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Q4 2018 AtriCure Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's Fourth Quarter 2018 Earnings Conference Call. (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

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. AtriCure's results may differ materially from those projected. AtriCure undertakes no obligation to publicly update any forward-looking statement.

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, everyone. We are pleased with our fourth quarter results and performance throughout 2018, and we continue our track record of strong, consistent revenue growth.

We achieved many milestones and accomplishments in 2018. We completed enrollment in the CONVERGE IDE trial, trained over 400 health care professionals worldwide, surpassed 170,000 AtriClip devices sold, launched the AtriClip FLEX V device, established a pain -- a dedicated pain management team and raised over $80 million, strengthening our balance sheet and creating financial flexibility.

2018 was also a foundation building year. We are maturing as a team, with more than 150 people in the field, robust training and education programs and a leverageable infrastructure across our entire organization so that we can efficiently scale. We believe the maturation of our teams is reflected in our performance this year, underpinned by our commitment to education, clinical science and innovation as the cornerstones of our success.

With this, and as previously announced, we expect full year 2019 revenue in the range of $220 million to $228 million.

Now turning to our fourth quarter performance. Total revenue for the fourth quarter of 2018 was approximately $53 million, reflecting

growth of 15% over the fourth quarter of 2017. This was highlighted by U.S. revenue of $43 million and growth of 19% to Q4 of last year. Our top line performance was driven by strong sales across our cryoablation and appendage management products.

Within our appendage management franchise, we believe we are seeing continued signs that' the market opportunity remains strong. Surgeons and other clinicians are increasingly recognizing the need to manage the appendage. Our AtriClip products work effectively as they work consistently, becoming the go-to choice for many surgeons.

We are also receiving steady, positive feedback on our innovative approach to advancing products in this franchise to meet clinical needs. Our approach, in conjunction with evolving market dynamics, is collectively driving our confidence in this platform and its potential. We are seeing everything from the AtriClip FLEX V device being used in open cases, enabling more CABG procedures to seeing greater uptake in conversion procedures.

As a reminder, we originally thought the AtriClip attachment rate and conversion would be less than 5%. However, we are -- we currently believe it is over 30%.

Turning to our open platform. Evolving guidelines and emerging clinical data are driving changing behavior. Patients live longer and do better with surgical ablation. It is that simple. This fact is making an impact, driving steady demand for training and increasing adoption. Throughout 2018, our courses were full and we expect the same in 2019.

As part of our commitment to developing clinical evidence, we are investing in the ICE-AFIB clinical trial. ICE-AFIB will evaluate the safety and effectiveness of the cryo ICE ablation system for the treatment of persistent and long-standing persistent atrial fibrillation during concomitant cardiac surgery. The trial is a prospective multicenter, single arm study of up to 150 patients and up to 200 -- up to 20 centers in the United States, enrolling patients with persistent and long-standing persistent atrial fibrillation undergoing cardiac surgery procedures for heart valve repair or replacement and/or coronary bypass procedures. Primary effectiveness is defined as freedom from Afib, atrial flutter and/or atrial tachycardia, lasting greater than 30 seconds and it will be evaluated at 12 months after the procedure. Long-term effectiveness will be evaluated at 3 years post procedure.

On that note, we are pleased to announce the first patient in the ICE-AFIB trial was enrolled in February of this year. We view the ICE-AFIB trial as a unique opportunity to generate systematic clinical evidence on the safety and effectiveness of concomitant cryosurgery for the treatment of Afib patients undergoing structural heart surgery.

Within our MIS business, we had solid performance in Q4. More than 200 sites have now done conversion procedures in the United States. As a reminder, the Convergent procedure is a multidisciplinary therapy in which a closed chest epicardial ablation is performed by a surgeon, complemented by an endocardial catheter performed by an electrophysiologist. The CONVERGE IDE trial is the first of its kind, evaluating the Convergent approach against catheter ablation for patients who suffer from the most serious forms of Afib. As a reminder, we completed enrollment in the CONVERGE IDE trial in August 2018.

Our next milestone will be completion of one year patient follow-up, which we expect in the second half of 2019, followed by a submission to the FDA for premarket approval of the AtriClip EPi-Sense -- or AtriCure EPi-Sense system for the treatment of persistent Afib using the Convergent approach. We expect to be in a position to disclose the data from the trial in 2020, in support of our anticipated FDA panel meeting as part of the PMA process.

We are also pleased to announce that we have received approval from the FDA in the fourth quarter to expand our DEEP AF IDE clinical trial to include an additional 40 patients. The DEEP AF trial provides another alternative for minimally invasive approaches, and we look forward to providing updates as the trial advances throughout 2019.

Switching gears to pain management. We recently announced the launch of cryoICE cryoSPHERE probe in the United States. The cryoSPHERE probe is the first device in the cryoICE platform solely dedicated to blocking pain by ablating peripheral nerves, temporarily blocking the nerves from transmitting pain signals. The block typically lasts several months, during which time the nerve regenerates. Because of the nature of the therapy, physicians are adopting Cryo Nerve Block or cryoNB therapy as a key part of their pain

management strategies, offering a unique solution for patients undergoing cardiothoracic surgery.

More than 80 cases have been performed, with the cryoSPHERE probe, and surgeons are noting remarkable improvement in postoperative recovery times, postoperative pain levels and patient satisfaction. We believe that Cryo Nerve Block Therapy, with the cryoSPHERE probe, also has the potential to contribute to combating the opioid epidemic. One recent study showed that 14% of patients undergoing surgery for lung cancer become persistent opioid users. The cryoSPHERE probe has the potential to reduce the need for long-term narcotic use postoperatively and, thereby, reduce the very real risk of addiction and abuse.

Last year, we established a small dedicated thoracic team to support the Cryo Nerve Block Therapy in select markets. We are seeing the early impact of these efforts, and in 2019, we will expand this team as we move forward with commercial launch of the cryoSPHERE probe.

Further, in support of this franchise, we are on track to complete enrollment in our FROST study in the near future. There are also other clinical studies being done by independent clinicians who are committed to developing the evidence for this novel therapy.

Looking ahead in 2019 and beyond, we are excited about the opportunities across our entire product portfolio and are committed to continuing innovation to deliver benefits to patients worldwide.

Internationally, our revenues were up 1%, constant currency for the fourth quarter. Our overall growth rate outside the United States was impacted by the fact that we did not take an order from China in the fourth quarter.

In Europe, we saw steady progress throughout the year, culminating a top line of 18% growth in the fourth quarter, with solid sales of the EPi-Sense device across the region. We are very encouraged by the maturity and cohesion of the European team and look forward to maintaining this momentum in 2019.

In Asia, we continue to experience strength in Japan, which we expect to transfer into 2019, with both AtriClip and the cryoICE platforms established in the market. Our partnership with Baheal Pharmaceutical Group in China is continuing to progress, with several new sub-distributors on board.

Turning finally to our investments in training and education. In 2018, we conducted a record number of training sessions both in the U.S. and Europe, training more than 400 health care professionals and providers worldwide. During the year, we also significantly increased our cadaver labs at the Maze IV courses to enable hands-on experiences. Through these courses, more than 100 cardiothoracic surgery fellows were trained, exceeding our expectations and target for the year.

In January 2019, at the 24th Annual International Afib Symposium in Boston, we received overwhelmingly positive feedback. We also learned that our Advanced Ablation course has received endorsement from the Society of Thoracic Surgeons. We are confident the support from these -- from leading medical institutions and societies, coupled with educational awareness, will lead to more patients getting access to care that extends and improves their lives.

With that, I will now turn the call over to Andy Wade, our Chief Financial Officer and will return for comments at the end.

M. Andrew Wade ***AtriCure, Inc. - Senior VP & CFO***

Thanks, Mike. For the fourth quarter of 2018, worldwide revenue increased 14.8% on a GAAP basis to $52.9 million. On a constant currency basis, worldwide revenue increased 15.3%. Revenue from product sales in the U.S. was $43.1 million, an increase of 19.1% from the fourth quarter of 2017. Revenue from open chest ablation-related procedures in the U.S. increased by approximately $2 million to $18.6 million, representing growth of 11.9%, driven by increasing volume across all open chest ablation products, with particularly strong results from the cryoablation platform.

U.S. sales of ablation products used in minimally invasive procedures were up 13% to $9.4 million, driven by a robust quarter for the AtriCure EPi-Sense system. U.S. sales of appendage management products during the fourth quarter of 2018 were $14.5 million as

compared to $10.6 million for the fourth quarter of 2017, an increase of 36.3%. Growth was very strong for both the Open and MIS AtriClip product platforms. We continue to be pleased with the performance of our AtriClip V products, especially the number of AtriClip FLEX V devices used in open procedures.

International revenue totaled $9.8 million, down 0.9% on a GAAP basis and up 1.4% on a constant currency basis as compared to the fourth quarter of 2017. The fourth quarter results reflect no revenue from China as we continue to transition to a new distributor -- distribution partner. We expect to have a more normalized order pattern from China throughout 2019.

In the rest of the international business, we saw strong growth throughout Europe, driven by the U.K., Germany and several of our larger distributor markets. Gross margin for the fourth quarter of 2018 was 73% as compared with 71% for the fourth quarter of 2017. The primary driver of the improvement was the change in geographic mix. U.S. sales represented a larger percentage of worldwide sales in the fourth quarter of 2018 than in Q4 2017.

Pricing continues to remain steady across both our product lines and geographies, with a small portion of overall favorability driven by our AtriClip V platform being sold at incrementally higher ASP.

In the fourth quarter, we had positive adjusted EBITDA of approximately $300,000 compared to a $300,000 adjusted EBITDA loss for the fourth quarter of 2017. Our operating loss for the quarter was $2.6 million compared to the operating loss for the fourth quarter of 2017 of $2.1 million. Our loss per share was $0.09 for the fourth quarter of 2018 compared to an $0.08 loss per share for the fourth quarter of 2017.

Note that a $4.1 million noncash credit to operating expenses was recorded in Q4 2018 related to the change in contingent consideration liability. For Q4 2017, we also recorded a $4.1 million noncash credit related to this liability. Without these noncash credits to operating expenses, our adjusted loss per share for the fourth quarter of 2018 was $0.21 compared to an adjusted loss per share of $0.20 for the fourth quarter of 2017. Note that adjusted EBITDA results for 2018 and 2017 both exclude noncash adjustments related to this contingent consideration liability.

Operating expenses increased approximately $6.4 million from $38.9 million for the fourth quarter of 2017 to $45.3 million for the fourth quarter of 2018, excluding the impact of the noncash adjustments to the contingent consideration liability. Research and development expenses, which include clinical and regulatory activities, were $8.5 million for the fourth quarter of 2018 or 16% of sales, an increase of $700,000 from the fourth quarter of 2017. The increase was driven primarily by personnel related costs and development efforts, with the reduction in spending for clinical trials, partially offsetting this increase.

SG&A expenses, excluding the noncash adjustments previously described, increased approximately $5.7 million from the fourth quarter of 2017 to a total of $36.9 million or 70% of sales. The increased results from our continued investment in the commercial organization worldwide and increase in share-based compensation and legal costs, with some offset for lower costs related to marketing and training activities.

For the full year 2018, worldwide revenue was $201.6 million, an increase of 15.4% or $26.9 million over 2017. On a constant currency basis, growth was 14.9%. For the U.S., sales grew 17.2% to $162.1 million. U.S. open chest ablation revenue grew 12% to $72.2 million. U.S. sales of ablation products used in minimally invasive procedures increased 1.8% from 2017 to $35.1 million, driven by increased sales of EPi-Sense products but offset by slightly lower revenue from other MIS products. U.S. sales of appendage management products grew 41.9% to $52.9 million, driven by strong performance of both Open and MIS AtriClip products.

International revenue grew 8.7% on a GAAP basis or 6.1% on a constant currency basis to $39.5 million. European growth was strong in 2018, balancing weaker results for Asia, driven by the China distributor transition.

Gross margin was 73% for 2018 compared to 72.2% for 2017. Loss per share for 2018 was $0.62 compared to $0.83 for 2017, and the adjusted EBITDA loss was $2.7 million for 2018 compared to $5.3 million for 2017. Our adjusted EBITDA loss for 2018 and 2017 both exclude noncash adjustments related to the contingent consideration liability. Without these noncash adjustments, the 2018 adjusted

loss per share is $0.94 and the 2017 adjusted loss per share is $0.96.

We ended the year with approximately $124 million in cash, cash equivalents and investments. In addition to the offering that we completed in October that netted approximately $83 million in proceeds, we also recently amended our credit facility with Silicon Valley Bank, reducing our overall cost of debt. We are planning to file an updated shelf registration with the SEC, concurrent with our 10-K filing as our current shelf is set to expire in June of this year.

Lastly, we are providing guidance for 2019. We anticipate top line growth of approximately 9% to 13% year-over-year or worldwide revenues of approximately $220 million to $228 million on a GAAP basis. We anticipate gross margin to be approximately 73% to 74% for the year as we progress toward our long-term goal of 75% gross margin. The improvement will be driven by both mix changes and cost control efforts.

We expect R&D expenses to be 17% to 19% of sales. Investment in this area include the ICE-AFIB and DEEP AF IDE trials, new and developing clinical science activity, along with R&D pipeline development.

We expect SG&A expenses to be approximately 66% to 69% of sales in 2019. The increase in SG&A expense is again driven by thoughtful expansion of our worldwide sales team as well as increasing investments in training and education, with continued leverage in the general and administrative areas.

We expect adjusted EBITDA for 2019 to be positive, with the range of $0 to $3 million, improving from the adjusted EBITDA loss reported for 2018. This translates into a loss per share between $0.68 and $0.78. As we reported quarterly for 2018 and years prior, we anticipate adjusted EBITDA results will improve as the year progresses. Therefore, while we expect full year adjusted EBITDA to be positive, we typically experience heavy expenses earlier in the year and expect to generate an adjusted EBITDA loss in the first quarter of 2019 of approximately $1 million to $2 million. This adjusted EBITDA loss for the first quarter of 2019 translates to a loss per share in the range of $0.22 and $0.25. Again, we expect to deliver positive adjusted EBITDA for the full year 2019.

At this point, I would like to turn the call back to Mike for closing comments.

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

Thank you, Andy. In closing, we remain confident that our fundamentals and business outlook remains strong. We're extremely pleased with our fourth quarter performance and our track record of sustained, double-digit top line growth. Looking ahead in 2019, we continue to focus on the 3 pillars critical to our mission, which are education, clinical science and innovation. We have created a strong foundation and culture that fosters a patient-first mindset and positions us well for the long term. We are deeply committed to improving the lives of Afib patients globally and remain steadfast in our efforts, and are confident the investments that we have made set us up for strong growth over the next decade.

With that, we will now open up to questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Rick Wise of Stifel.

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

It's Drew Ranieri on for Rick tonight. But just to start on guidance, can you just talk about the puts and takes for your 9% to 13%? It's a little bit wider than maybe your initial guidance versus last year, can you just maybe help us with some of the assumptions there to get us to the higher and lower end of the range?

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

There's nothing specific to say, Drew. We feel really good about the overall business as it stands right now. And we anticipate, obviously, a strong clip as we've talked about before. That clip is on a great momentum path right now, and the ablation business, both Open and MIS are solid as well in the United States. We do anticipate that China will come back in a good way and Europe will remain strong for the year. So I mean, we feel really confident with the overall guidance. It's not that much wider. I think it's a pretty close and similar percentage differential from last year. So I think we're pretty aligned with kind of the way gave out guidance last year.

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

Got it. And then just on the China order for the fourth quarter, the absence of -- is there any way that you can quantify that?

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

It's really, quite frankly, not that material to the over the overall number. It did obviously have an impact on the international growth rate because international growth represents only 20% of our business. So it did have the impact on that, but we don't give specifics by country per se. But we do feel really good about how 2019 is going to come together. Baheal was doing a great job, and we feel like we're in a really strong position there, long term.

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

Got it. And then just on the U.S. MIS ablation business, you had a nice bounce back in the fourth quarter. I understand that you're hampered, to some degree, since you can't cut end market CONVERGE or DEEP. But Mike, what are you focused on commercially in the MIS franchise in 2019? Kind of what's your playbook ahead of the data for CONVERGE in 2020?

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

The focus for getting ready for CONVERGE and getting things in 2020 is really, number one, is as you're aware, we've got a robust clinical education team for the Maze IV program. It's world-class. I talked about on the call today how we just got the STS endorsement. Our team has just done a wonderful job. We're now making sure that we are ready to go with as robust, if not more robust, plan once we get the PMA to begin to rollout that in a more aggressive way at that time. That's really the focus right now, is to get ourselves ready and prepared and make sure that we're doing everything we can to have a safe and effective procedure long term there.

Operator

Our next question comes from Jason Mills with Canaccord Genuity.

Jason Richard Mills ***Canaccord Genuity Limited, Research Division - MD of Research & Analyst***

I'm on the road, sorry about the background noise. Can you hear me okay?

M. Andrew Wade ***AtriCure, Inc. - Senior VP & CFO***

Yes, you're good. Thanks, Jay.

Jason Richard Mills ***Canaccord Genuity Limited, Research Division - MD of Research & Analyst***

Just a little bit about 2019, maybe I wanted to ask more broader, sorry, if this is a [morbid] question, Mike. In 2019, you're going to have a little bit easier comp OUS, the smaller part of your business, you have China coming back. Could you give us, qualitatively, some assumptions in terms of -- relative to your guidance, well, OUS, do you see it growing within that range? Is it a faster growth in that range, or slower growth in that range? And as I think about the U.S., tell me if I'm thinking about this wrong, the appendage management can grow faster than the guidance range that you've given on the overall basis. It seems like the MIS, I think, you've been cautious with respect to growth rates there until you have a label. So I'm thinking about that as perhaps about lower end of the range, if not a little lower -- lower end of the range, with -- that would be maybe a source of upside. And then Open, I suppose we think about it on the mid-to high single digits. But wondering -- and the second part of my question is pain management. What's the opportunity as for incremental revenue for pain management? And correct me if I'm wrong, pain management is going to be recorded within Open. So sorry about all the questions in there, but I think you get the gist.

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

Okay. There's a lot back in there, so I'll start with the first one. Good thing I wrote things down here. So on the OUS side, in terms of the growth rate, we anticipate that the growth rates, both for OUS and U.S., will be within the range. I mean, it will be consistent across that when you blend the various different companies, the puts and takes on all side of things. And we do anticipate that both will be at around that 9% to 13% range. So that's kind of how I would articulate that. As you look at the U.S., you are correct that on the clip side of things, that is our primary -- I mean, our fastest-growing franchise. We anticipate in 2019 that, that will continue to be our fastest-growing franchise for the year. As we look at the other ablation pieces of it, I think will be solid for the year. You mentioned it on the MIS side, you're right. It could be -- it's a little bit more volatile, overall, on a quarterly basis. But I think as we look over at the course of the whole year, I think Open and MIS will be reasonably consistent. And then, when you talked about pain management, we don't have a ton in there on pain management at this time. We are excited about the opportunity. It's really a big 2020 opportunities to build out the team this year, maybe the back part of the year as things begin to roll out. We've just rolled out the new product. We've got the team in place now that's beginning to go there. We're ramping up that team in the first half through the third quarter this year. And we anticipate, probably I want to have a ton of impact of revenue this year, but for sure, should have an impact on revenue in 2019 for us. And then I think the last one you asked was around the -- where it's going to fall in terms of an external reporting basis. We're actually still working through how that's going to come out, whether it's going to be in the Open or in the other bucket. But we'll make sure that we'll talk about that in the next call.

Jason Richard Mills ***Canaccord Genuity Limited, Research Division - MD of Research & Analyst***

Okay. And I was struck by the attachment rate in CONVERGE, Mike. I love your -- more color on your thoughts there, I'm guessing your pleasantly surprised. But tell me if I'm thinking about this incorrectly. Longer term, you talked about the MIS opportunity as being the largest TAM. And if the CONVERGE -- if the attachment rates for appendage management stays at this level, the TAM for appendage management is fairly low penetration as well, even as it stands today after a big run. Do you expect the attachment rate to moderate some over time? Or as you get into 2021, '22, and you see, hopefully, the data are good and the business builds in MIS, do you see appendage management's growth continuing to be strong, in large part because of its attachment rate to the MIS?

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

I think you're asking a real fair question around on the clip, and the clip has continued to be an incredibly strong performer for us. We do anticipate that the attachment rate will continue to be strong and only grow, more and more data is coming out. There is positive data about managing the appendage and that's obviously helping that franchise. We do know that our product works, and it works incredibly well at closing off that appendage. And so -- and we're looking for other types of advantages with the clip as well from a labeling standpoint as we look into future years. So we're excited about the clip opportunity. You're absolutely correct that we anticipate attachment to continue to grow in the -- not only this year, but into 2020 and 2021. On top of that, we've continued to innovate better in it. It's tough to really talk exactly what dollar amount is related to, really, innovation that we do. But bringing out the V clips, the new handle base, it has really made it much easier for more surgeons to be able to use our products on a more regular basis during their other procedures, and that's really driven a lot of our growth as well. It's just that consistent innovation. People know that we're dedicated to this area. This is what we do every single day, and that focus is really paying dividends for us.

Operator

Our next question comes from Mike Matson with Needham & Company.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

I guess I just wanted to ask about the penetration of the newer V versions of the AtriClips. And I don't know if you'll give us a number, but just as you start to lap the launches there, I don't remember the exact timing on that, but do you expect those to continue to contribute to a favorable mix in that business?

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

Great question. On both sides of it, we do see the PRO V, which was the one that we launched originally, that was the first one that is for the MIS side of things. We see more and more attachment to 2 different types of procedures, the conversion procedure for sure. So as CONVERGENT grows and as we gain attachment, the PRO V is really the preferred route that most people are taking down that path. On top of that, and also for patients that are undergoing mitral valve surgery, and they kind of go to transfer sinus from the right side when

they're doing many mitrals, that is another area where we see the V is the preferred method over the other one, just because it's got a much smaller profile and easier to get through those tight spaces. So that's really kind of getting new surgeons on board, relative to that. On top of that, on the FLEX V, that product is just so easy to use. It's got an automatic release of the clip on a -- where before you had to basically cut the sutures, it's made it a lot simpler. It's also -- ergonomically, doesn't put as much pressure on the hand. So we're seeing that people that just weren't willing or wanting to use the clip before because it was (inaudible) and more difficult to use, are now basically getting into that area. A lot of them are going into the CABG patients, so we anticipate that, that will continue to grow as well for the foreseeable future and be a big contributor to us, long term.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

So I guess, the short answer is that the mix that you're getting from the higher price of those products can carry on beyond just the kind of first 12 months of the product being on the market -- products being in the market.

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

Yes, there's a little mix in the price, but I mean, most of our growth, quite frankly, is volume-based. I mean, we have a volume based -- so that is getting into new procedures. Yes, there are more procedures, but quite frankly, the other thing is that people that used to use the old product, they are still using the old product. We're not necessarily taking them out because they're liking it, they're happy with the cost or happy with the results because it's a wonderful, wonderful product. We still sell more of that product than anything else. And so -- I mean, the volume has to continue to pick up for a long time, the prices are really a small portion of it. It's really -- we're getting new cases that we just didn't get before.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Yes, okay, got it. And then there was a comment made about the CONVERGE data being released in advance of a panel in 2020. So does that mean that we're definitely not going to see it in 2019? Or that's just where your best guess is right now for timing?

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

I don't imagine you'll see it. I mean, it's -- just a walk-through timeline, I think that's helpful for everybody because -- just to make sure there's complete clarity on the timeline of this. So the last patient we treated was August 21, 2018. Therefore, the last patient to be treated -- or the follow-up is going to be within 30 days of that, give or take, both either before or after. So, say, sometime end of August, early September, that patient will get treated. We'll then compile all of the data in the fourth quarter and then we'll be ready to go to the FDA. There's are really 2 paths with the FDA. We might have to go to panel or we don't go to panel. If you don't go to panel, and you don't get the approval, you'll get the date and time of the approval. If you go to panel, and you have to obviously -- you're presenting the results on that front, then you will release the data, basically, the day you're going to panel, and that's typically how they've done it in the Afib space. If you look at all of the other catheter-based technologies that were approved paroxysmal, that's exactly how they release the data, and we will be consistent with that to make sure we're in line with how the FDA wants to look at it. And again, this is all estimated, but -- so what do I anticipate? We anticipate sometime in 2020. Not the end of this year per se because we'll be compiling the data to send the information to the FDA.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Okay. And then just, finally, I wanted to see if you could talk a little bit more about the cryoSPHERE probe launch and the team that you've put together there, maybe the size of it if you want to disclose that. How many reps you're planning to add this year?

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

Yes, so we've built up a small cryoSPHERE team last year, the Cryo Nerve Block team last year. Obviously, they had the existing probe versus the older probe. The purpose-built probe was just rolled out 2.5 weeks ago with our sales team as we announced, and also, we're extending that team. We had 4 reps last year. We anticipate at least doubling that this year, with the potential growing larger than that to make sure that we're covering all the cases in getting into those spaces. So we're going to build out that team commercially, continue to invest in clinical data and getting more clinical data. And that team is really focused on the thoracic market. And so we're pretty excited about it. But again, we think it's going to take kind of the beginning part of the year as your -- really kind of make sure we're getting that launch up and running and going. But we do think, long term, it's going to have great results. On patient number 1 and number 2, it should have some good results for our financials.

Operator

Our next question comes from Matt O'Brien with Piper Jaffray.

Kevin Michael Farshchi ***Piper Jaffray Companies, Research Division - Research Analyst***

Mike and Andy, this is Kevin on for Matt today. My first question is on the MIS side. If I look at some of the numbers, I think it decelerated a little bit if you look at the comp adjusted basis for 2018. Is there anything specific to point out there? And then going into next year, as some of the clinicians are waiting for on-label, do you anticipate any kind of a slowdown as that dynamic plays out? Or could you just help us think through the growth rate currently, and then kind of going into '19.

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

I mean, we talked about earlier -- first of all, I just want to make it really clear. I mean, our products are on-label today for cardiac ablation. So they're being used on label today. What we're doing is we're going for a more advanced label, and that's really what allows us to get more aggressive in some of the training programs, et cetera, that we talked about. So that's really kind of what this data is going to help provide when we go to the FDA, et cetera. As it relates to the growth rates, we anticipate -- we've talked about it before. Because of that, and we're not able to kind of go full throttle on things for obvious reasons, what we have to do is -- it's a little bit more volatile on the MIS side, but we anticipate that the growth rates will be consistent with what the growth rates were in the U.S. -- I'm sorry, with the Open business, overall, and that the clip business will drive the upside, overall, for the range that we gave on the 9% to 13%. But we're not going to get specifics by a different category like that.

Kevin Michael Farshchi ***Piper Jaffray Companies, Research Division - Research Analyst***

Okay, that's still helpful directionally. My last question is -- and most of mine have been asked, but I don't think that this is that big of a deal because you're so underpenetrated in CABG. But how do you think about the business in terms of surgical volumes, i.e. on the aortic side with the upcoming TAVR low-risk data? Is this something that you think about as a company? Just kind of walk us through that and how you think about it, if you do at all.

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

Of course, we think about it because, obviously -- I mean, we have to be thinking about all the different procedures, where patients have Afib and surgical AVRs or patients that have that. We're going to basically have to figure out, obviously, as they go in that area. But quite frankly, the markets are so big and we're so underpenetrated today across the board. Still less than 30% of the patients that have Afib, that are on the operating table, are not getting treated. Now the good news is that number is up considerably from 5, 6 years ago when that number was closer to 15%. And so we anticipate that we're going to continue to work with our education and training programs to get greater and bigger attachment. Like you said, CABG is a big opportunity for us. Quite frankly, even AVRs are a big opportunity. Patients that have Afib, it's been shown that if you have Afib, you actually should get treated and should go down that AVR path. And so more and more of the Afib patients are kind of getting sent to surgery as a result of that. And so a lot of the patients that are going in for the TAVRs, if they've got the Afib, they're typically not getting treated and they're going to be pushed over to the SAVR side of things. That's not the case in every institution. Sometimes, we'll do follow-up Afib procedures later on. And so the way we look at it is that there's a huge underpenetration issue here. We've talked about that for years and gotten that question. We still think it's underpenetrated, and we still think there's lots of opportunity for growth on the Open side of our business.

Operator

Our next question comes from Rebecca Wang with SVB Leerink.

Fan Wang ***SVB Leerink LLC, Research Division - Associate***

So I want to ask a high-level question. You're a nice ICE side of the business. So now you guys already have CONVERGE complete the enrollment and then you made progress in the DEEP trial. So what is the role of the DEEP procedure in MIS? And how should we think about, now you have 2 procedures in this business?

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

It's a great question. So we -- philosophically, the way that we're building the business is to be able to provide a lot of tools for the physicians to choose from. And so some physicians do like the DEEP procedure a lot better. There's a huge cohort of electrophysiologist

and cardiologists that believe that, that is the right procedure. So we're investing in that clinical trial to get the advanced labeling on that side. It is a market in and of itself. And then for a little less invasive approach, conversion is really where that comes in and for EPs that kind of one thing out the back wall and deal with the substrates associated with that. So it comes down to EP preference. Some sites actually offer both, so they can be able to offer that to their patients. I see that happening more and more today because patients want choices, and these hospitals want to be able to provide those choices, especially the larger institutions want to be able to be a full-service to be able to say you can get -- you can basically choose between these different items. So that's why it's really important for us to have both and to get the data associated with both, so that they can make really concrete decisions relative to that.

Operator

Our next question comes from Suraj Kalia with Northland Securities. Okay, I'm not showing any further questions at this time. I'd turn the call back over to Mike Carrel.

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

Again, everyone, thank you for joining. I look forward to seeing many of you as the year progresses at the various different conferences and congresses. Thank you, and look forward to a great 2019.

Operator

Ladies and gentlemen, this does conclude today's presentation. You may now disconnect and have a wonderful day.