AtriCure

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Nathan Treybeck: Well, good afternoon everyone. I'm Nathan Trebeck, one of the medical device analysts at Wells Fargo. I'm happy to have management from AtriCure with us for our first day of the healthcare Conference. With us we have Mike Carrel, President and CEO and Angie Wirick, the CFO. Thank you for joining us.

Mike Carrel: Thanks for having us.

Nathan Treybeck: Great. So, let's kick things off with your recent performance and what it means for the rest of the year. So, growth accelerated from 13.6% in Q1 to 17.1% in Q2. Can you remind us what were the drivers of this acceleration and to what extent is higher growth sustainable, and how I've recent months informed your approach to raise guidance for the year?

Angela Wirick: Yes, I'd say the second quarter really reflects strength in product launches. I think a couple notable areas in our business, pain management, our open appendage management, you saw nice inflection in growth and that's because of new products, mainly cryoSPHERE MAX as well as our AtriClip Flex-Mini; both of those driving not only improved pricing on the devices but also increased volume, which we think is a really nice sustainable growth plan.

Another area that you saw, and I think this is a testament to our innovation, was our EnCompass Clamp. The EnCompass Clamp is a device we launched multiple years ago and what you've seen is continued adoption and penetration within this market and that's led to a really nice growth pattern in an area of our business that if you went back prior to the EnCompass Clamp, we may have been talking about kind of low double-digit, high single-digit growth. And what you've seen in the most recent quarter would say mid-teens, upper-teens growth coming out of that area of the business.

So, new product innovation really driving a really solid and continued top-line number. When we think about the second-half of the year and what informed kind of the guidance raise, I'd say it's the conviction that we have around the new product launches; the adoption that we're seeing there and that the totality of our business, the ability for us to continue to drive really nice strong top-line results.

Nathan Treybeck: Okay, great. And we'll definitely touch on the products. Just on the margins, is there a step down in incremental margins implied in your guidance in the second-half? Can you talk about the key considerations for margins for the remainder of the year, if you can just walk through the puts and takes?

Angela Wirick: Yeas, if you think about it, we'll start with gross margin and then hit OpEx margin. When you think about gross margin, I'd say your biggest headwind has been that our international business has outpaced the US growth and that comes as a headwind for impacting our overall gross margin. I think given the new product launches that we just touched on in the US, those actually were beneficial to gross margin, masked a little bit in the quarter by such a strong international quarter in Q2. So, we do expect that the new product launches in the US will continue, the adoption continues of those products for that to be beneficial to gross margin over a long term basis. And then from an OpEx perspective, seeing nice leverage, particularly in SG&A, it's an area of the P&L where we said we're really focused on driving efficiency in our business.

But, I'd say also the philosophy on bottom line. So, when you think about the guide that we gave for Adjusted EBITDA for the rest of the year, no different from our philosophy from top-line, which is we want to put out numbers out there that we feel really good about not just achieving, but that there's a pathway to beat as well.

So, some conservatism baked into the guide there.

Nathan Treybeck: Okay, great. You talked about the EnCompass Clamp, anyway to frame, I guess, what's supporting the strong growth there and how durable is this growth as we think about the second-half and into 2026?

Mike Carrel: Yes. I mean what you're seeing is the EnCompass Clamp originally came out about three years ago, as Angie talked about, and the whole concept behind it was to make it easier for people to do an ablation. So, they basically take the technical difficulty out of it. And what we've seen is basically going from about 40 minutes to procedure down to less than 10 minutes per procedure by using the EnCompass Clamp. And for coronary bypass surgeons to be able to have a much more approachable therapy for them to basically treat. And we've started to see that you combine that with reimbursement changes over the last several years that have happened, now we've taken down a couple of barriers that have allowed it to really kind of get into the market.

We're still only at 40% penetration in AFib patients, let alone non-AFib patients that we think could also benefit from an ablation. And so, we think we've got lots of years of growth in front of US. One is just continued adoption education of those people about the reimbursement, about the treatment algorithms that basically are there and helping them leverage EnCompass, and then longer-term going after and expanding the market to non-AFib patients that can benefit from it.

Nathan Treybeck: Perfect. You know, I know you're not going to guide for 2026, but you know, as we think out to next year, what are some of the key development and commercial milestones that, you know, investors should be aware of?

Mike Carrel: Well, a big piece, and Angie kind of alluded to it, is that when you look at all of our new products, when we roll out our new products, you're not just getting a benefit for one year. Historically, you'll see that that will drive growth rates up for five, six, seven years as we get market penetration within those areas. So, with the new cryo MAX that we just rolled out last year, just gaining traction right now, add that with our Flex-Mini, which is our new AtriClip device, those are going to drive a lot of growth into next year. Combine that with another new set of products like [XT], which is for extremities, for pain management, getting into that amputation space, a whole brand new market for us. As we look to turn into 2026, we think those are all going to be big growth drivers in addition to what we just talked about, which is the EnCompass Clamp, we're still so severely under penetrated in that area.

Nathan Treybeck: Okay. You know, I wanted to touch on your [LRP]. So, you're calling for a billion dollars of revenue and 20%-plus EBITDA margin by 2030. Can you just walk us through all the catalysts? And, I guess, the cadence to get to that target?

Angela Wirick: I'd say in the near-term, so, we gave two different numbers out there; something kind of midway 2028 and then the billion dollars in 2030. When you think about the near-term, it's more about innovation continuing to drive adoption, continuing to drive grow. But then we have a couple of clinical trials, notably our BoxX-NOAF, which is looking at prophylactic ablation on non-AFib patients. So, two-thirds of cardiac surgery patients that undergo procedures each year don't have a preop-AFib diagnosis. A pretty high percentage of them, as a result of that procedure, come out of the procedure having AFib. So, looking at post operative AFib, basically treating all cardiac surgery patients, whether or not they have AFib with an ablation and an AtriClip. LeAAPS is the other part of this story which is looking at the benefits in non-AFib patients, the same patient population in a stroke reduction benefit, if you manage the appendage at the time of open cardiac surgery.

So, near-term, it's innovation. When you think 2028, 2029, 2030, you're starting to see the results of those clinical trials read into the numbers and start to expand the markets and expand growth.

Nathan Treybeck: Okay, that's helpful. At your Investor Day, you stated that the products currently represent, I believe $5 billion-plus market opportunity growing $10 billion by 2030. Can you just walk us through, I guess, the building blocks or the bridge from that $5 billion to $10 billion, what are the key attributes to the market expansion?

Mike Carrel: Yes, so when you -- let's look at each one of those different areas. In cardiac surgery, the build goes from right now all we are selling to is patients. If you go into cardiac surgery and you have AFib, that's the market that we're treating, which is about 30% of all patients to undergo cardiac surgery. The market expansion is, as Angie was just describing, both of the trials that we've run, one which we just completed enrollment and the other one were starting enrollment in, BoxX and LeAAPs, they basically tripled the size of that TAM. And so, they basically take an existing TAM, let's call it two million patients that undergo cardiac surgery a year, 600,000 had atrial fibrillation. Now that 600,000 goes up to a two million TAM, patient opportunity that basically sits there. If you sell an EnCompass Clamp, you combine that with an AtriClip and possibly even a Cryo Nerve Block at some point time, you're talking about $8,000 to $10,000 per

procedure. You start to do the math on that, that's like a $20 billion market. Obviously we're not going to say we're going 100% penetration, but it begins to show you the size and scale.

So, we discount back from that kind of $18 billion to $20 billion dollar number down quite considerably. Not everybody's going to do it, but if you can get to 50% of that, you're starting to kind of approach close to $10 billion just within cardiac surgery. If you look at then our hybrid business, which is under a lot of pressure right now because of PFA, we are we are less than 1%, less than half a percent, of the total population of AFib that gets treated on a stand-alone basis.

If you just move the needle on that, just quite a little bit on that front, you begin to get into a very large population around that. We're not expanding that market. That market exists today. That market today is already a $3 billion-plus market opportunity. Pain is where we also expand though, quite dramatically, from now till the end of the year. Right now our market is primarily the 185,000 or so, [thoracotomies] in the US, call it 300,000 or 400,000 when you look at it internationally.

As we're expanding that indication and the usage into sternotomy, which more than doubles the size of it, then you get another doubling by amputation of the leg, and you think about other extremities that are there, you're now beginning to take it from a, call it, $750 billion market up to about a $2 billion to $3 billion market, which gets you over that $10 billion market number.

So, obviously lots of opportunity for market expansion and new areas and new therapies we're going after.

Nathan Treybeck: Okay, is there -- in terms of the products you kind of talked about. So, [inaudible], PRO-Mini [PFA] enabled EnCompass, I guess, is there a focus for you right now in the near-term on any specific product or are you kind of focused all across the board?

Mike Carrel: Well, it's within each category. So again, think of it as three different franchises. In cardiac surgery, we have the products for the near-term, which are our existing EnCompass Clamp with the new clip products. So, we basically have the Flex-Mini now and then there will be a new product that comes out in early 2027, which is a V-Clip product that's very similar in terms of size and scope on that. That's kind of within that area.

The major areas and catalysts in that are the area are the existing clip products, EnCompass and then longer-term it's the clinical trials that we talked about earlier. On the hybrid side, there's not -- we're not doing much innovation, per se, other than adding PFA to those technologies. That's a very long-term play. That doesn't affect -- there's no catalytic event in any kind of short term on that front. It's really just making that procedure a lot quicker, taking it from call it a 90-minute procedure down to about a 45-minute procedure. So, cutting it in half, maybe even more, in terms of procedure time.

But again, there's nothing in the near-term for that. That's more of a longer term investment. On the Cryo side of our business, MAX is the big one we're pushing right now. It's over 50% of our revenue in just over six months on the market and then getting

into XT is the other piece. But then -- those are the areas. So, within each one, we have a catalyst within each one, within each area, to focus on. It's not like one trumps the other, because we've got different sales forces as well.

Nathan Treybeck: Yes, I mean, it was more about just the cadence of how the products roll out. But it seems like they're all kind of contributing.

Angela Wirick: Yes, I think a big part of our DNA as a company is continued innovation. I mean, we -- I don't think we've reached an end state, so to speak, in any of the markets that we're in. I think we're looking for ways to continue to make it easier for our surgeon partners to use our devices, which ultimately will drive an enhanced adoption. As part of that, you're also looking at what ways may be a logical add-on. So, when you think about cardiac surgery, the company started really with the focus just on AFib patients. Now we're sitting here today saying, look, this is a much bigger market than we originally thought. You're taking technology that we've made incredibly easy for a surgeon to use that can expand the market. Doing that without that technology complement I think would have been difficult.

Cryo Nerve Block is another great example. It started with something that we knew would work incredibly well in thoracic procedures. I think we've multiplied the opportunity by looking at different places where, okay, the same technology, or the same idea behind the technology may be in different forms, easier to use, faster, more efficient, is ultimately opening up new market opportunities and helping us expand growth.

Nathan Treybeck: Okay, if we could just touch on hybrid. So, you know, you alluded to the fact that PFA has been a headwind for you, why are you confident in the eventual rebound of your hybrid business? And I guess as you were thinking about timelines, when should we expect kind of an inflection in that?

Mike Carrel: So, the real macro scale, if you think about cath or ablation just in the US for a moment, and there's about 600,000 catheter ablations this year. Obviously, that market is growing incredibly fast for AFib patients. We do about 2,000 procedures. So, as I mentioned earlier, we're less than a half a percent of that total market. Yet longstanding persistent patients represent 45% of that overall market. And the failure rates of those 600,000, even with PFA, PFA is a great technology and it is going to continue to grow at a very fast pace, as everybody knows. You're still going to see a failure rate. And even if they have to do a second one and have secondary failures, they're still only getting 65% to 70% success rates.

Those numbers drop eventually out of the funnel. There are going to be patients that are available, that are not responding to the PFA. That's really where we come in. We are the -- that didn't work, now let's add to that. We're not trying to replace it. We understand the benefits of that.

And so, when we try to do the math on those, take the 600,000, 70% success, 30% aren't responding rates, those numbers become very big numbers and enable us to, we think, have a huge market opportunity sitting in front of us for growth. Now the patients have to go through the funnel. So, that's not going to happen overnight. It's not like a patient comes in for a catheter today and then, you know, the 70% are going to be successful. So,

that's gonna -- that's awesome for that particular patient and you're never going to kind of see that person. But the 30% are going to eventually come down that funnel, usually it's like a year to two years or so that you're going to start to see a lot of those kind of non-responders. You're not going to see within three to six months. That's not -- that's not what you're seeing in the clinical evidence. But you are seeing a lot of non-responders to the year and that number is falling off quite precipitously at 18 months. That's why we've got confidence that we'll eventually see some of those patients, because what are they going to do with them? They've done everything they can with multiple catheter ablations with the PFA, they have to look for another solution. And we're the only ones on the market with another like that next solution for that failed patient, and it's a large patient population timing. We're not ready to get -- we said, the back of this year, we're still under pressure from PFA. We think that's going to continue. We do -- you know, we're hopeful for next year, but we're not ready to give kind of guidance. I think we're going to see kind of how the next three or four months ago.

What we do see is while we're not seeing it in our numbers yet, we do see sites that went to PFA 100% and are now starting to refer patients, not referring as many as they did before, but they're now starting to see those secondary failures. They're now starting to see it. So, that gives us confidence that you're going to start to see that funnel began to build over the coming year or two that we can begin to see some nice growth in that business again. And we saw that over in Europe as well. So, you've got -- because they started a little bit earlier on PFA. So, we saw some of that in Europe. Now they're not exactly, you know, apples to apples comparison between the two markets, but it does tell you that there is enough of a non-responding basis that should build more than enough of the market for us, long-term.

Nathan Treybeck: Okay, that makes sense. How much is hybrid a contributor to your LRP?

Angela Wirick: Yes, what we said at our Investor Day is our expectation is that this will rebound to become a growth engine for the company. But I think what you've seen in the second quarter is you're not relying on that to happen for the company to be able to hit the numbers that we put out there. So, our belief is long-term that will be the case, but don't need it to necessarily make the LRP work.

Mike Carrel: And to get to look at the numbers, like we grew 17% in the second quarter. The LRP is at 13.6% from kind of the March timeframe through the end of 2030. So, we're obviously already ahead of our plans. So, we're ahead of our plan on the top line than we even expected, just kind of two quarters in on the LRP.

Nathan Treybeck: Okay. You know, I think you alluded to this, but the hybrid performance in the US and Europe, there is a difference. And can you just talk about the trends you're seeing in these two markets, why the performance has diverged? Maybe it seems like you're saying PFA came out earlier in Europe. Is there anything else going on there?

Mike Carrel: Well, I think the primary piece is that the PFA came out earlier in Europe. But in Europe you also have, I'd say, less technology. They're not shopping around and going from the Affera [pulsed] to the Affera and checking out. Well, it didn't work with Affera pulsed, maybe I'll try it with Affera, then they're going to try -- like they're basically like, okay, PFA is kind of PFA generically and then they're seeing some of those failure rates kind of

happen. So, therefore, they're beginning to start programs. Specifically so they can serve a population that they can't serve with PFA. And they identified that. It took them about 24 months to get to that point. So, they were a little bit ahead of the US, like a couple of years, you have that -- some piece of that. I do think the US may take a little bit longer than Europe because they're willing to try a second or a third technology before they kind of see it kind of fall to the end of the funnel, and I'd say those are probably the two primary kind of differences between the two.

Do you want to add anything to that?

Angela Wirick: No.

Nathan Treybeck: And you still anticipated Europe hybrid growth to be a contributor to growth this year?

Angela Wirick: Yes. Across the international business, every franchise is contributing to growth.

Nathan Treybeck: Okay. How do you see electrophysiologists evolving in their identification of patients for hybrid, and what is your outlook on its long term adoption and success in treating long standing persistent AFib?

Mike Carrel: Well, we've got great relationships with EPs and electrophysiologists and HRS. I mean there's a -- we're an additive procedure, we're not trying to take away from what they do today. So, over the last 10 years, we've really built deep relationships with those physicians and so, I feel like that's really helped us out. Even though it's pressure there, I do think it enables us that when things begin to come back, as they try the technology, they should try new technologies and they should go down that path. So, we're not saying don't do that, but we are there with those relationships that we do anticipate that we're having conversations with them.

Okay, well wait, let's talk about this patient has failed twice, what are you going to do if they fail this next time or the patient failed once and maybe I'll just start sending my secondary failures right to -- We're having those conversations with them right now. But each site is a little different. Each EP has a little different algorithm in their head, and we're kind of developing it along with them.

So, we've got great relationships, we're in the field, we've got really good coverage on that front so that when -- we're there to have those discussions to hopefully drive their behavior in the coming years.

Nathan Treybeck: Gotcha. Okay, maybe let's shift to LAA and concomitant. So, the LAA clip market has had realized and rumored competitive entries. What are your views on competition and innovation in the clip space? How does AtriCure maintain its leadership and talk about if there are any key barriers that would be difficult for a new entrant to compete against?

Mike Carrel: Yes, I love this conversation. Because obviously there was a new entry that came in the market almost two years ago. We built the franchise that we feel like is a very strong franchise for a variety of different reasons. Number one is that we've got the best technology in the market and we haven't stopped innovating. If you just look at our history, we didn't just rest on our laurels and say the original clip was the best clip that

was in the market. It was, but we also said, well, we can do better. And since then we've -- We're now on our third generation of the clip. It's 60% smaller than anything that's on the market or even planned to come to market from any rumored competitors. It is an incredibly well researched product with over 700,000 implants, with an impeccable safety record that works every single time with almost 100% closure every time and there's immense clinical evidence that we've invested in the last 10 years to get to that point.

On top of that, we've built a -- we've done a trial recently called LeAAPS that Angie alluded to, which is the largest ever cardiac surgery trial, to demonstrate that our product specifically can reduce stroke and we'll be the only PMA level product in the market with that. We think that creates great difference -- differentiation to be able to demonstrate. Yes, our product by itself will be able to reduce that stroke rate for non-AFib patients. So, it's opening up the market but also creates a defensive mindset against competition to come to market.

So, it was offensive to expand the market, but defensive to ensure that as competition comes up, we're raising the bar clinically for what they have to prove to be able to say, hey, you're going to basically get that kind of price, you're going to have a product that works that well. How do you know that product works as well as the AtriClip on that front? And so, we think we've set some of those barriers up from a technical standpoint, because of all the innovation from a clinical standpoint. And then finally, if you -- our team is incredibly well versed like we have hundreds of people around the globe that understand how the heart works, they've seen how the appendage works in terms of the placement of it, how to place it, how it works, how you treat AFib. People are coming to us for that value. We train our team very specifically on that. Other companies are trying to come into the market, they're just looking for an easy win to generate a little bit more revenue. And they're never, and aren't going to, and aren't doing the investment necessary to have a team that's educated and training people in the field, in the OR -- they want us in the OR to help us help them with how to do the procedure and what to do there.

And so, I think that we have a huge differentiation and advantage with the team we've got in place, how knowledgeable they are and how well trained they've been. Not just like in the last six months we're talking about a team that's been trained for years in this particular space.

And then finally, I would say that we're dealing with the holistic nature of the disease. So, if you're just coming out of the clip and trying to sell the clip by itself, you're just solving one aspect of it. We solve the whole aspect. You have the EnCompass Clamp combined with this, combined with the cryo work that we do to treat the holistic AFib while you're in cardiac surgery. That is a huge differentiator for us because we're obviously already in the cases as the leader in that space. And we also invested a lot of money in clinical evidence in that area. And so, you combine all that together, I think that gives us a big differentiation.

Now to answer your question, how do we view competition? We welcome it because we think that competition is, one, validation and recognition that it's a big enough market for someone else to put some investment in, even though they may not put as much investment as we're putting in, they're going to put some investment -- they're putting

some investment and they're recognizing there's real growth in revenue there and it's got to be meaningful enough because the competition we're talking about are not small players. These are big players that are trying to come in. And they know that there's a recognized market leader that's invested in things that are important to the market. And so, by them trying to come in, it validates the space, it raises awareness. And if you don't believe me, just look at what happened when the competition came in the last time, they got some market share because we had 100%. So, over the last, call it six quarters, what have you seen since they've been in the market? The first quarter they were in 15% growth for us, 17% growth, 20% growth, 21% growth, 24% growth, 30% growth.

Now, you can attribute some of that to our innovation coming out with a new product. But a lot of that is that the markets just actually grown, like unit volumes have actually gone up because there's more recognition in the market and they're getting some share too. So, we're growing in the midst of all that where -- So, I think that that is kind of how we view the competition, we welcome it and we think it's validating your space overall.

Nathan Treybeck: Great. Can you talk about the results you're seeing with Flex-Mini and PRO-Mini? How rapid has the adoption been and how much is the price differential relative to your prior generation AtriClip devices driving the growth?

Angela Wirick: Yes, I think Flex-Mini has surprised us to the positive this year. We said, look, we think it's going to take some time before you see even kind of 20% of the volume and Flex-Mini well, that's where we landed in the second quarter. So, I said ahead of where we thought we would be at this point in the launch. As a reminder for everyone, we launched the device late in the third quarter of 2024, minimal contribution in 2024 overall and have seen some nice progress here. It is a pricing uplift depending on which device, open appendage management device, you're using today. For us, I'd say most of the cannibalization has come from our Flex fee, and that's about a $17.50 price point versus the $22.50 on the Flex-Mini.

So, our goal with each new innovation is to be paid for that innovation. We're bringing something to the market that's differentiated, which is, you know, why we warrant -- we believe warrants a higher price. If you're using it the original AtriClip device, which there's still a kind of a base of users that use that device, you're closer to about 1100. Again, most of the transfer over has come from Flex fee at this point in time. But as Mike talked about, we've also seen nice growth overall in procedure volumes.

So, while 30% growth in our open appendage management revenue in the second quarter, it's a little over 20% volume growth. So, I think this is a device that's helping us continue to penetrate a very large market. PRO-Mini, just early innings here. I'd say this one, you know, also get a nice price up lift too. It's again differentiated technology. We've put some innovation into that device without there being growth in the ablation side. So, in our converge procedures, tough for us to see, you know, significant growth coming out of PRO-Mini.

When you think about what the PRO-Mini does though, it more so than in an open heart procedure, the low profile clip is super beneficial when you think about in a closed chest setting, in a minimally invasive setting. So, we look at this and say long-term this will be -- this will help us augment growth in a nice way as well.

Nathan Treybeck: Great. I believe you finished enrolling in LeAAPS. Can you outline this trial for those who may not be familiar with it, and the opportunity that it presents?

Mike Carrel: Sure. So, the LeAAPS trial, for those that don't, aren't, aware of it, as I mentioned earlier, it's the largest cardiac surgery trial that has ever been done. It's 6,500 patients and it's for patients that are undergoing cardiac surgery that do not have atrial fibrillation. And the reason for that is that those that have atrial fibrillation, there was a trial done many years ago that said you must manage the appendage and [approve] the stroke reduction in AFib patients.

So, we said well, wait, there's almost 75% of patients that don't have AFib. So, what about those patients, and are they going to benefit from prophylactically doing something on them? So, the trial is designed that half the patients get an AtriClip and half the patients get nothing, and then we basically look at event rates and say how many events happen? And then when we get up to 470 events, which we anticipate is going to take five years to get to now that we're fully enrolled, that we look at the data and we say, you know, does the control arm have more strokes than you've got in the treatment arm?

And we believe based on all the feasibility studies we've done and all the trials that have been done since then, that there will be a big differential between them that we should win. We feel very confident in that. We do know that the safety profile is excellent, like there's no safety noise, we know that -- because we already know the safety data since we're fully enrolled in the trial, and so the safety is kind of off the table at this point. It's just looking at the efficacy aspect of it. And so, that's what the trial is about. It opens up the market basically and triples the size of the overall kind of addressable market for us for stroke reduction for every patient that undergoes cardiac surgery.

Nathan Treybeck: Okay. I guess what are the next key milestones? And do you -- like, is it structured, like is there going to be an interim readout and when can we expect that?

Mike Carrel: Good question. So, right now we're in a little bit of a waiting game, but a lot of what's happening is we're going to be producing papers around what do the demographics the trial look like, to kind of keep it top-of-mind as we're kind of going through this. But the milestones from getting visibility to it is that we will be able to look at the data at 50% of the events and at 75%.

I will say that -- and the numbers you have to hit for differentials between the two arms at 50% and 75%, just the powering of that means you have -- I mean the differential has to be quite frankly something that I don't think that we're going to achieve on that front. But I do believe we'll achieve it by the time we get to 100%. So, anticipate five years, could be sooner. I mean, we're hopeful that it's going to be sooner, but right now we're looking at in five years. But we might have an early look, possibly.

Nathan Treybeck: Okay. I believe some physicians are using AtriClip per the LeAAPS label today in cardiac surgery patients without history of AFib. Can you talk about, I guess, the incremental opportunity? Like is it already being used in a substantial part of the market or do you believe there's still a significant portion that's not addressed today?

Mike Carrel: It's being used, I wouldn't say in a substantial part of the market. I mean, so I think that if you look at the overall addressable market, we're in the US less than 20% penetrated when you look at all cardiac surgery patients that are undergoing cardiac surgery that would qualify in the LeAAPS labeling, call it. It's less than 20% overall today. So, there's still a huge avenue for growth once we get that label. And [in the OUS] it's even bigger because we're less than 10% on an OUS basis and LeAAPS was an international trial. We had ten countries in it that were represented throughout Europe and Asia and the Americas, so we feel like we've got a very good cross section of patients that we're going to be able to kind of lobby to the different reimbursement organizations in the different countries around the world as well.

Angela Wirick: Yes, I think if you take a step back, there's a -- that that our internal team gave, which was over 500 physicians, 500 surgeons, who participated in the trial over 100 sites, over 500 surgeons, I think that alone tells you the interest that the clinical community has in driving this data and making it successful. I think it's also an indication there are treaters today who are saying, look, whether or not I've got the data, I believe it's the right thing to do. But I think it's a nice number that tells us, look, the pace of enrollment, the interest that we had from physicians in the trial, think this says long-term, you're going to be really successful within this market.

Nathan Treybeck: You highlighted the BoxX-NOAF trial for investors, can you just outline what the trial is about, what the opportunity is? And, I guess, similar question, is there an interim readout for this trial as well?

Mike Carrel: This trial is the same exact patient population. This is a patient that does not have AFib going into cardiac surgery. And the reason we're addressing it is because again, the AFib patients Level 1 guidelines and reimbursement and everything already exists in a big way for that patient population. However, patients -- the other patients undergo cardiac surgery, 35% to 40% of them go into what they call post operative AFib, which is very debilitating to that patient but also to the physician. They've got to put them on amiodarone, they've got to manage their heparin drips. They've got to keep them in hospital for a longer period of time. By -- we believe, and through several studies that we've done, kind of feasibility studies in advance, you can reduce that 35%, 40% down to less than 10%, which is considerable savings to the healthcare system and to that patient.

So, that's -- that's the kind of premise behind it. And then to look at that patient, do you stunt the progression of AFib long term as well? Every one of them will have [ILRs] and you look at them over a three-year period. So, the trial is randomized, 960 patients, one to one ratio, very similar to LeAAPS, and we believe we can enroll that in a couple of year period of time. The good news about this is that post op-AFib is measured in that first 30 days. So, you don't have to wait for all those strokes to accrue over a five year period. We'll enroll in two years, 30 days later, we'll pretty much know the answer to it. So it's going to be a lot quicker to the answer relative to this particular trial for that first primary endpoint. We'll probably have to adjudicate and look at the data and probably, yes, it's 30 days, but maybe it's, call it, three or six months later, we'll probably have data to be able to present at that time.

Nathan Treybeck: Great. Can you talk about your PFA development program and I guess what are some of the next key milestones?

Angela Wirick: Yes, so the PFA development program, I'd say take a step back. As a leader in the AFib space, we said we needed to offer different tools for surgeons in order to fully capture this market. So, we're investing in PFA in kind of two different paths. So, the first one is an open cardiac surgery enabling our EnCompass Clamp with PFA to further enhance kind of quick procedure time in that area. One of the big milestones would be a first in human use later this year, so that's a big step for us. Then expect to start clinical trial development in 2026 and kick something off there. This will require clinical trial in the same path as saying, okay, then look at the standalone AFib market. So, our hybrid procedure looking at the device that we have there, the EPi-Sense device or something similar to that in the minimally invasive application. If you were to enable PFA, you could drive quite a significant time savings in those procedures. That similar thing follow-on with first in human sometime likely in 2026 and then kick off a trial later on.

Nathan Treybeck: Okay. In the last few minutes we're going to shift the pain management. You know, you talked about it briefly, but can you just talk about the long-term outlook for the pain management business, including drivers of growth, upcoming expansion into the extremity amputations?

Angela Wirick: Am I allowed to say awesome? I think the long term outlook is really good here. This is an area where we had early success. We debuted the product in 2019, have had really good success in thoracic procedures. Now you've seen the development of a new device which takes, the CryoSPHERE MAX, which takes the time to do the Cryo Nerve Block down in half, so that's clearly driving accelerated growth. You saw that in the 1st and in the second quarter in our results in the US where the device is available.

Also exciting to look at different areas and different procedures where we can apply Cryo Nerve Block. We're starting to see some early success in sternotomy; so, open chest procedures. We had tried with the previous device and I think the feedback we got from surgeons was, if you're leaving a patient's chest open for an extra 25, 30 minutes, that's a little long. You know, not sure that we want to do that. The benefit may not be there. With CryoSPHERE MAX cutting the time in half, we're starting to see some early success in sternotomy. Still have a ways to go there, but then the development and launch of our Cryo XT, specifically for amputations, that's a completely new market, not a revenue stream for us today. AtriCure is the leader in this space, too. I think the outlook, pretty awesome here. When you start to think about the areas that we're accumulating to a really nice market size overall and being the leader in the space as you have first mover advantage. And we're not stopping there, continue to look at places where Cryo Nerve Blocks -- so, think of surgical procedure, the nerve is exposed, I think that's where we really differentiate and we've got a head start on anybody else in the space.

Nathan Treybeck: Great. Well, I think we have about 40 seconds left. Mike, Angie, any closing remarks?

Mike Carrel: Just thanks for having us here today and being able to talk about what we believe is a really exciting business over the next 5 to 10 years. So, appreciate you having us.

Nathan Treybeck: Thank you for coming.

Angela Wirick: Yes, thank you.

Mike Carrel: Awesome, thanks.

Angela Wirick: Thank you. It was really nice to meet you, well done.