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PRESENTATION

Operator

: Good afternoon, and welcome to AtriCure's Third Quarter 2020 Earnings Conference Call. At this time, all participants are in a listen-only mode. We will be facilitating a question-and-answer session towards the end of today's call. As a reminder, this call is being recorded for replay purposes.

I would now like to turn the call over to Lynn Lewis from the Gilmartin Group for a few introductory comments. Lynn?

Lynn Pieper Lewis ***Gilmartin Group LLC - Founder & CEO***

: Thank you. By now, you should have received a copy of the earnings press release. If you have not received a copy, please call (513) 755-4136 to have one e-mailed to you. Before we begin today, let me remind you that the company's remarks include forward-looking statements.

Forward-looking statements are subject to numerous risks and uncertainties, many of which are beyond AtriCure's control, including risks and uncertainties described from time to time in AtriCure's SEC filings. These statements include, but are not limited to, expectations regarding the timing of FDA review, expectations regarding the FDA's response and whether it will approve CONVERGE, the potential CONVERGE launch timing, the potential market opportunity for CONVERGE, and the adoption of the CONVERGE procedure.

AtriCure's results may differ materially from those projected. AtriCure undertakes no obligation to publicly update any forward-looking statements. Additionally, we refer to non-GAAP financial measures, specifically revenue reported on a constant currency basis, adjusted EBITDA, and adjusted loss per share. A reconciliation of these non-GAAP financial measures with the most directly comparable GAAP measures is included in our press release, which is available on our website.

With that, I'd like to turn the call over to Mike Carrel, president and Chief Executive Officer. Mike?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

: Thanks, Lynn. Good afternoon, everyone, and thank you for joining us. We know that it's been a challenging time for all and hope you are remaining safe and healthy during these times. Even with the backdrop of the pandemic and the difficulties that has caused many, we continue to focus on the physicians we support and the patients they help. We are dedicated to our strategic priorities of helping those affected by arrhythmias, strokes, and post-operative pain.

Yes, the pandemic is still with us, but we have rebounded well, and we are in the enviable position to have many strategic catalysts coming to fruition and expect to significantly expand our markets and growth rates in the coming years. It is truly an exciting time to be a part of AtriCure.

For today's call, I will begin with an overview of our third quarter revenue and current trends that we are seeing in hospital procedures, followed by an update on CONVERGE, and our other key initiatives.

Total revenue for the third quarter were $54.8 million. In the U.S., the quarter began with a modest decline from the revenue trends we experienced in June as we saw regional variability due to the surge in COVID cases in some key markets. As the quarter progressed, we saw some growth and stabilization in September, which continued into October. Hospitals have become better at managing through these resurgences of COVID-19, and we believe cardiac surgery procedures in most areas have returned to approximately 80% to 90% of pre-COVID levels as of the end of the third quarter.

Internationally, we experienced similar trends to the U.S. with a strong recovery in certain countries, namely Germany, the Netherlands and Japan, offset by countries experiencing a slower recovery, including the U.K. and parts of southern Europe. We are encouraged by our third quarter results and the increasing number of procedures.

Through numerous discussions with surgeons, electrophysiologists, and hospital administrators across the United States, we see a clear desire to treat Afib patients. Procedures in which our products are used are generally economically favorable, and the clinical results are effective. However, these procedures consume hospital resources, specifically ICU beds, which must be kept available to respond to the pandemic.

Because of this dynamic, we believe cardiac surgery volumes will remain slightly below full capacity and will experience ongoing variability through the end of the year and into 2021. That said, we do expect to see continued incremental sequential improvement in our top line results as we navigate a return to normalcy.

Now, turning to several strategic initiatives and highlights. I will begin with CONVERGE, but we are closer to completing the regulatory process to allow us to market the hybrid conversion therapy for treatment of advanced forms of Afib. As a quick reminder of the activity this year, data from the CONVERGE trial was released as part of the late-breaking clinical trials during the virtual Heart Rhythm Society conference this past May. The data demonstrated superiority against the primary and secondary endpoints, namely freedom from Afib and other arrhythmias, and a 90% or greater reduction in Afib burden.

Since then, we have engaged in active dialogue with the FDA to answer questions about the data, provide additional analysis, and dive deeper into the real-world evidence in support of this therapy. In particular, we have examined data for the long-standing persistent patients in the trial, which demonstrates compelling efficacy and durability.

While the trial made its efficacy endpoint for the entire population of both early and long-standing persistent patients, the clinical benefit among the long-standing population was significantly greater at 12 months than the blended trial results. The improvement over the control arm of the catheter ablation only actually increased with time for the long-standing persistent patients in the trial, with results almost double that of the overall trial at 18 months.

Unlike patients with lone persistent Afib, those with long-standing persistent Afib currently have no stand-alone FDA-approved treatment options. Additionally, there have been published articles and abstracts on physician experience treating long-standing persistent Afib patients using the same lesion set that was used in the CONVERGE trial. The published results from those articles are consistent with the results for the patients with long-standing persistent Afib in the CONVERGE trial, further strengthening our confidence in the data for this cohort of patients.

As such, we recently completed our final submission to the FDA seeking a label for the treatment of patients with long-standing persistent Afib and now await a response from the FDA indicating whether or not an advisory panel will be required, something we expect to know in the coming months.

The collaborative manner in which our team has engaged in with the FDA has been immensely valuable in the regulatory approval process. If approved, we believe the hybrid Convergent therapy will provide a compelling treatment option for the unmet need for stand-alone therapies for long-standing persistent Afib patients.

I now want to take some time to cover a couple of important points in our CONVERGE update, the data for long-standing persistent

patients, and the corresponding market opportunity. First, to the data.

As I discussed previously, the deeper that we looked into the data, the more convincing and differentiated the procedure looked for patients with the most advanced form of Afib. The analysis of long-standing persistent patients in the CONVERGE trial demonstrated clear superiority in the hybrid Convergent arm compared to the endocardial catheter ablation arm with an approximately -- an approximate 29% absolute difference in effectiveness at the 12-month endpoint. This is a significant improvement over catheter alone.

As mentioned earlier, we recently completed the analysis of 18-month follow-up and the overall trial results for long-standing persistent patients actually improved significantly over the 12-month data, essentially doubling the blended results and demonstrating the durability of the procedure. Looking beyond the CONVERGE trial, there are journal articles reporting outcomes for long-standing persistent Afib patients that were consistent with this analysis. Further, there is evidence in both the literature and HRS guidelines that the ablation targets that are sufficient for paroxysmal in early persistent patients may not be enough to control long-standing persistent Afib.

The ablation targets that contribute to the perpetuation and sustenance of long-standing persistent Afib are difficult to address with just a catheter alone. This is the premise for why we believe the hybrid conversion procedure to be effective. Thus, we believe the totality of the evidence from the CONVERGE trial and real-world practice is compelling, demonstrating the hybrid Convergent procedure has a larger, more consistent and durable effect for long-standing persistent Afib patients than any other clinically available stand-alone treatment alternatives today.

Once the regulatory process is complete, we expect the strength of our data to change standard of care for millions of patients in the most expansive market opportunity. Which leads us to a discussion on the total addressable market.

The long-standing persistent Afib population represents well over 3 million patients in the United States alone or nearly half of all diagnosed Afib patients. This population is expected to grow to more than 4.4 million patients by 2025. These patients have no other FDA stand-alone treatment options and represent a total market opportunity that is multiple billions of dollars today and expected to grow. Let's dig deeper into these numbers and how we expect this market opportunity to unfold.

Looking at the 3 million long-standing persistent Afib patients in the United States, roughly 25,000 are being treated annually with catheter ablation alone today. Based on expected growth in catheter ablations, those procedures will increase to approximately 45,000 by 2025. This is a clear opportunity in front of us since the hybrid Convergent procedure is additive, not competitive to the catheter ablation.

Yet today, there are only 1,800 hybrid Convergent procedures done in the U.S., and we believe the trial results and related evidence shows that all long-standing persistent Afib patients will benefit by having EPi-Sense added to catheter ablation procedures. This alone is a $500 million addressable market and our opportunity increases by 50% with the inclusion of left atrial appendage management to hybrid Convergent procedure, a trend that we have seen emerge and strengthen over the last few years. But this is merely the starting point. And our addressable markets are far more expansive when considering both the strength of our clinical data and efficiency this procedure brings to the patient treatment.

Another data point we observed in the clinical -- in the CONVERGE trial is that the hybrid Convergent procedure significantly improves electrophysiology lab efficiency by reducing procedure times by approximately 35 minutes. Considering patients with advanced Afib also require more extensive ablation when performing catheter ablation alone, this should improve throughput and EP lab capacity, enabling more patients to be treated. Applying this logic to the market, we believe this will result in a higher penetration of long-standing persistent Afib patients being treated.

Therefore, if we assume an improvement in treatment to just 5% of total long-standing persistent Afib patients who go untreated today for approximately 150,000 incremental patients per year in the U.S., our opportunity increases to more than $2 billion. Additionally, as I mentioned earlier, the inclusion of left atrial appendage management to this procedure will further expand the opportunity within our reach.

The market for long-standing persistent Afib patients is clearly large and vastly underpenetrated, and importantly, there are no existing comparable stand-alone treatment options to the hybrid Convergent procedure. We at AtriCure are leading the way in this high-growth market opportunity with a hybrid Convergent procedure, and we're aiming to provide care to this undertreated patient population and clear benefits for every EP lab. Simply put, we expect this to have the greatest impact to patients worldwide and will accelerate our growth after we receive approval. As we await the next milestone of PMA approval, we are investing in our sales and training teams to ensure that we are fully prepared to launch the hybrid Convergent therapy upon approval.

Turning to additional achievements in the third quarter with respect to our upcoming catalysts. Even during the pandemic, we made meaningful progress on our other landmark clinical study, the aMAZE trial, a 600-patient randomized controlled trial designed to show superiority. In this trial, superiority is catheter ablation plus our LARIAT LAA exclusion system versus catheter ablation alone. Following full enrollment in the trial last December, the FDA approved expanded patient enrollment under a continued access protocol, which we began in earnest this quarter. We submitted our second module to the PMA -- and we submitted our second module to the PMA for the FDA.

We have also made excellent progress on patient follow-ups. Notably, there have been no patient fallout to date. We expect to complete patient follow-ups in early to mid-2021 to be followed by subsequent analysis of the data and our full PMA submission.

Switching gears now to the cryoSPHERE probe, our innovative and dedicated device for managing postoperative pain and cardiothoracic patients. We continue to see positive upward trends in sales, carrying the momentum in sequential quarter growth since the launch of the cryoSPHERE probe in the first half of 2019. Our growth has been coming from a variety of procedural applications, including general thoracic surgery, trauma cases, and pectus repair. Although still in the early innings, we are investing in our sales teams and clinical resources to build on this momentum and to support this long-term growth opportunity.

Continuing with our open ablation platform and our focus on innovation, we are progressing towards 510(k) clearance of our new EnCompass Clamp and are preparing for market launch in early 2021. The EnCompass Clamp provides a simpler and faster approach to ablating heart -- the heart in open procedures. We expect this clamp to appeal to high-volume cabin surgeons where we have minimal adoption today. As a result, we expect this new clamp to be accretive to our open ablation revenue.

As you can probably tell, we are truly excited about the strength of our fundamental business and market expansion opportunities, driven by CONVERGE, aMAZE, cryoSPHERE, and EnCompass, which paves the way to drive accelerated growth over the long term.

With that, I will now turn the call over to Angie Wirick, our chief financial officer, and will return with closing comments.

Angela L. Wirick *AtriCure, Inc. - CFO*

: Thanks, Mike. Third quarter 2020 worldwide revenue was $54.8 million, a decrease of 3% on a GAAP basis and a decrease of 4% on a constant currency basis compared to the third quarter of 2019. U.S. revenue was $44.7 million, a decrease of 3% from the third quarter of 2019. U.S. sales of appendage management products were $17.4 million, showing improvement over 2019 with 3% growth. Open ablation product sales, which include our Cryo Nerve Block business, were $19.9 million, which is relatively flat to the third quarter of 2019.

Minimally invasive ablation sales in the U.S. were $7 million, down 23% from 2019, reflecting the procedural trends that Mike mentioned in his opening comments. As our appendage management and open ablation products are used concomitant to procedures, which are less likely to be deferred as compared to minimally invasive ablation procedures. International revenue decreased $10.1 million, down 4% on a GAAP basis and down 7% on a constant currency basis as compared to the third quarter of 2019. We saw increases in the appendage management franchise in our Asia markets, while both open and minimally invasive ablation had a slower recovery.

Gross margin was 73.7% for the third quarter of 2020, consistent with our third quarter 2019 results of 73.8%. Following a temporary reduction in manufacturing operations during the second quarter, we returned to normal production volumes in the third quarter of 2020. And now, turning to operating expenses.

Excluding onetime acquisition costs incurred in 2019 and the recurring effect of noncash adjustments to the contingent consideration liability, our total operating cost decreased $6.5 million from $50.6 million for the third quarter of 2019 to $44.1 million for the third quarter of 2020. This decrease was primarily driven by lower variable compensation expense as well as decreases in travel, training and meeting costs due to continued limitations on in person group events and trade shows that were canceled, delayed, or transitioned to virtual platforms. Offsetting this temporary decline in operating expenses, share-based compensation expense increased $1.1 million from the third quarter of 2019.

Additionally, this quarter marks the anniversary of our August 2019 acquisition of SentreHEART. Incremental costs from SentreHEART, which are primarily the aMAZE clinical trial and PMA readiness efforts, drive the slight increase in research and development expenses in the third quarter of 2020 compared to 2019.

The resulting operating loss for the quarter was $4 million compared to an operating loss of $8.6 million for the third quarter of 2019. In the third quarter of 2020, we had positive adjusted EBITDA of $4.2 million compared to an adjusted EBITDA loss of $2.2 million for the third quarter of 2019. The majority of this improvement is driven by lower variable compensation, travel and training, and other commercial costs, which we expect to be restored to historical levels as our top line improves.

Our loss per share was $0.11 for the third quarter of 2020 compared to a $0.25 loss per share for the third quarter of 2019, while the adjusted loss per share each period was $0.11 and $0.33, respectively. We ended the third quarter with $250 million in cash and investments.

Finally, we would like to provide an update to our outlook by providing guidance for the fourth quarter 2020. As Mike mentioned earlier, we are pleased with our third quarter results which reflect a recovery across major geographies and products on a sequential basis. While cardiac surgery volumes improved significantly in the quarter and have held through October, most of our customers are not yet operating at full capacity, and we have seen variability as COVID-19 cases spike.

We think the ongoing impact of the pandemic in the United States and other parts of the world could cause periodic disruption in our revenue until the pandemic is contained. Therefore, we are assuming a continued impact from the pandemic in the fourth quarter, with worldwide revenue improving on a sequential basis to $56 million to $60 million. In 2021, we believe there will still be uncertainty as a result of the pandemic, yet our sequential growth trends will continue. Additionally, we expect to achieve our original guidance for 2020 EBITDA loss of approximately $10 million as certain variable operating costs remain temporarily low.

We are committed, first and foremost, to the safety and support of our people, patients, and partners as we navigate the return to normalcy over the next year together. At this point, I would like to turn the call back to Mike.

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

: Thank you, Angie. While this year has been challenging, it has not altered our mission or vision. If anything, it has solidified our conviction that we are building AtriCure into something truly differentiated with a world-class and robust pipeline for the next decade. We are on a great path, and we are at the forefront of meaningfully expanding our addressable markets, potentially treating many more patients who do not have any other options. Concurrently, we are adding resources across our teams to support our growth with the backdrop of ongoing focus in investments in launching hybrid therapies of CONVERGE and aMAZE and strengthening our penetration in open with EnCompass while building new markets in pain management.

These investments and the progress we've made put us in a better place today than at the beginning of the year and enable us to begin 2021 from a position of strength. Please stay safe and healthy, everyone, and thank you again for joining us. And with that, I will turn it over to questions.

QUESTIONS AND ANSWERS

Operator

: (Operator Instructions). Our first question comes from the line of Robby Marcus from JPMorgan.

Unidentified Analyst

This is actually Lilly on for Robby. So, what assumptions are baked into this guidance range? Are you guys assuming current trends hold steady? Or is there the potential for a material disruption in volumes with cases on the rise? And how much visibility do you feel that you have into this range at this point?

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

Yes. I think we've got pretty good visibility into the range for the quarter. We feel very confident in the numbers that we put out there. I mean, what we're thinking about with it, we've obviously gone through the first 5 weeks or so of the quarter. So, we've got really good visibility to almost 1/3 of the quarter kind of behind us at this point as we kind of enter into it. And we're assuming -- I mean, obviously, case volumes are coming up. Hospitals, as we mentioned, are doing a really nice job of being able to manage it. You do see some areas where they have a temporary slowdown for a couple of days or so as they kind of modify and go through things, and we've put all that into our assumptions and guidance for the quarter.

Unidentified Analyst

Okay. Great. And just a quick follow-up on CONVERGE. What are you guys doing now to prepare ahead of the panel and/or a potential panel, I guess, and eventually approval? I understand that you've been preparing for this for some time now. But is there -- are there any missing pieces that you feel you need to work through and finalize ahead of the launch?

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

Yes. Well, thank you for the question. There really are no missing pieces at this point in time. We feel like we are -- the only missing piece is obviously getting through and getting to the approval and getting that complete. But from an operating standpoint and ready to go to market, we've been building out the team for the last 3-plus years ever since we bought the company back in 2015. We've added significant resources to our commercial team, to our education team. We've got training plans in place, training centers and sites, a whole education program to get more and more surgeons and sites up and running.

We've also put together full marketing campaigns that we'll be ready to be able to support our customers as well. So I think we are good and ready for it as soon as we kind of make it through the process.

Operator

: Our next question comes from the line of Rick Wise from Stifel.

Frederick Allen Wise *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

And great to see the excellent quarter. Just want to make sure I understood the comments. I understood the fourth quarter guidance. But Angie or Mike, when you said '21, did I hear you correctly, you expect sequential improvement? Are you talking about year-over-year or each quarter sequentially better than the quarter? I just want to make sure I understood your thinking there.

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

Yes. Not year-over-year, but sequential growth. So, we anticipate -- we're not giving specific guidance to next year. But as we look into next year and as we begin to kind of see the trends that are happening and anticipating that COVID is going to be around and with us for a while, we do anticipate that we're going to continue to see sequential growth from Q4 and then into next year.

Frederick Allen Wise *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

Right. And each quarter, as we think about modeling it, Mike.

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

I mean, there was a little bit of a -- I mean, obviously, you've got -- the third quarter is a little weird because it obviously -- we all know the summer months can be changed on that front a little bit. But I mean, in general, yes, the sequential growth.

Frederick Allen Wise ***Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst***

Great. And just to take a couple of points you made -- again, maybe you could just expand a little bit. Cardiac surgery volumes, who knows back at that something approaching 90%, maybe or 75% to 90%, who knows?. But it's like -- in your view, how long to get back to normal from your perspective? And maybe just one other laggard. Obviously, international, some parts did better than others. How are you thinking and modeling and factoring that into your thinking for the fourth quarter and for '21?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. I think that as we -- I wish I could be the one to tell you that when exactly it's going to come back to normal, Rick. I mean, I think some of that's going to depend upon everything that's happening within the pandemic and when do we get treatment options that are going to work and the vaccines, et cetera, and the timing of that? And how -- when does it get mass distributed? And I don't think any of us really have a complete clear picture to that.

We do know there's going to be spikes. And as we look at this quarter and then even into next year, we believe that cardiac surgery, obviously, is something that people have to have at some point. And so, you will probably be in that kind of 80% to 90% range for a bit. And we kind of anticipate that. But hopefully, we'll, again, see some sequential growth as the quarters kind of come out next year. That's kind of how we're looking at it right now, even in the face of some of the COVID because hospitals are just getting better and better at managing both the COVID patients but also at kind of running their hospitals and kind of segmenting the patients so they can bring the cardiac surgery patients in as well.

Frederick Allen Wise ***Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst***

Great. And just 2 last for me. Maybe you could -- you talked about investing in the CryoSPHERE sales team. Maybe give us some color, where are you now? What are your goals over the next year? What you -- in terms of building a team? Just maybe give us some color there. But last, you've been very clear on the CONVERGE and the likelihood or your assumption of a panel. Have there been any recent conversations about this? Is a dialogue underway? And I know this is all complicated by COVID, the election, everything. But when do you expect to have a little better sense, if you could? Anything incremental, obviously, would be welcome.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

There's 2 questions there. So I'll hit the first one, Rick, which is CryoSPHERE. We've built out that team, and we've really built it up quite a bit this year. We're well over 10 people on the team. We're continuing to hire. You can check online. You can see the hiring that we're doing right now. We believe we've got to cover all the mass markets in the United States there. Every area we go into, we wind up making progress because the treatment works. And we've been very excited about that. So we're really beginning to build out that team.

If you recall, at the beginning of this year before the pandemic, we actually put it into sales for the first time. And they've been in a market development role before that. We moved it into sales. This was the first full year there, and it just got better as the year went on, and we anticipate that we'll continue to add resources there, both from a selling standpoint and from a clinical support because the volume is definitely going up.

As it relates to CONVERGE and the panel, we did submit -- we had many different pre sub meetings with the FDA, as I had mentioned, lots of great positive interactive conversations with the FDA and working collaboratively on that front. From a panel standpoint, we submitted, and now we're kind of awaiting feedback. So, as I mentioned, hopefully, within the next couple of months, we'll have some feedback from them, but I can't choose the FDA time frame at this time, but it should be in reasonably short order.

Operator

: Your next question comes from the line of Danielle Antalffy from SVB Leerink.

Danielle Joy Antalffy ***SVB Leerink LLC, Research Division - MD of Medical Supplies & Devices and Senior Analyst***

Mike, I just have a quick question for you on CONVERGE. And it felt your focus -- it felt like the focus was shifting more to the long-standing persistent. And maybe I'm missing something, but I just want to make sure 2 things. Number one, from a market opportunity perspective, there's no real change here in the addressable TAM, at least as far as I can hear, but just tell me if I'm wrong there. And then number two, just if there's any more color you can give on the back and forth with FDA. I mean, it sounds like it took a

little bit longer. I think back in August you thought you'd submit the final response somewhere around then. I know you never committed to a time frame. So, realistically, when should we hear -- what's the latest, I guess, I would say that we'd hear about a panel?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. I mean, I'll start with the latter one first, which is that we've submitted to the FDA. So, we've now got -- everything's in, and we're now awaiting feedback I anticipate in the next couple of months or so. Obviously, give or take, that we anticipate kind of getting feedback. That's really all I can give in terms of it right now. But yes, I do believe it's going to be in reasonably short order that's not too far away. And again, as I mentioned, we've had really good interactive productive conversations with the FDA. So, I feel like it's moving down a good path.

As the addressable market, the overall addressable market, you're correct. Overall, it's the same. I really wanted to highlight because our submission was for that specific in what I'd like to call the extremely differentiated label of long-standing persistent patients because that market alone right now is -- we're the only ones in the world or in the market that are going to have that level of differentiation. And we're the only ones that have done a trial to show this, and the results are incredibly compelling, as you probably heard within that patient population.

And so, I really want to focus because that is the market that we're going to really attack and really go after because we believe that's where the biggest unmet need is. We know that our products are incredibly additive to what the catheters are doing today. Again, as I mentioned, they're additive, not competitive. And already in the United States alone today, there are 25,000 catheters for long-standing persistent patients, and we're only in 1,800 of those procedures. And our trial proved and showed that they will benefit by adding on top of that catheter the EPi-Sense ablation.

And we believe that is going to be the most robust and beginning part of the market because it's the most unmet need. It's the most differentiated, and that is something that we believe provides what we like to call internally extreme differentiation.

Danielle Joy Antalffy ***SVB Leerink LLC, Research Division - MD of Medical Supplies & Devices and Senior Analyst***

Got it. Okay. So, it's less about you not being able to target the persistent patient population, also more about like you're going to be focused and sort of giving us a sense of the go-to-market strategy here. Is that fair to say?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

I don't know I would say that. We're focused on -- the label's going to be for and what we submitted for is for the long-standing persistent population. That is what the label is going to be for. That being said, and that's where most of the patients that get treated today are. As I think we all know, there were 2 products that were recently approved on the catheter side for the persistent side. I mean there's a lot of failures after that. As you know, they have a lot of success and do good work, which is obviously why they got approved. But then there's also the failed catheter ablations that they could lead to into the future. But our focus is going to be really on that long-standing persistent market because we believe we're additive in that environment, and there are so many patients in the unmet need is biggest there.

Operator

: Our next question comes from the line of Matthew O'Brien from Piper Sandler.

Matthew Oliver O'Brien ***Piper Sandler & Co., Research Division - MD & Senior Research Analyst***

I guess, Mike, I'd anticipate there's going to be some investor consternation about the Q4 guide. And I think it's probably helpful to unpack things a little bit there from a U.S. and then an OUS perspective. So if your -- the volumes are still down 10% in the U.S. roughly on a year-over-year basis, and that's what you're expecting for Q4, but you're expecting things to sequentially get better versus Q3, it would seem that there's some improvement that you're seeing from a clip perspective, from an open perspective in terms of more clinicians or more utilization to get to that number? Is that fair?

And then secondly, the international number, you had a really tough comp. There's areas of Europe that are shutting down right now. And so, it seems like it's more of an acute issue internationally that could be a little bit of a headwind versus anything really durable as we kind of come out of this. So, just any kind of comments about that would be -- that long-winded question would be helpful.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

No, that's okay. I mean, I feel great about our Q4 number. I think in the face of everything that -- and I've seen what all the other companies are kind of out they're talking about right now. I think in the face of what's happening with COVID, the fact that we're going to see a strong sequential growth. To your point, as we look at Q4, we anticipate that the cardiac surgery volumes are going to be in that 80% to 90% kind of range from a procedure volume standpoint, not necessarily from ours, that's just kind of like cardiac surgery procedures in terms of kind of where they are from a capacity standpoint and how they're basically getting those patients back into the hospitals.

And then -- so you're right. I mean if we are, obviously -- that's down 10% to 20%. And if we're closer to -- we're not going to be down that much as a result of that. We're obviously growing within there. It's actually across all of our franchises that you see it. We're getting more penetration in the open in the procedures that are occurring. You're getting clips, and you're beginning to see some procedures come back on the minimally invasive side of our franchise as well. So, kind of -- it crosses all barriers. We feel really good about how we're able to manage through this and understand what's happening in cardiac surgery. And that's kind of how we're going into the market. And I feel really good kind of about where we are right now.

And you had a second question, and I apologize. If you ask it again, I can make sure I answer it.

Matthew Oliver O'Brien ***Piper Sandler & Co., Research Division - MD & Senior Research Analyst***

Yes, that was a super long question. So just the international, I mean, you have the toughest comp of the year. And so, with parts of Europe shutting down too, that's why the Q4 number may ostensibly look a little softer than people had expected, but you're just factoring those things in off of a tough comp.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes, that's correct. Yes, there's no question about that from a -- but it's -- I don't -- when you say tough comp, you mean tough comp from Q4 of last year?

Matthew Oliver O'Brien ***Piper Sandler & Co., Research Division - MD & Senior Research Analyst***

Exactly. Yes.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. And I mean, right now, I mean, I think the best way for analysts and investors to not just look at AtriCure, but to look at most companies is really, are you seeing improvement in case volumes every week? Growth year-over-year is -- we've got to get cardiac surgery volumes back to normal and get that kind of -- but we're improving penetration, and we're seeing that sequential growth happen. So, year-over-year comparisons are just tough to do.

Matthew Oliver O'Brien ***Piper Sandler & Co., Research Division - MD & Senior Research Analyst***

And then just next few questions, I'll ask them together because I'm getting long here. But the MIS piece of the business has been slower to recover. Can you talk about why that is? It's just -- again, it's a different patient population, but just why is that slower? And then have you made any incremental investments on the MIS side of the business in anticipation of CONVERGE that you can talk to? If it's more and more sales reps you're adding now or back office folks, anything along those lines?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Sure. Yes. MIS, we -- is coming back slower per se because it came from a lower base. When the pandemic hit back in April, that got hit the hardest. Those are the most elective procedures, those are the ones that could push out the most. A lot of cardiac surgery, you just can't push out. So, you tended to see the volume get hit the hardest on MIS. It did have a faster recovery. But obviously, it's coming from a lower point back in the April, May time frame, and it is still the most elective portion of our procedure base. But obviously, once things

kind of get back to more normal, that should kind of come back nicely. It is economically viable for it. There are a lot of patients that need it. And obviously, we're going to build off of when we get the approval from that standpoint.

In terms of adding and investing, yes, we've been investing in our team, a lot of team on the field. The big areas are the ones I talked about earlier. First is not only having the team out in the field and making sure that they're trained and well prepared, but also making sure we've got the educational platform in place. We've got sites ready to go. We've moved to a very creative mobile cadaver lab where we can begin to train people around the country during COVID, and we will be rolling that out quite extensively after we get the approval as well to make sure that we can effectively train people all over the place without having everybody have to get on airplanes because docs can't get an airplane, et cetera. So, we've been making some investments in those areas so that when we get to that, we are ready to go.

Operator

Your next question comes from the line of Mike Matson from Needham & Company.

Mike Matson *Needham & Company, LLC - Senior Analyst*

Just given the potential for the long-standing persistent label with Convergent, are you aware of any other trials for any other devices or products out there for these patients? This category of the AF patients.

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

There are no trials out there right now for this category of patients. There are trials that are for the persistent patient population. So, for that 12 months or less. We are -- the only trials out there for more than 12 months are 3 trials run by AtriCure. The first trial is CONVERGE, which is the one, obviously, we're part of right now. But we've already got the data. We've seen, as I mentioned earlier, how compelling that data is for that patient population, and there are no other treatment options for those patients.

The second trial is the aMAZE trial because the aMAZE trial is also for patients that are out to 3 years in Afib. So, it kind of covers 2 of those years as well. And that will be additive to what we're talking about with CONVERGE. And then our DEEP trial is the other one as well that also takes in the long-standing persistent patients. So we're the only ones. That's why it's a lot of differentiation. There's nobody else that's in the market with a clinical trial going on today.

Mike Matson *Needham & Company, LLC - Senior Analyst*

Okay. And then assuming that you do get the FDA approval, how do you see this being used for that particular group of patients? Because I think I've heard some discussion of patients being treated with a catheter first and then seeing how they do. And then if they don't get enough improvement, then they'd be brought back for the surgical portion. But that -- maybe that's more for kind of this persistent as opposed to the long-standing persistent. So, are you guys going to kind of push for just doing a true hybrid and really doing both just upfront?

Michael H. Carrel *AtriCure, Inc. - CEO, President & Director*

Yes. I mean, what our trial showed was that you should do this on de novo patients upfront as the first-line therapy. I mean, that is essentially, we achieved superiority. As I mentioned, the delta at 12 months in the long-standing persistent patient population was 29% at 18 months it was even greater than that in terms of the delta between the catheter and the Convergent arm. So our -- obviously, what we're going to be talking about is saying, look at that delta. It tells you you should be doing this all upfront.

So, all 25,000 of those patients in our minds should be getting the Convergent procedure, this hybrid procedure at the same -- basically de novo and as the first-line therapy. And we think the trial shows that data. I mean, that's what we will be talking about from that standpoint.

Mike Matson *Needham & Company, LLC - Senior Analyst*

Okay. And then on the aMAZE trial, is there any possibility we could see the results of that in 2021? If it's going to -- the trial's going to be done I think you said mid-2021. Or is it really going to be more realistic in '22?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

We anticipate data coming out at the end of 2021. For the aMAZE trial. Absolutely.

Operator

: Your next question comes from the line of Suraj Kalia from Oppenheimer. All right. Next question comes from the line of Marie Thibault from BTIG.

Marie Yoko Thibault ***BTIG, LLC, Research Division - Director & Digital Health Analyst***

I appreciate it. I'll ask just one more on CONVERGE. Really focusing -- we're moving past FDA approval, really focusing on the launch. I know in the past, you've said 2021 would be kind of a building year, and we'd see more in 2022. With the time lines now, I know they're a little bit up in the air, but how do you envision this launch rolling out? How long after FDA approval do you think it might be before we start seeing material uplift in the sales?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Yes. I think we think the same. Obviously, we're in the face of COVID in 2021. So, there's just a lot going on at hospitals and at sites and getting programs up and running. But we do believe that we'll get the approval. And then, like we said before, we do see an acceleration happening in 2022. I mean that doesn't mean that next year, we're not going to get new sites up and running, and then we're not going to begin to get some revenue. But to predict the exact time frame of that, it's difficult to do kind of sitting here right now until I know exactly when the approval comes in and everything is going on with COVID. But we're very confident that by 2022, we'll be -- things will begin to really get going at that point in time.

Marie Yoko Thibault ***BTIG, LLC, Research Division - Director & Digital Health Analyst***

Okay. So, no change there. Great.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

No change.

Marie Yoko Thibault ***BTIG, LLC, Research Division - Director & Digital Health Analyst***

And then I wanted to ask one on EnCompass. You mentioned that a clearance would get you into kind of the high-volume CABG surgeons where you don't have a whole lot of penetration so far. Are you needing to build out a new small sales force for that? Is there anything necessary in terms of standing order to make that a successful launch?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Not at all. I mean, we actually have relationships. That's actually one of the things that we've built over the many years here is that we've got wonderful relationships pretty much with every cardiac surgeon in the country, CABG, mitrals, aortics. This is just a new and innovative clamp that allows them and makes it easier for them to not have to open up the atrium to do the ablation. And so, we're really excited about it. We've got relationships with most of them. And so it's not going to be any kind of additional add from that standpoint in terms of head count or needs.

Operator

: Last question comes from the line of Bill Plovanic from Canaccord.

William John Plovanic ***Canaccord Genuity Corp., Research Division - Analyst***

A couple of questions just on the FDA discussions regarding CONVERGE. One, in terms of the label, it sounds like you've pretty much gone through all the label discussions and you have final label at this point. Am I reading that correctly?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

I wouldn't say that we've got final label at this point. We've submitted for that. We've had lots of conversations with them about the label, but we submitted it, and now we have to kind of wait for final feedback as to whether or not it will go to panel or not at this point. We have lots of conversations, but we've submitted -- they gave us a list of questions back earlier in the year. We responded, we basically

worked with them over the summer. That was a lot of the back and forth on the additional analysis that we did. And a big part of that was actually looking at this long-standing persistent patient population because the difference was so dramatic and so compelling, had lots of conversation with them and then we submitted recently for that long-standing persistent label.

William John Plovanic ***Canaccord Genuity Corp., Research Division - Analyst***

Right. But I mean the actual wording of the label in the IFU, has that been worked through yet? Or where are you in that process?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

No, we just submitted. I mean, we literally -- we've just recently submitted that. So what I'm suggesting is that we will be -- I mean, we might be in conversations with them, and we anticipate that could happen, but that's not happened yet.

William John Plovanic ***Canaccord Genuity Corp., Research Division - Analyst***

Okay. And then in terms of just manufacturing, and have they done a site audit? Or would you expect them to come and audit manufacturing prior to launch?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

We've gone through lots of site audits. At this point, we've gone through many manufacturing audits with the FDA. We've gone through customer site audits. I can never guarantee that we're not going to get audited again, but I think we're in a very good place.

William John Plovanic ***Canaccord Genuity Corp., Research Division - Analyst***

And then have you started building inventory for the launch yet?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

We have enough inventory built. We've been building inventory for a long time, and we're in a very solid space from that standpoint.

William John Plovanic ***Canaccord Genuity Corp., Research Division - Analyst***

Great. And then I think just in terms of a distribution standpoint, have -- you've talked, I think, pretty detailed about being prepared for the launch. Should we assume, just as we look at the operations of the business that you now -- it's more of a normal cadence going forward in terms of adding your direct reps and your clinical reps and all those different components of your field force? How should we think about that cadence going forward?

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

I'm not sure when you say normal what normal would be. I mean, what we will do is we've built out a robust team right now, which has both a management layer and also kind of our direct reps and clinical specialists out in the field. We will be adding quite a few more as we roll out. We've got open headcount right now. We'll be opening up more into next year. We'll continue to expand. We think this is a very large opportunity. So we're going to continue to expand and build out that team. I'm not sure what normal is. I'm not going to give a specific number yet because some of that depends on kind of the timing of what happens and the approval, et cetera. But I mean, we're in a really good spot right now because we spend a lot of time and energy building out a big portion of that team over the last 3 years.

William John Plovanic ***Canaccord Genuity Corp., Research Division - Analyst***

Great. Okay. That's all I had.

Operator

: I don't see any questions at this time. I will turn it over to Mike for (inaudible) remarks.

Michael H. Carrel ***AtriCure, Inc. - CEO, President & Director***

Well, again -- once again, everyone, thank you so much for joining us tonight. As you can tell, we are excited about our opportunities in front of us. We appreciate all of the questions, and have a wonderful and safe evening. Talk to you soon.