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ATRC - Q3 2018 AtriCure Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to AtriCure's Third 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 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 today. We had another solid quarter marked by several significant achievements. During Q3, we completed enrollment in our CONVERGE clinical trial, surpassed the 150,000 milestones of AtriClip devices sold worldwide and made excellent progress along multiple operational initiatives. We also recently strengthened our balance sheet and created financial flexibility through a public offering, bringing net proceeds of over $80 million.

Total revenue for the third quarter was approximately $50 million, reflecting growth of 18.5% over the third quarter of last year. Our top line performance was largely driven by the strength of our appendage management products with that franchise continuing to demonstrate accelerating

growth. As a result of this continued momentum, we are updating and raising our guidance for 2018 to revenue expectations of $198 million to $201 million for the year.

Starting first with our CONVERGE IDE clinical trial, we completed enrollment in August with 153 patients. Patients were enrolled at 25 sites across the United States and 2 in United Kingdom. I would like to thank the many AtriCure employees supporting this trial as well as the study sites and the principal investigator, Dr. David DeLurgio for their tremendous efforts that have brought us to this important milestone. The CONVERGE study is the first of its kind, evaluating the convergent approach against catheter ablation for patients who suffer from persistent or long-standing persistent Afib, the most serious forms of atrial fibrillation. As a reminder, the CONVERGE approach is a multidisciplinary therapy, in which a closed-chest epicardial ablation is performed by a surgeon, complemented by an endocardial catheter ablation performed by an electrophysiologist.

Our next milestone will be 1-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 AtriCure appendage system for the treatment of persistent Afib using the CONVERGE approach.

Switching gears briefly to pain management. Earlier this year, we established a small, dedicated thoracic team to focus on this opportunity in a few select markets. We are starting to see their impact already as we push forward efforts with the development of a pipeline of products. We expect to launch a new dedicated pain management cryoprobe, optimized for intercostal nerve block procedures in early 2019.

On the clinical science front, we are on track to complete enrollment in the near future in our FROST trial. There are also many critical studies by independent clinicians who are committed to developing evidence for this novel therapy. We are particularly excited about the prospect that our pain management products may reduce the use of opioids in some patient populations.

Moving to operational performance. We are continuing to build out our pipeline of products and platforms. Today, we are seeing the benefit of our development efforts, most meaningfully in our appendage management franchise. Since launching the AtriClip PRO V device in the U.S. late last year and the AtriClip FLEX V device in March of this year, the cumulative effect has been a drive in increasing volumes and has also enabled us to expand into new accounts while maintaining our strong pricing. Additionally, we are experiencing halo effect across our business and incremental adoption of left atrial appendage management in all of our open procedures.

Internationally, we had strong results with revenues up 16.2% in the quarter. We are at a point that we have a cohesive team and critical mass in Europe, particularly in the key country that we serve. In Asia, we continue to see strength in Japan and are confident that we are well positioned with our new partnership with Baheal Pharmaceutical Group in China. We recently returned from a visit into these markets and came away impressed with the teams and confident in our multiyear distribution agreements. In China, we are also in a process of pursuing additional product approvals over the next several years to eventually bring our full portfolio of surgical ablation and left atrial appendage management devices into the market.

Finally, I will turn to another important pillar of our business, training and education. We are on track to complete a record number of provider training sessions in 2018, both in the U.S. and in Europe, and we have already started planning for 2019. As we discussed in our last call, we have expanded our programs to go beyond just the surgeons and electrophysiologists and now include a higher mix of nurses, fellows and other health care professionals. Of particular note, our fellows program is going extremely well and we are expanding it further in 2019. There is a large impact in getting to clinicians early in their career and educating them on the benefits of treating Afib in managing the left atrial appendage. We have also added incremental faculty to the training team with specific focus on adding Afib treatment to CABG procedures. In addition, we have significantly increased our cadaver labs at the Maze IV courses to enable in-depth discussions and hands-on experiences. We are gaining momentum with our training courses and programs laying the groundwork for long-term growth through broad awareness and education. We continue to believe that clinician data from leading medical institutions and societies, coupled with education and awareness, will ultimately improve patient care and support growing procedural volumes.

The clinical community is increasingly recognizing the benefits of surgical ablation and the management of the left atrial appendage and the downside of nontreatment. As such, we remain well positioned to drive and take advantage of these market tailwinds.

With that, I'll turn the call over to Andy Wade, our Chief Financial Officer, and will return later for closing comments.

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

Thank you, Mike. For the third quarter of 2018, revenue increased 18.5% on a GAAP basis to $49.9 million. On a constant currency basis, worldwide revenue increased 18.6%. Without the hurricane impact to the third quarter of 2017, we estimate our growth was approximately 16%, continuing the strong growth trends this year. Revenue from product sales in the U.S. was $39.8 million, an increase of 19.1% from the third quarter of 2017. Revenue from open chest ablation-related products in the U.S. increased by approximately $2.6 million to $18 million, representing growth of 16.9% driven by increasing volume across all open chest ablation products. U.S. sales of products used in minimally-invasive procedures was $7.9 million in the third quarter of 2018, down 13% and reflecting soft results across MIS products, including a decline in EPi-Sense device volume for the first time. Notably, this decline is in comparison to a very strong third quarter of 2017. We are encouraged by the number of centers buying the EPi-Sense device, which has stayed strong. We continue to expect some volatility in our MIS business. U.S. sales of appendage management products during the third quarter of 2018 were $13.5 million as compared to $8.5 million for the third quarter of 2017, an increase of 59.2%. This increase was driven primarily by volume across AtriClip product lines and boosted by a moderate pricing impact from strong sales of both the AtriClip FLEX V and Pro V devices, which carry higher average selling prices than legacy AtriClip products. As we discussed in the third quarter last year, the appendage management franchise was disproportionately impacted by weather events in 2017 with Florida representing our largest U.S. market for this franchise. Excluding the estimated impact of hurricanes on 2017, our third quarter results still reflect the strong growth rates seen in this franchise throughout 2018. We continue to remain confident and robust and sustained growth rates for both open and MIS appendage management products.

International revenue grew to $10.2 million, up 16.2% on a GAAP basis and 16.9% on a constant currency basis as compared to the third quarter of 2017. We had solid performances from Germany, the U.K., France, Australia and in some of our smaller markets in Europe. Similar to U.S. results this quarter, appendage management products led growth in our international markets.

Gross margin for the third quarter of 2018 was 72% as compared with 73.4% for the third quarter of 2017. The current quarter included a onetime charge of approximately $500,000 for share-based compensation driven by the retirement of an operations team leader. Without this charge, gross margin would've been in line with our expectations at approximately 73%. We had an adjusted EBITDA loss this quarter of approximately $457,000 compared to a $958,000 adjusted EBITDA loss for the third quarter of 2017. Our operating loss for the quarter was $6 million compared to an operating loss for the third quarter of 2017 of $6.8 million. Our net loss per share was $0.22 for both the third quarter of 2018 and 2017. Note that a $780,000 noncash credit operating expenses was recorded this quarter related to a change in the contingent consideration liability. Without this credit, the third quarter of 2018 adjusted loss per share was approximately $0.24, and we had an adjusted operating loss of $6.8 million.

Excluding the impact of the noncash adjustments to the contingent consideration liability, operating expenses increased 13.3% or approximately $5 million from $37.8 million for the third quarter of 2017 to $42.8 million for the third quarter of 2018. Research and development expenses, which include clinical and regulatory activities were $8.6 million for the third quarter of 2018 or 17% of sales, a $600,000 increase from the third quarter of 2017. SG&A expenses increased approximately $4.4 million from the third quarter of 2017 to a total of $34.2 million or 69% of sales. The increase was primarily due to personnel additions in our domestic and international sales organizations as well as an increase in variable compensation costs due to strong revenue performance, and partially offset by lower meeting and demo product costs. We ended the quarter with approximately $40 million in cash, cash equivalents and investments, up approximately $3 million from the second quarter. We completed a stock offering on October 10, which generated net proceeds of approximately $83 million. We anticipate bank paying down debt during the fourth quarter.

Lastly, we are updating our guidance for 2018. We now anticipate full year 2018 revenues in the range of $198 million to $201 million on a GAAP basis. We continue to anticipate gross margin to be approximately 72.5% to 73.5% for the year with the bottom end of this range representing a slight increase from the 2017 gross margin. We continue to make investments on our operations to support growth, and we are still targeting long-term gross margins of 75%. We expect R&D expenses to be 17% to 19% of sales in 2018, a slight improvement compared to 2017. Significant investment in this area include the CONVERGE IDE trial, other clinical science activities and product development programs.

We expect SG&A expense to be approximately 65% to 67% of sales in 2018, which includes the noncash adjustments to the contingent consideration liability recorded this year. The overall increase in SG&A expenses is mainly driven by expansion of our worldwide sales team and training and education expenses along with heavier legal expenses. We now expect an adjusted EBITDA loss for the full year 2018 in the range of $1 million to $3 million, primarily due to continuing legal costs related to the DOJ matter as well as efforts associated with our China market distributor transition.

While lower than originally expected for 2018, it is an improvement from the 2017 adjusted EBITDA loss of $5.3 million despite the incurrence of significant unplanned legal cost in 2018. This translates into a loss per share between $0.69 and $0.74 for 2018 and an adjusted loss per share range of $0.89 to $0.94 excluding the adjustments made to the contingent consideration liability in the second and third quarters.

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. Before closing, I want to take a quick moment to acknowledge the many employees at AtriCure who have been personally affected by atrial fibrillation. We showcase some of these stories as part of a social media campaign throughout September as part of Afib Awareness Month. We've historically used this month to generate -- to help generate interest and awareness about the work that AtriCure and others do to educate physicians and improve patient lives.

Continuing on that momentum that we have built over the last few years, we utilized all of our social media profiles to tell a story about Afib and AtriCure's role in furthering solutions to solve the global Afib epidemic. We are deeply committed and remain steadfast in our efforts.

With that, and in closing, we remain confident that our fundamentals and business outlook remains strong. We are extremely pleased with our third quarter performance and are on track of sustained, double-digit, top line growth. Our current product portfolio and focus on clinical data, education and the development of an innovative pipeline collectively position us well for the long term and will benefit patients worldwide for many years to come. Our mission is simple. We are intent on decreasing the global Afib epidemic and healing the lives of those affected. With that, I'll now open up to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Danielle Antalffy with Leerink Partners.

Danielle Joy Antalffy - *Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices*

Just wanted to push a little bit on -- I'm not expecting you to give the 2019 guide, of course, but if we look at what you've done so far year-to-date, I mean, you've driven accelerating sales growth in each of the quarters in the mid-teens range, in the first half of the year on tough comp. Obviously, comps in 2019 get tougher. You don't have CONVERGE approved yet. How do we think about the sustainability of the current growth rate? Because it does feel like there is momentum in the open ablation business as well as appendage management. So I can point just positives and also tougher comps and not having minimally-invasive yet, just wanted to get your view on how you're starting to think about 2019? And how sustainable you think current growth rates are?

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

Yes. I think you hit on it pretty well. I mean, obviously, we're -- we feel very confident in the overall health of the business in terms of where we're going. Now we are 24th straight quarter of double-digit revenue growth. Like you said we have some acceleration and some really strong points in the appendage management portion and open has been very strong in contributions given the guidelines of the training that we continue to do and kind of the expansion of that market overall going after the CABG space that we've talked for the last several years so, but you're right. I mean, on the MIS front, I do think that we do have some volatility to some degree relative to looking at waiting for CONVERGE to get the approval and other things like that. So I think we're optimistic about next year without giving any kind of specific top line guidance, but I don't know that I would get too far ahead of myself at this point in time.

Danielle Joy Antalffy - *Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices*

Got it. Okay. And then just a follow-up question on your sales comments. Could you talk about -- I know price has been helping on the AtriClip side of things, can you talk about what was volume versus price specifically in this quarter? If anything was notable there?

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

Yes. Vast majority of the impact on the appendage management is volume, and we're seeing tremendous volume in that part of our business across, in fact, the fastest growing portion of it is our -- as I was mentioning before, there this halo effect that's going on because of the treatment of the appendage. I think that the -- our AOD, which is the original clip is actually one of the fastest-growing pieces of our -- of that clip franchise and doing very, very well. And so price is having a small impact with the Flex V and the Pro V having impact on the market, but it is a -- vast majority of the growth is really on the volume.

Operator

Our next question comes from Jason Mills with Canaccord.

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

So first question on the appendage management. I know last year was an easier comp weather related, but if we sort of average that comp out a little bit and assume that if the run rate last year was looking like it would have been for -- in the U.S. appendage management, let's say, $9.5 million, is still accelerated growth of about sort of pseudo- comp, if you will. And just curious, I hesitate to ask if this is a new normal for growth in that business because I know that you'd probably say, no. You wouldn't want us to be modeling sort of 35%, 40% kind of growth, but maybe talk about it in terms of the opportunity and talk about it in terms of the breadth of the product line and the extent to which you can continue to add accounts in the sort of the components of the growth that you see confidence going forward?

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

I mean it's a great question, and I think you hit on it right. I mean, I don't want people to get too far ahead of themselves on it and I would caution on kind of saying anything is a new normal. These are incredible growth rates. They are indicative of, quite frankly, a strong market. I mean, there is -- if you think about it from a market standpoint, a big portion of this is actually happening in our open business, and we're just getting more and more attachment to ablation procedures and to these CABG procedures. People are wanting to and feeling that it's necessary to treat the appendage on a regular basis. There are 900,000 cardiac surgeries in the world every year. We view that as our total market opportunity. Last year alone, we sold 34,000, so we just scratched the surface in the market. You can get a sense for obviously will be well above the 34,000 this year overall and I feel like we're going to continue to make progress marching towards that front. Some of that's going to come from the great pipeline. We've rolled out really innovative new technology over the last year with the V clip and the access through trocars in less invasive environment, also easier to manipulate in tighter spaces that make it easier to put on. It's got some automatic release capabilities that make it simpler for the surgeon to use. All of those things really lead to adopting and putting it into new accounts and new surgeon's hands that otherwise had previously not been using it. It's also a much smaller profile as well, so a lot on the technology front. In addition to that, we continue to gather data and we continue to look at data that is in CMS and other places and all the papers that are being written to basically show that managing the appendage is the right thing to do and so I anticipate more of those papers coming out over the coming years to continue to help bolster and build the clinical data portfolio there. So and we'll continue to innovate in this space as well. We don't have a new clip coming out in the next year or so, but we are making less invasive clips to come out in subsequent years and so we're in a really good position. We feel like we're coming into this coming year in a strong way. But again, like you said, I don't know that I will get too far ahead of myself.

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

So only -- good follow-up on that, Mike. That's helpful. It almost feels like as you talk about the target market being the total number of cardiac procedures, it's almost like the message is if you cut the patient, clip the patient. I'm wondering -- obviously, you'd like to do Afib ablation on a good majority of those patients because a good majority of those cardiac surgery patients have Afib. But in lieu of that, do you have a marketing initiative underway given that the appendage management tends to be a bit more superfluous perhaps as an opportunity ablation to target those physicians that have heretofore been reticent to do ablation? Maybe you'll get them eventually, but the appendage management is something you can lead with in accounts where you haven't had success in ablation as of yet. And I have one more follow-up if you allow me.

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

Sure. Yes, I mean, we do have conversations with sites around appendage management on a regular basis and are they managing the appendage in these Afib patients on a concomitant basis? What are they doing to do that? Do they want a simpler and easier way? And if all they're doing is managing the appendage today, the clip is obviously a great way to do that. It is a starting point for many people, as you described, especially, if you don't want to open up the atrium. I'd say that is a natural place for many of the surgeons to begin the process of kind of developing their Maze IV skills with the goal of eventually having a full Maze IV ablation and the clipping as well so they've got it all on those Afib patients. I am indicating that as you look long term and more broadly speaking at the market, that we do believe that long term that there are a lot of benefits to managing the appendage. If you've got the patient open, it is a very efficient way to do it, incredibly safe. We've got over almost a 160,000 clips implanted in patients today so we know that it's incredibly safe product. We do believe that there are benefits there, and we just got to get the clinical data done to kind of prove that. We don't -- so I do view that as when you think about the overall large market long term, and I'm thinking long term, that is a -- that's critical for us longer term.

Operator

And your next question comes from Mike Matson with Needham & Company.

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

This is David Saxon, on for Mike. I guess, congrats on the CONVERGE enrollment. Just wanted to start on CONVERGE. So at the Analyst Day, Dr. DeLurgio presented data on his first 100 patients. And I mean, the data looked pretty good. So I was just curious given that CONVERGE's 153 patients, how many of the -- those patients are coming from out of Emory?

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

These are small portion of the overall patients. It's 153 patients total. 102 patients were in the treatment arm and the control arm with the other 51 patients. To give some context to it, I believe he was around 10 or 13 total. I don't know his mix between surgical and not and just in catheter only. So I couldn't give you that specifically.

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

Okay. And then I guess, following up with the equity offering, I mean, it looks like you'll have a good amount left over after you pay down some debt. Any thoughts on M&A? And I guess, whichever go up the AF care continuum into kind of cardiac monitoring?

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

On the first one in terms of M&A, I mean, we've raised the money very specifically to create flexibility in our balance sheet and to make sure that we could be opportunistic if the right type of opportunity came up. We've done 2 acquisitions successfully over the last 6 years, and we would look

opportunistically. That money doesn't itself allow us to just go by. Somebody just gives us flexibility to possibly look at the right time. I mean, and but we don't -- nothing to announce or discuss at this point in time relative to that, but it does give us the flexibility to be able to in the future. In terms of kind of going upstream, I don't have any specific comments on getting into the data market at this point in time.

Operator

Your next question comes from Matthew O'Brien with Piper Jaffray.

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

Just and forgive me, I'm bouncing around calls a little bit, so I may have missed this. But the U.S. MI ablation number was a little bit light versus what we were expecting. I think you said that the EPi-Sense catheter sales this quarter were lower than you've seen before. I'm just curious if there is anything specific that you're noticing there and it may have led to that modest softness? I don't know if TCT being in September versus October had anything to do with it, but just any commentary on that would be helpful.

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

Yes. There's nothing specific. I think it's just order patterns within that particular area. If you get 1 customer that kind of get the bolus of patients and -- or the opposite. It's a more concentrated area than our open business or even our clip business in terms of the number of people buying from us every single quarter. So you can have swings in a particular account but there was nothing specific that we're concerned about long term. But that's also why we talked about this a little bit more -- difficult to predict the exact numbers in that area while we got strength in the other 2 pieces of our business quite substantially.

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

Okay, Mike, that makes sense. And then as far as the appendage management goes, I know there are some questions on this, and it sounds like it's volume related, but -- which is great to hear, but the halo effect that you're getting here, can you talk about the legs there left on that as far as utilization in some of these cases? And then, again, other trends on that segment of the business specifically doesn't sound like it's really function of pricing. It's just more may be ease-of-use of the newer devices. Because the growth there has been pretty eye-popping in the last several quarters. So just the dynamics there that are influencing that and then how we think about that business going forward?

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

Yes, Matt -- and when you think about the legs under them, we're just scratching the surface overall in terms of the volume and the number of patients that are going in for cardiac surgery, so we feel like there's many, many years to go of a growth and impact in that area. Now as I mentioned earlier, I wouldn't get ahead of myself on the growth rate as we get into tougher comps next year and things like that. I think that would be too aggressive on anybody's part, but do we feel good about kind of where we are and that we're going to be able to sustain strong growth in that area? We do feel good about that. And there is just a lot of patients that aren't getting treated both here in the U.S. and internationally. We just entered into the Japanese market. We're starting to see some traction in Europe really for the first time in a meaningful way and different countries. And so the halo effect is that people that may have been uncomfortable talking about the appendage before are now talking about it. They're now -- some of them are putting on the V clip, maybe they now get exposure to the entire clip franchise and they decide to go even for the other clip. Or just because it's been talked about throughout the hospital, just the more and more that it sells, you're kind of hitting some tipping points that places about just kind of making sure they're treating every appendage they see when they see the heart.

Operator

Our next question comes from Rick Wise from Stifel.

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

It's Drew Ranieri for Rick tonight. But I just wanted to ask a question about the cryoprobe. I know you mentioned that you're launching a new probe in 2019 and purpose-built and I know it's separate from the AF space, but how's the pilot sales team progressing these early days? Kind of what are your expectations and vision for the business? And could this product category potentially helpful through your broader surgical AF product portfolio? Or at least get a conversation going over the potential account?

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

There's a lot to unpack in that question, but they're all really good questions, so I'll try to kind of get to all that, Drew. The first piece, yes, it's a purpose-built probe for cryonerve block. The team is doing very well in the 4 select cities that they're in today. They're in L.A, Houston, Tampa and New York City. These were pilot areas that kind of -- to really begin to target very specific accounts. They've gone very well. We've seen some modest incremental business but also definitely access into new areas and new accounts. The results have been, quite frankly, remarkable in terms of the pain reduction that you see in many of these sites with their patients. That's why we'll wind up expanding next year for sure as we do a full launch of the new probe. As we do look at that probe, we do a reps in others today that do use the cryo nerve block as a way to get into -- in the pain management as a way to get into an account. I'd say that it's few and far between that are able to kind of make that leap and jump. Quite frankly, but maybe in the future, that could happen. I'd say that is a -- that's definitely a possibility for us, but the teams are calling on separate people right now. And then as we kind of look into next year, I mean, some of the things that we're excited about is not only is it the probe, but the end of the trial -- the FROST trial and the data that will come out with that and the papers that are being written relative to that and also just in general around the reduction of opioids and the possibility of that in some of these patients. That's something that we're looking into heavily and I think it could have a meaningful impact long term.

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

Great. And just a follow-up on Jason's question earlier. You mentioned that you need clinical data really to get after those 900,000 potential patients for the AtriClip. And can you just talk about -- I know the ATLAS trial was just a hypothesis-generating concept, but where do you stand on potentially starting a trial with the FDA to kind of get that data?

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

Yes, we're evaluating the use of either real-world data when you look at CMS data and other data relative to that. We're definitely kind of unpacking where we can find some of that information leveraging some of the work that we've done on the ATLAS trial. There's also a lot of single center data that we're looking to as well that as that data comes out, we think that it will continue to show benefits of treating the appendage.

Operator

Our next question is a follow-up question from Jason Mills with Canaccord.

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

The follow-up is just with respect to the CONVERGE business, EPi-Sense business. Just you mentioned and we've seen this over time, volatility is going to be here to stay until you have a chance to train physicians around the country and have it on a label. But in the meantime, you mentioned account ordering and existing accounts as fairly strong. I'm wondering how it's going for you with respect to new accounts in this stage before

FDA approval? Just what can you tell us about the sales force productivity and then sort of limbo time period here? And any additional granularity you can give us with respect to green shoots you're seeing let's say in that business, although we should expect volatility for a little while.

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

We've got a lot of solid accounts. Why we don't have as many net new accounts coming online or as many as we were having for a period of time there. Now it's really a focus on making sure the accounts they're doing, they're doing it well and doing it right. And that they're getting more and more confident with the procedure and so that's really kind of where the focus has been in supporting them, doing the case coverage. And I'd say that's kind of really where the biggest focus is as we kind of enter next year and get ourselves closer to 2020 when the possibility for the label comes into play.

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

Okay. That's helpful. And then with respect to that, this investigation and, obviously, there's a sensitivity to on-label, off-label in every space, especially Afib given the history and you and I both know that going back 15 years. So has there been any sort of incremental conservatism on the part of the company as it relates to minimally invasive given that you want to be completely straight and narrow as it relates to how you're marketing the EPi-Sense product line? And sort of in advance of the FDA clearance perhaps whenever it comes?

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

There's really been no change because as I've mentioned in the call before, we've been confident in our compliance programs. Since I've joined the company, we've accelerated our investments in it while we were under the CIA. I joined in 2012, if you recall, and the company was under corporate integrity agreement at the time. Since that period of time, we've actually accelerated and put even more procedures and processes in place. We added a chief compliance officer. We added a whole compliance team. We added a position under the Board of Directors and a whole committee relative to compliance and review. That was all done kind of on our own above and beyond what they had recommended to do us before. We've had training programs of our sales team, our entire company relative to that. So our approach quite frankly has not changed. I'm very confident in the way that we've done it. We've been incredibly aboveboard and have always been incredibly careful with that and there have been no changes in our approach since getting that. And again, I feel very confident in kind of the way we've approached it for many, many years.

Operator

And I'm not showing any further questions at this time. I'd like to turn the call back to Mike Carrel for closing comments.

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

Great. Once again, thank you, everyone, for joining today. We look forward to another strong quarter here in the fourth quarter and talking to you again in early 2019. Thank you, and have a wonderful year.

Operator

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