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AtriCure, Inc. (ATRC)

[BEGINNING OF AtriCure, Inc. (ATRC).mp3]

Matt: Good morning, everybody. Thanks for joining us. My name is Matt O'Brien. I'm one of the med tech analysts here at Piper. Next up on the agenda is AtriCure, which is a fantastic cardio company. From the company, we have Mike, who is the CEO of the company, and then Angie, who is the CFO. Thank you so much for coming out.

Mike: Thanks for having us.

Matt: We do appreciate it. So, maybe talk, Mike, for starters, on the Clip side of the business. That growth that we saw in Q3, it was 18.5%. You had a tough comp on a two-year stack. It was 18.5%. That's an acceleration versus the previous six quarters, which I don't think people quite understand. What drove that acceleration on the Clip side?

Mike: FLEX-Mini in particular. We came out with a new product in the fourth quarter of last year. FLEX-Mini is 60% smaller than any products that are on the market today. As we all know, there was a competitor that came into the space. This product is 60% smaller than theirs and RV-Clip that was out there. It's easier to use, easier to put in place, a lot better visibility with it. And so, people are basically wanting to get it in and wanting to get in their system. So, we're in almost over 30% of the systems right now -

Matt: Yep.

Mike: -- across the country, and that's really been the big driver for growth for us in the U.S.

Matt: OK. So, let- -- you know, for the layman that I am, --

Mike: Yeah.

Matt: -- right, you've got the left-atrial appendage. You're trying to clip it off. Why is smaller better to -- you know, in that situation? What is it that's easier for the clinician, generally speaking? And then, you know, with your existing competitor or others that are coming, how difficult would it be for them to try to replicate what you're doing with a Mini-type product?

Mike: Well, first, why do you want something smaller? Because you're putting an implant in. The first thing is that you want visibility. So, by having it smaller, you get a lot more visibility about all the structures around it. You're working in really tight spaces. Think about the box that you've got when you're going into cardiac surgery. So, having a smaller device to be able to manipulate it around, to be able to know that you've got complete coverage, you're going down to the base of the appendage, that visibility is absolutely critical. And so, the smaller that device is, the much easier it is to do that and to manipulate -- to manipulate it.

Two, is that by being smaller, you know that you're not going to be impacting or impinging on any of the external or other structures around it. It just gives them more confidence when they're doing it. It's so much easier to place. And then thirdly, as I mentioned, getting down to the base. You get really good visualization of what that looks like from that standpoint. Incredibly difficult for any competitor to come out with a product that would compete against this at this point. We spent many years actually recreating and doing new designs so that -- with this Clip. And the spring mechanism in this Clip was something we worked on for over three years just to get to this point.

So, if you look at the Clips that are coming out from existing or even oncoming competitors, almost all of them are going after our V-Clip technology.

Matt: Yeah.

Mike: They're like copycats of that technology, which is great technology. And it works incredibly well. We've got great closure, 100% closure with that, that you see with it. So it's a great device, but it's a little bit bigger. And so, for them to come out with something smaller, they'd have to kind of re-engineer everything they're doing and spend the kind of time that we just did, but they're not going to do that right now. They're coming to market with that new product. And so, from our standpoint, I think we're way ahead of them on that.

In addition to that, we've talked about the next generation of the Clip as well. And so, this Mini Clip is kind of a rectangular version of it. So, you go all the way around the appendage. Some of the clinicians like that, --

Matt: Yep.

Mike: -- just for the way that it gets used. Others, if they want to still use that V-Clip orientation, we will have a version of the V-Clip that is smaller than this. So, it'll still be 60% smaller than anything on the market that is going to come out sometime in early 2027.

Matt: Oh, interesting. OK. So, I mean, I --

Mike: We've got innovation coming upon --

Matt: Yeah.

Mike: -- as well on this new spring technology.

Matt: I can think back to PRO-V and FLEX-V and how well those were adopted. I mean, --

Angie: Yeah.

Matt: -- you know, you're taking it another step further. How quickly -- you know, you're up to 30% penetration on the Mini side -- How quickly did you get to 30% with PRO-V or FLEX-V?

Angie: Yeah -- that- -- Couple years.

Matt: And this is happening in months.

Angie: Yeah.

Matt: So --

Angie: Yeah.

Matt: That's just kind of -- OK. How high can you get with FLEX-Mini in terms of penetration?

Angie: I think if FLEX-V is a good indicator, it could become the predominant Clip that we sell. So, faster than that launch, we're in a better place compared to the FLEX-V launch. FLEX-V was about 75%, 80% of our volume in open test

procedures. So I think that the FLEX-Mini could get there, if not better.

Matt: Got it. OK. And then Angie, maybe talk a little bit, because I know you and I have talked about this, what is it about your technology that's patented ver- -- that others can't replicate, and what does that preclude them from doing?

Angie: Yeah, I think two things stick out. The fabric around the Clip, which helps ingratiate the Clip in place, then also parallel closure. So, the mechanism of action, the way that the Clip closes. You know, our competitors are speaking to, you know, the ability of the curvature of their Clip and different things. Those are two areas in particular where our technology is defined, and it makes a difference.

Matt: OK, understood. And then what kind of ASP bump do you get on the Mini side versus... [crosstalk 0:05:02.7]

Angie: It's a good bump when we're innovating and we're putting new technology out into the field. We feel like we should be paid for the innovation that we've put into the device. If you're swapping out from a FLEX fee, which today I think the majority of customers are adopting the FLEX-Mini coming off of a FLEX fee, \$1,750 to a \$2,250. If you're using the original AtriClip, which we still have on the market, it's a low-cost option. It's \$1,100 to a \$2,250 ASP.

Mike: And that's important to note. We've kept that low-cost option. We get a lot of questions about, is a competitor gonna come in and try to lowball price and come in? Well, we have a low-cost product that's on the market today that works incredibly well. It's a little bigger, it's a little bulkier, but people will use it if they're truly sensitive to price. But nobody's gonna be able to beat our price on that. You can see it even with the competition that's come to market. They've actually come above our price on the V when they've come to market. It'll be very difficult for them to meet that on that front. It's gonna be a smaller and smaller percentage of the overall market over time, but we have it just in case.

Matt: Yeah. Mike, how big a deal is pricing though in cardio? I mean, is it something that comes up like, "Well, we want a much cheaper product?" I mean, think about what you're operating on, is that really an issue?

Mike: Yes. Strange as that may sound. I'd say, 10 years ago when we first came out with the AtriClip, everybody said, "\$1,100 for that. I can just use my proline and sutures and

I'm done." I think now we've kind of helped educate them that, "No, this is a lot better than doing that." That it's worth to spend some more money on it. We still get it occasionally, pricing relative to that. They still get pressure from their hospital. And so, I'd say that the biggest pressure they get is when people start using it prophylactically.

If they're using it with an AFib patient, there's no pressure on it because the DRG, now that that has increased quite dramatically over the last three years for just doing an ablation with the AtriClip on it, you don't really get pressure there. But if they're gonna do it prophylactically, which many sites do that, especially after the trial with LeAAPS, you're starting to see people do that. If you start to get some volumes, they're not getting any additional reimbursement for that. They've got to articulate why they're doing it back to their hospital now.

Matt: OK. That's interesting. I do wanna chat about that a little. What about on the EnCompass side? That continues to exceed expectations. And again, more technology there, more innovation there than I think people realize. Maybe just talk a little bit about, you know, what's going on with EnCompass and how much juice is left to squeeze out of that business.

Mike: We're just beginning with EnCompass. We've made a tremendous amount of progress. So, a reminder, the reason we did EnCompass was that there's a huge market potential that people were not doing any ablations, even for patients with AFib. We needed to make it simpler and easier for them to do that ablation. And so, we took procedure time down from 30, 40 minutes to do a full-blown maze procedure and got it under 10 minutes with the EnCompass clamp. In addition to that, we made it easier for a surgeon who is not used to doing and getting behind the heart to do this procedure without having to go behind the heart. Those two pieces have changed the game for this, which is why it represents over 50% of our revenue today in the U.S., which is that clamp. When people use it, they never want to go back because they get a super robust lesion. It's really easy to do.

In addition to that, the other reason for it was this concept of, well, if you're going to prophylactically ablate somebody because they get benefit from it, both near-term with post-op AFib and long-term with clinical AFib, you need to have a device that you can use and do really quickly. And so, EnCompass clamp has that huge opportunity in front of it. So, if we're still sitting at 35%, 40% of patients in the U.S. just with AFib being treated, meaning there's a 60%

penetration goal there. When you add on the non-AFib patients, you've got like 80% penetration still left to go once we get that in place. So, EnCompass clamp is all about that.

Matt: OK. Is that the BoxX-NoAF?

Mike: That's the BoxX-NoAF.

Matt: OK. So, help me understand BoxX-NoAF because I didn't realize so many people came back or ended up with AFib post-op. How is that study going to look? And then I don't think the follow-up is very long, so when can we start to see some data from that?

Mike: Yeah. So, trial is approximately 1,000 patients, 960 patients. These are patients that do not have AFib going into cardiac surgery. Half the patients will get an EnCompass clamp with an AtriClip. The other half will get current standard of care, which is nothing done for them because they don't have AFib, so they're not getting treated at that time. So, the idea here is that today, in that standard of care, 35% to 40% of those patients go into post-operative AFib. And if you talk to any cardiac surgeon, they will tell you the bane of their existence is post-op AFib. Why? Because they have to keep them in the hospital longer. They've got to put them on heparin drips. They've got to put them on amiodarone. They've got to go manage that patient much more aggressively at that point in time. And that person's not recovering because if they're in AFib, they're not recovering from the cardiac surgery they just had. And so, it just takes a lot more time and attention to take care of that patient that's in post-op AFib. And as I mentioned, it's 35% or 40% of those patients.

In addition to that, most of those patients, it is a precursor for getting AFib over the next three years. So, it's kind of like a marker that you're going to probably get AFib or go into clinical AFib in that period of time. So, the way the trial is designed is we're going to have two primary endpoints. We're going to first look at, "Can we reduce that post-op AFib from 35%, 40% down to a much lower number?" The trials that have been done today, there have been three different trials in recent years, have demonstrated, using our technology, you can get below 10%. Thirty-five percent, forty percent, down to less than ten percent that we believe that you can kind of see that kind of differential. That's the short-term because it's only a 30-day look. All you're doing is looking, "Did they go into post-op AFib in that first 30 days?"

So, primary endpoint number one, we can win very quickly. But in addition to that, we're going to kind of have another look at the data, and we're going to put ILRs in everybody, loop recorders, and we are going to track the burden of these patients over a three-year period. And we're going to see, "Do you have less AFib over that three-year period if you were ablated and had a quick put on than if you didn't?" And we believe the answer to that is going to be, yes. And so, that's going to be the second endpoint. That endpoint is much further along, but we're going to be able to go into the FDA and get an advanced label just after the post-op AFib one.

Matt: Got it. OK. So, from 35% down to 10%? Is that the metric?

Mike: That's not what it takes to win the trial, but that's what we've seen in the single-center data that have actually been done and the trials that have been done so far. We've actually seen kind of between 5% and 7%. We don't need to be that low to actually win the trial.

Matt: OK. And why is two years the right timeframe to enroll? There's so many patients out there to potentially treat.

Mike: Well, we looked at our experience with LeAAPS. It's effectively the same patient population that we saw. It's the prophylactic, the patient that is at high risk of getting AFib in their life. And we were able to enroll very quickly in that. It's 75 sites. Just based on our experience, we think it could be... I mean, hopefully, it'll be faster than two years, but we want to be conservative and say that it's going to take us two years. The good news about this is we're already up and running. We have well over 10 sites already doing enrollment in this. We have many patients already enrolled in the trial. We're already exceeding our internal enrollment goals. We haven't talked about them publicly. So, we're in a really good place and feel like the trial is off and running in a good place.

Matt: OK. And would we potentially see some data, maybe in early '28? Is that the timeframe we should expect?

Mike: That'd be the time frame, yeah.

Matt: OK. And can you put this to rest once and for all on the LeAAPS side? Because I keep getting inbound questions like, hey, we're going to see some data next year from LeAAPS, right? I'm like, no, you're not. You're not seeing data for a

long time. Is that right? Like, we're not going to see any kind of LeAAPS data probably until the end of the decade.

Mike: Correct.

Matt: OK. All right. Once and for all, hopefully everybody hears that. No data on LeAAPS next year, but still no less enthusiasm for LeAAPS though.

Mike: Yeah, I mean, the -- right now -- we'll get some looks at some of the data in terms of understanding: Are we on track? Are we doing well so far? All that is thumbs up. Things are going well. We know that. We don't know the division between the two different arms of the trial. We are accumulating events faster than we had anticipated before the trial. We think that's a good thing because these patients, again, did not have AFib, therefore most of them were not put on anticoagulants, which means that if any of them have some sort of AFib and they're not on anticoagulants, if they don't have a clip, there's probably a good chance that they're actually kind of having strokes even before they know or have identified themselves as having had AFib.

Matt: OK, OK. Understood. Let's move over to the pain management business, which continues to do exceptionally well. Again, I think, you know, based on my math, it was the second-best two-year stack performance we've seen in the last seven quarters. Is that really cryoSPHERE MAX? Is that what's driving that?

Angie: Absolutely, yeah.

Matt: And the thing that you said on the call I thought was interesting was, obviously, thoracotomy, you're doing really well.

Angie: Yep.

Matt: Are you starting to see that uptick in sternotomy? And is that because of cryoSPHERE MAX, or is there something else going on?

Angie: No, it's cryoSPHERE MAX. I mean, the feedback that we got when we tried to launch the cryoSPHERE within sternotomy procedures was two minutes per freeze is too long. [When?] you add it all up, the procedure time, patient's got an open chest, it's too long. cryoSPHERE MAX, cutting it in half, we went back to accounts who were excited about it, using in sternotomy procedures and said, look, we've got something that

will reduce the procedure time, take another shot. And our team has been very diligent when they're going to accounts where they've got a surgeon who's interested. It's saying: Go beyond just one patient. We want you to see the experience in multiple patients. We think that it'll be definitive and a positive, what you see coming out of those patients. And our team has had some success there.

Matt: OK. Isn't sternotomy bigger than minithora- -- or, sorry, thoracotomy?

Angie: Yes.

Matt: OK.

Angie: Bigger overall market. I think the likelihood that we penetrate to the same percentage that we would in a thoracic procedure is probably lower.

[?Matt?Mike?]: Yeah.

Angie: But these are big markets. I think the exciting thing about our pain management business, when you start to add the different opportunities that we've cultivated together, you are talking about a pretty big overall opportunity between thoracic, sternotomy, and now, amputations with the XT device.

Matt: So, speaking of XT, do you need a new sales force to go after that patient population?

Angie: We don't think so. Not yet. It is a different call point than our team works with today, but they are pain experts. They understand the device. They understand why it works incredibly well. They understand how to work with our generator. They're focused on -- with XT, they're focused on accounts that already are using our cryoSPHERE devices. So they already believe in pain management to some degree. And then they're working through the vascular orthopedic surgeons who do the sternotic- -- or do the amputation procedures, starting with one. So, one account really focused, install that therapy, and then go broader. I think this is an area when we look out into 2026 and beyond, if we feel like there's good momentum and need to add to the sales force or maybe a dedicated team, we will do that.

Matt: OK. And so, how do we think about the impact? Or I guess maybe, can you help frame up that market opportunity and, like, the potential impact of the pain business over the next couple years?

Angie: Overall market opportunity in the U.S. is about 180,000, 190,000 amputations. A little over half of that is in lower limb, which is where we're focused to begin with. The pricing of the device is a bit higher than our cryoSPHERE MAX, about \$3,500 for the device on an amputation procedure. It's a really nice market. I think this is time we're going to have to start in 2026, really focus on getting accounts up and running, and we'll start to be more meaningful beyond that. I think it can be meaningful in the second half of '26, but on a full-year basis, I'd say probably beyond 2026.

Matt: Got it.

Angie: Completely new therapy area within the procedure.

Matt: Ninety thousand-ish cases you're pursuing in the US?

Angie: Yes.

Matt: How many on the thoracotomy or sternotomy side?

Angie: A hundred and fifty thousand in thoracic procedures and about 250,000 in sternotomy.

Matt: OK. All right. So, another meaningful new opportunity. Are there other opportunities for XT outside of these three areas? Not that you don't have plenty of opportunity to go after in the [crosstalk 0:17:02.5] [?three?] --

Angie: Yeah, the XT device is really focused on an amputation procedure. So if you think about the way the device -- it's not the ball tip ending. It's kind of a U-shaped ending that ultimately gives you a place to anchor the nerves that have been severed as part of the procedure. In Cryo Nerve, [?lots?] are used in other procedures beyond the three markets that we talked about. Yes, we believe that is the case and are working to cultivate those markets too.

Matt: OK. OK. Understood. So, I don't know if this is for you, Mike, or for you, Angie. When I look at your domestic pain management business is the third largest franchise you have right now. I mean, can it eventually be the second? I mean, it seems like there's those kind of legs available.

Angie: It's going to be a tough race there because we think in our cardiac business, which have one and two, you have opening up new markets in those areas as well, and you've got the

benefit of new technology. So, I'd say, it's a race of three very competitive areas to win.

Matt: OK. I don't think there's anything wrong with that because if the other two are growing faster than pain management or still growing quickly, it's still going to be larger. That's great for you guys, overall.

Angie: Yes.

Mike: The open business has LeAAPS and BoxX-NoAF to expand that market opportunity. That is a massive multi-billion-dollar expansion to that overall market. What pain has is new therapy areas. Like what we're doing with the extremities right now, that there's going to be other new therapies that we'll be able to go after as well that get the size to almost the same size, but not quite. You have to kind of add up a bunch of different areas for that to happen.

Matt: Got it. So, that all makes sense. So, the one problem, child, I'm sorry, and I know you love all your children, but the MIS business has been soft, obviously, of course. Is it because... I mean, we all know that PFA doesn't improve efficacy. It's a much faster case. It's much safer. Understood. Not more efficacious. Is that because you're not seeing people come back into the U.S., yet because, "All right, we're going to do single shot." "All right, that didn't work all the way that we wanted. Let's do a redo with another PFA catheter." And then you could start to see patients progress on to persistent, long-standing persistent where AtriCure would really come in. Is that what we're waiting for?

Mike: The answer is, yes. A definitive, absolute yes. That's what's happening in the market. The data, as you mentioned, is incredibly compelling that when you add an outside ablation, epicardial ablation to the endo-ablation, whether it's PFA, RF, A, or Cryo, you double the efficacy, and even more than that, when you start to look at durability over a two, three, four-year period. So, we know this works, and we know it's incredibly safe. That's the good news. So, we don't have to go convince anybody of that. And most physicians you talk to will agree to that.

However, what you're describing is exactly what's happening in the market. And EP says, "Hey, this is really easy. This is super safe and fast. I can do that first ablation with the Medtronic device. Then maybe I'll try the Farapulse. And then sometimes we'll even go to a third ablation." But I think once they get to that point that they've done two or three

ablations, what are they going to do next? What they're going to do next is going to do ours. And we're such a small, small, small company. We don't need a lot of growth to, quite frankly, make everybody in this room and on this call incredibly happy. I mean, the numbers come down so low in terms of the percent of our business, etc. We still think this is a very important therapy to have out there. We think that it will eventually grow. We're just not ready to predict when it's going to grow. But the way you described it is exactly what's happening on the field.

Matt: OK, makes total sense. How do we think about the importance of this PFA component that you're going to put into your product, eventually? I mean, when are we going to get more updates on that? Why is that so critical to what you're trying to do, eventually?

Mike: We're a leader in AFib solutions regardless of the energy source that's out there. So, we need to have energy sources that can adapt to whether Cryo, RF, or now, PFA. And so, we feel like we need to be a leader in this space. As we talked about our Analyst Day, the uniqueness of our device is that it's going to have both RF and PFA in the same device. So, you're going to get the benefits of both of those, which are important clinically. And then from a speed standpoint, you're going to be able to get faster ablation times on it.

As I mentioned earlier, EnCompass took the procedure time from 30 minutes down to 10 minutes. This will take the ablation time down from, call it, 2 minutes down to like 30 seconds. And so, it does save you some time. It's not as much time as you saved from the other piece, but it does save you some time on that. Whether or not it's going to improve efficacy, if you've got them both combined there, those are things that we're working on and we'll have our first in human by the end of this year. So, you should see a press release very soon about first in human with our PFA combined with RFA, our advanced RFA in that coming out by the end of the year.

Matt: Got it. OK. And then Angie, maybe a couple for you. You've done exceptionally well on the EBITDA side. I remember your EBITDA hat that you were wearing recently. So, the absolute improvement in EBITDA this year is about \$25 million. That compares to \$12 million in '24 of EBITDA improvement. How do we think about that metric going forward? I don't know if you can do \$25 million improvement again, but the LeAAPS study obviously is winding down. So, can we continue to see around this level of EBITDA improvement from you guys?

Angie: Super pleased with the bottom-line progress there. When you think about LeAAPS, we'll start to just consist of follow-up costs offset in part by the BoxX-NoAF study ramping as well. I mean, our goal would be to continue to invest in areas of R&D that are pipeline drivers for us in the long-term. We talked about it at our Analyst Investor Day about 100 basis points of EBITDA on margin expansion each year. We're pacing well ahead of that. And I think that says in the coming years that we'll continue to be on track if not better than that metric.

Matt: Got it. So, speaking of the bottom line, I think in Q4 we're going to see a milestone in the history of the company, which is net income.

Angie: Potentially. Potentially.

Matt: I think that's... Well, I think so. But as I think about, you know, you guys have only 48 million shares outstanding. How do we think about the earnings power of this business? Is this one that could kind of surprise people as far as the EPS growth goes? I know you still have investments to make, but can we get some really big EPS or earnings power over the next several years?

Angie: Yeah, I think that's the potential. When you have a company that is a strong double-digit revenue growth, 75%-plus gross margin, and we've shown the ability to leverage while still making investments that will help us maintain growth, I think in the end it says the bottom line could surprise people to the positive.

Matt: Got it. OK. I guess maybe really quickly on that point, double digits. I mean, you've been growing mid-teens for a while. Why is mid-teens not the right number? I know you said strong double digits, but I mean, how do we kind of frame up how to think about the business in the future? Just, you know, should we expect low double digits, or should we expect teens?

Angie: Yeah. Again, our guidelines at the Analyst Investor Day, giving a view into a longer-term basis, said this would be kind of the mid-teens range when you think about the billion dollars by the end of the decade. Again, 2025 execution has led to higher than kind of where we needed to be in that first year. And our goal would be to continue to beat, you know, every year to be at that billion dollars quicker.

Matt: OK, got it. Well, I'm not sure what's wrong with mid-teens growth in cardiology with profitability about to ramp,

in my opinion. So, for whatever that's worth. All right. I think we're out of time. We'll cap it there. Thanks so much.

Angie: Thanks, Matt.

Mike: Thank you. Appreciate it --

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