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Q1 2019 AtriCure Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's First Quarter 2019 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've not received a copy, please call 513-755-4136 to have one e-mailed to you.

Before we begin today, let me remind you 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 measure 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. We have started 2019 with a solid first quarter of 15% revenue growth, our 26th straight double-digit growth quarter. We again had meaningful contribution from our appendage management products, launched a Why Treat marketing campaign focused on concomitant ablation, and made excellent progress along multiple operational initiatives.

Our team continues to deliver strong, consistent revenue growth, driven by our patient-first culture, technologically advanced products and investments in innovation, clinical trials and education. Coupled with the diverse nature of our business and vast under penetration of concomitant ablation in all types of major cardiac surgery, we are confident we are well-positioned for continued growth.

We are seeing in the field that evolving guidelines and emerging clinical data are driving behavior change, leading to steady demand for training and increasing adoption of our products. Demonstrating our confidence in our business, we are pulling up the bottom end of our 2019 guidance, which we now expect to be in the range of $222 million to $228 million, corresponding to growth of 10% to 13% for the year.

Now turning to our first quarter performance. Revenue for the first quarter of 2019 was $54.0 million, reflecting 15% growth over the first quarter of 2018. This was highlighted by strong performance in the U.S., led by our appendage management products and international growth of 28% compared to 2018 first quarter.

Our appendage management franchise continues to outperform with first quarter growth of 32% year over year. We have now sold over 180,000 AtriClip devices worldwide. We anticipate this business will be our fastest growing franchise for the foreseeable future. In the field, we receive 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 long-term potential.

On the minimally invasive side, we are seeing the attachment rate in convergent procedures increase steadily. On the open side, we are approaching the 1-year mark of having AtriClip FLEX V device available in the U.S., and we are hitting our stride as it's being used in incrementally more open cases, especially CABG procedures.

Turning more broadly to our open ablation platform, guidelines and emerging clinical data are driving changing behavior and increasing adoption. We continue to see a large opportunity in open procedures and are sustaining our investments in training and education to address this market.

As one might expect, we have gotten several questions over the course of the last few months on low-risk TAVR and what it means for our business, so I'd like to take a minute to address this. As a starting point, this is something that we have factored into both our guidance, and more importantly, how we think about our business going forward. So from that standpoint, we don't foresee impact to our short or long-term expectations.

At a higher level, though, we can also break down the market to what the potential impact could be. Based on market data, there are approximately 55,000 surgical aortic valve, or AVR procedures, annually in the United States. Roughly 16,000 of these patients have Afib. Of those, 25% are treated. This means the remaining 12,000 patients that are already on the table today are not getting treated, and the guidelines say that they should be.

Taking this dynamic aside for a moment, if 100% of the surgical AVR market were to migrate to TAVR, we estimate that less than 7% of our business would be impact. This, of course, is not expected to happen. The overriding factor here is pushing trends in the upward direction is the dramatic under penetration that I referenced earlier. So even if that 16,000 patient number sees downward pressure, it is more than offset by the large under penetration prevalence that still exists. This penetration gap is even larger when we look at the CABG market where there are 160,000 to 180,000 procedures every year. Of those, about 40,000 have Afib and only 10% are getting treated today.

Our opportunity in open procedures is real and is large. With the combination of updates to guidelines, our innovation, education and training, we are just scratching the surface still. We just launched our Why Treat marketing campaign, which we believe will bolster adoption even further.

As mentioned on our last call, we began enrollment in our ICE-AFIB clinical trial in the first quarter of this year. We have 3 sites activated and are on track to add several more throughout this year with additional enrollment following. The ICE-AFIB trial is a unique opportunity to generate systematic clinical evidence on the safety and effectiveness of concomitant cryo surgery for the treatment of Afib patients undergoing structural heart surgery. We are confident our continued commitment to developing clinical evidence will support growth in the concomitant treatment and allow us to educate and train at a much deeper level for better treatment and better patient care.

Within our MIS business, we experienced some softness in the first quarter. Our MIS results continue to fluctuate quarterly due to a small number of sites comprising a relatively large portion of the MIS volume. We expect this trend of quarterly volatility to remain until we receive the FDA approval for the EPi-Sense system using convergent approach, and we have factored this into our guidance for the year.

As a reminder, our last patient in CONVERGE trial was treated in August of last year. All CONVERGE patients are followed for 1 year post treatment. We will then work with our principal investigators and be in a position to submit the data to the FDA as part of an application for premarket approval of the AtriCure EPi-Sense system for the treatment of persistent and longstanding persistent Afib using the convergent approach.

As we've disclosed previously, for planning purposes, we are anticipating an FDA panel and would expect to disclose the data around the time of that meeting. Until then, we continue to make investments in our training programs. We currently have a team of clinical experts well versed in the EPi-Sense system and who understand EP well. That team will be prepared to ramp up our outreach and education programs quickly upon receipt of the PMA for treatment of persistent and longstanding persistent Afib patient population.

We are also pleased with the progress in our DEEP AF IDE clinical trial, which as previously mentioned received FDA approval to include an additional 40 patients. As a reminder, DEEP AF provides another alternative for minimally invasive approaches, and we look forward to providing updates as the trial continues to advance throughout 2019.

Our investments in these prospective clinical trials continue to bolster our position as a leading innovator in the market. We expect that upon the successful conclusion of these trials, we will be able to market our technologies and therapies as a comprehensive platform for a dramatically expanded group of physicians and patients.

Now, switching gears to pain management. We launched a cryoICE cryoSPHERE probe in the United States in mid-February, and we are already seeing good activity from this product. As a reminder, the cryoSPHERE probe is the first device in the cryo platform designed specifically for Cryo Nerve Block. In Cryo Nerve Block therapy, the cryoSPHERE probe is used to block pain by ablating peripheral nerves. This prevents peripheral nerves from transmitting pain signals for several months during which time the nerve regenerates. Physicians are adopting Cryo Nerve Block therapy as a key part of their pain management strategies, offering a unique solution for patients undergoing cardiothoracic surgery.

Last year, we established a small, dedicated thoracic team to support Cryo Nerve Block therapy in select markets. The team is currently up to 7 people -- a manager and 6 therapy awareness reps -- and we expect this number to expand as the year progresses. We are receiving positive feedback from our customers, and we expect the cryoSPHERE probe to offer significant opportunity as we look to 2020 and 2021 and beyond.

Turning to our investment in training and education. This quarter, we have continued to drive adoption of surgical ablation in the concomitant setting for our AtriCure-sponsored educational programs, as well as collaborations with professional societies. We talked earlier about the STS guidelines and the impact of our ability to speak with surgeons about that requirement to treat. Also though, the guidelines are enabling us to further accelerate our training programs. We have expanded our list of KOL trainers around the country, and our courses are almost completely full. As we announced earlier this year, STS has endorsed our training program, which is a strong statement on the quality of such program.

We're also having an incrementally larger presence at scientific meetings. Just last month, we were at the International Symposium of Left Atrial Appendage, ISLAA, 2019 meeting. In past years, AtriClip devices were part of the clinical discussion. But this year, the AtriClip line was featured prominently in discussions, symposia, live cases and presentations and was an important part of the overall conversation.

Turning now to our international performance. We had strong results with revenue growth of 28% in the first quarter. In Europe, we saw particular strength from the UK, France and Germany with AtriClip and EPi-Sense devices driving the momentum. In Asia, we are now seeing consistent order patterns and expect strength in those markets throughout the year. While international business represents roughly 20% of our overall revenue, with investments in the past years, we expect it to be consistently steady and strong grower for the business.

Overall, we are pleased with the maturation of our team and our business, and we're off to a strong start to the year. With that, I will now

turn the call over to Andy Wade, our Chief Financial Officer, and I'll return at the end for closing comments.

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

Thanks, Mike. For the first quarter of 2019, revenue increased 14.8% on a GAAP basis to $54.0 million. On a constant currency basis, worldwide revenue increased 16.0%. Revenue from product sales in the U.S. was $43.0 million, an increase of 11.9% from the first quarter of 2018.

Revenue from open chest ablation-related products in the U.S. increased by approximately $1.4 million to $19 million, representing growth of 8.1%, driven by solid cryo probe growth and the including the launch of our new cryoSPHERE probe.

U.S. sales of products used in minimally invasive procedures was $7.8 million in the first quarter, down 9.9% and continuing the trend of volatility on the low volume of this business.

U.S. sales of appendage management products during the first quarter of 2019 were $15.7 million, an increase of 32.8%, driven by very strong growth of the AtriClip FLEX V device. We remain confident in strong and sustained growth rates for our appendage management products.

International revenue grew to $11.0 million, up 28.1% on a GAAP basis and 34.4% on a constant currency basis as compared to the first quarter of 2018. As a reminder, we had no sales to our distributor in China for Q1 of last year. Outside of China, starting to return to a more normal order pattern, we had strong growth throughout Europe, particularly in the UK, France and Germany. Appendage management in our international markets had a very strong quarter at 36.5% growth year over year.

Gross margin for the first quarter of 2019 was 73.9% as compared with 73.4% for the first quarter of 2018, due primarily to improvements to operations and lower costs, partially offset by unfavorable geographic and product mix due to a higher concentration of sales in Asia and other distributor markets. We are making strong progress toward our long-term goal of a consistent 75% gross margin.

In the first quarter of 2019, we had an adjusted EBITDA loss of $605,000, compared to a $3.3 million adjusted EBITDA loss for the first quarter of 2018. Our operating loss for the quarter -- for the first quarter of 2019 was $5.3 million compared to the operating loss for the first quarter of 2018 of $9.4 million. Our loss per share was $0.15 for the first quarter of 2019 compared to a $0.31 loss per share for the first quarter of 2018.

Note that a $1.7 million non-cash credit to operating expenses was recorded in Q1 2019 related to the change in contingent consideration liability. No adjustment was made in the first quarter of 2018. Without this non-cash credit to operating expenses, our adjusted loss per share for the first quarter of 2019 was $0.20 compared to the reported loss per share of $0.31 for the first quarter of 2018.

Operating loss for Q1 2019 would have been $7 million without the credit, compared to the reported $9.4 million loss for Q1 2018. Note that adjusted EBITDA results for all periods exclude non-cash adjustments related to our contingent consideration liability.

Operating expenses increased approximately $3 million from $43.9 million in the first quarter of 2018 to $46.9 million in the first quarter of 2019, excluding the impact of the non-cash adjustment to the contingent consideration liability.

Research and development expenses, which include clinical and regulatory activities, were $8.2 million for the first quarter of 2019, or 15% of sales, a decrease of $900,000 from the first quarter of 2018. The decrease was due to lower expense related to the timing of product development project activities and lower clinical trial expense. These decreases were partially offset by higher expense from increased headcount for product development, regulatory and clinical activities, and increases in various operating costs.

SG&A expenses, excluding the non-cash adjustments previously described, increased approximately $3.8 million from the first quarter of 2018 to a total of $38.7 million, or 72% of sales. The increase results from our continued investment in the commercial organization worldwide, an increase in share-based compensation and other operating costs, with some offset for lower costs related to legal activities.

We ended the quarter with approximately $101 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, heavy trade show spend and internal training meetings.

Lastly, we are adjusting our guidance for 2019 by pulling up the lower end of our previous revenue range. We anticipate top line growth of approximately 10% to 13% year over year, or approximately $222 million to $228 million on a GAAP basis. We continue to anticipate gross margin to be approximately 73% to 74% for the year. The improvement over 2018 gross margin 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 includes 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 a range of 0 to $3 million, improving from the adjusted EBITDA loss reported for

2018. This translates into an adjusted loss per share between $0.68 and $0.78. Consistent with prior years, we anticipate adjusted EBITDA results will improve as the year progresses. We expect to generate positive EBITDA in the second quarter of 2019 of approximately $500,000 to $1.5 million. This adjusted EBITDA for the second quarter of 2019 translates to a loss per share in the range of $0.15 to $0.18.

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 are extremely pleased with our first quarter performance and our track record of sustained, double-digit top line growth. We are confident we will continue on this trajectory for the foreseeable future. Our platform of growth is diverse, and we continue to focus on the 3 pillars critical to our mission, which are innovation, clinical science and education. With that, I'll now turn it over to questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question is from Danielle Antalffy from SVB Leerink.

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

Mike, just to follow up, thank you so much for the color on the surgical aortic valve market. I was wondering if to maybe dig a little deeper into that, you could talk a little bit about there's obviously 3 different markets for your open ablation business: mitral, aortic and also CABG. And I think you've talked in the past about CABG being the fastest growing. Wondering if you can give any color about sort of how the growth breaks down amongst those 3 markets to maybe put people even more at ease that -- my sense is that CABG is really the growth driver here, so any color you can add there would be great. And then I have one follow up.

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

Sure. I can't give you specific data on a quarterly basis because it takes time for STS and others to kind of report all that data. So typically you're looking back at the wrong times on that. But I can tell you from surveys that we've done with our sales force in the field that CABG is absolutely where the growth is. That's where our focus and efforts are around training. People that are coming to the courses are all coming on the CABG side. So that's really where a vast majority of the growth that we've got today is coming. And we've also got new innovations coming on the pipeline likely next year for that CABG market to make it even easier for those physicians to treat the CABG patients as well. So it's under penetrated, less than 10% today of the market, and it is definitely the fastest growing. The mitral valve and TAVR market had been I'd say relatively consistent overall and growing a little bit, and obviously offsetting some of the pressure on the TAVR side like we had expected. But like you said, CABG is the largest one, without giving too many specifics on it.

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

Yes. No, but that's very helpful. And then my one follow up is as we think about CONVERGE coming and the potential FDA panel meeting sometime in the first half of 2020, can you talk about or give us, I assume you guys talk at least somewhat frequently with FDA, what we should expect as far as the issues that FDA could raise at the panel. Are they going to be more focused on efficacy or safety? Is it going to be both? Because my sense is that we all know this is effective and also pretty safe. So just curious what FDA is going to be focused on at a panel meeting just to sort of give people a heads up as to what to expect when that comes to fruition. Thanks so much.

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

Really fair question, and I think you've hit on them. They are going to look at both safety and efficacy within the trial in terms of what events might have happened, what do our rates look like relative to other trials that have happened and the catheter rates. Like you said, it's an incredibly safe procedure. Convergent is well in line, quite frankly, with just using a catheter by itself. So quite frankly, I think what they'll look at is how much efficacy are you getting for basically no difference in safety. I think that will likely be the conversation and the risk/benefit in the conversations that we'll be having with the FDA. Obviously you have to wait to find out what those specific numbers

are. We've got a very good handle and understanding of the safety side of things, and again, feel very good that it's going to be about just the benefit that you're getting off of it, because on the safety side, you're right; it's an incredibly safe procedure.

Operator

Our next question's from Rick Wise from Stifel.

Rick Wise

Mike, just it's hard not to take notice the fact that you're starting -- you're feeling incredibly confident about the outlook for the year. Obviously you had a strong first quarter this year. You actually started off last year with a strong first quarter. I was just wondering just at a high level, why the confidence to sort of raise numbers at this point in 2019? Is it the data? Is it the momentum in the business? Is it some of the new products? Is it the performance of U.S. ablation? I'd just be curious to hear at a high level what's making you so much more incrementally confident this year as you look at the year ahead.

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

Yes. As we looked at the bottom end of the range on that -- so it's a really good question, Rick -- is we looked at that and said we just have a tremendous amount of confidence looking at what's happening. We just finished a quarter at 15% growth, well above the overall range, and we looked at that bottom end and just mathematically thought -- we feel incredibly good about what's going on within our clip business. The open ablation business is doing very well. And well cryoSPHERE, we're really looking at having impact at the kind of 2020, 2021 time frame. We could see some upside on that later in the year as well. And so those are the kinds of things that kind of get us and make us bullish overall for our business. Those are really the big drivers at this point. International has obviously been solid and is in a really conformable space and has been very consistent over the last 9-plus months. And so that consistency also give us some confidence on that as well.

Rick Wise

And you also emphasized the guidelines, Mike. The STS guidelines have been in place for a couple of years now, and I know some of the societies have over the last year or two raised their level of evidence, et cetera. And you indicated that guidelines are driving change in behavior. Maybe talk a little bit more detailed about how are you seeing the changing, evolving, strengthening, stronger guidelines translate into business, and again, that that's making you call it out now as a factor. Thank you.

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

It takes time for guidelines to work themselves through because they get published. People then have to go to training classes to actually learn how to use it. So it's really encouraged that surgeon that was doing a CABG and maybe not doing an ablation to say, hey, you know what, there really is benefit to doing it. Not only is it safe, these patients live longer and do better and the guidelines are telling me that I should do it. And then so what happens is our guys go in, they show them the papers, have those conversations with them relative to that, bring them to training courses. Our training courses continue to get better. We've added cadaver labs at the end of every one of them now. Those kinds of things just over time begin to build momentum in the market in the space. And so when I say the guidelines, it's that continuing drumbeat that basically occurs that our team has those conversations in the field at the scrub sink, et cetera, that drive that overall long-term behavior and the changes. Now, it doesn't happen overnight. It continues to happen and it's -- you're converting kind of one surgeon at a time. And that's why the Why Treat campaign is now coming out as well now is that's going to -- we're going to continue to provide further ammunition to show the benefits of treatment and why patients do better. Most importantly, this is about patients doing better, and people are seeing better and better results when they do the procedure properly. And so they get the data, it leads to trending, that leads to more patients being treated.

Operator

Our next question is from Robbie Marcus from JPMorgan.

Robert Justin Marcus ***JP Morgan Chase & Co, Research Division - Analyst***

I thought that was a great way to frame the discussion on the metrics you gave about the 7% exposed to the business. And I also think it's really interesting that there is still so much opportunity of the patients that are on the table not having the treatment today for ablation. So what do you see as something maybe in the near to midterm that you can do as a company, or whether it's you or the societies or how you drive it to increase that penetration in the already existing market that exists today?

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

That's a great question. There's several items that we can do. I'll start with the Why Treat campaign that we've just rolled out. So we've been pulling data from not just the guidelines, but more and more publications have come out over the last 2 years showing the benefits of treatment. And we've launched the campaign to our entire sales force globally about why it's important to treat, why these patients do better. And we've done a really proactive campaign, both at the surgeons first and then also at the cardiologists that are referring to show the benefits to the patients that they're referring to get them to treat and kind of move down that pathway of actually helping those patients out long term. That's kind of step one is this continued drumbeat of awareness, awareness, awareness, and we're doing a lot of work from a marketing front on that to kind of create that awareness. Two is to continue to advance our advanced courses. Many of the people that come to our courses are people that have been 2, 3, 4 times. They come back for more because they want to get taught right here from different teachers from different experts in the field. They come back to learn. They come back to get their hands on cadaver labs to kind of get better. And so we have to continue to really advance that, again, worldwide. We're doing it over in Europe and in the United States. We've really expanded our education in Europe. We'll train almost as many people in Europe as we will in the United States. This year, the team has just done a remarkable job on that front. And then longer term -- I know those are more short-term items, meaning they're things that we're actively doing right now. Longer term is very specifically for the non-atriotomy cases, which is primarily the CABG cases. For those cases, it's about -- it's also continuing to look at our technology and come out with technology that makes the procedure easier. So our technical team is looking at that. And I feel like if we look out over the next 18 to 24 months, we'll be in a good position to have a product that'll make it even easier and to increase penetration longer term in that CABG market and really take advantage of it. So you've kind of got a hit on all those different fronts. And then finally I would say is, and it relates to training, but we talked about the ICE-AFIB trial, which is that there are some surgeons that are doing this procedure with cryo only today. And the ICE-AFIB trial is really geared towards those surgeons that are doing that to make sure they're doing it right, get the clinical data out there on that. Almost all the clinical data out there today is using RF technology plus cryo. What this enables us to do to have a broader body of evidence covering all of our products, but also allows us to do deeper dives in the training to help them do a good job if they're going to do a cryo-only device. So hopefully that gives you a sense for the breadth of activity that we have going on in the company to kind of attack that market.

Robert Justin Marcus ***JP Morgan Chase & Co, Research Division - Analyst***

Great color. And then on international, even when adjusting for the year-over-year that maybe there wasn't a million or so in China sales first quarter 2018, it was still a phenomenal growth rate. So maybe just walk through the puts and takes and how sustainable that growth trajectory is here. Thanks.

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

Yes, as you said, it was strong across the board even with that China adjustment, like you mentioned. And it's really strong in particular in Europe, but it was strong across the board. I mentioned Germany. The UK in particular we're very strong. We saw lots more clips and a lot more EPi-Sense being sold there. We've put a dedicated team that's focused on MIS over there now, and that's really starting to have an impact across the continent. We started that last year. The other thing I mentioned, and people talk about it, but the team there is really beginning to gel. They've been working together real closely for 2, 3 years. And now you're starting to see that the maturation of that team. They understand the markets, they understand how they're selling and how to create that market. And that's really driving a much more consistent growth coming out of the European market for us across all of those countries. We've got great leadership over there, and I'd say that's really driving a lot of the consistency that we saw in the first quarter and we anticipate for many years to come, quite frankly. If you look at the other markets in Asia, you mentioned China and Japan. Japan's just been consistent for many years. And we really look at them on an annual basis as opposed to a quarterly ordering pattern, and so -- but they were strong for the quarter, they were solid, but we anticipate a really good year out of Japan coming again. They're the second largest country in the world. They've got clip and cryo in those markets now, and it's -- that continues to get high level of adoption.

Operator

Our next question's from Jason Mills from Canaccord Genuity.

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

So first question generally about guidance and the calculus behind your guidance. So let me put it into context. It looks like the midpoint of your range, just looking at the trends in each of your businesses over the last several quarters, it's sort of high-single digits, mid to high-single digits, open U.S. Appendage management's been growing faster, but if we're modeling 25% thereabout going forward, and then flat MIS, which has got some volatility, with 10% international growth, which you did better than this quarter, you'll -- that's kind of the midpoint. So I suppose the question is, is that -- in general, I probably oversimplified it, the calculus that goes into your guidance. And then you're going to see upside as you drive these programs in the nearer term in open ablation. And then if you just continue to see 30%-plus growth in appendage management and perhaps some kicker outside the United States, that's where the top end comes into play. Do I have the calculus in part right?

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

Yes, I think that's an in general fair characterization of kind of the franchises of the business and in terms of kind of where we sit. And there's the upside that you talked about and the gives and takes, but I think that's a fair overall assessment of it.

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

Okay. And then so I guess just a two-part follow up question. Where would you, and based on your field feedback, where do you feel the most confident perhaps seeing some more strength relative to that midpoint of your guidance going forward? It would seem like it would be open in appendage management, but I'll not put words in your mouth. And then the second unrelated part of my follow up is on the CONVERGE. And sort of following up on what Danielle was asking, I'm getting increasing number of questions from investors about this space, and more specifically the historical context from a data perspective. In other words, what does the literature say about treatment success rates for this patient population historically, and what do you think clinicians would respond to positively when they see the CONVERGE data set? If you can be at all quantitative based on what the historical literature says, that'd be helpful. Thanks, Mike.

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

Yes. So kind of the confidence, as you mentioned, and it hopefully came across on the call today, we've got confidence across the diversity of the business in general. I think that's probably the primary piece that we've built a really diverse base of business that allows us to be double-digit revenue growth when you start to add up all the pieces and the gives and takes in any given quarter. And especially as you kind of look out for the year, that gives us great confidence because you just got a lot of cylinders going across many different areas. So for one quarter something isn't quite as good, you've got this balance across those that I think really provides for a really strong long-term business for us to continue to see double-digit revenue growth for a long time. That being said, if you want a specific area, the clip is obviously an incredibly strong juggernaut for us right now. We're doing really well in that space, and we continue to see momentum in that area. We saw it in the first quarter. The products are very well received, as I mentioned. The innovations that we've come out with, the way they've been adopted, we just continue to see increasing activity in that space. And I'd say that probably gives you the most confidence relative to overall hitting the numbers as well. As it relates to CONVERGE, I think it's an excellent question. Like you, we've definitely gotten more and more confidence -- or more and more questions on the data. When you look at the data that's out there in the market relative to CONVERGE and how CONVERGE was kind of put together, if you look at the 2017 HRS consensus statements, and that really indicates kind of a 30% to 40% treatment effectiveness in what would be our comparator arm, the catheter only. It really depends on which exact lesion set that you do. When you look at some of the data relative to that, it was closer to 30%. But if you look at some of the more recent ones, when you're trying to do some linear lesions on it, you get to mid-30s. So I'd say that that 30% to 40% is kind of consistent across the literature with the forceps and catheters and others that have been out there in the market. You may see single center data that might be better in one person's hands, but when you look at the consensus statement, I think the 2017 consensus statement really states it pretty strongly there. When you look at kind of what's going to be clinically relevant when it comes to market, it's not going to be just the endpoint I do not believe, because more and more of the EPs today are talking about Afib burden and durability of the lesions that they have. A lot of people do this because they like to do this substrate reduction. They really take out that back wall. They believe that that has much stronger durability to this. And they're not necessarily looking at that pinpoint number, per se. So I think they're going to look at a multitude of factors when they actually make their clinical decisions, and it's going to be looking at a combination of what is Afib burden look like? What does -- how much -- I'm not adding any risk, but I get some benefit. What does that

look like and how does that affect my clinical practice and the referral profile, et cetera? I think that's what you're going to start to see, and it's going to come down to really logistics, at the end of the day, and how do I make it work in my hospital and things like that.

Operator

Our next question's from Mike Matson from Needham & Company.

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

Just wanted to start out with the minimally invasive business. I understand the comments around volatility, but it was down a bit more than we've seen in some time, particularly in the U.S. So, just want to make sure that you don't have any of the physicians that are kind of backing away from the procedure, anything like that. And then just looking over the longer term, it's never really been like a real high-growth business. Is that just mainly because you're sort of handcuffed by the lack of the FDA approval, and that's what should really change once you get the FDA approval hopefully next year?

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

Yes, to answer the last part, absolutely, I think that's the biggest piece, which is that upon getting the FDA approval, that obviously gives us a lot more armamentarium to be able to discuss and push the procedure. Right now we're more reacting to sites that want to do this back wall ablation. We're capable of doing that. And so you're right on that front. The volatility is, like we saw, if you look at Q3 last year, we were down 13%. Then we had a big -- we were up 10 -- plus 10% or so in the fourth quarter. We were down this quarter. That's kind of the volatility. It's going to be up and down, depending on the patient flow at some of these sites. And again, without that -- when we get that FDA approval and we kind of move down that path, I think that'll -- we'll be able to control that and the market becomes a lot bigger. It's an absolutely enormous market. These patients are not getting treated today. And even if they are trying to treat them, the first-line therapy, it's not very durable. So they have to come back at a later date. And so there's nothing fundamental going on within the business there, quite frankly. We've got a lot of really good sites and they're comfortable with the procedure, and so it's just a matter of kind of patient flow. And again, once that FDA approval comes in, I think that we'll be able to treat more patients at that point.

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

Okay, thanks. And then just wondering if you could give us more color on the cryoSPHERE launch. And then just curious which category you're putting that revenue into. I thought I heard Andy say it was in the open heart category, but I just wanted to make sure that was right.

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

Yes, most of the activity -- it's only been on the market for 6 weeks now, so it's not really about revenue right now. It's just about we're getting lots of activity from sites who are trying it out for the first time. They're testing the products. We anticipate that for the first 6 months. We'll do a lot of that, and we want to make sure people are trained properly on it, using it correctly. And we're getting really good feedback from the sites that are using it, and they kind of want to test it and then kind of see how it comes together. So right now, it is in the open business, like you mentioned. And we'll look at where the geography in the future, but for right now it's sitting in the open business yet.

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

Okay, thanks. And just with DEEP getting restarted here, do you have any sense for timing on that in terms of when you could potentially complete the enrollment, or is it just too early to tell?

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

It's really too early to tell, Mike. I'd love to be able to say that. We are enrolling patients. We've enrolled, as we've talked about, the first patient we announced earlier this week. We've had a couple of other enrollments since then. We anticipate having up to 8 sites or so enrolling by sometime in early Q3 or so. And so we've got the sites kind of getting back to the IRB process right now. So we're kind of in that initial phase. As we learn more, we'll kind of update everybody on that, but I don't have an end date on it right now. But it is good in terms of a lot of these sites. I'm really excited that we're still committed to this. These are people that are committed to treating this way, and they're really excited that we're still committed to providing this solution for patients.

Operator

Our next question's from Matthew O'Brien from Piper Jaffray.

Matthew Oliver O'Brien ***Piper Jaffray Companies, Research Division - MD and Senior Research Analyst***

Just quick housekeeping. When will we know the timing of the panel? Is that kind of a Q3/Q4 event we'll actually know the timing of the panel?

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

At this point, I don't know that. I'd be rendering a guess at this point in time. So we'll finalize the -- we'll pull the data together in the fourth quarter of this year likely and submit sometime some of the information in the early part of next year, and then it'll be up to the FDA to come back. I don't want to hazard a guess at this point.

Matthew Oliver O'Brien ***Piper Jaffray Companies, Research Division - MD and Senior Research Analyst***

Okay. Fair enough. I have two questions. First of all, on the calculus question that Jason had earlier, I look at the performance of the international business this quarter, very strong. And then I look at the comps that you have in the U.S. business for the back half of this year. So isn't it fair to think about -- I just want to make sure I'm modeling things appropriately -- that most of the, or the biggest chunk of growth this year probably will come OUS, especially in the back half of the year with the U.S. maybe quote-unquote decelerating with tough comps? Is that the right way to think about that? And then within that question, as far as the appendage management business goes, how do we think about you lapping that clip launch early last year and being able to drive growth there?

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

I'll hit on both of those and let Andy kind of chime in as well. When it comes to the overall growth, we actually think there's going to be balanced growth across the whole -- across geographies. We were stronger this quarter for sure, but if you look at the overall growth rates, I think we'll by the end of the year be relatively consistent within a couple points of each other. There won't be far exceeding one way or the other. Maybe international will be a little stronger because of the China scenario, but beyond that, I think you'll see overall relative consistency between Europe and the U.S. for sure. As it relates to the clip, what we're seeing is volume increases. And most of the growth that we're seeing is actually coming from volume increases and not necessarily from any kind of pricing changes. We're actually just getting more and more clips sold. We get a little bit of bump, but it's not much. And I don't see -- the lapping is going to be, last year we grew 40%. Now we're at 30%. Obviously, we're not predicting or saying that we're going to be growing at 32% every single quarter, so there might be some little pressure on that. But we are really bullish on the volume that we're seeing as well, so we feel comfortable with it as a business.

Matthew Oliver O'Brien ***Piper Jaffray Companies, Research Division - MD and Senior Research Analyst***

Okay. And then last one for me. It's a two-parter for Andy. Andy, there was more currency impact this quarter than I thought. And actually you guys grew 16%; not 15% when adjusting for currency. So how do we think about the impact of currency throughout the course of this year? And specifically, wouldn't the 10% to 13% growth rate that you've guided to actually been higher? And the same kind of question goes for EBITDA, not necessarily on the currency side, but Q1 is typically your low water mark for EBITDA. It was much better than I was modeling. Why shouldn't we expect something closer to the higher end of the range you've guided to?

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

Yes, Matt. We try to do our best with the currency rates. The FX rates don't typically take a real strong stance going one way. So we kind of think about the rest of the year around where we are today. As far as the impact on EBITDA, because of our general being around EBITDA positive, the FX tends to affect both the revenue margin side and the expense side, so we're a little bit in a unique spot at this point there. Hopefully that makes sense to you.

Matthew Oliver O'Brien ***Piper Jaffray Companies, Research Division - MD and Senior Research Analyst***

Yes, fair enough. Thanks so much.

Operator

Our next question's from Suraj Kalia from Northland Securities.

Suraj Kalia ***Northland Capital Markets, Research Division - MD & Senior Research Analyst***

Pardon the background noise. I'm on the road. Andy, Mike, look; when you look at the different buckets of your business, you guys have done a phenomenal job in terms of managing the different buckets. Maybe you can give us some color. How do you view new store sales versus recurring or same store sales? I guess what I'm trying to understand is any -- directionally any color you can provide, look; this is what a recurring business looks like, this is what new biz every quarter looks like, so that we can somehow start mapping it as some of these structural changes in the market come online?

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

Yes, and what we -- I'm not sure that I can give you an exact number there, Suraj. And I know what you're looking for, and I wish I could say it would be a perfect dynamic from that standpoint. We do sell to -- last year we sold into over 1,024 cardiac surgery centers in the United States out of the 1,050. So we're selling into just about everywhere. So a lot of what we're doing now is expanding within sites to get to more surgeons to treat. That's really the focus now, because we're in just about every site with at least one of our products. And so our focus is we're no longer getting new sites, per se, as relationships. We're getting them to expand and expand usage. So they might be using the RF clamp today and we get them to use the clip. Or they're using the clip and we start to get them to use something else. And so we're kind of expanding within products and within each surgeon, and then we're expanding the number of surgeons as well. If they've got 5 surgeons at a site and 2 are doing the procedure, we're trying to get after the other 3 that aren't treating. And that's kind of been the focus. A big part of the focus of the Why Treat campaign is to really kind of make sure we've got more blanket coverage across every surgeon in the United States and having that kind of impact. So it's kind of the best -- that's how we think about it and how we're attacking it, but it's more difficult to kind of do a same store sale, per se. We obviously look at what the dollars look like, but usually that's a retrospective look as you typically have to look at that once a year after the data comes out, and by then, we're far ahead in our planning to looking forward in terms of what's going on and putting things in place.

Suraj Kalia ***Northland Capital Markets, Research Division - MD & Senior Research Analyst***

Fair enough. And Mike, one last question. This question about the hybrid procedure was asked, and I believe it was Jason that asked about how the clinicians, how would they look upon the efficacy data. Let me flip that question a little bit. So next year, when the data comes out for the hybrid procedure, one of the things that we keep picking up in the field is all the clinicians say Suraj, I love the reimbursement. I'm getting upwards of 50k for the procedure. Can you venture to give us some goalposts in terms of, you know what, this is what the delta and incremental efficacy -- and I mean efficacy; not safety -- would have to be to justify this level of reimbursement? I guess, I think it's almost well understood right now that this procedure is safe, we are going to have excellent level of efficacy. I'm just trying to understand that delta X where you can get a healthy reimbursement and be able to be off to the races. Thanks for taking my questions.

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

Yes, the reimbursement for various procedures is out there today, so I'm not sure exactly how to answer that question specifically, Suraj. I'd say that, again, I think it's going to come down to multiple factors in terms of how they're clinically treating and what's in the best interest of that particular patient. They're going to look at their -- I believe once all the data comes out, they'll look at, again they'll look at the Afib burden. They'll look at the fact that, again, it's safe and that they're getting a lot of durable, long-term benefits to it. It's not just about the 1-year data. I think you'll wind up seeing more and more data come out at 2 and 3 years, more and more papers coming out with that as well. As many of you may know, we've got a registry called Track AF, and we're tracking much of the data not just at 1 year, but 2 years and 3 years, and the data is very strong on that front. And again, I think that that's what clinicians will be looking at is both the long-term data, the Afib burden. They will be looking at 1-year data, of course, but I don't think there's going to be one pinpoint on that. So that's kind of I guess the best way that I know how to answer that question at this point.

Suraj Kalia ***Northland Capital Markets, Research Division - MD & Senior Research Analyst***

Fair enough. Thanks.

Operator

Thank you. At this time, I am showing no further questions. I would like to turn the conference call back over to Mike Carrel for closing remarks.

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

Great. Again everyone, thank you for joining us and look forward to talking to many of you out in the field and at next quarter's call. Have a great one. Bye.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the program. You may now disconnect.