

Transcription Services Provided by 1888TypeItUp.com AtriCure, Inc. (ATRC)

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

Matt: Thanks so much for joining us. My name is Matt O'Brien. I cover MedTech here at Piper Sandler. Really excited and privileged to have AtriCure here with us this morning. From the company, we have Mike, who's the CEO, and Angie, who's the CFO of the company. Thanks so much for coming out.

Michael: Thanks for having us.

Matt: Really appreciate it. I wanna get into the business, you know, in open and MIS and clip and pain management. If I get one more question on this unnamed PFA partner, it's just crazy how much, you know, inbound interest I'm getting on this. I know you can't name or talk much about that at this point, but what kind of technology are you thinking about in terms of integrating that PFA technology into, and then what can that do for the company? I know it's gonna take a little while to get that to the market.

Michael: Sure. So, I mean, the reason that we had to announce it was because we were obviously doing the deals, but we weren't ready to kind of announce the full timeline of things and disclose the name of the company we're partnering with. But what we're basically doing is they're bringing us kind of expertise on the generator side, and they've effectively already had that PFA generator, for lack of a better word. And, you know, we're taking that technology, combining it with what we've got with RF as well, and we're gonna integrate it into every one of our devices over time. And so, we'll probably start with our clamp technology and then move into other technologies over time. We've done all that work, like in terms of already having it integrated, tested, etc. So, we're at that point now of kind of just making sure we understand what we could actually do for first in human sometime next year.

And then from there we will obviously put out a timeline that everybody can understand, okay, first in human, to clinical trials. So, it is a long timeline. But they're not too different than what we've done on the RF side. We don't actually manufacture the RF generators. And that's kind of what this is. So, it's being customized to our product very specifically. We've done a lot of that work already. And that first milestone was really why we paid the money and actually had to announce something at that time.

Matt: Got it. And is this a technology that was developed from the ground up, or is it kind of a repurposed RF system?

Michael: Ground up.

Matt: Ground up.

Michael: Ground up.

Matt: So, this is gonna be a very unique technology that you build into the system.

Michael: A hundred percent, and it's very specifically built for what we bring to the table in terms of our clamps and our devices. And also, you know, how can you bring that with RF technology as well? You hear about, like, the J&Js of the world and others who are putting out and combining RF or even the FARA that came out recently that has RF and PFA kind of combined in that. Like, we have an expertise in RF. Bringing those together and understanding that is really kind of where we're going overall.

Matt: Got it. And to be clear, though, this is gonna be built into the open business. You're gonna go after, you know, like, FARAPULSE and FARA.

Michael: We are not going into the endocardial business.

Matt: Okay. Just making sure. As I look at the RF business for open, you know, it's very successful outcomes, you know, it should be used more, I think. But I'm one guy. What is the benefit of building in PFA other than just kind of the buzzword of PFA?

Michael: Great question. I think that if we're gonna be a leader in treating atrial fibrillation and PFA is being used so extensively on the endocardial side of the world, we need to have something on the epicardial side of the world, and we need to be able to understand how does it work and what

happens with it, and is it better? Is it more effective? I don't think we really know the answers to those questions. So, we felt like four or five years ago, when the endocardial was going that path, we needed to invest in and begin to understand how does it affect, and could it be used in our devices? Could you get the same efficacy? Can you get it at a faster speed on the ablation times?

RF does work incredibly well with our clamps, as you well know, but we also understand that customers are going to be influenced by... While there is PFA out there, it is becoming the predominant use of energy on the endocardial side. We need to be ready for that on the epicardial side as well. And so that's why we made the investment. Do I know yet whether or not this is gonna be some sort of game changer to our business like it was on the other? Probably not, but I do think it's an important piece to have in our armamentarium as we kind of have a full, broad solution for our customers and as people do talk about PFA.

Matt: Got it. Okay. All right. So, it's exciting. It's gonna take a little while to get that. But what about the core business? What are we seeing? I mean, the clip performance in the quarter was good, especially versus expectation. You know, where are we at in terms of the whole, you know, competitive trialing? Is that fully behind us? Is that still something that's gonna be a little bit of a headwind for the next several quarters? How do we think about that business?

Michael: You know, go back, I mean, it was literally a year ago at this meeting. Matt: I remember, yeah.

Michael: I think, literally, I was in the hallway here when all of a sudden I get the phone call that our stock is down some ridiculous amount because now, you know, a big medical device company is gonna be competing against us in the clip. And I think what I said on this stage last year was when competition comes in, if you're the only player in a space, that space does not grow. I mean, you're effectively creating that market. If a major player comes in and actually becomes competition, that means the space is really big. There is a very large market for that, and the market is going to grow. And I think what you saw this year was a testament to that, which is that we saw accelerated growth in our clip franchise throughout the year. Why? Because there's another player out there talking about the benefits of managing the appendage.

And I also felt confident in our product that we've got the best world-class product in the market. It's been tested, it's been studied. We know that there's closure, we know it's incredibly safe. I mean, our safety rates are absolutely impeccable with this product. And so, I had confidence in the product combined with the fact that I felt like competition is actually good for any space and industry. And I think I used some examples of ... you can look at what happened and with Watchmen and Amulet, you can look at what happened with TAVR when it originally came out. And so, we believed that that was gonna happen. And I think we're starting to see that. Medtronic's not going away, they're not gonna just get rid of their product tomorrow. They rolled it out. But I think what we're seeing in the market is that our products are superior, our products are exceptional. And then on top of that, we've continued to invest in innovation, both on the clinical side and on the technology side.

And so, what you saw most recently was our most recent release of the FLEX-Mini device, which is a device which is significantly smaller than any device that's on the market today. It will have a little bit of an upcharge in terms of kind of some pricing benefits to it for us as well. And we're already getting great feedback. We're seeing great traction in just a month or so of the launch. We anticipate that next year that'll have some sort of impact on that as well.

Matt: Got it. What kind of feedback are you getting on mini...? Are there other anatomies that you're able to treat now that you weren't able to?

Michael: The visualization is just incredible. So, because it's such a small profile that when you're looking at the heart and you're looking at the appendage and you're trying to kind of get access to it and get around all the lobes of the heart, you can see great access to it. And so, when you put it on, you can see the circumflex, you can look around it. I mean, people are like, "I don't need a new technology. I love the technology that you already bring to the table." They try it out once, and they're like, "Oh my goodness. Like, that's pretty incredible." And I really know that I'm getting to the base really effectively. I'm getting around the entire appendage. So, it's a really nice thing to have in our armamentarium.

Matt: Got it. And Angie, I don't know if you're gonna shut me down on this, but typically when you guys come out with new technologies, you get about a 10% price premium. Is that roughly what we should think?

Angela: It's more than that over the FLEX-V, which is the most commonly sold open AtriClip. It's around a 20% to 30% uplift. And then if you're an original AtriClip user, which is a price point around \$1,100, it's almost double that of ASD.

Matt: Oh, wow. Okay. Okay. Got it. Is there a... How do you think that's gonna evolve in terms of utilization? Do you think everybody's gonna kind of move over to the Mini or...?

Angela: Time will tell. I think physicians will be selective at first in part because of the price premium. I think they'll say, you know, in this specific anatomy or this specific use case, I think the more that they'll use the device, if we follow the same trajectory as Flex-C, they'll really like the new technology, and that has the potential to become the bigger clip that we sell.

Matt: Got it.

Angela: But I think time will tell on this one.

Matt: These cases are pretty profitable for hospitals, though, right? So, I don't think... Is cost that big of a consideration during these cases?

Michael: We're always looking at some margin. So, I mean, anytime you're increasing the price, there's a conversation. You got to go through the VAX, you got to go to the committees, you got to get it done, and you got to get it utilized. But I mean, to your point, it's not such a big increase that it's gonna have that much of an impact, but it's definitely a conversation.

Matt: Okay. Okay. Do you have to go through the VAX with this product?

Angela: Yeah.

Michael: Yeah.

Matt: And so, is that gonna be a process, I don't know, for the next couple of several quarters? How's that going?

Michael: Pretty much. That's effectively what's happening right now. This quarter, we're starting to see sites utilize it, go through their committees. So that's why I think... not much impact on revenue this year, but you'll see an impact on revenue next year.

Matt: Got it. Okay. Appreciate that. What about on the competitive trialing side? How many...? I don't know. We don't really talk numbers here. But have you seen a lot of folks come back to you after trialing Medtronic? And, you know, what is that looking like?

Angela: I'd say increasing through kind of the end of the second quarter and more so in the third quarter. We saw many sites that had committed to a trialing period, kind of came back and said, "Look, ultimately, we think AtriClip is the superior product, and that's what we'll go with longer term." I think, at best, for the competitor using both products, and say, "Look, I'll switch off and on between the AtriClip and the competitive product." But I'd say more so in the third quarter, we started to see sites kind of coming back. And just a reminder, I think our presence with our open AtriClip devices, we're in almost 1,000 accounts in the U.S. Almost every cardiac surgery center in the United States uses our AtriClip product, or we're talking about the competitor product. You're talking in the dozens. So, I think there's still, you know, a pretty big barrier in terms of the number of overall accounts that we're in.

Matt: Got it. And I don't wanna sit here and slander anybody, but what is it about AtriClip versus Penditure where they were like, "I don't like this about Penditure. I'm going to go back to you guys," because I think a lot of people, you know, when it came out, were like, "Oh, these are pretty simple devices, you know. You can flip back and forth easily." We did a bunch of work. And with your help, Angie, I'm like, "No, no, no. There's a lot of differentiation here." What's resonating with those docs where they're like, "No, that's not for us. We're gonna go back."

Michael: I think that... I'm not gonna slander the competition. I think that the biggest thing is the quality of our product. If you look at our product and how well it's been used, we've got over 16,000 patients that have been studied, 95 peer-reviewed papers that have shown that the device closes exceptionally well. We've got a safety rate that's 0.0002%. I mean, it's like in terms of reported events that have ever happened with our product, people just have confidence this product works every single time. That's tough for somebody to ignore. In addition to that, when you put your hand on our product, you feel like you're using a high-quality product. So, it's kind of like... I guess the best way to describe it is we all drive cars, and when you drive a really nice car and you put your hand on the wheel, you're like, "Wow, this just

turns a lot better than the rental car that I got from National where they kind of cut corners on things," right? We've all been in those cars.

When you drive our car, you know that this...and you use our product, it's just a super quality device that you know is gonna work every time. You're in heart surgery. You want it to work every single time. I'm not saying theirs doesn't. I just know that people just look to ours and say we bring out highquality products. We've had 600,000 implants, and it works every time. And then on top of that, I think people also understand that we're investing in the space. So, we came out with a brand-new product that has a much lower profile and is as high quality. I think people look to us and say, "Well, why am I gonna go someplace else when I've got something that works exceptionally well?" And it's not like we're resting on our laurels and not investing. You add that we're also investing in clinical evidence, and people are saying, "Well, who's gonna make the investments necessary to kind of further the field forward?" Again, I think they look to us on that as well.

Matt: Got it. Okay. So, sticking with new products, one thing you guys introduced that I didn't realize was coming was a new EnCompass Clamp. What's unique there? And again, are we getting a little bit of an ASP uplift as well?

Angela: Yeah. The short version of the EnCompass Clamp, very similar to our legacy RF clamps, two different sizes of jaws. It's just a slightly smaller footprint. We initially started with the bigger of the two, the long version of the EnCompass Clamp, same ASP. I think what we're seeing, though, is for accounts or physicians who initially used the EnCompass Clamp, going back and seeing kind of a smaller footprint product, having a little bit more comfort with using that product. The EnCompass Clamp is an amazing product, amazing technology. But when you look at the long version, it's big, it's bulky, and you think about how am I fitting this into the chest space? I think going back and seeing something that looks a little bit more manageable has given us some nice growth in certain areas.

Matt: Got it. And didn't the guidelines get upclassed recently? Have you seen the impact of the open business from that? I know it did on the MIS side. Trying to remember.

Michael: And the guidelines have been updated for a while on the open side.

Matt: Yeah, maybe thinking of...

Michael: The big guideline that changed recently was over in Europe, and that is at EACTS, which is the major surgical society meeting. It was kind of rolled out in a big way, but it wasn't just surgery. It was actually the equivalent of the ACC over there. Basically, they came out with new guidelines that said you should treat the appendage every time, you should ablate them every time when they're basically on the operating room table and they have AFib. In addition to that, they upclassed all of the hybrid guidelines over there as well. They really didn't have guidelines over there before. Now they've actually got them in the guidelines with a high level of evidence. All of that was actually built on ActriCure's evidence, data that we did in all the trials that we've done over all the years, whether it was the CEASE, or the DEEP, or the other trials that we've done, those are the ones that really influenced it.

Matt: Got it. Okay. Heading over to the cryo business. What are you seeing so far with Plus? How's it working in cases? How much faster is it? What are you seeing?

Michael: And Plus, that has been a game changer. We did not put any kind of price uplift on that because we wanted everybody to move over. We got a cost of goods benefit to it, and it was just a better and easier product to use, and we knew we had another one coming off after that. It reduces the time by about 25%, and it also is easier to use. And what I mean by that is there's kind of an insulator shaft around it that did not exist on the other one. So, the other one, never really had any safety issues, but you had to be really thoughtful as you were entering kind of the space to not hit the skin or any other kind of adjacencies.

Now what you're seeing is you don't have to worry about that as much, and you can be a little bit more aggressive to kind of get in there and actually do the ablation with it. And we've seen, you know, rapid conversion over to the Plus just in the last six months, and we're now starting to see with the Max, which you can reduce the time by 50%, we're starting to see some uplift in this quarter, and we're gonna get a price uplift with that as well.

Matt: Got it. Okay. What are you seeing...? Where is the utilization the strongest with that? Is it the mini thoracotomy? Are you seeing it in post-oncology cases? Where are you seeing the real growth on the pain management side of the business?

Michael: Thoracotomies.

Matt: Still thoracotomies. Okay.

Michael: Thoracotomies are the proper...

Matt: Any update on sternotomy there? I know that's still an ongoing process.

Michael: You know, sternotomy. I do believe that Max will impact the mindset to actually try it in sternotomy. I think we're starting to see that a little bit, but I don't wanna get too far over my skis on that because I think we did that once before. We got really excited, and then people... but they told us, "If you can reduce the time, we might actually deploy this technology." And so, I think next year will be a big year where we're gonna learn a lot about how does that roll out. I'm not gonna put it in any of my numbers, but I do think that we'll get some good feedback throughout next year. So, it's probably a better question to ask me in six to nine months.

Matt: All right. I'll ask you this next year.

Michael: Yeah.

Matt: So, okay. I guess I'm just putting all this together, Mike and Angie, you guys... like, a lot of investors love new product stories, right? New product cycles. Like, it sounds to me like you have one of the better new product cycles in MedTech right now. So, is that fair? And then, you know, to that end, you know, are you still kind of a mid-teens grower for the next couple of years just based on the backs of the strength of those products?

Michael: I don't know that I can... I'm not here to compare against other players, but I mean, we've invested a lot and thank the investors who have kind of given us the money to invest in R&D. We put 18% to 20% in R&D for a reason. So, we can come out with new products, we can change the markets from that standpoint, make it easier for patients to get treated. And so, I think we've got a great pipeline, as you just described, that can drive really strong growth for many years to come. Yes.

Matt: Got it. Okay. Got it. Okay. What about on the MIS business? I know convergence has kind of seen some slowdown just because of the PFA growth. When do you think we're gonna get past that? I mean, we're probably 20%, 25% penetrated in

PFA now, and that's probably going much, much higher. I mean, is this a couple of year headwind on the MIS business?

Michael: I mean, you've definitely got a headwind on it for sure for next year. I mean, through next year, we're gonna have a headwind relative to that. What's interesting is we've actually... we're not seeing sites walk away from using our products. They have a patient population they know that needs to get treated with this. What we're just seeing is that they're incredibly distracted by putting new systems in. How many new systems are coming on board, which ones to use, what's their workflow look like? They're just not having the time to now think about some of these other patients that are out there. So, you're losing a little bit of volume in some of the sites, and that's really where the pressure is kind of coming from. We are getting new sites, though, and we are now starting to see people that saw... like, went to zero and are now coming back because they're now starting to see failures where they're having these patients come back where they tried to do it on a persistent or long-standing persistent patient, which is really our primary area. And so, I think that you're going to start to see, you know, some light come through next year a little bit, but I think we're gonna feel pressure for sure throughout next year.

Matt: Okay. And then...

Michael: Now the rest of our business, obviously... fortunately for us, we've got a very diverse business for a small company like ours. And because of that, we are able to do the mid-teens growth that you just mentioned and feel really confident and comfortable in that area even with the pressure from this part of our business.

Matt: Yeah, and it's still a small piece of the overall business too. I think that needs to be pointed out. Does having these hybrid PFA, RF products that can do more persistent cases create a longer-term headwind for that business or...? I still don't think the efficacy is as good as everybody realizes with PFA. It's fine, but it's not more efficacious than RF or Cryo.

Michael: I think the opposite is gonna happen. I mean, you're seeing volumes in the endocardial catheters go up so much. And I mean, it's natural what happens. They're treating more, they're more efficient in their labs, they get the patient through. And so, what are the numbers? They think that's gonna make \$600,000 by 2026 or something like that in endocardic catheters, up from \$400,000 last year. Those are some big

numbers. But the failure rates are the same. That means that there's that many more patients that they could not treat and did not respond to that therapy that are now... What are they going to do with that patient population? Well, they're gonna have to find a solution for it. And I actually think that's gonna actually be a tailwind for us as you look up... What I can't tell you is that gonna come in Q3 of next year, Q1 of 2026, where that's... I think you're going to start to see it just build as that volume builds and they're treating more patients. It takes 9 to 12 months for those failures to occur, but they're going to occur, to your point, and we're gonna wind up seeing those patients. So long term, I really feel great about this business. Short term, there is a lot of headwind pressure.

Matt: Understood. Okay. All right. So, Angie, a couple of questions for you. At '23, you improved EBITDA by just over \$20 million year over year. It's an amazing performance. And it looks like this year is gonna be about \$10 million bucks, so up to about \$30 million, just under in our model. So, congrats there. Should we expect more of a '23 improvement or a '24-improvement next year just given all these investments that you're still making in, you know, Heal and IST and then LeAAPS, etc.?

Angela: Yeah. I think we're not ready to guide for 2025 yet. But you hit on two important things. We're committing to improving profitability. You saw that once we moved over from kind of negative EBITDA for a string of years and we said, look, with 2023, when we came out with the guidance, we said, look, this is positive, but improving thereafter. So not just reaching positive EBITDA. The other part is our focus on where we're investing. I mean, Mike talked about R&D investments, 18% to 20% of revenue. Our goal is to continue to fuel the pipeline for growth longer term. And we're starting to see leverage in our P&Ls, SG&A commercial footprint areas where we made investments, pretty big investments leading up to different product launches and markets that we entered. So, committing to improving profitability and, you know, continuing to invest in our business as well.

Matt: Got it. So that 18% to 20% is pretty set as far as the R&D investment goes.

Angela: Yeah. Our goal would be to continue to be high teens in that area.

Matt: Okay. And I don't know if this is for you or for Mike, are those investments for more product iterations or potentially new categories for you to go after?

Angela: I'd say both. It's a little bit of both. I mean, one of the areas where you talk about kind of new product, new area would be extremities for cryo nerve block. We've talked about thinking about, okay, we have a real specialization in the thoracic space. Are there other areas or procedures, meaning, you know, an amputation, where cryo nerve block could work incredibly well? So, it's a mix of both.

Matt: Okay. Would you go after that kind of market, the ortho market, on your own, or would you partner with somebody there?

Michael: Right now, we're going after it on our own. I was actually... in my first case a couple of weeks ago on the amputation, and we have relationships with thoracic surgeons who have relationships with the orthos or vascular surgeons, quite frankly. And you're in the same hospital, you're on the same floors. We're able to kind of do it from that standpoint, at least right now. But I don't anticipate us partnering in the short term.

Matt: Okay. How big an opportunity...? I didn't really wanna get into that too much, but how big of an opportunity is that? Because it's an area that... I mean, there's tons of cases, unfortunately, on the amputation side, but on other ortho applications as well. I mean, how big could that be on the cryo business?

Michael: The natural place, if you just look at kind of belowthe-knee amputations, there's about 85,000 of those in the U.S. every year and about 200,000 or so globally. So, those are decent number. It's not a multibillion-dollar market by any means, but it's a really nice add-on market to what we're doing today. And then if you start adding all amputations on top of that, you get double those numbers, quite frankly. And then you start to look at other areas in ortho, and obviously, it gets a lot larger. We're starting small. Like, you know, we know ourselves, we know... You know, we're not trying to think to the big size yet. We gotta figure out, you know, does this work in these below-the-knee amputations? What we're seeing ...? We've seen about 250 cases that have been performed in the U.S. so far. So far what we've seen is great results where they've reduced that phantom limb pain and/or taken it away completely, and they've reduced a lot of the postoperative pain. They're sending patients home basically within 24 to 36 hours, which is guite remarkable.

Matt: Okay. And do you need a lot of data there before you start to see a proliferation in using this?

Michael: I think we do need data. I mean, data is obviously important in any medical device that you're gonna deploy like that. And so that's why we've been studying it for so long, so...

Matt: Got it. Okay. Angie, what about cash burn versus adjusted EBITDA? Like, how similar are those two, and then how do we think about, you know, cash burn for the business?

Angela: Yeah. There's a little bit of lag on cash burn. So, while we're EBITDA-positive today, I think for the full year, we said very modest overall burn, and that will include the upfront milestone payment for our PFA platform, but still tracking toward a very mild burn in 2024. I think it would say we're real close to breakeven and generating cash on a fullyear basis in the near term.

Matt: Okay. And I'm going to ask another long-term question that I probably won't get an answer to, but do you think you can be net income breakeven by the end of '26? Is that a decent target, or should we expect a little further out? Angela: I think if you rolled forward with past performance, that's a reasonable expectation, but again, not ready to guide.

Matt: Got it. Okay. All right. That's good to hear. Maybe the last 30 seconds, Mike. You know, historically, you guys have done some tuck-in deals. Are you in a position now where you're thinking about doing some tuck-in kind of bolt-on acquisitions, or are you still just like, "We just have so much opportunity in our core business. There's just no point in doing that right now."

Michael: The latter. I mean, right now, we're really focused on our core business. There's so much opportunity with... You mentioned earlier the product pipeline, the clinical pipeline, what we have in place right now, and these new markets, like the below-the-knee amputation that I just mentioned. There's more than enough within what we've got today. I'm not gonna say we wouldn't do something, but it's not a priority for us at this point. We're really about executing what we've got in front of us.

Matt: Got it. Okay. Sounds like there's a lot of good things going on. Look at the clock. We are all out of time. So, we'll cap it there. Thanks so much for all the feedback.

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