
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

**PURSUANT TO SECTION 13 OR 15(d) of the
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): January 7, 2019

ATRICURE, INC.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction of
incorporation)

000-51470
(Commission File Number)

34-1940305
(IRS Employer Identification No.)

7555 Innovation Way
Mason, OH
(Address of principal executive offices)

45040
(Zip Code)

Registrant's telephone number, including area code: (513) 755-4100

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On January 7, 2019, AtriCure, Inc. (“AtriCure” or the “Company”) issued a press release announcing its preliminary financial results for the fourth quarter and full year ended December 31, 2018. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

During the week of January 7, 2019, the Company is holding meetings with investors discussing, among other topics, an overview of the Company’s business and growth strategy. A copy of the investor presentation, which is available at www.atricure.com, is furnished as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

The Company’s presentation discloses certain financial results both in accordance with generally accepted accounting principles (“GAAP”) and on a non-GAAP basis with adjustments for certain items. The Company’s management believes that presentation of these non-GAAP financial measures and their related reconciliations are useful to investors because the non-GAAP financial measures provide investors with a basis for comparing the results to financial results from prior periods.

Information in the presentation contains forward-looking statements regarding future events and performance of the Company. All such forward-looking statements are based largely on the Company’s experience and perception of current conditions, trends, expected future developments and other factors, and on management’s expectations, and are subject to risks and uncertainties that could cause actual results to differ materially, including, but not limited to, those factors described in the presentation and in the Company’s filings with the Securities and Exchange Commission. The Company disclaims any intention or obligation to update or revise any financial or other projections or other forward-looking statements, whether because of new information, future events or otherwise.

The information in each of Item 2.02 and Item 7.01 of this Form 8-K and in the press release attached as Exhibit 99.1 and the presentation attached as Exhibit 99.2 is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section. The information in each of Item 2.02 and Item 7.01 of this Form 8-K and each of Exhibit 99.1 and Exhibit 99.2 shall not be incorporated by reference in any filing (whether made before or after the date hereof) or any other document under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filing or document.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No. Description

[99.1](#) [Press Release dated January 7, 2019](#)

[99.2](#) [Investor Presentation](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ATRICURE, INC.

Dated: January 7, 2019

By: /s/ M. Andrew Wade
M. Andrew Wade
Senior Vice President and Chief Financial Officer

For immediate release
January 7, 2019

AtriCure Reports Preliminary Results for Fourth Quarter and Full Year 2018

MASON, Ohio, January 7, 2019 – AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage (LAA) management, today announced preliminary financial results for the fourth quarter and full year 2018 and provided 2019 financial guidance.

Preliminary, unaudited revenue for fourth quarter 2018 is expected to be approximately \$52.9 million, reflecting growth of approximately 15% over the fourth quarter of 2017. Based on this preliminary estimate, revenue from U.S. customers is expected to be \$43.1 million, reflecting growth of 19% and driven again by strong sales of open-heart ablation products and appendage management products. Revenue from international customers is expected to be approximately \$9.8 million, a decrease of 1% as reported and an increase of 1% on a constant currency basis.

Preliminary revenue for full year 2018 is expected to be \$201.6 million, reflecting growth of approximately 15% over full year 2017. Adjusted EBITDA (a non-GAAP measure consistently calculated as in previous releases¹) for the full year 2018 is currently estimated to be a loss in the previously communicated range of \$1 to \$3 million.

“We are pleased with our fourth quarter results and performance throughout 2018, as 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 healthcare professionals worldwide, surpassed the 170,000 AtriClip milestone, launched the AtriClip FLEXTM device, and established a dedicated pain management team,” said Mike Carrel, President and Chief Executive Officer of AtriCure. “We are well positioned to continue executing on our strategy and positively impacting patient lives.”

2019 Financial Guidance

Management projects 2019 revenue of approximately \$220 million to \$228 million, reflecting growth of approximately 9% to 13% over full year 2018. Adjusted EBITDA, a non-GAAP measure, is projected to be positive for 2019.

About AtriCure

AtriCure, Inc. provides innovative technologies for the treatment of Afib and related conditions. Afib affects more than 33 million people worldwide. Electrophysiologists and cardiothoracic surgeons around the globe use AtriCure technologies for the treatment of Afib and reduction of Afib related complications. AtriCure’s Isolator[®] SynergyTM Ablation System is the first and only medical device to receive FDA approval for the treatment of persistent Afib. AtriCure’s AtriClip[®] Left Atrial Appendage Exclusion System products are the most widely sold left atrial appendage management devices worldwide, with more than 170,000 implanted to date. For more information, visit AtriCure.com or follow us on Twitter @AtriCure.

Forward-Looking Statements

This press release contains “forward-looking statements” – that is, statements related to future events that by their nature address matters that are uncertain. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, visit <http://www.atricure.com/fls> as well as our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q which contain risk factors. We do not undertake to update our forward-looking statements. This document also includes forward-looking projected financial information that is based on current estimates and forecasts. Actual results could differ materially.

CONTACTS:

Andy Wade
AtriCure, Inc.
Senior Vice President and Chief Financial Officer
(513) 755-4564
awade@atricure.com

Lynn Pieper Lewis
Gilmartin Group
Investor Relations
(415) 937-5402
lynn@gilmartinir.com

AtriCure Investor Presentation

January 2019

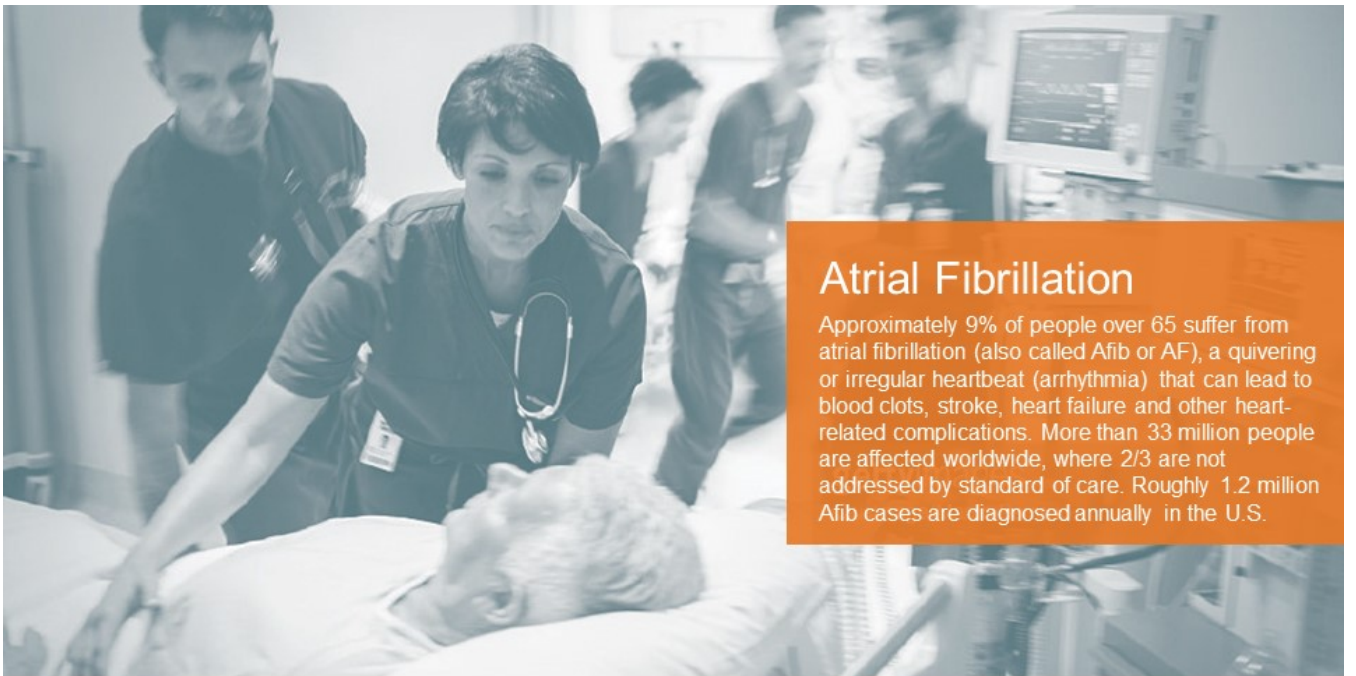
Forward Looking Statements

This presentation contains "forward-looking statements," which are statements related to future events that by their nature address matters that are uncertain. All forward-looking information is inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, see our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC and available at <http://www.sec.gov>, which contain risk factors. Forward-looking statements address our expected future business, financial performance, financial condition as well as results of operations, and often contain words such as "intends," "estimates," "anticipates," "hopes," "projects," "plans," "expects," "seek," "believes," "see," "should," "will," "would," "target," and similar expressions and the negative versions thereof. Such statements are based only upon current expectations of AtriCure. Any forward-looking statement speaks only as of the date made. Reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to differ materially from those expressed or implied. Forward-looking statements include statements that address activities, events or developments that AtriCure expects, believes or anticipates will or may occur in the future. Forward-looking statements are based on AtriCure's experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances and are subject to numerous risks and uncertainties, many of which are beyond AtriCure's control. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. We undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise unless required by law.

Non-GAAP Financial Measures

To supplement the Company's consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, the Company uses certain non-GAAP financial measures in this presentation.

Adjusted EBITDA, which the Company defines as earnings before interest, taxes, depreciation and amortization, adjusted for share-based compensation and the change in fair value of contingent consideration, provides an indication of performance excluding certain items. Management believes that in order to properly understand short-term and long-term financial trends, investors may wish to consider the impact of these excluded items in addition to GAAP measures. The excluded items vary in frequency and/or impact on our continuing operations and management believes that the excluded items are typically not reflective of our ongoing core business operations. Further, management uses adjusted EBITDA for its strategic planning. A reconciliation of adjusted EBITDA to the most comparable GAAP measure for the respective periods can be found in the Supplemental Information section of this presentation. The non-GAAP financial measures used by the Company may not be the same or calculated the same as those used by other companies. Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for the Company's financial results prepared and reported in accordance with GAAP.



Atrial Fibrillation

Approximately 9% of people over 65 suffer from atrial fibrillation (also called Afib or AF), a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications. More than 33 million people are affected worldwide, where 2/3 are not addressed by standard of care. Roughly 1.2 million Afib cases are diagnosed annually in the U.S.

Afib: A serious and costly problem



Stroke is leading cause of long-term disability



Afib increases the risk of stroke by **5X** times

3X

People with Afib have three times the risk for heart failure

Afib is second leading cause of stroke

#2



Total cost of Afib to U.S. healthcare each year

\$26
BILLION

73%
higher medical costs related to Afib



Key Investment Rationale

Addressing an underserved and growing population of patients

- About 17 million chronic Afib patients globally
- Current standard of care does not adequately address this population

Portfolio of Standalone/Minimally Invasive (MIS) solutions to drive long-term growth

- Two PMA trials underway for hybrid approaches; CONVERGE trial is top priority
- Early in market development process – key driver of future growth

Appendage Management business complements multiple procedures

- Most widely used Left Atrial Appendage (LAA) device with over 170,000 sold to date
- Delivering novel products, driving volume and ASP growth

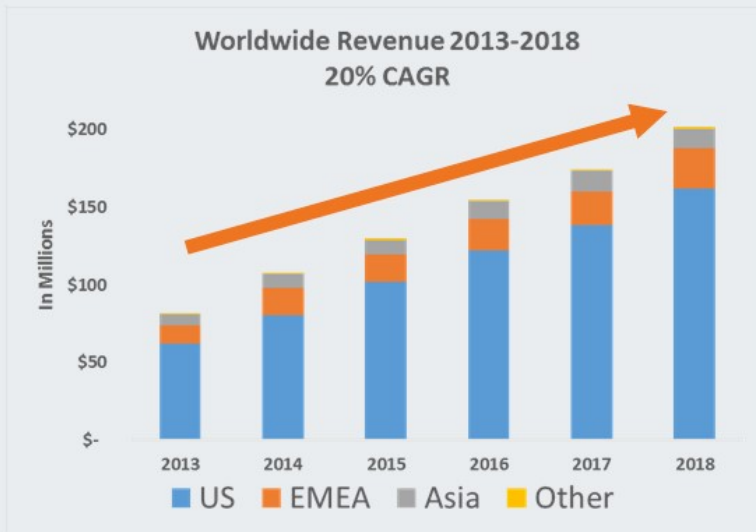
Can deepen penetration of Open Heart Ablation through training

- Only PMA product for the surgical treatment of Afib
- Product improvements and salesforce focus have driven growth
- Recent guidelines have driven broader adoption

2018 Highlights

- Achieved over \$200 million in revenue and annual growth rate of 15.4%
- Completed enrollment in CONVERGE clinical trial
- Trained over 400 healthcare professionals worldwide
- Impact of innovation continued with successful product launches in 2018
 - AtriClip Flex·V® device in March (U.S.)
 - Limited US launch of cryoSPHERE™ device for nerve block in November; full U.S. launch in 2019
- Built Cryo Nerve Block pilot commercial team
- Partnered with BaHeal Pharmaceutical Group for distribution in China
- Strengthened balance sheet with stock offering in October

Strong Financial Performance



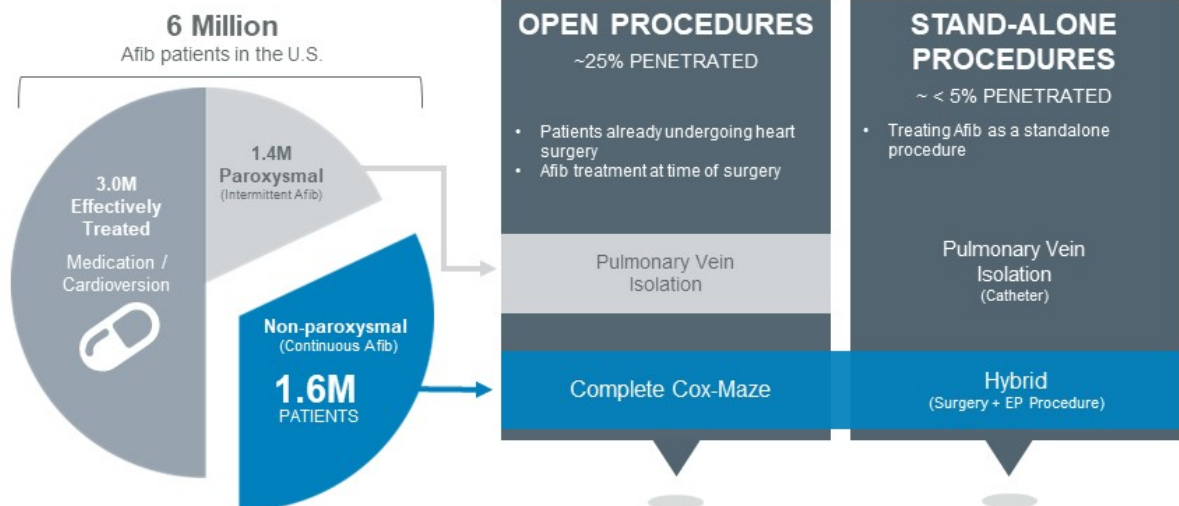
25
Straight Quarters of Double-Digit YoY Growth

Consistent growth

\$201.6M
2018 Revenue

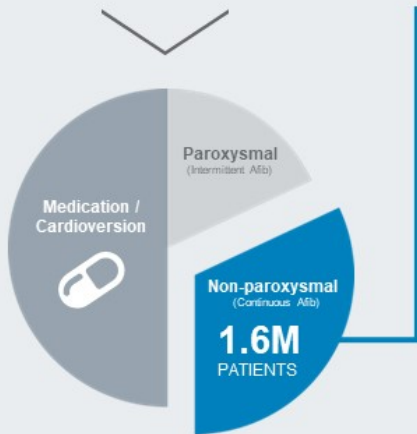
15.4% YoY Growth

Two Distinct Patient Profiles



Looking Forward ... U.S. Market - \$1 Billion Opportunity

6 million Afib patients in the U.S.



ADDRESSABLE MARKET OPPORTUNITY



OPEN ABLATION

\$270M

Market applies to major forms of structural heart surgery (CABG, AVR, MVR)



APPENDAGE MANAGEMENT

\$290M

Market applies to both open chest and minimally-invasive procedures

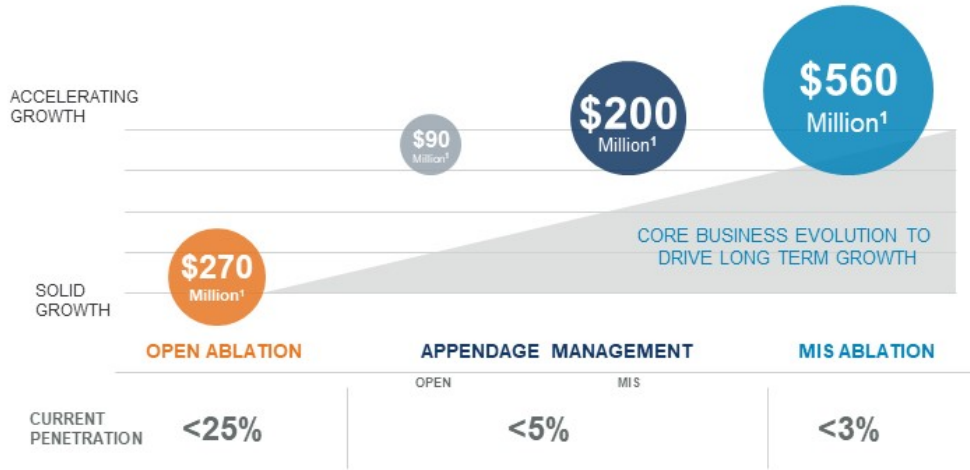


MIS ABLATION

\$560M

Market includes ALL non-paroxysmal Afib patients for whom "management" has not worked

Business Evolution to Drive Long-Term Growth



Core business is evolving to serve the MIS market and capture more of long-term growth opportunity

¹ Estimated market opportunities; see Supplemental Information section of this presentation for calculations
 © 2019 AtriCure, Inc. All rights reserved.

U.S. Open Ablation

90K

Cardiac surgeries on patients with pre-existing Afib

\$270M

Market size

Competitive Advantages

- Labeling advantage in the U.S.
- Robust portfolio across two technology platforms
- Solid gross margins
- Strong physician education programs



OPEN ABLATION

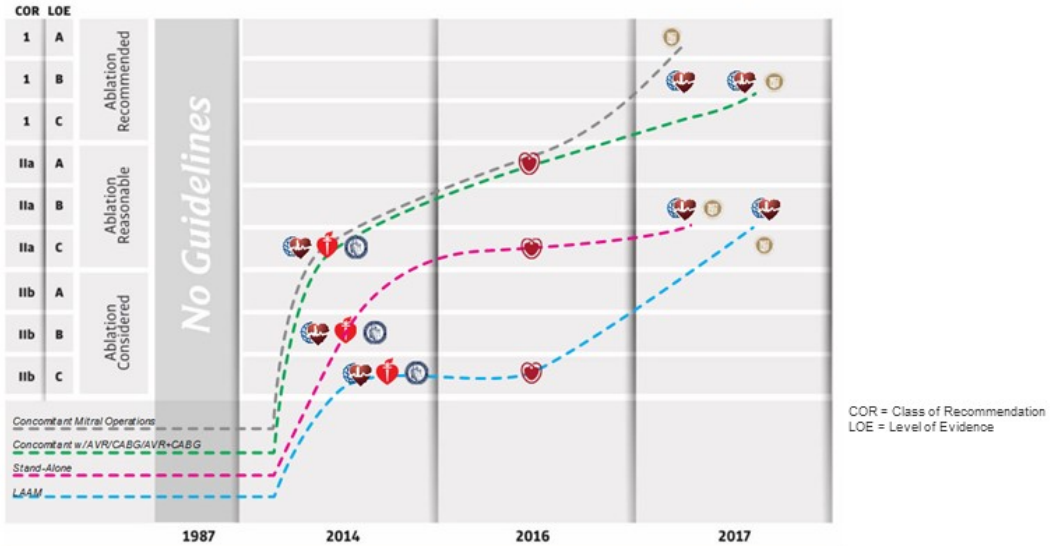
AtriCure has the only ON-LABEL product for the surgical treatment of Afib (FDA approved)

Growth will be driven by increased market penetration

Growth Drivers

- STS/HRS Class 1 recommendations
- Focused sales force
- Major emphasis on physician education and training
- Continued market penetration driven by CABG opportunity

Surgical Ablation Guidelines are Advancing



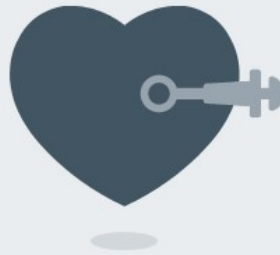
U.S. MIS Ablation

\$560M
U.S. Total Market

High growth opportunity in underserved and underdeveloped market

Competitive Advantages

- Favorable reimbursement environment
- High gross margin portfolio
- Pipeline of continued development
- Leveraging expertise in epicardial ablation to serve non-paroxysmal opportunity



MIS ABLATION

Upcoming clinical data expected to support market development

Growth Drivers

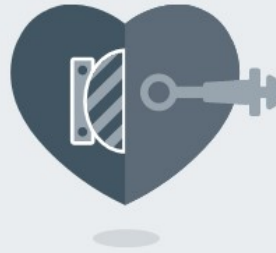
- CONVERGE IDE trial for Afib labeling expansion
- Cardiologists looking for definitive treatment solutions
- Tough-to-serve patient population lends itself to multi-disciplinary therapy

U.S. Appendage Management

APPENDAGE MANAGEMENT OPEN and MIS

Open Growth Drivers

- Broadening awareness of benefits of LAA management (science and society endorsement)
- Launched AtriClip Flex-V® device in March 2018 – benefits include ease of use and lower profile



MIS Growth Drivers

- AtriClip PRO2 device continues to gain traction w/ higher ASP
- Launch of a more versatile AtriClip PRO-V™ device in September 2017
- Future opportunity for adding MIS AtriClips to other procedures

\$290M
U.S. Total Market
\$90M
Open Ablation
\$200M
MIS Ablation

APPENDAGE MANAGEMENT

*Highest growing of our franchises – over 30% CAGR for past three years
Over 170,000 AtriClip Systems implanted worldwide*

AtriCure Product Portfolio

<p>OPEN ABLATION</p>	 ISOLATOR® SYNERGY™ CLAMP	 cryJOICE® CRYOABLATION PROBE	 cryoFORM® CRYOABLATION PROBE	 ISOLATOR® TRANSPOLAR PEN		
<p>MIS ABLATION</p>	 ISOLATOR SYNERGY ACCESS® CLAMP	 COBRA FUSION® 150 ABLATION SYSTEM	 EPI-SENSE® DEVICE	 SUBTLE® CANNULA		
<p>APPENDAGE MANAGEMENT</p>	<p>OPEN</p>    <p>ATRICLIP® LONG DEVICE ATRICLIP® FLEX DEVICE ATRICLIP FLEX-V™ DEVICE</p>			<p>MIS</p>    <p>ATRICLIP PRO® DEVICE ATRICLIP PRO2® DEVICE ATRICLIP PRO -V® DEVICE</p>		

Expanding Product Portfolio

- Launched 6 products in last four years (1 from acquisition)
- Track record of organic and inorganic execution
- Future pipeline focus across all franchises – Open clamp, linear ablation, minimally invasive AtriClip
- Innovation toward less invasive, simpler, easier to use, and more efficient products
- Strong commercial pricing discipline for new product introductions



© 2019 AtriCure, Inc. All rights reserved.

17



Long-term Goal

Continued expansion of products in both core and new markets

AtriCure

Advancing Clinical Outcomes

Robust clinical program with several studies underway to generate clinical evidence

CONVERGE PIVOTAL	Trial designed to support FDA approval of EPI-Sense device specifically for the treatment of persistent Afib through an abdominal approach
DEEP PIVOTAL	Trial designed to support FDA approval of various devices specifically for the treatment of persistent Afib through a bi-lateral totally thoracoscopic approach
CEASE AF	Randomized trial of hybrid bi-lateral approach (same as DEEP) versus catheter ablation in persistent and longstanding persistent Afib

...and many other clinical science studies and activities!

CONVERGE Pivotal Study



Trial designed to support FDA approval of Epi-Sense device specifically for the treatment of persistent Afib

STUDY DESIGN

Summary

Multi-center, prospective, open label randomized 2:1 (Convergent procedure vs endocardial catheter ablation) pivotal study.

Number of Subjects and Sites

Up to 153 subjects
Up to 30 sites (27 U.S. and 3 O.U.S.)

Study Duration

5 year follow-up of all subjects

PRIMARY ENDPOINTS

Effectiveness

The primary efficacy endpoint is success or failure to be AF/AT/AFL free absent class I and III AADs except for a previously failed or intolerant class I or III AAD with no increase in dosage following the 3 month blanking period through the 12 months post procedure follow-up visit.

Safety

The primary safety endpoint for the study is 12% freedom from MAE's as adjudicated by the CEC for the procedural to 30-day post procedure time period.



CONVERGE HIGHLIGHTS

- Completed enrollment in August 2018

Summary of U.S. – Large, Underpenetrated Market Opportunity



U.S. GROWTH DRIVERS...

- Continued penetration into the **Open Market**
- Growing **MIS clinical data** and continuing **commercial execution**
- **Appendage Management** business **complementing growth** of Open / MIS Ablation

Aligning Expertise With Opportunity

Sales structure and talent – maximizing productivity

- Shifting headcount growth from Regional Sales Managers to Ablation/Clinical Specialists
 - Solid case coverage while managers build relationships, broaden adoption
- Onboarding and training current team is a top priority
- Each Area Includes:
 - 5-6 Regional Sales Managers
 - 4-8 Clinical Specialists
 - 1-2 Minimally Invasive Manager(s)



Key Sales Positions	2013	2016	2018
Area Directors	8	11	11
Regional Sales Managers	37	53	52
Ablation/Clinical Specialists	22	44	58
Minimally Invasive Managers	0	10	15

International Market = \$2 Billion Opportunity

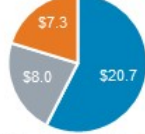
Mid-teens growth driven by product expansion and reimbursement

Growth Drivers

- Product expansion in Asia
- Reimbursement in the EU
- Clinical Data – CEASE AF
- Sales team coverage



2017 International Revenue (M)



• Open Ablation • MIS Ablation • App Mgmt



\$525M
OPEN ABLATION



\$600M
APPENDAGE MANAGEMENT



\$985M
MIS ABLATION

Financial Performance

Revenue growth expectations fueled by stability in Open ablation and high growth in MIS ablation and Appendage Management



© 2019 AtriCure, Inc. All rights reserved.

- Strong historical revenue growth across the business – 25 quarters of double digit year-over-year growth
- Historical **gross margins 70 – 73%** with expansion opportunity
- Continued improvement in profitability profile
- 2019 Revenue Guidance: \$220 million to \$228 million (9% to 13% growth)

*Non-GAAP measure; see historical reconciliation of Adjusted EBITDA to net loss in the Supplemental Information section of this presentation

AtriCure

Investor Highlights

Leader in \$1B+ U.S. addressable market for atrial fibrillation solutions



Market Leadership

- Only on-label (FDA) product in the persistent/long-standing persistent Afib market
- Robust product portfolio and pipeline focused on minimally-invasive solutions
- Most widely adopted LAA product on the market



Strong Growth Opportunity

- Large and growing market; vastly underpenetrated
- Evolution to minimally invasive therapies will drive growth
- Diverse profile of solutions to treat persistent Afib



Solid Foundation

- 20% 5-year revenue CAGR through 2017, with improving profitability
- Commitment to innovation, education, and clinical science



GROWTH DRIVERS

- Updated society guidelines recommend treatment of Afib for specific procedures
- Continued penetration in the Open market
- Growing MIS clinical data and portfolio of solutions
- Appendage management business driving growth
- Strengthening commercial leadership and team
- International expansion



Thank You!





Supplemental Information

Note that citations/references for any comments, statistics, or figures in this presentation are available upon request.

Revenue / Market Overview

Geography	2016 Full-Year Revenue	2017 Full-Year Revenue	2018 Full-Year Revenue	Global Market Potential
United States	\$122.4M +20%	\$138.4M +13%	\$162.1M +17%	\$1B+ Annually
International	\$32.7M +19%	\$36.3M +11%	\$39.5M +9%	\$2B+ Annually
Overall	\$155.1M +20%	\$174.7M +13%	\$201.6M +15%	\$3B+ Annually

Franchise / Business Overview

Focus Areas	Products	Keys to Success	Trials/Data
OPEN Ablation (Concomitant)		<ul style="list-style-type: none"> FDA PMA label for Afib (2011) Advanced Training – CABG/AVR/Fellowships Conversions and add-on sales – cryoFORM adoption Guideline changes w/ Societies 	<ul style="list-style-type: none"> ABLATE IDE = PMA PMA Post Approval Study (365 Patients) STS/Medicare retrospective studies Guidelines key – supporting many grants TRAC-AF registry
OPEN Appendage Management		<ul style="list-style-type: none"> EXCLUDE trial (510k data) Continued education and awareness Tie to ablation growth Flex-V AtriClip in 2018 ATLAS and other data 	<ul style="list-style-type: none"> EXCLUDE – Complete ATLAS/future data opportunities
MIS Ablation		<ul style="list-style-type: none"> Trials – DEEP and CONVERGE Collaborative care Convergent growth 	<ul style="list-style-type: none"> CONVERGE IDE DEEP IDE TRAC-AF Registry
MIS Appendage Management		<ul style="list-style-type: none"> Awareness Future trials/studies Product expansion (Pro2, Pro-V) 	<ul style="list-style-type: none"> Stroke Safety Feasibility Complete Investigating opportunities
International		<ul style="list-style-type: none"> Product expansion in Asia Reimbursement in EU Sales team coverage 	<ul style="list-style-type: none"> CEASE AF (DEEP for EU) HISTORIC AF (Complete) Several AtriClip registries

AtriCure Portfolio Designed to Treat Afib

2017 U.S. REVENUE BY PRODUCT CATEGORY



OPEN ABLATION

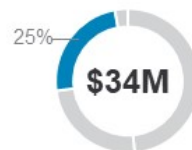
2017 STS and HRS guidelines **recommend** surgical ablation for the treatment of Afib at the time of MVR, AVR, and CABG



APPENDAGE MANAGEMENT

OPEN
2017 STS Guidelines include LAA Management as a **reasonable** procedure to minimize risk of stroke

MIS
Strong existing product line with new product innovations continuing to drive the shift to MIS procedures



MIS ABLATION

CONVERGE trial underway to support FDA approval of the EPI-Sense® device for the treatment of persistent Afib

Keys to Market Development

Expand Product Portfolio

Innovative pipeline to drive Open ablation penetration and build MIS market

AtriClip PRO-V device, AtriClip PRO2 device, cryoFORM probe, Cryo3 probe, etc.



Increase Education and Awareness

Afib training programs delivered to 2,000+ surgeons

UPDATED GUIDELINES

- STS/HRS Class 1
- AATS



Advancing Clinical Outcomes

Multiple clinical trials underway (PMA and company-sponsored)

CONVERGE – Top priority for company... drives MIS opportunity



Commercial Talent and Expertise

Strong commercial leadership and sales infrastructure

Increase size/expertise of MIS-focused team, continue to be seen as Afib resource!



Increase Education and Awareness

Investment

- Significant resources toward physician education
- Multiple options including didactic, hands-on, proctoring, and case observations

Steering Committee

- Comprised of highly regarded KOLs

Strong Network

- Established strong network of revered physician trainers

Society Involvement

- AATS Fellowships, STS and EACTs endorsed training program



Trained over 2,000
surgeons worldwide

Helping physicians address
the growing Afib epidemic

AtriCure

Guidelines to Fuel Adoption

2017 STS Guidelines

- Applies to **ALL-COMER Afib patients**. Previously only “symptomatic patients refractory or intolerant to at least one AAD”.
- Surgical Ablation is **RECOMMENDED** not just reasonable; it doesn't increase operative risk.
- **LAA Management** is mentioned for the first time in the STS Guidelines; LAA Management is reasonable in conjunction with ablation or alone during cardiac surgery.
- Acknowledges the positive impact of **hybrid ablations**.

2017 HRS Guidelines

- Mitral Valve Replacement is **RECOMMENDED** for all symptomatic patients refractory or prior to antiarrhythmic drugs.
- Surgical Ablation is **RECOMMENDED** for CABG and AVR patients who had initiated antiarrhythmics prior to surgery.
- Stand-Alone / Hybrid is **REASONABLE** for long-standing persistent symptomatic patients refractory or intolerant to at least one AAD and have failed one or more attempts at catheter ablation or prefer a surgical approach.

© 2019 AtriCure, Inc. All rights reserved.

32



WHAT'S NEXT?

- Continuing to educate the market
- Generate evidence
- Influence other major societies

AtriCure

Society Guidelines for Treatment of Afib

SOCIETY	RECOMMENDATION
STS (2016) ¹	Surgical ablation for Afib can be performed without additional operative risk of mortality or major morbidity, and is recommended at the time of concomitant isolated aortic valve replacement, isolated coronary artery bypass graft surgery, and aortic valve replacement plus coronary artery bypass graft operations to restore sinus rhythm. Surgical ablation for Afib can be performed without additional operative risk of mortality or major morbidity, and is recommended at the time of concomitant mitral operations to restore sinus rhythm.
AHA/ACC/HRS (2014) ²	An Afib surgical ablation procedure is reasonable for selected patients with Afib undergoing cardiac surgery for other indications. A stand-alone Afib surgical ablation procedure may be reasonable for selected patients with highly symptomatic Afib not well managed with other approaches.
HRS/ACC/AHA/STS/EHRA/EAS (2012) ³	"It is advisable that all patients with documented Afib referred for other cardiac surgeries undergo a left or biatrial procedure for Afib at an experienced center, unless it... will add significant RISK..."
ISMICS (2009) ⁴	"Concomitant surgical ablation is recommended to increase the incidence of sinus rhythm both at short- and long-term follow-up to improve ejection fraction and exercise tolerance to reduce the risk of stroke and thromboembolic events and to improve long-term survival."
UK NICE (2014) ⁵	Surgical ablation of Afib should be considered in patients with persistent Afib, or with symptomatic Afib undergoing cardiothoracic surgery.
ESC (2010) ⁶	Surgical ablation of Afib should be considered in patients with symptomatic or asymptomatic Afib undergoing cardiac surgery. Minimally invasive surgical ablation of Afib without concomitant cardiac surgery is feasible and may be performed in patients with symptomatic Afib after failure of catheter ablation.


1. Beshwar et al., Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation, *Ann Thorac Surg* 2017; 103:329-41
 2. Craig et al., 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation, *JACC*, Vol 54, no 21, 2014
 3. Calkins et al., HRS/EHRA/EAS Catheter and Surgical Ablation, *Heart Rhythm*, vol. 9, no 4, April 2012.
 4. Ad et al., Surgical ablation for atrial fibrillation in cardiac surgery, *Innovations*, vol 5, no 2, March/April 2010.
 5. National Institute for Health and Care Excellence, Atrial fibrillation: management, clinical guideline, June 18, 2014.
 6. Camm et al., Guidelines for the management of atrial fibrillation, *European Heart Journal*, 2010.

Society Guidelines for Appendage Management

SOCIETY	RECOMMENDATION
STS (2016) ¹	It is reasonable to perform left atrial appendage excision or exclusion in conjunction with surgical ablation for Afib for longitudinal thromboembolic morbidity prevention.
AHA/ACC/HRS (2014) ²	Surgical excision of the left atrial appendage may be considered in patients undergoing cardiac surgery.
UK NICE (2014) ³	Consider LAA occlusion if anticoagulation is contraindicated or not tolerated and discuss the benefits and risks of LAA occlusion with patient.
EJCTS (2013) ⁴	We conclude that there has been no proven benefit of surgical LAA exclusion in terms of stroke reduction or mortality benefit... If exclusion is contemplated, devices designed for appendage exclusion should be used rather than a cut-and-sew or stapling technique.
EHRA/EAPCI (2014) ^{5,6}	OAC (with VKA or NOACs) is the standard therapy; however, for patients who are contraindicated or refuse (N) OACs... the main indication for LAA occlusion is a relative or absolute contraindication to (N)OACs in patients with Afib and a CHADS2 score of ≥ 1 or CHA2-DS2-VASc score ≥ 2 .

1. Badhwar et al.; Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation, Ann Thorac Surg 2017;103:329-41
2. January et al.; AHA/ACC/HRS Atrial Fibrillation Guideline, JACC Vol. 64, no. 21, December 2, 2014.
3. National Institute for Health and Care Excellence. Atrial fibrillation: management, clinical guideline. June 18, 2014.
4. Dunning et al.; Guideline for the surgical treatment of atrial fibrillation, European Journal of Cardio-Thoracic Surgery, Vol 44, 2013.
5. Meier et al.; EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion, EuroIntervention, 2014
6. Tambo et al.; The future of left atrial appendage occlusions: When extraordinary claims require evidence... Archives of Cardiovascular Disease 2015 vol 108.

U.S. Open Market Work-Up

Total Open U.S. Procedures	300,000
30% with Afib	
U.S. Procedures with Afib	90,000
	
~ U.S. Annual Opportunity ¹	\$270M
~Current U.S. OPEN Ablation penetration, 25%	
2017 U.S. OPEN Ablation Sales	\$65M



1. Assumes Open ablation procedural pricing of \$3,000

U.S. Appendage Management Market Work-Up

OPEN APPENDAGE MANAGEMENT

Total OPEN U.S. Procedures	300,000
30% with Afib	
U.S. Procedures with Afib	90,000
~U.S. Annual Opportunity ²	\$90M

MIS APPENDAGE MANAGEMENT

Non-paroxysmal Pts Annually Treated with Cath Ablation	80,000
~Unsuccessful Outcomes with Cath Ablation, 70%	
MIS Ablations (Non-paroxysmal, post Cath)	56,000
~ Annual U.S. MIS Ablation Opportunity (Post Cath) ¹	\$200M



2017 U.S. Appendage Management Sales

\$37M

~Current U.S. OPEN / MIS Appendage Management penetration, ~10%



1. Assumes average pricing of \$3,600 for MIS AtriClip
 2. Assumes average pricing of \$1,000 for Open AtriClip

U.S. MIS Market Work-Up

Non-paroxysmal Pts Annually Treated with Cath Ablation 80,000

~Unsuccessful Outcomes with Cath Ablation, 70%

MIS Ablations (Non-paroxysmal, Post Cath) 56,000

~ Annual U.S. MIS Ablation Opportunity¹ \$560M

~Current MIS OPEN Ablation penetration, ~5%

2017 U.S. MIS Ablation Sales **\$34M**



1. Assumes MIS ablation procedure pricing of \$10,000

Additional Growth Drivers with Appendage Management

Prophylactic treatment for Open Appendage Management

Additional \$500M global market

Total OPEN U.S. Procedures	300,000
70% without A-fib	
~U.S. Procedures without A-fib	210,000
~U.S. LAA Prophylactic Annual Opportunity ²	\$215M

Sole Therapy Appendage Management Market

- Competition includes implants and EP closure (without FDA approval)
- Stroke trial key to success

Treatment Resistant A-fib Patients in the U.S.	333,333
10% treated annually	
~Annual Market Opportunity ¹	\$120M

MIS Appendage Management with Heart Procedures

- Opportunity for other MIS surgeries, such as valve repair
- Market is currently small but fast growing

Yearly MIS Heart Procedures (Valve Replacements, MIS CABG)	333,333
~Annual Market Opportunity ¹	\$540M

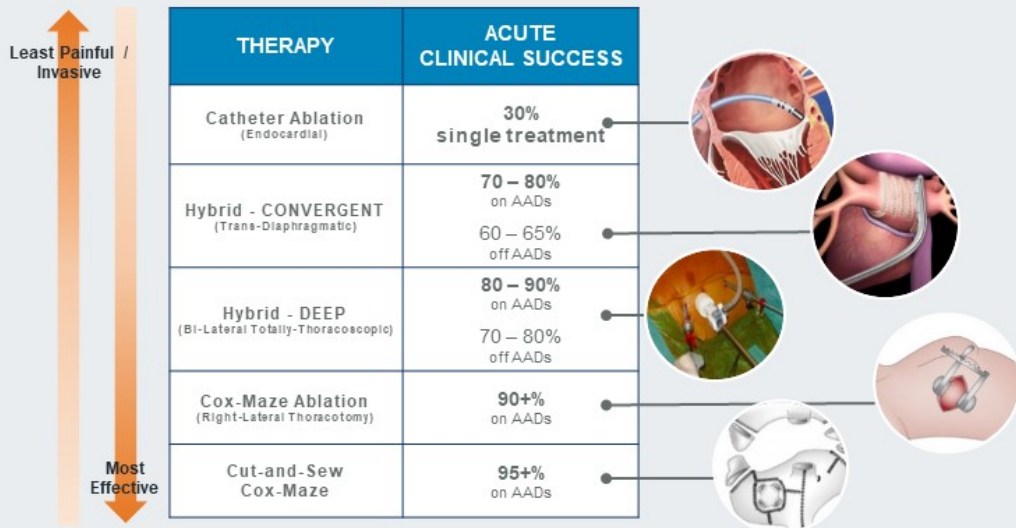
1. Assumes average pricing of \$3,600 for MIS AtriClip
 2. Assumes average pricing of \$1,000 for Open AtriClip

Adjusted EBITDA Reconciliation

(millions of dollars)

	2014	2015	2016	2017
Net loss, as reported	(\$16.2)	(\$27.2)	(\$33.3)	(\$26.9)
Income tax expense	\$0.0	\$0.0	\$0.0	\$0.0
Other (income)/expense, net	(\$0.2)	\$0.5	\$2.2	\$1.9
Depreciation and amortization expense	\$4.8	\$6.3	\$9.3	\$9.1
Share-based compensation expense	\$7.6	\$9.0	\$11.7	\$14.6
Change in fair value of contingent consideration	(\$8.0)	--	\$1.0	(\$4.1)
Adjusted EBITDA	(\$12.0)	(\$11.5)	(\$9.2)	(\$5.3)

Non-Drug Options of Care For Non-Paroxysmal Afib



Cox-Maze IV Procedure

