Company Name: AtriCure, Inc. (ATRC)
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<<Mike Matson, Analyst, Needham & Company, LLC>>

Good afternoon. Thanks for joining us again at the 23rd Annual Needham Healthcare Conference. I'm Mike Matson, and I lead the MedTech & Diagnostics Equity Research team at Needham & Company. I'm pleased to introduce AtriCure. Presenting today from AtriCure, we have CEO, Mike Carrel; and CFO, Angie Wirick.

Instead of a standard presentation, we're going to do a Q&A session or fireside chat. If you do have questions you'd like to submit, you can send them through the Needham website or you can feel free to email it to me at mmatson@needhamco.com and I'll do my best to squeeze them in.

So we're going to go straight into the Q&A here. I'm going to kind of go through some of the different product categories that AtriCure offers. And we're going to start with open-heart ablation. So the open-heart ablation seen some really strong growth in recent years. I know that reimbursement guidelines have been a tailwind, but the EnCompass product has been a big driver as well. So maybe you can start out by just talking about how penetrated do you think that this market is in the U.S. and outside the U.S.?

<<Michael H. Carrel, President and Chief Executive Officer>>

Sure. I mean, you're right. Thank you, Mike, and thanks for having us today. You're absolutely correct. And we've seen some great growth because of the new EnCompass product. Penetration today in the U.S. is around 30%, 35% in Afib patients only. And OUS, it's less than 20%. And the reason I distinguish is, because more and more studies and data has been coming out that actually if you do an ablation on a patient who does not have Afib, you can have two potential benefits for that patient as well.

The first is that you can reduce that post-operative Afib. And the second is that you can reduce significantly the long term Afib rates as well. And the reason I say that is, because with these studies, we believe that that's going to open up the opportunity. When you add those in, we're less than 20% penetrated in the U.S. overall in terms of ablation. And I do believe that the data is going to show that it does make clinical benefit to the patient, to society, if you ablate pretty much every patient.

And so we're going to be running some clinical trials on that. We'll be talking about it in more detail later on this year. We're pretty excited about it. We've done a lot of work and we feel like that's going to open up the market quite dramatically for cardiac ablation.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, so that's sort of similar to the concept of using it prophylactically. This would be sort of prophylactic ablation, if you will.

<<Michael H. Carrel, President and Chief Executive Officer>>

You do it for everybody. I mean like the thought is that there's 2 million patients that undergo cardiac surgery around the globe, and that almost every one of those patients would get an AtriClip ant to reduce the stroke, and they would get an ablation to reduce both post-op Afib and reduce their incidence and chances of getting Afib in their lifetime. And so we're going to run a second trial after LeAAPS. LeAAPS has done so well. We've gotten such great feedback on it. The enrollment has been just fantastic. And so we're pretty excited about both of these trials, really more than tripling the size of the overall market that we've got.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. And then just in terms of EnCompass, I think it's been about two years since you launched the product originally. Can you just remind us about the benefits of the product and why it's seen such strong growth?

<<Michael H. Carrel, President and Chief Executive Officer>>

Yeah. The great thing about EnCompass is that it is simple and easy to use and reduces the time to get a really fulsome ablation on the part. So we've just made it simple. We've taken a 30, 40-minute procedure, and we've reduced it down to less than 10 minutes. So it's an efficiency gain, and it's easier for surgeons who were uncomfortable getting behind the heart. This product, the way that it's ergonomically built, really enables you to get behind the heart very easily.

You don't even have to get behind the heart. You go through the sinuses, and you can get a really fulsome ablation with that. And so we're pretty excited about the product in the way that it's actually had a big impact, reducing time, and quite frankly, making it easy for somebody who did not want to do something to now do an ablation.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. And do you have a feel for how many of the ablation procedures it's being used in, sort of the penetration of EnCompass, and how far can that go, and should we seen two years of strong growth? I mean, can this continue to be a driver for the open-heart business?

<<Michael H. Carrel, President and Chief Executive Officer>>

I think it goes back to your first question. We're still only – we're less than 35% overall penetrated in Afib patients, and less than 20% overall. There's a lot of growth for a decade plus, quite frankly in this space. And so we feel like there's a tremendous amount of growth in front of us within this area. In terms of the volume today, it's probably about 25% of the total volume and about more than that on the revenue side, because we obviously get more for the product overall.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. And then just in the open-heart business, you really only have one competitor, Medtronic. But I know you've been taking share from Medtronic in this category for a long time. They are, I guess, running this terminate AF study of their Cardioblate and CryoFlex ablation systems. This some – I haven't heard them talk about it recently, but is this something we should be concerned about that could turn Medtronic into a more viable competitor in this category if their trial was successful?

<<Michael H. Carrel, President and Chief Executive Officer>>

I mean their trials fully or partially enrolled, I should say they plan on having data later on this year and probably sometime next year. I can't speak to their timelines on all their products on that front. We've competed against them in this space and against this exact same product set. So we feel really comfortable with the products that we have are the best products on the market. We feel like EnCompass was a major move forward for the industry to really significantly reduce the time, make it easier to do a fulsome ablation, and help those patients out quite dramatically.

We've also got a lot, not only a better product line, but also a field team that understands Afib and can really educate and train people incredibly well also. So we feel like we're in a great position. If they do decide to push into the space, it's a really underpenetrated space. And much like I said when we talked about the clip before, it's we believe that they actually help us grow the overall market. And so from that standpoint, we think the competition, we welcome it.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. And then just also on the competitive front, Pulse Biosciences have submitted a 510(k) for surgical ablation clamp using pulsed field ablation or PFA. What are your thoughts on PFA for this particular application? I know there's a lot of hype on the catheter side, but I don't know if the advantages are significant on the open part side of things.

<<Michael H. Carrel, President and Chief Executive Officer>>

I mean, first, we think that PFA, we need to have PFA into our armamentarium as well, and we've got plans to have PFA incorporated into every one of our devices. So if you think about our RF devices today, we anticipate having PFA. We've done the development work on it. We feel really good about our programs in that space.

What I don't know is that it doesn't have the natural savings that you're going to get relative to what you saw on the catheter side. On the catheter side, they were really trying to solve a safety issue and then an efficiency issue. You don't have as many of those same issues on the open side of the business. Our EnCompass Clamp really reduced the time considerably already from that, like 20 or, I'm sorry, 30 to 40 minutes, down to less than 10 minutes for a full ablation on that

front. So the benefit of having how much faster and you might save a couple of minutes maybe in the overall ablation time relative to doing it.

I'm not sure that that is or is not going to happen. That being said, we're still going to have the technology, because we believe as a leader in the space, we need to make sure that we have PFA embedded in our technology as well to give people a choice, and then we let them choose cryo RF or PFA and give them that opportunity to make that kind of distinction and choice. I love the fact that you've got people that are interested in the space because it tells you that there's a lot of room for growth. There's an underpenetrated market both on the Afib side and the non-Afib side. So we view it as a positive that people are actually making investments and coming into the – into our arena.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. And so I guess I wanted to follow that up by asking what would be required to incorporate or to offer PFA with your current platform. So would you need to develop a new generator? Could you use the same clamps? Or would you have to – does it need a complete redesign, but a completely new platform to do it, or can you incorporate into what you – what's already out there somehow?

<<Michael H. Carrel, President and Chief Executive Officer>>

Without getting into too many specifics, we've been working on it for the last four years, so this is not something new. But obviously, with all the buzz out there now within PFA, both on the catheter side and the potential for someone to come into this particular area. We're now talking about a little bit more just around it. We do anticipate that there'll be a new generator that would be needed relative to that of which we've already spent the time and energy to build and develop that. So that's kind of in process of getting fine tuned and then incorporating it into existing devices.

Now we'll have to make some modifications because PFA is a little bit of a different technology. So there may be some modifications that have been made to finalize some of those pieces. But I mean, we've made a lot of efforts. We're in product development stage at this point in time, not in kind of research side.

<<Mike Matson, Analyst, Needham & Company, LLC>>

And then, I mean, if you've been working on it for four years, I'd have to believe you've filed some IP or patents on this technology and open-heart ablation or maybe other areas. So is there any potential that there's, you could use that get some of these competitors potentially coming in with the PFA products?

<<Michael H. Carrel, President and Chief Executive Officer>>

PFA is such an open technology. I mean, you're seeing on the catheter side, there's 10, 15 companies that are there. Everybody's got their different waveform and things like that. But the

IP in particular is not something that I'm concerned about on either side. I mean, in terms of the ability to operate openly on this side and also capture it. Obviously we've got IP on our devices and the way that our devices work. So there's clearly IP on that front of somebody decided they wanted to use technology similar to those that we've already got on the market on that front. That would be something that we'd have to kind of evaluate depending on what they come out with.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. I want to move on to the pain management business. So your cryoSPHERE has been kind of a wildly successful home run product for AtriCure. I think the sales have gone from zero in 2020 to over $50 million in 2023. Can you give us an overview of this product, what it does and why it's been so successful?

<<Michael H. Carrel, President and Chief Executive Officer>>

A simple overview is that today the product is primarily being used in thoracotomy. So anytime you're going in through the ribs and you're stretching and you're putting pressure on those nerves, your nerves get very angry and it's very painful. So if you're going in for a cancer resection, for like a lung resection surgery, or you're going in for what they call a Nuss procedure, to kind of punch out the chest in children. Those procedures are incredibly, incredibly painful.

What the Cryo Nerve Block does is it basically freezes that intercostal nerve. It goes kind of right along your ribs, and by freezing it, you freeze everything on the inside and kill it temporarily. But the sheath kind of remains intact. So with nitrous oxide, it goes to negative 70. It's like the perfect temperature to freeze to. If you go too much higher in temperature, you'll actually freeze the sheath. Because of that, it actually can regenerate and come back. And it basically, by killing it for that period of time, it blocks the pain signals going to the brain for about a six-week period, which enables them to recover more quickly, not feel that excruciating pain. Right. When they come out of surgery, they can kind of sit up, they can breathe more easily.

And that's why it works. That's why people like it. That's why it's taken off so much, because they see significant reductions in pain. They see their ability to recover more quickly in some cases and there are many papers have been written about a significant reduction in opioids that are being used. And so those are the kinds of benefits that many of these patients are seeing when they're – when cryo nerve blocks apply during some of their thoracic surgeries.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. And I guess starting with thoracotomy; I want to talk about sternotomy in a minute. But what are the reasons that you're hearing from customers as to why they're not using this? I mean, I know it's been pretty adopted pretty strongly among certain surgeons, but…

<<Michael H. Carrel, President and Chief Executive Officer>>

There's only two reasons, and they're very simple, time and money. Time, meaning that it takes about 30 minutes to do the procedure. So there's definitely an increased time while you're in the OR they've got to work through that. They've got to spend time doing the ablation on that front. So they have to basically weigh that in their head. Is it worth the time?

And two is that there's a cost associated with it and there's not a direct reimbursement for the product. So that even if they're – when they put it in the procedure, there's an overall DRG that covers the cost. So they've got to look at other reasons as to why they're going to do it. The clinical benefit to the patient, the faster recovery that I just mentioned, fewer calls back into the ER later on, maybe a reduction in length of stay. But the value added committees kind of look at that as they're kind of evaluating the use of the technology. But those are the two primary items that we have to overcome.

<<Mike Matson, Analyst, Needham & Company, LLC>>

And are there things that you can do from a design perspective to improve those? I mean, I guess not. Sorry, not on the time aspect, at least. Maybe not on the reimbursement.

<<Michael H. Carrel, President and Chief Executive Officer>>

Actually there are things on the time aspect. So we've got two new products coming out this year, the cryoSPHERE Plus and then the cryoSPHERE MAX, later on this year. Both of those are targeted to reduce that time. So right now every freeze is two minutes. Our goal with those is to, by the end of the year, with the cryoSPHERE MAX to reduce that time in half. So their freezes are only going to be one minute. We think that will have a significant impact on time.

You can't get to no time, but to reduce that time in half. We think that by the end of the year, so that as we look at next year, we'll be able to talk about that. And we're doing all the research now to be able to kind of give that kind of advice that they could reduce that time significantly. The reason we're able to do it, it's a larger ball at the end, so it covers a larger surface area.

In terms of the reimbursement, there's obviously things that we're doing relative to our trials. We've got about 15 trials undergoing right now. Where they are single center trials and all of them have an economic component to them that the totality of all that. We hope that over time will get CMS comfortable with the fact that they should do some sort of reimbursement for this. But those things take time. You've got to get those trials done and you've got to have them incorporated into publishing, et cetera.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Yeah. Understand. And then you're also trying to get this into sternotomy – drive it into sternotomy procedures. So how much – can you compare the TAM between thoracotomy and sternotomy? And how does cryoSPHERE use in sternotomy compared to thoracotomy, I guess.

<<Michael H. Carrel, President and Chief Executive Officer>>

That's a great. So right now, not a lot of usage in sternotomy, but the TAM in sternotomy is about, almost twice the size. It's about 255,000 patients versus about 150,000 patients or procedures every year in the United States alone. So the TAM is obviously quite, almost twice the size. When you look at in a sternotomy, however it is, they are much more sensitive to that first one, that time aspect that I talked about before, not as much on the cost side, but on the time aspect, that 30 minutes is a lot to add to a cardiac procedure.

And so that reduction in time that we're talking about with the MAX, the cryoSPHERE MAX that's the target, is really to probably help sternotomy more so than helping thoracotomies. I mean, it obviously helps in thoracotomies, but that is going to help us quite dramatically. So right now, we've got a handful of customers that do use it in sternotomy. They see great benefit, but they're balancing the benefit against the 30 minutes they would have to add to the procedure.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Yeah. Okay. And then I know you have a dedicated pain management sales team now, so you can talk about the, if you're willing to the size of that as of last – end of last year and whether or not you're planning to add more reps this year?

<<Michael H. Carrel, President and Chief Executive Officer>>

Angie?

<<Angela L. Wirick, Chief Financial Officer>>

I would say we ended the year around 60, 65 in total in that team. Think about 30, 35 reps and then about 30 clinicals. I think our goal in 2024 would be to add to both areas of the team, continue to add to reps, but then also for case coverage purposes, augment with a clinical specialist. We haven't, don't have specific targets. I'd say initially when we started this team back in 2019, a footprint of 10 or less on that team, we've been really good about going where there's good momentum and saying, look, we've not been able to penetrate just because we can't get to certain areas, and we'll continue that same philosophy as we operate in 2024.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. And then, I mean, we talked about reimbursement, but what about guidelines? Is there any potential for this to be included in guidelines?

<<Michael H. Carrel, President and Chief Executive Officer>>

That's a great question. We're working with ERAS, which is kind of a support after surgery. They've actually talked about incorporating into some of their guidelines. And we're working with STS and some of the other societies to figure out is there a way to get that incorporated? So the answer is nothing yet, but something that we're definitely working on and could be over the next several years.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. And I think most of the sales so far have really been in the U.S. So, I think you're starting to try to penetrate the international markets, and I think there's been some really strong growth there, admittedly off of really small base. But can you just talk about the opportunity outside the U.S.? And I know that some of those markets, particularly Europe, tend to be a little more price sensitive or cost sensitive. So is that going to be an issue? Or do you think you can overcome that?

<<Michael H. Carrel, President and Chief Executive Officer>>

Angie, you want to grab that?

<<Angela L. Wirick, Chief Financial Officer>>

I was going to say multiples of the patients that you see in the U.S. So in terms of opportunity, we think it's pretty sizable, but you hit the nail on the head. I mean, this is an area where reimbursement really matters. And I'd say in Europe in particular, a lot of sensitivity to the cost of the device. We're at a nice price point in Europe around €1,800 and have seen really good activity in the UK, the Netherlands, and starting into Germany, and would expect to continue to expand.

I'd say the nice thing about this therapy is it's a pretty immediate feedback loop to physicians when they do the procedure. They can use a cryoSPHERE device. They can see the impact on the patient. And I'd say that's been compelling for a lot of operators to want to start to adopt in pain management. We've also had some success in Australia, where we've got a direct sales team as well. And I'd say, again, same kind of calculus there. Once they get into the hands of physicians, you tend to find physicians who are very passionate about this and are willing to kind of fight against the economics. But I do think that the, kind of reimbursement landscape outside the U.S. is probably a bigger barrier.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, and then what about expanding outside of cardiothoracic procedures? It seems like there's a lot of potential opportunities there. Not to say you don't have a lot of runway left in cardiothoracic.

<<Michael H. Carrel, President and Chief Executive Officer>>

It's a great question, and we do get asked that all the time about where are we taking it from here? And we're careful not to get too far out kind of over our skis. But there are areas in particular right now, we're looking at below the knee amputations, and that's an area where we're starting to see people begin to use the product and start to test. What's the best approach for it?

You may or may not know, but a lot of patients undergo amputations, have what they call phantom limb pain. There have been several sites that have done a really long series where they've seen significant reduction, if not complete reduction, of that phantom pain and pain after surgery at the site, which is pretty dramatic using some – product, it's a very small n at this point in time, we want to learn why that is happening and what's going on, but that is an obviously a very exciting area. If we could help that.

In the United States alone, there's about 100,000 amputations. That number is obviously significant, more than that globally as well. And so we think that that is another large market opportunity in this area that we are exploring. It's the next natural one for us to go into, and we'll keep looking for those. The biggest thing for us in this area with our existing products is it's really for large nerves. So areas, because that's really where we have the most impact.

If you've got really small nerve endings or you can use percutaneous approaches that might actually be more effective and efficient than using an approach like ours. And ours is very effective with these really large on nerves.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. All right, so moving on, I want to look at your appendage management business. So AtriClip has been another really successful product for AtriCure. Can you just give us a quick estimate of the penetration in both open-heart and minimally invasive procedures?

<<Michael H. Carrel, President and Chief Executive Officer>>

On the open-heart penetration is, we believe, less than 20% overall. We're running a LeAAPS trial for the prophylactic use of it. And when you add in all patients undergoing cardiac surgery, the U.S. were less than 20% penetrated. Globally, we're less than 5% penetrated, and we believe we're enrolling very fast in that trial. We're almost a third of the way through the overall enrollment in the trial just within a year's time. We've got over 70 sites that are doing enrollment. We're about to start up in Europe here in the next week or so. So we're making great progress on that trial to really continue to expand it. So we're less than 20% overall penetrated in this area.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. And then you've continued to improve and iterate upon AtriClip over the years. And I know you're about to launch a new version of it, the FLEX Mini. So can you just give us an overview of this and how it sort of fits in with the portfolio of clip products that you're offering?

<<Michael H. Carrel, President and Chief Executive Officer>>

Yeah, I mean, we're trying to make a smaller device for several reasons. One is to just make it a lot smaller for when you're actually placing it on. So the FLEX Mini is about a third of the size of the existing product. Our product today is smallest product on the market, and so this is to make it an even smaller product. The feedback we got from customers over the last five years

was if you could just make it a little bit smaller, that would be great. So that's the big innovation there is, to make it smaller and just have a lower profile on the body.

In addition to that. That lower profile when it goes from the first device is going to be for the open chest procedures. But when we go minimally invasive, it will allow us to go into a seven or possibly even a five millimeter port. That's incredibly important, because that's obviously a lot smaller and a lot less pain for those patients when they're actually putting it through the ports and they put it down that pathway. So what we're pretty excited about it from that standpoint also.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. And I think you just gave some numbers on LeAAPS, but at least as of the fourth quarter of the enrollment was around 1,700 patients. I forget the total. I think it's what, 6,000 maybe is what – what's the total number?

<<Michael H. Carrel, President and Chief Executive Officer>>

6,500?

<<Mike Matson, Analyst, Needham & Company, LLC>>

Yep. 6,500. So at that rate of enrollment, it would be sort of like three and a half to four years. But would you expect, sorry to reach full enrollment, but would you expect the rate of enrollment to kind of continue to accelerate over time? And what's your best guess on, like, when the enrollment's completed and when the trial would be done?

<<Michael H. Carrel, President and Chief Executive Officer>>

Sometime next year is when we anticipate that the trial will be complete. We haven't given the date. We have seen obviously, as we add more sites, as we go into Europe, as we go into Asia over the next quarter or so, that we anticipate that to have an acceleration on the overall rate. Right now we've got a really good, consistent rate coming in every single week. Very active sites, as I mentioned, about 70 plus sites in the U.S. and we're almost at about a third full enrollment at this point.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, wow. So it's the one that's really accelerating then.

<<Michael H. Carrel, President and Chief Executive Officer>>

Yep.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. All right. And then I have to ask one about Medtronic's Penditure device. What are you – what is, I know it's only been a couple quarters since they launched it, but are you hearing anything from your sales reps, surgeon customers about the product and consensus says AtriCure growing 15% this year. Based on what you're seeing from Penditure is that a reasonable estimate?

<<Michael H. Carrel, President and Chief Executive Officer>>

Yeah, I mean – we don't give like segment level growth, but we do get – we obviously feel good about the overall growth. We give guidance of 15% to 17% for the overall business. We have not changed our thought process on the guidance relative to that. We'll obviously give more details when we only announce our results in a couple of weeks or three weeks from now. But overall, I mean, the 15% to 17% is something that we gave at the beginning of the year and feel really comfortable with that. With puts and takes from all of our franchises obviously, relative to that.

I mean, they're definitely out in the market. You can see them on social media, they're promoting that product. They're having conversations. We've seen their product being used and trialed out in the marketplace from that standpoint, there's not a lot to suggest that they're taking over in anyway shape or form. They're definitely having the trialing that is going on. But overall, we feel really good about our position both short-term and long-term. With the AtriClip in the market.

We know our product is exceptional, and it is a great product that works every single time. We've got 550,000 implants. There's data out there on over 15,000 patients to show almost complete closure of that with zero leaks whatsoever. The safety rate is impeccable. I mean, it's, there are almost no events that have occurred in the history of that product. So we feel really good about our product and what we've got.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. All right, I want to move on to the fourth business. So minimally invasive ablation. I think we're almost three years into the or post the EPi-Sense's approval. The product has been, I guess it might be a little disappointing, probably, in your view, too. But – and I know you get this question all the time, but what do you think are the main reasons that this hasn't seen wire adoption? And then what is AtriCure doing to, I know you've been out there training, training doctors and trying to kind of get some momentum behind this procedure, but what are you doing to try to address this, I guess.

<<Michael H. Carrel, President and Chief Executive Officer>>

I mean a couple things, and I think that one of the really positive things that has actually happened just in the last four months is that for the first time ever, all EP societies, HRS and era, both just kind of ACC and AHA all came out and basically actually put on a guideline as Level 2A. They've never even had that on for hybrid ablation. So they're recognizing the fact that there are several trials that are out there, randomized controlled trials, to demonstrate that this is a benefit for patients. I mean, there's no question that there is an absolute benefit.

There's no doubt about the data. If you talk to EPs, they know and believe that this does add value for that. I think what we saw, and if you look back, I think there's a couple things that happened, obviously, coming out of COVID elective procedures and new programs were really tough to establish, especially ones where we had to have two disciplines working together within staffing constraints. And I think we under – not underestimated, because who would have estimated COVID to hit us as we were kind of coming out and rolling this out.

But it definitely had a big impact on our ability to get programs up and running, and I think that was maybe the slower start that everybody had wanted. I think a big result of that was because of kind of what we faced coming out of the COVID. And as staffing concerns were a really big concern on that front. Now, we've made a lot of progress. As you know, last year we really said to everybody, hey, we've got to get through these. We've got to get these programs working together.

That workflow's got to come together, and we've seen great progress throughout the year. Every quarter. We got better last year. More and more procedures, more and more sites using it, deeper penetration within the sites. We feel like we are in a great place relative to getting those new sites and the trainings that have occurred and getting workflow much better and consistent across the country on that front. So, we're starting to see some really good results relative to that you saw in the fourth quarter. And we feel really bullish about this for the rest of this year as well.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. And then the approvals of the PFA, the two PFA catheters so far, how does that, does that have any impact on this business? I mean, look, I know those products aren't approved for longstanding persistent AF like convergent or Epi-Sense, but there seems to be a belief that they're just safer, particularly for bleeding the back wall of the heart. So I don't know, just give me your thoughts on that and why that.

<<Michael H. Carrel, President and Chief Executive Officer>>

It's actually the opposite. I think that. I think PFA is great. PFA will absolutely improve our business. Let me repeat that. PFA will improve our business. Why? Because what, the promise of PFA was safer, as you described, and maybe they could do more on the back wall. That means they're going to treat more patients. They're going to treat more patients, but there's going to be a lot of non responders. Right now, we are less than 1%, more like 0.5% of the market today is what of the ablations that are happening here. And 45% of the patients have longstanding persistence.

So we have so much room for growth, we're never going to get all those. You're always going to have a catheter being used first, whether it's PFA or RF or some combination of PFA, RF and cryo on that catheter side. But what happens when 30% of them are non-responders, after one or two ablations, the epicardial ablation, and we've proven it through now four different trials over the course, that that's why it got upgraded to a Level 2A? A just recently hybrid improves that almost doubles the efficacy rate when you actually add the epicardial side of it.

PFA is not going to solve that problem per se; I just don't see it happening. And in fact, I think what's going to happen is it's going to illuminate the fact that more and more patients are getting treated. So 400,000 is going to balloon. I think many people think it's going to be 600,000. Well, that means more patients are going to be non-responders, which means there are more to be put into the funnel from the hybrid standpoint.

So we benefit, in my mind, from the increased efficiency of PFA. And so we think it's a positive, actually, that they're out there with that technology. Sure. There's going to be people that are going to try it like you described, but you're still going to have a lot of non-responders.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, yeah, that makes sense. And then I want to talk a little bit about your international business. So can you just give us a quick overview of the bit – your international business and sort of what markets and regions that are the biggest opportunity in your view?

<<Michael H. Carrel, President and Chief Executive Officer>>

Angie, do you want to do that one?

<<Angela L. Wirick, Chief Financial Officer>>

Sure. So international was about $65 million in revenue in 2023, between 16% and 17% of the overall company revenue. But we saw really good growth, around 23.5% growth for that business for the course of the year. I'd say slightly more in Europe than we do kind of everywhere else in the world. And in Europe at this point in time, we've got almost all of our products cleared or available to be sold on that market. We've done a lot of work within the EU MDR to make sure that we're able to continue to sell our products.

We're excited for the back half of this year to see the introduction of the EnCompass Clamp, which would be a new product introduction into that market, and think Europe, there's still significant under penetration there. Similar to the U.S., they've seen some nice improvements in guidelines. We've also made some efforts, and this is more on a by country basis with some reimbursement activities over there. So expect for that business to continue to see really, really strong growth.

Outside of Europe, I'd say, a mix between distributor and direct markets. We've had some success in some countries selling direct or converting from a distributor model to a direct market. Those tend to be markets, I'd say, outside of Europe and the U.S., where we've got a limited product subset. So you are growing off of a smaller base of products available to grow bigger activities there will continue to focus on continuing to add products into each of those markets where it would make sense either from a reimbursement or kind of the overall opportunity perspective. And just expect for the international part of our business, which used to be a bit of a drag on the overall growth rate, for that to continue to be a strong contributor. I think we talked

in a couple of quarters calls in the past. New leadership has made a really big difference in that area of the business, and we're excited to see what they can do going forward.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. And then I'll wrap up with a few financial questions. So you guided a 15% to 17% revenue growth for 2023. And that's. I went back and looked, that's kind of basically the same guidance you gave heading into last year. Sorry, for 2024, you got it to 15% to 17%. It's the same as what you guided to for 2023, but you ended the year with 21% growth. So how conservative is the 15% to 17% for this year versus last year? And have you baked in any sort of impact from these competitive things like Medtronic's Penditure and this Pulse Biosciences clamp?

<<Angela L. Wirick, Chief Financial Officer>>

Yeah, we believe in the context of the guide for the full company, we've baked in potential pressure that might impact the overall numbers. That being said, I think, you know, that we try and give guidance for the year where we feel really good about executing, but there's still the opportunity for upside. And we think about different areas within our business. The upside has come from a lot of different components of the overall revenue number, whether it's new products like EnCompass or cryoSPHERE, generating kind of outsized revenue growth or starting to activate converge, or international business feel good that the totality of the business can deliver the 15% to 17% for the year with potential for upside.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. And then the gross margin, it's been pretty stable, kind of in the mid 70s. So is this where you expect it to stay and what are the factors that could drive it higher or lower over the next few years?

<<Angela L. Wirick, Chief Financial Officer>>

Yeah, I mean, I think we guided for the year to be about flat to last year. I think there's potential headwinds and tailwinds, both directions that say, look, kind of set the expectation about flat to 2023 as we operate in 2024. Mix is probably the biggest driver, Mike, of the fluctuations in margin that you see quarter-to-quarter. We just talked about our international business as that continues to grow and be a bigger percentage, that is a headwind to the overall margin number and then certain products, until we complete some of the leaning activities, whether it's cryoSPHERE Plus launches and becomes a bigger percentage of the revenue at a lower cost of goods or reductions that we've talked about on the EnCompass Clamp, putting those into place kind of back half of this year.

I think there's potential for upside, but most likely not to have a big impact on 2024, but in years in the future. I think tailwinds to all of this is mix can also work in our favor. We've talked about the converge area of the business. That's one of our highest gross margin products. I think as you continue to see strong execution and growth within that particular product line, that's beneficial

to margin. We've also been very intentional with our product development efforts, not only to ask for seek a higher ASP pay for the innovation that's been built into those devices, but also really intentionally at looking at what is the cost to make these devices. So that every time we innovate and put a new product on the market, that we're able to enhance our margins. I'd say the balance between the two of those would say in the near term you probably would expect flat, but there is a runway to see modest improvements longer term.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. And then in terms of EBITDA, I mean, you're expecting pretty strong growth in your adjusted EBITDA for the year $26 million to $29 million this year versus $19 million last year. Is that what's driving that? Aside from the revenue growth, obviously, where's the leverage coming from? Is it primarily SG&A leverage?

<<Angela L. Wirick, Chief Financial Officer>>

Yeah, that's correct. You would expect leverage in SG&A. I think a good way to think about this is SG&A grows at a rate that's below the top-line growth rate. And that R&D, the balance of that is that it's growing above the top-line growth rate. I think part of this is a full year of LeAAPS activity. And Mike also touched on a couple of areas within product development where we're making expenses and just making sure that we've got good opportunities to line up across each one of the franchises. The balance of that, that says look good, bottom line improvement, but pretty modest. We're not trying to maximize the bottom line at this point in time, just given the opportunities within each of the markets that we're operating in.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, got it. And then from a cash flow perspective, it looks like consensus has positive cash flow from operations and breakeven cash free cash flow in 2024. Is that reasonable? If not, is that more realistic for next year?

<<Angela L. Wirick, Chief Financial Officer>>

Yeah, we haven't commented. I'd say specifically on cash flow. I think we said a modest cash burn for the year and would expect to continue with improvements to the bottom line, which where we are committed to continuing to improve. Bottom line that you would see that as an impact to cash flow. I think we're within striking distance of a year where we are generating cash overall as a business free cash flow. I'd say the priority though, there in the near term, though, is just making sure from support perspective facilities, when you think about some of the areas of CapEx that were in a good spot to continue to be able to fuel and fund the growth.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay. All right. And then my last question is just on the balance sheet. So you do have about $137 million of cash and short term investments. What do you plan to do with this? And is there, would you look at M&A, if you saw the right opportunities?

<<Angela L. Wirick, Chief Financial Officer>>

I think we would be very selective with M&A. I mean, I think our primary focus is on internal organic R&D efforts. I'd say the cash at this point in time is, we're in a great position on the balance sheet to fund to the point where we can fund operations organically on an annual basis. So, I'd say no specific use of the cash at this point in time. I think it would take big M&A activities. I think it would take more than what we've got on the balance sheet for us to be able to do that. As we've looked at M&A opportunities, I think we've talked a lot in the past. It's got to be accretive to the top-line. We want to see some clinical differentiation.

But another area of screen that we put into kind of our calculus is, look, if this is going to take us steps backwards on profitability, that we probably don't have the appetite at this point in time. So I think that with that screen being added more recently, it would say very, very selective on M&A activities and more of a focus on internal development efforts.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Okay, great. That's all for my questions. I don't see any from the viewers. So I think we're going to wrap up there. But thanks, Mike and Angie, for coming to our conference and hope you had some good meetings.

<<Michael H. Carrel, President and Chief Executive Officer>>

Appreciate it. Thanks for inviting us. Have a good day.

<<Angela L. Wirick, Chief Financial Officer>>

Yeah, thanks Mike.

<<Mike Matson, Analyst, Needham & Company, LLC>>

Bye.