration within our accounts. This isn't just new kind of new users adding to the base. And similar, when you think about the accounts added in Cryo Nerve Block and our pain management franchise, that was kind of double-digit account growth. Again, majority of those being in the U.S., yet our Cryo Nerve Block revenue was growing -- 30% plus within the U.S.

So, I think what we're finding and where our team is really focused is, yes, expanding customer use space and physician use space, really making sure when they install each of these therapies that they are going incredibly deep and increasing adoption even with existing users and making sure that it's less about patient selection and that every patient who's applicable ultimately gets treated.

Suraj Kalia^ Got it. Appreciate it. Mike, I just want to follow up on Danielle's question and your comments about repeat touch-ups in Europe. I believe the 35% number to PFA catheters was indicated. Mike, more fundamentally and just out of curiosity, let's say you treat with RF, let's say, you treat with PF, right?

You have a certain responder rate. You have a repeat touch-up. Your comments about this will be a new TAM opening up, new funnel for AtriCure. Help us understand what is going to change in these patients? The substrate is already quite a bit modified.

Are you talking about AtriCure's PFA products? Are you talking about RF products? And if so, what is going to be so different that is going to be able to tackle these patients who have come back for a repeat ablation?

Michael H. Carrel^ Yes. I mean I think you set up perfectly exactly what Convergent is about. What we're referring to is that stand-alone Afib patient that has not responded to an endocardial catheter ablating the back wall or the veins. And really where we come into here is that coming in epicardially is really where that benefit is.

And we've demonstrated that through many randomized clinical trials with RF, and we're seeing it with patients with PFA as well out in the field today that big benefit of kind of sandwiching that atrium, both epicardially and endocardially is really what you're after. When you're going endocardial alone, you're not getting to the substrate, as you kind of talked about relative to the epicardium. It just doesn't happen.

It doesn't happen on a regular basis. That's why you see a lot of these non-responders because they just can't get to it. There could be fat pads there or other tissue depths and areas that aren't working or it could be the way the PFA works in terms of how you're attacking it.

You may see an acute showing of it on a map that shows you endocardially, you've actually captured it, but you do have -- you wind up getting reconnections coming back on the epicardium. That's where AtriCure comes in.

That's where Convergent or our DEEP procedure plays big. And the results from both the DEEP procedure and from our Convergent show super long durability, not just at one year, but at three

years and at five years, where we've demonstrated that it's incredibly durable when you come from both sides.

So that's what I'm referring to is that when these patients have failed on the endocardial catheter several times in a row, the epicardium becomes a critical area to go after to demonstrate that reduction in Afib and the durability of it long term. So hopefully, that kind of gives you a more detailed answer on that, and I appreciate the question.

Operator^ We have a follow-up question from the line of Matthew O'Brien with Piper Sandler.

Matthew O'Brien^ I'm missing the Analyst Day, so I'm going to keep trying to front run it here. Mike, you mentioned the LeAAPS trial is going to be done by the end of this year as far as enrollment goes.

I think that's a five-year follow-up, if I remember correctly. Are we going to get any interim looks? And then I think you're expecting to add almost 2,000 patients to that trial. Is there any kind of revenue headwind next year as that enrollment finishes up?

Michael H. Carrel^ Yes. There's no revenue headwind. I'll answer that last one first, which is that if you think about that trial, there's about 2,000 patients or 1,900 left to go. Half those patients won't get an AtriClip, half of them will. And so, it's a de minimis amount of overall revenue.

Quite frankly, it's -- and then when you look at the fact that some of those sites are actually already treating some of those patients prophylactically, you kind of have lost that revenue in the arm that doesn't get the AtriClip. So, there's really no impact on revenue whatsoever. We don't anticipate that to be the case whether this year or even into next year, et cetera.

As it relates to the timing of it, we do anticipate kind of being fully enrolled sometime kind of in the latter part of the year, probably in the third quarter sometime. That being said, like you said, there is a five-year follow-up from that last patient.

It is what they call an event-driven trial. So, we'll be able to look at that when we get to the full number of events. It's powered to show the reduction when we get to the full number of events. So, the five-years - that's the anticipated time it will take to get to those number of events. We could get to those numbers earlier for sure.

And that is something that is something we'll obviously update everybody on relative to that. We will have an ability to look in the trial when we get to half the events and then when we get to a 75% number.

But I just want to make sure, and I've talked about on this call before, we don't anticipate based on the powering of the trial that, that's going to show enough of a differentiation at that early of a stage. We do believe you're going to have to go all the way out to the final follow-up on that front.

Matthew O'Brien^ Got it. And then one more quick one, sorry. Did you mention an expansion as far as clip goes into other ablation cases? I think maybe you said VT ablation or something like

that. I just wanted to make sure I understood. If I was -- I just want to make sure I'm understanding that right. And isn't -- aren't there a ton of VT ablation cases done domestically every year?

Michael H. Carrel^ I don't -- I didn't mention anything about a clip going on to a VT ablation case, no. That must have been -- I'm mishearing that.

We don't -- I mean the clip -- the AtriClip is used concomitant all the time today in cardiac surgery and obviously concomitant to our ablations when it's done on a sole therapy basis with -- in conjunction with like a Convergent or a DEEPprocedure. That's when the AtriClip is used but not during VT. I didn't mention that.

Operator^ Ladies and gentlemen, I'm showing no further questions in the queue. I would now like to turn the call back over to Mike for closing remarks.

Michael H. Carrel^ Great. We appreciate everybody joining. I look forward to seeing you on March 26. Hopefully, you can tell that we are excited about 2025 and what's to come. And again, look forward to seeing everybody in person in Mason, Ohio, on March 26th. Have a great evening, everyone. Bye now.

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