AtriCure Inc

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Lily Lozada: Hi, everyone. Thanks for joining. My name is Lily Lozada. I'm part of the Medtech Research team here at J.P. Morgan. I'm happy to have the AtriCure management team with us here today. I'll pass it over to CEO Mike Carrel for a presentation. Then we'll do some Q&A.

Michael Carrel: Thank you, Lily. Thank you, J.P. Morgan, for having us at your conference again this year. Excited to tell you about the AtriCure story a little bit.

For those of you that know the story, you're going to hear some things you've probably heard from me in the past. You'll get a good perspective of why we're excited about this business, not just for 2025 but, actually, as we look into, quite frankly, this decade and even setting up for the next decade beyond that. Pretty excited for the work we're doing at AtriCure.

We've got the obligatory slide. Let me hit on why we're excited in general. First and foremost, the markets that we're going after at AtriCure are not multibillion, but we're talking about markets that today what we're looking at are over $10 billion in market opportunity that we're going after. These are large markets.

What's interesting today is that we are just at the beginning of the penetration into these markets. What's unique about AtriCure, and the thing to think about, is that AtriCure is number one in every one of the markets that we're in.

We've got markets that have an end user base that is 10 billion-plus and growing. We are today the number one player in that with a large body of evidence showing that the products that we have for both atrial fibrillation and for pain management work incredibly well. We've made those investments over the last 15-plus years as an organization to get there.

These are large markets and growing markets. Our portfolio is both a combination of great products, and I'll show you some of the innovations, but on top of that is the clinical evidence behind some of those products, which leads us obviously to a bright future.

When you think about the strategic focus at AtriCure, before I get into the disease state and what we work on, it's first and foremost to understand the baseline of who we are, is that our belief is that you have to create innovative products that actually improve patient outcomes and patient care.

Innovation is a core piece of who we at AtriCure are. Just over the last year, we've had five net new products that have actually been rolling out. We've got two more new products coming out this year. That is a big generator of the growth overall into our market. We have a belief that, yes, it is nice to have great innovation, but without clinical evidence to support that innovation, nobody is going to adopt it.

We make outsized investments in clinical science so that our data is proof-worthy, not just for the physician, but for the societies to change guidelines and to eventually change reimbursement. I'm going to touch upon a couple of those things, about the progress that we've made where our innovation plus the level of evidence has then led to changes in guidelines and reimbursement.

What that does is when you get a combination of innovation, the science is there, the guidelines have changed, reimbursement has changed, then what you get is opening up an expansion of markets. We are at that great point right now where those markets are beginning to really open up and expand for us at AtriCure.

One of the unique things is we've been around for a long time, and so today, I'm able to get up in front of you and talk about profitable growth. We've had the fortunate nature of getting and raising a lot of money over time, having investors put their trust in us and their money in us, and now we're beginning to get to the point of profitability.

We just announced our fourth quarter results, and we announced our guidance for this coming year in 2025. For the first time in company history, we are going to be cash flow positive in 2025, generating about $40 to $44 million of adjusted EBITDA. We are going to grow that number every year hereafter.

We've hit that inflection point, as you say, from a profitable growth standpoint, where we can continue that growth, make the investments in the areas I talked about, but also do so profitably. Let's take a step back and find out, why does AFib matter?

I know if you're here, you're at J.P. Morgan, you've been to all the big company presentations, and everybody knows AFib is a problem. It affects a lot of people around the globe. Why is it a

problem? First and foremost is when you have AFib, people are worried about, am I going to have a stroke?

Secondly, is that if you have AFib, you typically do not live as long. In fact, most people that get diagnosed with AFib live a shorter lifetime than most people that actually get diagnosed with cancers. It's pretty remarkable when you look at the data behind that.

AFib is an absolutely serious problem that can also lead to heart failure. Because you're not getting enough oxygen to the rest of the body, the rest of your body begins to break down. AFib itself isn't going to kill you, but it is going to help accelerate things that are going to cause very unfortunate effects for patients.

AFib, bad disease, increased stroke, increased heart failure, and increased mortality. It affects almost 60 million people around the globe. Yes, it is an epidemic. Those numbers continue to grow, not just in the United States, but everywhere in the world.

At AtriCure, we tend to focus on the most complicated to treat patients, and I'm going to talk about that a little bit more on the next slide. Those patients alone in the United States represent 3.5 million people. We are just scratching the surface on the number of patients to serve.

Let's look at that patient profile. We have three patient profiles to talk about. The first patient profile is you're undergoing cardiac surgery. If you're undergoing cardiac surgery for valve or for bypass, about one-third of those patients today have atrial fibrillation. The bad news is that 15 years ago that number was about 10 percent of people that were getting treated.

The good news is that since that period of time, we've moved up to 35 percent that are getting treated today. We are number one in this market, representing almost 90 percent market share with ablation and a product called the AtriClip that takes out the appendage, literally takes it out completely, where we've implanted over 600,000 of those today.

There are over two million patients around the globe. Let me repeat that, two million patients around the globe that undergo cardiac surgery today. Of those two million patients, if one-third have AFib, that's about 600,000 or so patients that could be treated and the guidelines say you should be treating when they hit the operating room table.

We're treating about 100,000 to 125,000 or so a year today. Severely under-penetrated, yet the guidelines are there to change it. I'll talk a little bit more about what we're doing to change that

outcome.

In addition to that, we've got expansion opportunities within this particular area. The expansion opportunities are around those other 1.4 million patients have a higher likelihood of getting AFib in their lifetime. We believe that if you actually ablate and put an AtriClip on them, you can reduce their stroke rate and reduce their incidence of AFib long term.

That is market number one, our core market with massive market growth opportunity in front of it. Number two is what we call the hybrid market, which is all you have is AFib, so standalone atrial fibrillation. This is where you hear from all the big companies and where a lot of their focus is. When somebody has AFib though, it's a lot like cancer, which is, it's a progressive disease.

When you're earlier on in AFib, meaning you've had it for a shorter period of time, your heart hasn't remodeled quite yet. If you get in early, it's really effective to use both drugs and the catheters that most of the major companies use today. As that disease progresses, and you get into what they call long-standing atrial fibrillation, which means you've been in AFib for over a year, simply put.

You've been in AFib for over a year, what happens? Your atrium gets larger. It's more difficult to treat even with the newer technologies like PFA. There is only one company in the world that has run the clinical evidence, done the science behind demonstrating proof that if you add a surgical procedure, add it to what you're already getting with the catheter-based technology, you will get double the results.

Let me repeat that. Double the results without really any safety hit as a result of that. We've run those trials. We have that data today. Now, this part of our business has been the part that's had the hardest hit over the course of the last year or so as PFA has rolled out, but that funnel is getting larger and those failures are getting there on those patients, and they can't treat these long-standing persistent patients.

There is only one company in the world that has labeling that says it will work if you do the hybrid procedure to treat atrial fibrillation in this area.

Then the third area of our business is our pain management business. We got into pain management in order to accelerate some of our treatment of atrial fibrillation. This is now the fastest-growing part of our business. What it is, is it's the patients that are undergoing today thoracotomies typically. When you spread those nerves, it's incredibly painful.

When you go in for a lung resection, or you've had a car accident, anytime you're hitting that nerve ending, the intercostal nerve space, it's incredibly painful. It increases your length of stay, and about one in seven people that undergo surgery like that wind up having an unhealthy relationship with opioids.

We have a non-opioid device that freezes the nerve, and by freezing the nerve, you block the pain signals to the brain. This is, again, one of our fastest growing parts of the market. Those are our three areas of our business today that we're in, and I'll go into a little bit more detail here in a moment.

If you look back 15 years ago in 2010 and I was standing up here, I would talk about a billion-dollar market opportunity, and we were excited about that. We said cardiac surgery, open ablation, AFib patients, treating their appendage management. We had just rolled out our AtriClip for the first time in the first generation.

Today, we look at a five-billion-dollar market opportunity with the existing products and labeling that we have today. I talked about hybrid cardiac surgery in the left atrial appendage and in the pain management space. You can see in the dark blue there, that's the penetration rate.

If we did nothing and we didn't expand anything, you already have a massive market opportunity just with the products, the therapies, and the data that we have today in the market. However, there's more to it. We've had natural extensions to that, and I mentioned earlier that our market opportunity is over $10 billion worth of market opportunity sitting in front of us today.

On the left-hand side, what you see is our core market today in the three different areas. Within each area that you look at there, I'll start with on cardiac surgery, I talked about doing a prophylactic management of the left atrial appendage. Meaning, everybody that undergoes cardiac surgery, put an AtriClip on them because you can reduce their stroke.

We've got the largest clinical trial in cardiac surgery being run right now to demonstrate that. We're over almost two thirds through enrollment on that. We anticipate being fully enrolled by the middle of this year.

Combine that with another trial that we've proposed and gotten approval by the FDA called the BOX no AF and what you're going to do is an ablation, a prophylactic ablation for those same two million patients.

We've expanded that market opportunity, and our vision is that as we enter into the next decade, that you are going to see every patient that's undergoing cardiac surgery to get our EnCompass clamp and our AtriClip to manage both their AFib and their stroke risk long term.

Then expansion in pain management is natural. Thoracotomy is not the only time that you're actually affecting nerve endings when you're doing surgery, and so we're going to begin to grow. As we've seen such great growth in this area, we're being pulled into some new areas like the extremities area for amputations in particular.

In the US alone, there are about 150,000 or so amputations. Of those, about 100,000 or so are for below the knee. That's going to be our first foyer into that particular area, and it's another almost quarter of a billion-dollar market opportunity for us to extend within there while we're growing in the thoracotomy space as well.

Because I talked about innovation before and you look at how well we've done over the years, one of the reasons we've been able to drive our growth as a business is through the innovation. We're celebrating our 25th year here at AtriCure today, and you can see as you look across that slide, the acceleration from the investments that we've made towards innovation.

Just in the fourth quarter of this year, we announced two new launches of something called our cryoSPHERE max for our pain management business. We launched our FLEX-Mini product to open up the open left atrial appendage business.

Those two areas are both a combination of they will expand the market, we'll get pricing increases, and it's more innovation technology that we can bring to it. Why? Because we're making it much more efficient and easier for the surgeon or the physician to treat that patient. Those are just two examples of some of the market expansion opportunities we've got in front of us.

I mentioned earlier that in order to grow a market, you've got to have proof points that what you're doing and the data that you're bringing in that technology actually influences the guidelines. What you see here that looks like a very busy slide, if you look over to the left where it says 2014, you can see in 2014, there were zero.

Let me repeat that. 2014, there were zero of our procedures and the use of our technology that was a level one guideline. Zero. You can see several of them like hybrid ablation, there was no

guideline whatsoever at that time. By making investments in that clinical evidence for the technology that we had, what you can see in fast forward to 2023 and 2024, almost everything is up to the right is a level 2a or a level 1 guideline.

What that is telling you is that all the societies, and this covers your heart rhythm society, your surgical societies, they are telling you, American Heart Association, they are saying you must and should treat every time you've got a patient on the table. They're saying, it is not just OK to treat it, it is something that we are recommending you do every single time.

It's great. They're telling you to go do that, but does that matter? Well, it does matter because guess what? Now CMS is saying it matters. Then CMS, over the last four years, has changed and actually increased reimbursement for almost every one of our procedures. You can see that, and all of this was driven by evidence that AtriCure put together and ran trials on.

In 2021, if you added a ablation to a CABG, now you can add anywhere between $8 and 14 thousand for that procedure. This is CMS telling you, we want you to do this. They're not just adding that kind of money to the procedure for goodness sakes.

They're doing it because they want you to treat that patient that's on the operating room table because they know not only does the patient do better, they live longer, they have fewer strokes, you cost the healthcare system less money over time. Then what did they do? In 2023, they actually made that for double valve procedures as well, and they added almost $24,000 to it.

What you're seeing is that evidence is leading to guideline changes that's leading to reimbursement changes that we anticipate obviously leads to long term growth and being able to capture and take that dark blue I showed you several slides ago and make that dark blue almost cover the entire slide and the entire market opportunity over the next 5 to 10 years.

That's the opportunity that sits in front of us here at AtriCure. I hit on most of the items on each one of these, but I'm going to touch upon a couple of key areas within each one of the slides here on each one of those franchises. As I mentioned, two million patients undergo cardiac surgery every year.

Our vision is that every single one of them are going to undergo a ablation plus an AtriClip as we close out and go into the next decade. That is going to be a combination of the unique technology that we have today with the reimbursement that's been put in place, with new clinical evidence to show stroke reduction and AFib reduction in non AFib patients as well.

If you expand that and looking at the hybrid therapy, there's three and a half million patients that have long standing persistent AFib, and there's only one company in the world that has a label in this area and that's AtriCure. There's only one company in the world that has ever run a trial, started a trial, and looked at this patient population, that's AtriCure. We treat 3,000 patients every year.

That's abysmal. There are literally millions of patients that can benefit from the therapies that we bring to the table every day, and our products are all work in conjunction with the catheter-based companies, whether it's PFA, cryo, RF, it doesn't matter to us. We're agnostic to it. Our products work in combination with them.

Then finally, the pain management solutions that we basically bring to the table are unique solutions. Again, we are number one in the world developing this market. We've seen this market take off and is the fastest growing part of our business. We've had several new roll outs and new product generations over the course of the last several years.

Just this last year, two new products that basically reduced the time they had to spend on it that we believe is going to increase adoption overall. It's going to make it easier for physicians to treat these patients. As I mentioned earlier, we're going to expand into the extremity business as our first foyer outside of the thoracic area.

Three main markets, all markets where we're under penetrated and have huge market expansion opportunities sitting in front of us. How well did we do in this most recent year? We announced our guidance most recently.

We had 17 percent growth in 2024, 26 percent growth on international, the LeAAPS trial that I talked about, which is 4,200 patients that we've enrolled in this trial out of 6,500 total patients, the largest trial ever done in cardiac surgery.

Starting a new trial to expand the market to ablate all of those patients as well. We pride ourselves on being a great place to work as well. We've won honors in this area, both for a great place to work, but also great place for innovators.

In fact, Fast Company named us the number one place for female innovators in the medical technology area today. We're proud of that fact and the investments that we've made in this area. Most importantly, sitting right at the front, like most medical device companies, putting patients at

the front of everything we do, we treated almost 190,000 patients in 2024. We anticipate that number going up.

As we look forward into 2025 results, it's important to look back over the last several years. If you look back five, six years ago, we talked about accelerating our growth rate from a low double-digit number. We were really good.

I'd come up and stand up in front of everybody and say, "We have had 48 straight quarters of double-digit revenue growth," but it was typically low double-digit revenue growth as we are growing. We said, "Hey. We're making these investments to expand our growth rate."

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We told everybody we're going to be growing at 15 percent or north. Just look at it, over the last five years, you can see we've had a four-year run where our CAGR has been almost 20 percent. Now, the numbers are getting larger now. We're crossing over that half-a-billion-dollar mark in 2025.

While we're crossing that over, we're going to continue to expand our profitability. We reaffirmed our guidance this year, where this year, we did $26 to $29 million or so in EBITDA. We're going to grow that to well over $40 million in 2025 and be cash flow positive.

This is an important point in time for us as a company as we continue to expand and grow our top line while also contributing to the bottom line in a meaningful and expansive way. Hopefully, before we get into questions, you can close out today.

We had a strong 2024 despite headwinds that we faced from the PFA and other competition that were in the market, where we grew exceptionally well at 17 percent, driving discipline to the bottom line, showing you that our guidance for the upcoming year is strong from a financial standpoint. We've got great confidence in what we're looking forward to.

On top of that, we're not just about a 2025 story, but we've got expansive new products that are going to drive revenue, not only in 2025, but almost every one of our product launches in 2024 and 2025 will drive revenue growth for the next five years through the end of this decade.

I want to close by saying, we've got an analyst day on March 26. We're going to hold it in our headquarters. We welcome everybody to come join. It's in Mason, Ohio. We're very proud of

where we make our products. We'd love to be able to show off the innovation and pipeline that we have there, and what to look forward to over the coming years.

We obviously wouldn't be holding an analyst day in person at our site if we weren't super confident with where we're going and what we've got ahead of us in front of our business. With that, I will ask Lily to come join back up, and we'll answer questions. Thank you.

[applause]

Michael: I hit your 20 minutes. You said 20 minutes. It was 22.

Lily: Looks like you have 17 left. You pre-announced good fourth-quarter results, so maybe we could start there. Could you talk through some of the trends you saw across the segments and what drove the strength in the quarter?

Michael: Sure. In the fourth quarter, what we saw was really good strength from our cryo business. Cryo nerve block business was our top growing business for the year, and also in the fourth quarter. We saw acceleration of growth throughout the year, and the fourth quarter was just an amazing growth.

A lot of that trend was because both adoption is increasing, and also, we rolled out our cryoSPHERE Max, which is our second new product in that category, which reduced the time so physicians can adopt that technology easier.

On top of that, our AtriClip on the open franchise where we faced the competitive threat that everybody was nervous about. When we were up here a year ago, everybody was asking about the competitive threat on AtriClip.

Today, what we're seeing is that we've actually accelerated throughout the year. We saw 15 percent growth in that area in Q1, 17 in Q2, 20 percent in Q3. We had another great quarter in Q4 in that area. We believe that that market is continuing to grow.

We capped that off with a roll out of a new technology called the AtriClip FLEX-Mini, which is about 60 percent smaller than any product on the market. Super low-profile product that we're excited to bring to market. We started to bring it to market and got great results from our customers.

Then internationally, we saw really good growth for the year as well. We saw 28 percent growth in the fourth quarter, another acceleration on that front. We're seeing that engine begin to pick up. On the international front, we saw growth across every segment pretty equally.

It was actually good growth. One of the things to highlight is in the US, we did see a trend, which we've talked about before, where there was a little bit pressure on our hybrid business. We anticipate that to occur throughout 2025.

If you look at international, though, our international hybrid business actually grew incredibly well partially because they're through that initial PFA wave. PFA has been on the market there for three years. You're now starting to see sites that before would not do it and were only doing PFA for some of these patients have now really expanded for these complex patients to include a hybrid therapy.

In the US, we're at the beginning part of that. We felt it in Q4, but I think that there's a bright light looking at Europe to see that maybe not in 2025, but likely in '26 and beyond, you'll start to see that come together for us as well.

Lily: Looking to 2025, you pointed to sales of 517 to 527 million, or growth of 11 to 13 percent. What are some of the underlying assumptions for that guide? What gets you to the high end versus the low end? Any color on how we should be thinking of growth across each of the segments?

Michael: We got a lot of feedback from investors over the course of the last year or so that they really want to make sure we had guidance to them. We beat every quarter this year, but they want to make sure that we had guidance that they felt like the street had a perception that we could beat every single, throughout the year. That definitely went into our mathematical thought around looking at it.

If you look at the components of it, we are going to have strength in cryos in the cryo pain management business. We will have strength in our AtriClip open business, and we will have strength in our open EnCompass and ablation business. Much like what you saw in 2024.

We will have pressure from hybrid. Those three that I just talked about will be above the corporate average growth. We'll see below corporate average growth, if not actually, our hybrid business will probably shrink a little bit in 2025. Anticipate probably longer term that will come back and grow again.

Even despite that pressure, because of such great growth that we're seeing in those other three franchises and our great growth on the international front, we can obviously still have really good numbers for the year.

Lily: Any thoughts on cadence for next year or this year?

Michael: Pretty consistent throughout the year.

Lily: Maybe shifting to some of the specific business lines starting with open, EnCompass has been on the market for a while now, but it's still delivering really impressive growth with, I think, 50 percent growth in the US last quarter. What's been driving this momentum for so long? Do you think the open business can continue to be a double-digit grower as a result?

Michael: We absolutely think the open business can be a double-digit grower for...You saw the numbers up there. We are so under-penetrable. Only 35 percent of AFib patients, let alone some of the prophylactic use that'll eventually happen once we get BOX no AF up and running.

We feel really good that that part of our business is going to grow. Why is EnCompass growing fast? Because it took a 45-minute procedure and brought it down to 10 minutes. Now ablating a patient is accessible to every cardiac surgeon out there. There's no excuse at this point in time not to do an ablation. EnCompass is that easy.

This year, you saw a little bit of an acceleration in growth because we took our original rollout, which we called the long version of it, and made it a little bit shorter to make it even more accessible for certain surgeons. That obviously accelerated and got it in even more hands from that standpoint. We think that that's going to be a trend not just for 2025, but for many years to come.

We just got that product also into Europe as well. We won't see much growth out of it this year as it gets introduced into the market, but there's a lot of excitement there. We've got to make sure it can get paid for, but we anticipate over the course of the next 12 to 18 months, you'll start to see similar momentum there that you saw in the United States over the last three years.

Lily: Shifting to MIS, you mentioned PFA. Maybe we could dig into that a little bit deeper. The rollout has obviously been really strong. I think there's still a lot more room to run in terms of the conversion from RF and cryo to PFA.

First, how have those PFA headwinds been trending into the fourth quarter and early 2025? Are you seeing customers come back after trying PFA if they were non-responders and coming back to CONVERGE? Second, should we think about this as being a lingering overhang over the next few years as that conversion to PFA continues?

Michael: I'll answer the last part first. I don't think it's an overhang for the next few years. I think it's an overhang into 2025 for sure, and we've put that into our guidance, overall. What's happened? As we all know, PFA has rolled out and had tremendous adoption and effect in the marketplace which is an exciting new technology in that area. People are going to try it, and they're going to try to do it on...

One is they're incredibly distracted because it's not just one technology that's come to market. They've got now three systems. A fourth or fifth system's going to come in in 2025. They've got to train their staff, they get distracted, and then they therefore, dealing with the logistics of working with the surgeon sometimes gets in the way in that. We definitely feel a little bit of that.

We also feel that some of them are saying, it's really safe. What's the downside of doing an extra ablation relative to that? That's what we saw over in Europe. We anticipate that then you're going to start to see some of those failures because what's happening is they're ablating so many people now that that 400,000 a year that they used to ablate is now going to be up 500,000 in '24, probably almost 600,000 this year.

When you look at those numbers, the failure rates are still the same as they were from before. What do you do once you've tried everything on that patient? They're going to come back to CONVERGE. I think what gives us a lot of confidence, one, is the experience we had in Europe I talked about.

Two, and as importantly, is if you look at the number of sites, we actually had more sites buy and use CONVERGE in 2024 than we did in 2023 despite all of that pressure. Why is that important? They're doing less procedures per site. They still believe in the procedure for those complicated-to-treat patients.

They're just making an attempt to do one more time with PFA for the difficult-to-treat patient and see what's going to come of that. We think that since that funnel is so big, it actually is going to be an accelerator as we look into '26 and '27. We're not quite there yet. 2025 is going to be tough. There's no question about it, and we're going to be in that.

Fortunately, for us, the rest of our business is growing so well that we can still have great growth numbers overall for the business, but we're definitely going to feel a pressure in 2025.

Lily: Before PFA came into the picture, you were working to get CONVERGE ramped up, but it was a bit slow to get off the ground. Part one, what do you think went wrong there? Second, where do you stand today in building the market for CONVERGE? What's it going to take to get this meaningfully off the ground?

Michael: One wrong there was COVID. Once we got the approval, COVID hit. Elective procedures went away, and we had to get that coordination back going with the surgeon and the EP that we'd spent three or four years before getting ready before we got the approval.

The biggest thing that happened was we had about a 9 to 12-month big hit relative to COVID, because the rest of our business that did not rely upon people working together at the hospital, you had staffing shortages. You had people that had to try to work together. We were impacted by that.

If you saw, we came off of that, spent a year getting that workflow back together, and we started to see really good growth before PFA came in. You saw on the end of 2023, 28 percent growth, 30 percent growth in that part of our business. I believe that was a result of people starting to come back after COVID.

Unfortunately, I guess, recommendation, don't get an approval in the middle of COVID because that can obviously hurt the launch of a new product and a new product line from that standpoint. At this point, we've just got to wait for the PFA to settle down and for us to get back and have that pipeline come through.

Lily: You've mentioned that you have your own PFA underway and have understandably been a bit tight lipped on what exactly that'll look like. What can you share with us at this point? Any color on launch timing, who you're partnering with, and how you're integrating it into the portfolio?

Michael: Our PFA focus, we're not trying to compete on the endocardial side. That's not where our strength is. We're not going to go put in that effort at this point in time. There's a lot of great players doing a lot of great work for that patient population.

What we're trying to do is as a leader in this space, we need to make sure that we've got all

technologies available to our physician partners. That's the goal here, is to basically have PFA as an adjunct to cryo and to the RF technology we have today.

Mechanically, we've built the best product on the market with the EnCompass clamp. We've taken a 45-minute procedure and made it 10 minutes. Our procedure is incredibly safe. You can look on all the databases and look at...This works pretty much every single time with RF today. Great technology.

What PFA does is people, because they're so excited on the endocardial side, we've got to make sure that we have that as something for to offer to people at that point. It depends I'm not sure what that's going to do from a growth standpoint.

I think the most important thing for growth is going to be the clinical evidence coming from the trials that we have, both BOX no AF and LEAFs overall to get the full treatment for that overall patient population.

I believe that our EnCompass clamp is so unique and differentiated that that's going to drive more growth necessarily. I think we have to give people the option to choose between a PFA technology and that. That's for our open business.

We have been clear we're also going to plan on putting it into our hybrid business, into our Epi-Sense technology. In that area, there is a speed benefit. There's no real speed benefit on the open side of the business because that's not what takes time in an open business.

In the hybrid side or when you're doing surgical with the Epi-Sense technology, what you have there is we could probably take out almost half the time that a surgeon is doing it. We're going to work on bringing it to market with both of those technologies.

The biggest thing for us, we'll talk about it on analyst day, is really helping people understand this is not something that's happening tomorrow. All of these have to go through a PMA process, and so you're talking about three, four, five years out before something's going to be on the market in this area.

Lily: Shifting to appendage management. Like you mentioned, you had a competitor come to market last year, though it doesn't really seem to have much of an impact on the open side of the clip business.

Can you give us your updated views on what you're seeing in that market on the competitive front? I know there was some trialing initially. Have you seen those customers come back to AtriClip eventually?

Michael: The market data would tell us. When we were probably sitting here a year ago, I would tell everybody, this is going to help grow the overall market. Having a second competitor come to the market is a good thing for the market overall. It's good to have competition, to challenge you, to push you, to push both the company, but also to push the physicians to treat more.

That's what we saw. You saw throughout the year an acceleration of overall growth. We've got great growth in this market. Having that second competitor has raised awareness to treat the patients every single time. You've got another player out there validating the space on that front, and you're seeing it in the numbers. I anticipate the same thing's going to happen in 2025.

On top of that, we've rolled out a net new product. That is, quite frankly, the best product in the market, the lowest profile, easiest to use product. We're pretty comfortable with the technology leading edge we have. Plus, we feel it's good to have that competition in the market to push us.

Lily: I know your competitor doesn't report numbers for this product, but any sense of what share looks like and how big of a presence they have?

Michael: Everybody can pull the market data. It looks like from the market data, we pulled anywhere between 5 and 10 percent in any given month in the open part of our business, is what it looks like.

Lily: You mentioned the new product that you're launching, FLEX-Mini. What's the feedback and receptivity of the product been like? How are you seeing it impact your competitiveness, and how does it impact the TAM for AtriClip?

Michael: I don't know that it impacts the TAM. The TAM is two million patients that basically could get an AtriClip. That's the number of people that undergo cardiac surgery. We anticipate with LeAAPS, that's the big market. What it does do is accelerate adoption.

It makes it super easy and simple for someone to place this on. They have better visualization with it. It clearly differentiates us from any competitive threats that were out there because this is the smallest profile product on the market by far, super easy to use.

The reception has been fantastic. A lot of times, it'll be interesting. You talk to a physician, like, "I don't need it. I'm really happy with my technology today." You say, "Just try one." They try it. They look at their staff and say, "I never want to use another clip again." They just love the product. It's that easy to deploy.

Lily: You've put up really strong growth in appendage management year after year, even in the face of competition. I'm wondering where penetration stands on the open side of the business with the indication that you have now, and how long you think you can sustain this growth profile?

Michael: On the AtriClip?

Lily: Yeah.

Michael: On the AtriClip, in the US, if you look at 300,000 patients that undergo cardiac surgery every year, of those 300,000, about 90,000 or so have AFib. Of those 90,000 patients, we probably treat about 50 to 60 percent of the total patient population in that area.

If you look at it holistically against the LeAAP's patient profile, the whole 300,000 patients, you're talking about 20 percent penetration at that point in the US. Those numbers get cut in half when you look at it on international front. There's tremendous market growth and opportunity sitting in front of us.

Lily: In the last few minutes that we have here, shifting to the P&L, you've had several quarters of EBITDA profitability under your belt. I think you're pointing to 40 to 44 million this year? What areas of the P&L are driving that leverage?

Michael: SG&A, primarily. We are a big believer in continuing to make major investments in the research and development area. I talked about it in my presentation in innovation and clinical evidence. The percent of revenue, we might get a little bit of leverage off of that, but very slight.

We think that that's super important to continue to do that so that we've got growth engines for many years to come, but we will get significant leverage off of SG&A as we look into 2025 and beyond.

Lily: Any color on how we should be thinking about gross margin trending, especially as you launch a lot of these new products?

Michael: Right now, gross margin, we anticipate being relatively similar at the 75 percent, in and around that area. Primarily, we got all these new product launches that have price increases and better margin profiles.

However, you're also seeing our international business, which is a good thing growing really fast, but that comes at a lower margin profile. The balance of the two give us that we're going to be consistent on that 75 percent.

Lily: I think we're almost out of time, so maybe this is a good place to wrap it up. Thanks so much, Mike, for presenting, and thanks, everyone, for joining.

Michael: Thank you.

[applause]
