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Q1 2020 AtriCure Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's First Quarter 2020 Earnings Conference Call. My name is Josh, and I will be your coordinator for the call today. (Operator Instructions) 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 Pieper Lewis Gilmartin Group LLC - Founder & CEO

Thanks, Josh. 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. 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, and thank you for joining us today. Before moving to a review of the quarter results, I would like to first take a moment to acknowledge the COVID-19 pandemic and its impact on our world, our employees here at AtriCure and all of our stakeholders.

We are navigating through an extraordinary time of uncertainty but remain resolute in our focus on our people, patients and partners. We are truly grateful for the selfless dedication of our caregivers battling on the front lines to secure the health and safety of our patients and our communities.

For today's call, we are going to reverse the order of discussion. Andy Wade, our Chief Financial Officer, will start with a brief overview of our first quarter performance. I will then comment on our response to the pandemic and our commitment to supporting physicians and Afib patients, current trends in our business and our positioning for the long term.

With that, I'll turn the call over to Andy to review our financials.



M. Andrew Wade AtriCure, Inc. - CFO

Thanks, Mike. Our financial results were significantly impacted by the ever-changing landscape caused by the COVID-19 pandemic as revenue in the U.S. started to decline in the second week of March, with sales in the final weeks of the quarter down roughly 70% compared to the earlier part of Q1. These final weeks are when we would typically experience strong results with an increase in daily bookings. As a result, first quarter 2020 worldwide revenue was \$53.2 million, a decline of 1.4% on a GAAP basis and a decline of 1% on a constant currency basis when compared to the first quarter of 2019.

U.S. revenue was \$43.5 million, an increase of 1.1% from the first quarter of 2019. The slow growth was due to the impact of COVID-19 on the last 3 weeks of the quarter. U.S. sales of appendage management products grew 11.2% to \$17.4 million for the first quarter of 2020. The U.S. open ablation-related product sales increased to \$19.2 million, representing growth of 1.2%. These increases were offset by the continued volatility of our minimally invasive ablation franchise. U.S. sales of products used in minimally invasive procedures were \$6.6 million in the first quarter, down 15.5%.

International revenue decreased to \$9.8 million, down 11% on a GAAP basis and 9.4% on a constant currency basis as compared to the first quarter of 2019. The decline was caused largely by COVID-19, which included not receiving an order from our Chinese distributor in the first quarter. Since then, cases have started to ramp back up in China, and we have received our first order in early April foreshadowing a slight rebound.

Gross margin for the first quarter of 2020 was 73.1% as compared with 73.9% for the first quarter of 2019. Gross margin remains consistent with the fourth quarter of 2019 as we continued production at comparative levels for the quarter and continued to absorb higher manufacturing costs from SentreHEART operations.

Looking at operating expenses, excluding the effect of noncash adjustments to the contingent consideration liability, our operating costs increased \$5 million from \$46.9 million for the first quarter of 2019 to \$51.9 million for the first quarter of 2020. This increase is largely due to the incorporation of approximately \$3.7 million of SentreHEART costs, which were not present in the first quarter of 2019. As a reminder, SentreHEART operating expenses consist primarily of the aMAZE clinical trial and supporting field team as well as PMA readiness efforts. Organic expense drivers included an increase in product development and training activities from the first quarter of 2019 while incremental head count costs in 2020 were offset by decreased variable compensation and travel spend.

Our operating loss for the quarter was \$15.5 million compared to the operating loss of \$5.3 million for the first quarter of 2019. In addition, the increased operating expenses just noted, the increase in operating loss this quarter also stems from a \$4.1 million change in contingent consideration adjustment as a result of a \$2.4 million charge for accretion of the SentreHEART-related liability in the first quarter of 2020 and versus a \$1.7 million credit related to the nContact liability in the first quarter of 2019. In the first quarter of 2020, we had an adjusted EBITDA loss of \$6.1 million compared to an adjusted EBITDA loss of \$491,000 for the first quarter of 2019.

Our loss per share was \$0.42 for the first quarter of 2020 compared to a \$0.15 loss per share in the first quarter of 2019, while the adjusted loss per share each period was \$0.36 and \$0.20, respectively.

We ended the quarter with approximately \$68.5 million in cash, cash equivalents and investments. As a reminder, our cash burn is seasonally higher in the first quarter due to year-end variable compensation payouts, taxes on vesting of equity awards heavy trade show spend and internal training meetings.

Due to the unpredictability of the duration and magnitude of the impact from the COVID-19 pandemic, we withdrew our previously announced financial guidance for 2020 on April 9. As I mentioned, we saw an almost 70% decline in the final weeks of the quarter and into the first 2 weeks of April. As Mike will discuss, and as you have likely heard on other calls, we have started to see increased activity in the past 1.5 weeks as states and hospitals are starting to do more emergent and elective procedures where our products tend to be used. This is a positive trend, and we do expect case volumes to increase in May and June and into the summer, but we do not want to get ahead of ourselves and cannot predict exact numbers.



As noted in our April 9 release, in response to the changing business conditions, we have implemented several measures to reduce our operating expenses, taking out over \$25 million in costs including delaying certain capital investments and hiring, reducing executive management and Board compensation and reducing nonessential sales, general and administrative expenses where possible, all without sacrificing investments in critical strategic initiatives. While we may take additional action to further reduce our operating costs as the year progresses, we believe our current cash, cash equivalents and investments are sufficient to fund our continuing operations.

At this point, I would like to turn the call back over to Mike.

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

Thank you, Andy. We continue to experience unprecedented uncertainty as we collectively combat the COVID-19 pandemic. The situation remains fluid, particularly in the health care space, where many hospitals and resources are centered around the treatment of those who are affected by this virus. As many of you are aware, nonemergent procedures have been indeterminately deferred in order to preserve resources for COVID-19 patients and caregivers and to protect patients from potential exposure to COVID 19.

While some [HQ] procedures may be insulated from this delay due to an emergent need, the variability is too great to allow us to measure the true impact of this disruption to our business into the future. However, we are confident that a large majority of procedures that have been deferred will return and patients will receive treatment. Every day, we are seeing states and sites across the country from Florida to Oklahoma, to California and Washington begin to open up and perform more cases for patients in need. Additionally, our teams in the field have done a wonderful job of staying positive, doing what they can to ensure the best possible customer care.

Early on, we took measures to ensure the protection and well-being of our employees, patients and communities and to position our business to mitigate the disruption without weakening our readiness for a strong future. Following federal, local and agency guidelines, most of our employees continue to work remotely and are restricted from nonessential travel with few exceptions, which are primarily our field support teams.

Additionally, we are continuing critical manufacturing, assembly and fulfillment of our products. We have taken essential steps to streamline and implement processes to mitigate potential health and safety risks to our employees posed by COVID-19.

Without a doubt, one of AtriCure's key differentiators is the personal touch that we bring to our work. Our health care partners trust our products and rely extensively on the expertise of our field teams. It's a privilege that we have earned by working tirelessly and often in person to forge authentic relationships with each other and those that we serve. These strong connections have helped immensely as we now rely on virtual communication tools to innovate, learn and support cases in new ways. Our field team remains available to our physician community through on-site visits, if permitted, as well as virtual and telephonic platforms.

I want to share a few wonderful examples of the creativity of our team and their commitment to our mission. A surgeon in the northeastern United States was able to perform an ablation procedure and AtriClip placement on a patient with a virtual support of AtriCure's regional sales manager and his team despite hospital rules that bar vendor personnel due to the pandemic. The AtriCure team utilized virtual communication platforms to connect with the staff member's phone in the operating room and they communicated with the surgeon beginning at 6:00 a.m. at the scrub sink and through the end of the case.

In another case, a clinical support specialist in the New England area answered the last minute call of the thoracic surgeon in New York, who requested the help with a cryo nerve block case. Again, utilizing virtual communication, our clinical support specialists walked the surgeon staff through the procedure from setup to proper placement of the probe. Afterward, this surgeon said, the willingness to go the extra mile did not go unnoticed.

In addition to continued case coverage support, our teams are in regular communication with customer sites, providing encouragement and gratitude as well as clinical help when needed. Our field team also remains very focused on education and training to continue building our market by utilizing online interactive training opportunities to enable remote learning for our customers and employees. At the time of this call, our teams across the globe have already completed hundreds of hours of programming, including sessions on ablation, conversion procedures, appendage management and more.



There is no shortage of examples of stellar work like this across all functions of our company. We have an amazing group of resilient people at AtriCure, whether they are building products, supporting cases or volunteering to make face shields for their local community. The spirit, thoughtfulness and creativity of our team is truly amazing. Responses like this make me even more proud to be part of the AtriCure team. Operationally, financially and strategically, AtriCure is well positioned to navigate through the current business environment and our continued commitment to our pillars of innovation, education and clinical science will enable us to help millions of patients over the next decade.

Turning now to our strategic initiatives. We are prioritizing our investments in CONVERGE and aMAZE trials as well as the progression of our new product development pipeline. As many of you know, the trial results of CONVERGE, our landmark IDE clinical trial, were accepted as part of the late-breaking presentations at the Heart Rhythm Society, or HRS Annual Meeting. Since the in-person physician meeting was canceled, the late-breaker presentations will be conducted via webinar hosted on the Heart Rhythm 365, the society's digital information platform. Dr. David DeLurgio, Director of Electrophysiology at the Emory Heart and Vascular Center Emory and the National PI for the CONVERGE trial will present the results on the morning of May 8. Additionally, the abstract will be published in a supplement in the May issue of the Heart Rhythm Journal.

We will be hosting a virtual analyst and investor meeting and briefing on May 8 at 1:00 p.m. Eastern Time, which will feature Dr. DeLurgio as well as Dr. Hugh Calkins, Director of Cardiac Arrhythmia Services at John Hopkins and Dr. Christian Shults, a cardiac surgeon from MedStar Washington Hospital in Washington, D.C., who was also a PI for his site. The clinicians will offer brief presentations on the data and its implications as well as take questions. We will announce the details of the webcast in short order.

As a reminder, the CONVERGE trial is designed as a randomized, controlled superiority trial, comparing our hybrid approach to catheter ablation alone for this patient population, the first trial of its kind in the Afib market. In addition to our late-breaker at HRS in May, there will be other nonrandomized controlled trials studying some advanced forms of Afib. Needless to say, the CONVERGE trial is uniquely differentiated. We firmly believe that we are investing in the future with both CONVERGE and aMAZE trials, both of which have the potential to substantially increase our addressable markets.

As you might expect, this is an exciting time, and I am thankful for the expertise and focus of our clinical and regulatory teams on CONVERGE as well as all the other clinical trials. There is still much work to do after the CONVERGE results are presented, and our teams are actively working with the FDA to complete the regulatory process and make this therapy broadly available to patients suffering from advanced forms of Afib. We continue to expect the FDA to convene a panel later in 2020.

In addition to our advancements in the clinical data and science, the strength of our innovation remains steadfast. The V clip line of products launched in 2018 continues to be a driver of growth for our appendage management business. In the open ablation platform, we are awaiting 510(k) clearance for our new open clamp, EnCompass, and the team is preparing for market launch. This new clamp provides a simpler and faster approach to ablating the heart in open procedures. We expect the EnCompass clamp to resonate with surgeons in the open concomitant space and to be accretive to our open ablation revenue in future years.

As we look out over the next several months, we expect meaningful portion of AtriCure procedures across the United States and globally to be deferred with the largest impacts falling in the second quarter. Further, we believe progress back to normalcy will occur at different rates and time lines throughout our markets. We have completed an extensive demand analysis, hospital by hospital, and we monitor this daily. There are early and encouraging signs in certain regions and hospital systems that are beginning to come back online, such as Florida, Texas, Seattle and throughout California. And just the other day, we heard HCA and UPMC plan to start some elective cases again in May.

In Asia, procedures in China are also starting to resume. While it's too early to call a trend, we are optimistic that there is light at the end of the tunnel, and the majority of procedures that have been deferred will return, and patients will receive treatment.

Before closing, I want to thank our team at AtriCure for the strength and effort they have shown through these tenuous times. Every day, they are working to improve the lives of patients and dedicating their time and expertise to helping hospital customers in response to the



pandemic. I am incredibly proud to be part of this team and the foundation we have built together, a pipeline of new products, robust, randomized clinical data and a continued commitment to world-class education all of which will enable us to help millions of patients over the next decade. I have full confidence that together we will come out of this period even stronger as a company.

Now I will open up for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Robbie Marcus with JPMorgan.

Lilia-Celine Breton Lozada JP Morgan Chase & Co, Research Division - Research Analyst

This is actually Lilia on for Robbie. Can you give us a sense of how we should be thinking about the deferrability of your various business lines? How emergent are minimally invasive versus open versus AtriClip procedures? And how have each of those have been trending in recent weeks?

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

Yes. I mean I'm not going to talk about the specific trending by weeks because I don't think that's, quite frankly, very illuminating or doesn't give much. But what I will tell you is, if you look at our business, there's really 2 major portions of it. The open business tends to have more emergent cases. So CABGs and aortic are -- those are things that are actually getting some treatment today. And it depends on -- from that standpoint, things are getting deferred, but a patient that has mitral valve disease is going to get treated. It's just going to get deferred a month or 2 months, and that's what you're seeing at the hospitals. It's also one of the reasons that you start to see a pickup on that open side of our business, not just our business, but just in general in those types of cases which is that eventually these patients need to get treated.

And so they may be able to defer them for a little bit, but they can't defer them forever. And you hear different reports all over the country about how they've got to get some of these patients back into the OR so they can treat them.

On the more elective side, are the patients that fall into like the Convergent or the DEEP-type procedures, those procedures -interestingly enough, though, we do anticipate there will be some bounce back with them because we do treat with the most
complicated and sickest patients. And so as a result of that, they tend to kind of fall in line. And we do believe that we're starting to see
some things pick up for the May, June and July time frame. We're already starting to see ORs open up for some of those elective cases.

But it's going to be tough to really know. Each hospital is going to be very different in terms of how to handle it. As you might imagine, the Northeast is pretty much not doing a lot of procedures right now, if any. I heard -- I mean you heard Governor Cuomo recently talk about going back and getting some elective procedures. So there might be some movement there. But in other parts of the country, like the Central U.S., as I mentioned, California and many other states, you're actually starting to see them come back and come back on a more regular basis.

Lilia-Celine Breton Lozada JP Morgan Chase & Co, Research Division - Research Analyst

Great. And one more quick one. How are you thinking about the recovery of volumes over the coming months? Are you assuming we pick up any lost procedures?

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

The way we're thinking about the recovery is more along the lines of April and May are going to be bad months, I think, for just about everybody. We are -- as we both mentioned in our comments, you're starting to see like this week was better than last week. You're starting to see cases begin to get booked in May and June and July. So we do see an incremental growth back throughout the second quarter. But the second quarter is going to be a rough quarter.

I think the third quarter, you'll begin to see that's going to be a little bit better than the second quarter. I think you'll start to see it



increasing by months. And hopefully, we're back to more normalcy by the fourth quarter. I can't think an exact date when that's going to happen per se or what week it's going to happen in, but I do anticipate that beginning to kind of build back up.

You're hearing from different places around the country that over the summertime, they're going to be working weekends and they're going to be working and trying to get that extra case in every single day. While I'm optimistic and hopeful that something like that could happen, we're not going to plan for that just because the logistics are going to be difficult. And I think everybody is going to be in a learning mode over the next couple of months to find out how realistic is that. But again, I do see it incrementally every month getting better to getting closer to normalcy by the fourth quarter.

Operator

(Operator Instructions) Our next question comes from Matthew O'Brien with Piper Sandler.

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

Mike or Andy, just to follow-up on the last question there with what you were saying, Mike. So it's fair to say that things kind of bottomed the first couple weeks of April as far as procedure volumes go. Was that just strictly a domestic comment? Or was it a more global comment?

And then how do we think about -- just framing things up, you said things got a little bit better here the last week. So kind of hit the bottom first couple, maybe down 50-ish last couple and then still down over the next probably couple of months before fully stabilizing sometime in Q3. Is that the best way to kind of characterize that? And then again, is that on a domestic basis or a global basis?

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

Yes. I'll hit on the different geographies, and then that will help. It's a great question, Matt. So let's start with Asia. Asia was really bad in Q1. We had 0 revenue, as Andy mentioned, from China. We did not have an order, and the case volumes were almost 0 throughout the month. But they started to pick up at the end of March, and we actually already got an order from them. So Asia is actually pretty close to back to normal at this point. They're not quite there, but they're beginning to move down that path and make some good progress. I anticipate that by the end of the quarter, they'll be kind of back to a more normal place. Obviously, that's a much smaller -- that's a smallest geography of business.

For the U.S. and for Europe, it was a similar trend that happened in the U.S. as many companies, and you've heard it on a lot of my conference calls, you saw at the end of that kind of the kind of last 2.5 weeks, volumes just declined precipitously during that period of time as people went into lockdown mode. And then that continued for a total of about 5 weeks, I would say, where it was just really bad and really low. It was down up to 70% from what we were doing at the beginning of March, and we would have expected it to actually have gone up at the end of March versus it going down by almost 70%. And then it kind of maintained that level for that period of time for that 4- to 5-week period.

And as I said, this week -- last week, it started to go up near the end of the week. We're starting to see it come up again a little bit this week. And in the U.S. and Europe are actually very similar. They've been trending very similarly. In Europe, what you're seeing is the southern countries are pretty much still in not ordering mode, but in the more northern countries, so Germany, The Netherlands and the Nordic countries, Switzerland, some of those areas are actually -- there is -- they're kind of getting back to work and actually treating patients again as well. So those countries is where you're kind of seeing it over in Europe right now. But the southern countries like France, Spain and Italy, which we don't do a ton of business in those areas, but in general, they're still pretty much in lockdown.

As you look at the United States, I'd say it's more similar to some of the northern countries. But it really is -- depends on where you are in the United States. As I mentioned, the Northeast has been hit very hard. And we have not seen any kind of comeback there yet, but we are starting to see it in pockets of, as I mentioned, like Oklahoma or California, in Minnesota or Texas in places like that, where we're starting to see things begin to open up a little bit. And it's not coming back, like everything is opening up right away. It's slowly coming back. So I anticipate that you'll just kind of get a little bit better every single week as the quarter continues to progress. Does that help, Matt?



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

Yes. That's really helpful, Mike. And then again, either for you, Mike or Andy, just on the OpEx reductions. I think I know the answer to this question. I just want to hear it from you guys. But as far as the investments go, as you think about prepping for convergence going forward, none of the \$25 million reduction that you guys talked about is earmarked for slowing things down as far as adding folks to be able to sell, Convergent more aggressively or education or anything else along those lines?

And then better than that question is how durable is that \$25 million going forward? Is there \$10 million that you found that you -- that you don't think you'll need to spend next year or even in '22 if things are minimalized?

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

I'll answer the beginning part, and I'll let Andy answer the other one. I mean what we've done for CONVERGE and then for aMAZE is that we've really made sure that fortunately for us, we have a great team in place. We did buy SentreHEART last year. So we took the opportunity to accelerate some of the training for that team. So we have a very robust EP team that is ready and in place for when we get that approval. We're cross-training people. We're taking advantage of this time to make sure everybody is cross trained in all of our product lines to be ready for that launch. We will have more than enough people to be ready for when that comes back, and the teams are already beginning to talk and do their planning in their territories, getting ready for when that occurs. And so I'd say that we're super well positioned from that standpoint. Andy, can refer or talk to the other costs if any of them can be saved.

M. Andrew Wade AtriCure, Inc. - CFO

No. I look at things like projects, Matt. So other research and development projects, outside of some of the things Mike mentioned like EnCompass, those things are more deferral rather than thinking about stripping out of the cost structure? So it's just a matter of sort of pushing off as we could navigate through the pandemic time frame.

Operator

Our next question comes from Jason Mills with Canaccord.

Jason Richard Mills Canaccord Genuity Corp., Research Division - MD of Research & Analyst

Mike and Andy, glad to hear everyone's healthy. Can you hear me okay?

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

Yes.

M. Andrew Wade AtriCure, Inc. - CFO

Yes.

Jason Richard Mills Canaccord Genuity Corp., Research Division - MD of Research & Analyst

Super. So I wanted to pick up on the last thought, Mike, about CONVERGE and training and hitting the ground running when and if you get an FDA clearance. So assuming you're on the same time line and assuming you're right that we are back to some semblance of normalcy in and around the fourth quarter, are you anticipating that in 2021 what you had modeled maybe heretofore with respect to site activation, new customers, doing Convergent procedures. At this point in time, are you changing that model? Do you -- have you thought about either focusing a little bit more on certain regions or doing anything differently as it relates to the rollout strategy, specifically in training for CONVERGE post-FDA approval?

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

Yes. I don't think that we've necessarily changed much, but we have taken advantage at the time to solidify business plans and hospitals and where we're going to go first and the ordering of that and also in cross-training people across the business to make sure that we have more and more people trained in understanding both Convergent and then eventually the LARIAT product for 2022. So we've taken advantage of the time to put together a lot of deep internal training as best you can without going to labs to make sure those teams are ready to rock and roll.



So it's going to be a combination of the -- how we've strategized by market. We've accelerated a little bit more on that side, and we basically accelerated some of the cross training that would have otherwise happened. But from a go-to-market standpoint and which ones, that has not necessarily changed. Obviously, we're playing it day-by-day in terms of, one, when do we get the approval because that's not in our control at this point. And then two, is what happens with COVID, does it come back in the fall time, et cetera. Those will obviously be things we'll have to react to at the time when they come. But we're planning as if we're going to get that approval and move forward.

Jason Richard Mills Canaccord Genuity Corp., Research Division - MD of Research & Analyst

Good to hear. So on that last point, as a related follow-up, how do you, at this point in time, model the -- not only the number of sites that will want to activate, but their ability to interest -- I'm sure the interest level in treating persistent Afib has not and will not wane. I'm wondering if you could give us any insight vis-Ã -vis your conversations with physicians or any patient surveys you've done to try to ascertain what the patient response is going to be to coming back into the hospital and also what the physician's bandwidth is going to look like as they're trying to catch up perhaps on some of these procedures, like mitrals and -- you mentioned, et cetera that -- or in the case of electrophysiologists, other -- ablation or other things that electrophysiologists do, pacemakers, et cetera and fitting in new procedures, will that be something that we should think about over the medium term as well?

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

Yes. I think that absolutely is going to impact the medium term. I mean again, it depends on when we get the approval and does the approval come soon after things have gone back to normality or what is the exact time we get that letter. And again, we don't know the answer to that, I mean until it does come. I mean meanwhile, obviously, the data will be coming out next week for people to digest from that standpoint. But in terms of all the nuances and tentacles that you just talked about are absolutely factors that we have to look into and that we have looked at, played out the different scenarios. And we've got to do our best to make sure that we're staying in front of our customers and helping them as best as they can, helping educate them about this.

From EPs that we spoke to and have spoken to throughout, I mean, everybody is looking forward to seeing the data. And then obviously, when we get to the FDA and get the approval, we can then go market more broadly at that time.

So yes, I think everything you just talked about is going to be out there for us to consider, and we'll just have to kind of wait and see kind of how things progress as people kind of have to come back overall.

Operator

Our next question comes from David Saxon with Needham.

David Joshua Saxon Needham & Company, LLC, Research Division - Associate

I guess just another one on CONVERGE. I just wanted to gauge your expectations. So can you talk about what you think the data need to show to be clinically meaningful?

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

Yes. I mean as we've talked about on this call before, we don't really kind of hit on that directly. What we basically say is that we've got to be statistically and clinically significant. That's what you need to look for. If we're statistically significant, it will be clinically significant because the n is so small in 153 patients. The delta has got to be large enough in order to have some clinical significance to hit that statistical number.

So I think that's probably the best way to think about it at a very objective level. The next one to look at is not just the primary endpoint, but it's going to be the -- you're going to want to look at the burden rate reduction as well, and that's going to be something that is obviously going to play into clinician decisions over time also.

David Joshua Saxon Needham & Company, LLC, Research Division - Associate

Okay. Great. And then can you give an update on the aMAZE trial? And I'm assuming there's going to be some sort of delay. So any color there would be helpful.



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

Fortunately, on the aMAZE trial, it happened. We had finished enrollment on December 13 of last year. So fortunately for us, enrollment was complete. We don't have any delay on the enrollment. Now it's on follow-up. We fortunately also have a reasonable window to kind of follow-up on that patient. So we're tracking it literally every day and week looking at what patient is supposed to come back that has hit that I year window that we have to follow-up on. And so we're fairly confident that we won't see too much of a delay in those follow-up procedures and that we should be in a fine position.

So the time behind it, as a reminder, is that the last patient should have follow-up in kind of the March, April time frame of next year. And after that, we will accumulate the data and submit it to the FDA. It took us about 4.5 months to do that with CONVERGE. So you can assume that sometime mid- to late summer, we would be submitting and then working through the fall and into 2022 on getting the approval at that time. And obviously, then there's just the back and forth that is the natural occurrence once it's in the FDA's hands at that time. So that hopefully gives you a pretty good time line of kind of how things are going to basically transpire over the next 1.5 years with aMAZE. But we don't anticipate any significant delays because the enrollment is complete.

Operator

Our next question comes from Suraj Kalia with Oppenheimer.

Suraj Kalia Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst

Hope everyone is safe and healthy. So Mike, Andy, a couple of questions. Mike, let me -- I know this has been asked by other folks also, and I'll try to come at it from a different angle. The first is from a housekeeping perspective. I think so I heard you guys say 70% reduction in the last 2 or 3 weeks in March. I guess I'm trying to understand what is the denominator? Maybe a different way of looking at it is how many regions in your opinion are open? How should we look upon, for example, Q2? What does the 50% reduction mean? What kind of business has done in the last 2 weeks of the quarter? Was it down 70% from that? Just any additional color you all can provide from a housekeeping perspective would be great.

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

Yes. I mean I'll try to do my best for here, Suraj, to give you meaningful information. But when we talk about a 70% reduction we're talking about, if you look at our first week of March, then that week had passed and then you look at the next week, we were down 70% or so in that next week and then the coming weeks thereafter. So it was off of that number. We would have expected that to have gone up. We're not giving weekly numbers. We're not going to get in the game of doing that because quite frankly, doesn't help you out. And there's a lot of different cadences that happen throughout any given quarter. And so if somebody's capable of giving you exactly what they should do on a specific day year-over-year, I think they're -- that's very, very difficult for anybody to do, quite frankly.

So from our standpoint, we looked at it as, hey, what we're doing a week before and did we see a drop. We saw the drop for about that 5-week-or-so period and then we're starting to see it kind of come back.

In terms of the number of places that were kind of shut down, as you say, I mean, for a period of time, there have been very few places were open up in the United States. Originally, you saw a complete shutdown on the West Coast for kind of the March time frame and the beginning part of April. And then you started to see the West Coast begin to come back in line here, not in line, but you started to see some cases get booked and begin to get booked as it became less significant and they started seeing declines. The best thing to do is look at when you hear of places saying that they're allowing elective procedures or they're seeing declines in the number of COVID patients, that's when those places are beginning to open up. The Northeast, I will say, is still pretty much -- pretty shut down. I mean it's just not -- that part of the country is not doing a lot of volume at this point. But other parts and pockets are doing it, especially in the Midwest and on the West Coast right now and parts of the kind of Southeast and southern parts of the country.

Suraj Kalia Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst

Got it. And Mike, a lot of questions on CONVERGE. I think a question was just asked about what you are expecting in CONVERGE. Let me again come at this question from a slightly different perspective. We know the trial design in terms of its statistical significance and you articulated it pretty nicely. U.S. shepherding the company how would you see -- what kind of results you think would lead to a pull-through demand in the field versus a push environment once you get approved? What is it that -- let's say it is statistically



significant. I don't think so anyone is expecting otherwise. What are the key things are you seeing that you would say, "You know what, if this happens, this is going to lead to a pull-through demand in the field beginning, let's say, 2021?"

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

Yes. And I'm going to answer it similar to the way I've answered it before. And I know people want more information. But quite frankly, this is my belief. If it's statistically significant, it will be clinically significant and will provide excitement for a patient population that is not treated today. This is the only trial that has randomized control data for persistent and long-standing persistent patients. If you remember, this trial basically was looking at patients, and you could have basically out to 10 years, you could have an atrium size of up to 6 centimeters. No other trial compares to that. Every other trial on the market is an apples-to-oranges kind of comparison to their single arm.

This is a randomized trial. If we show statistical significance for that really complicated patient population, I feel like you'll get excitement for that patient population once we're able to market it. I mean we're not -- just because the data comes out in a week, that doesn't mean we're able to market at that point. We can't. And we will work with the FDA very closely over the -- as long as it takes to get the approval and to move forward on that. So again, I believe long term, if we get statistical significance, it will be statistically and clinically significant and long term, drive the treatment of some of these really sick patients.

And the other thing to remember is our procedure is a hybrid procedure, which means it's not just our product. There's actually the catheter-based product gets used during the procedure as well. So it's a combination of both that create the very durable and long-standing durability in those lesion sets.

Operator

Our next question comes from Rick Wise with Stifel.

Andrew Christopher Ranieri Stifel, Nicolaus & Company, Incorporated, Research Division - Associate

Mike and Andy, it's Drew on for Rick tonight. I also have a CONVERGE question. So we've heard from multiple specialties that they've been discussing potential post-COVID inefficiencies and recovering their lost procedures. But as you think about bringing Convergent to market, do you think the procedure could be -- adoption, could shift towards a more staged approach as the primary method versus single day? Because it just seems like that might be -- could potentially resolve any inefficiency or logistical considerations the hospital might have as well as maybe allow for easier MIS placement. Just what are your thoughts there?

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

Yes. I mean you can look at how it gets practiced today. The trial was run on the same day. So that is how the trial was run, so the efficacy and everything we're going to be able to talk about is if you're doing it in that same-day setting. To your point, many sites make a decision on their own for logistical reasons that -- and also for maybe the patient benefit for a variety of other reasons as well that they believe staging it is a better form. And today, about 60% of the sites that we work with, they make that decision to stage. We, as a company, are indifferent. However, they choose to do it, in the best interest of their patients or how they can care for their patients is how it happens.

To your point, many of them do that for logistical reasons. It will be interesting to see, with COVID, if -- because of that demand, it becomes more difficult and they do move more towards staging. I'm not 100% certain with that. I think what you do is you wind up getting believers that believe staging is the best way to go and others that believe doing it the same day, and they make those choices on their own. And I think that 60-40 percentage may hold true even after CONVERGE is approved.

Andrew Christopher Ranieri Stifel, Nicolaus & Company, Incorporated, Research Division - Associate

Got it. And then just kind of 2 questions, 2 follow-ups on that. When you -- the 60% are doing stage procedures now versus doing a single day, is there any noticeable difference in their AtriClip attachment rate? I mean you've quoted it before about being 50%, but just curious.



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

To your point, you would think that, that would be the case, but actually, it's not. I mean we have sites that do it same-day to do the clip. It really comes down to how that EP -- if that EP believes and what they believe in relative to managing the appendage and getting it over with and kind of combining that procedure. We do have many sites that do, do it same [day they] put it at the same time. So I wouldn't say that, that is a driving factor at least in the sites today. Now that may change as things evolve and we get out to more sites. But as it is today, I would say that, that's not necessarily the case. It's more dependent upon the EP's concept of the clip.

Andrew Christopher Ranieri Stifel, Nicolaus & Company, Incorporated, Research Division - Associate

Got it. And then just touching on cryoICE here for a moment. You launched the product in basically February 2019. Just hoping to hear how the first year went relative to your expectations. And how is performance trending heading into the pandemic?

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

It's a great question. We've been very happy. We've exceeded expectations overall. Now we setup low expectations for ourselves primarily because we're looking at a new market. And because it was a brand new market, we didn't know how much it was going to cannibalize the old sales that were already happening with it. And so we kind of wanted to balance all that when we set the expectation. What we're finding is we are getting a lot of net new sites. They are trying it, and they're very pleased with the results that they're getting.

Interestingly enough, during COVID, that's one of the products that continues to do reasonably well because they're a part of procedures to get -- a lot of times, they're using it to get patients out of the hospital faster. And so as a result of that, we're getting lots of phone calls from people trying to get them trained to learn how to use the products. And so it's been interesting to kind of see that happen. And see that that's actually been one of the bright spots in our business over the last month or 1.5 months.

Operator

Our next question comes from Marie Thibault with BTIG.

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

I want to ask a quick one on CONVERGE or really more around the approval of the technology. Just wanted to be sure that any of the logistical things like pre-approval inspections and audits that, that can be handled under the new environment? Or if you foresee any delays around that?

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

I don't necessarily see delays with that. Obviously, to be told as to what's going to happen within the FDA. But at this point, we're in very collaborative and active discussions with the FDA. They've been incredibly responsive, and we've been going back and forth on a variety of different matters, and they're continuing to move forward on the audits as well. So we've had many of the audits. The only audit really outstanding at this time is the one of our manufacturing facility, but all the other audits of customers, suppliers, they've continued to be active on that front and feedback. So to date, we have not seen that. I've not gotten any indication relative to that particular group that's working on that -- on our project that, that would necessarily get in the way.

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

That's great to hear. And then last one on HRS and thinking about the data release next week. Typically, these medical societies are kind of a chance for doctors to discuss the data and get a little bit of buzz on and that's a little tougher, obviously in kind of a virtual setting. So I'm curious if the PIs will be hosting things with clinicians to discuss the data in more detail beyond what they're doing with us? And then just generally, if you could frame up kind of the excitement or level of interest for the technology in the field at this point?

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

Yes. I mean we're taking maybe a little different approach on that. I mean the release of the data is as much -- I mean a lot of it's going to be for investors to get the data out into the market. Obviously, it's going to be a scientific session for customers to be able to debate and discuss it. But we are not going to be doing anything other than the scientific session that's there for customers, primarily because while we've got clearance for the product today, we do not have the approval to go promote it aggressively, and therefore, we're not going to be doing that. And so we're not going to be setting up the types of discussions between physicians on that front. At this time, we're going



to let the data speak, and then they can have, obviously, the rich discussions that they need to have in the scientific sessions. We will be hosting an Analyst Day and also Investor very shortly after, so that investors, and our analysts can ask the questions, and we can obviously have people that have been involved in the trial and an independent person, Dr. Calkins from Johns Hopkins, give you their perspective, many of the questions you're asking tonight about how do they see this in the market and rolling out over the next several years.

Operator

Our next question comes from Danielle Antalffy with SVB Leerink.

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

I just had a follow-up question on the recovery curve as you think about that. And I quess especially in the -- I get more the minimally invasive business, that feels a little bit maybe more elective, deferrable, less likely to get made up super quickly. But as we think about the open ablation business, it feels like these are tied to pretty urgent, relatively urgent procedures that you can't really delay all that long. So I guess I'm just curious to get your view on that, sort of piggybacking off the commentary you gave around hoping to get back to normal by Q4. And then I have one follow-up to that.

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

Yes. I mean it depends on the type. I mean CABGs are -- to your point, they are typically more emergent procedures. And -- but like mitral valves tend to be -- I mean if you think about how they're treating and they tend to treat to them earlier in disease state nowadays, those can be delayed and pushed off a little bit further. So interestingly enough, you're seeing more CABGs and the aortics going on now versus the mitrals that are getting pushed out.

And so that's why I think it's going to be just kind of it will come back, but it's not going to come back all at once. And they're obviously going to be talking about the OR rooms, et cetera. But from -- I mean they can push the mitrals off a little bit further, I guess, is probably the thing you should leave with on that front. I can't recall, Danielle, maybe there was a second question that you had.

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

Well, yes, no, I hadn't asked it yet. So you didn't forget anything. So my follow-up and you sort of started to allude to this is from a logistics perspective, is there anything about these procedures that logistically makes it tougher? I think about other service lines like TAVR, for example, and cath labs can extend hours. You mentioned hearing about physicians wanting to extend hours, but you also have to consider capacity at the hospital from a resource perspective, anesthesiologists, et cetera. So is there anything unique to these procedures that your products are used in that could make the logistics a little tougher on the recovery?

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

I mean I think you hit on the biggest logistical issues that I think is it to be told by hospital, how well they're managed and how they're managing their workforce. I think it's going to be a matter of everything you just described. Each hospital is a little bit different in terms of that. And those are going to be the pieces that are going to be obstacles at certain places. Do they have enough staff, nursing staff, anesthesiology, et cetera? Are they willing to work the extra hours during this time? And certain places we're hearing absolutely. Others like you were kind of mentioning, probably, maybe a little bit less so. And so I think that's part of the calculus as things begin to come back and how you want to meter that out.

The other one is just making sure that you've got the rooms available. I think that's probably the other big one, meaning the rooms and then the ICU beds and making sure that they've got enough of those available so that if they're actually operating 6, 7 days a week, do they have enough of that? Can they get patients out of that hospital faster, but also safely as well, they're going to be able to treat everybody. Those are the obstacles that are going to have to be overcome. I don't have a direct answer. I don't know all the answers to that because it's going to be hospital by hospital.

Thank you. And I'm not showing any further questions at this time. I would now like to turn the call back over to Mike Carrel for any closing remarks.



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

Great. Well, again, thank you, everybody, for joining tonight. We remain fully committed to support our people, patients and customers in our communities. Our strong foundation is built to weather this changing period for all of us, and we are well positioned operationally, financially and strategically for the long term. We look forward to talking to every one of you in just over a week. And stay safe, everyone, and thank you for joining us.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.

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