
**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 8, 2018

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 8, 2018, 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, 2017. 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 8, 2018, 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 8, 2018

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 8, 2018

By: /s/ M. Andrew Wade

M. Andrew Wade

Senior Vice President and Chief Financial Officer



For immediate release

January 8, 2018

AtriCure Reports Preliminary Results for Fourth Quarter and Full Year 2017

MASON, Ohio, January 8, 2018 – 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 2017 and provided 2018 financial guidance.

Preliminary and unaudited revenue for fourth quarter 2017 is expected to be approximately \$46.1 million, reflecting growth of approximately 12% over the fourth quarter of 2016. Based on this preliminary estimate, revenue from U.S. customers is expected to be \$36.2 million, reflecting growth of 11% and revenue from international customers is expected to be approximately \$9.9 million, an increase of 16% as reported and 10% on a constant currency basis.

Preliminary revenue for full year 2017 is expected to be \$174.7 million, reflecting growth of approximately 13% over full year 2016. Adjusted EBITDA loss (a non-GAAP measure consistently calculated as in previous releases¹) for the full year 2017 is currently estimated to be in the previously communicated range of \$4 to \$6 million.

“Our fourth quarter results demonstrate solid financial performance as well as several accomplishments, and our business recovered nicely from the impact of the hurricanes in the third quarter. In addition, we enrolled our 100th patient in CONVERGE, surpassed the 120,000 AtriClip milestone, and launched the AtriClip PRO•V™ device as a platform for current and future growth,” said Mike Carrel, President and Chief Executive Officer of AtriCure. “We are well positioned to continue executing on our strategy to deliver solid, balanced, results across our business while progressing forward with our clinical trials and strategic initiatives, and positively impacting patient lives.”

2018 Financial Guidance

Management projects 2018 revenue of approximately \$190 million to \$196 million. Adjusted EBITDA, a non-GAAP measure, is projected to be positive for 2018.

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® Synergy™ 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 LAA management devices worldwide, with more than 100,000 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.

¹ AtriCure will provide a reconciliation of non-GAAP measures to the related GAAP measure in the release of final 2017 results.

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AtriCure® Investor Presentation

January 2017

Forward Looking Statements

This presentation contains "forward-looking statements"—that is, 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, visit <http://www.atricure.com/fis> as well as our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q which contain risk factors. Forward-looking statements address our expected future business, financial performance, financial condition and 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. This presentation includes the use of non-GAAP measures. Reference AtriCure's Form 8-K filings which include the furnishing of our earnings releases for a reconciliation to the related GAAP measures.



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 – 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 patients are **5X** more likely to have a stroke

More deadly than non-Afib strokes



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

Unique company addressing an underserved and growing population of patients

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

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

- CONVERGENT approach – Over 8K procedures to date; CONVERGE trial is top priority
- DEEP / FUSION approach – Over 30K procedures to date; DEEP Trial underway

AtriClip business is high growth and complements multiple procedures

- Most widely used Left Atrial Appendage (LAA) device with over 110K sold to date
- ATLAS trial underway for non-Afib patients
- Delivering novel MIS approaches annually, driving volume and ASP growth

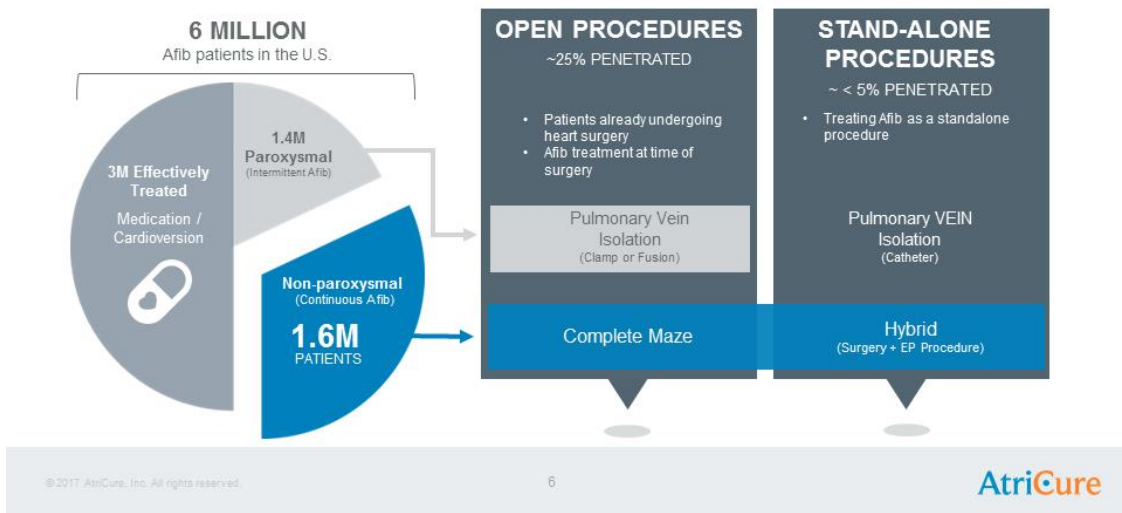
Can deepen penetration of open heart ablation through training

- Product improvements and salesforce re-focus will drive growth
- Cash generation of product line funds development









Plan to be EBITDA profitable in 2018

- Enables growth funding without dilution

Two Distinct Patient Profiles

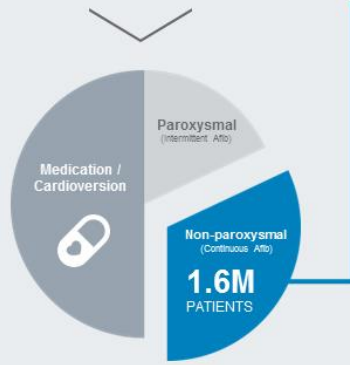


AtriCure Product Portfolio

<p>OPEN ABLATION</p>	 <p>ISOLATOR SYNERGY CLAMPS cyroICE CRYOABLATION PROBE cyroFORM CRYOABLATION PROBE COOLRAIL LINEAR PEN ISOLATOR TRANSPOLAR PEN</p>				
<p>MIS ABLATION</p>	 <p>ISOLATOR SYNERGY ACCESS CLAMP COBRA FUSION 150 ABLATION SYSTEM EPI-SENSE SUBTLE CANNULA</p>				
<p>LAA CLOSURE MANAGEMENT</p>	<table border="0" style="width: 100%;"> <tr> <td style="text-align: center; width: 50%;">OPEN</td> <td style="text-align: center; width: 50%;">MIS</td> </tr> <tr> <td style="text-align: center;">  <p>ATRICLIP LONG ATRICLIP FLEX</p> </td> <td style="text-align: center;">  <p>ATRICLIP PRO ATRICLIP PRO2</p> </td> </tr> </table>	OPEN	MIS	 <p>ATRICLIP LONG ATRICLIP FLEX</p>	 <p>ATRICLIP PRO ATRICLIP PRO2</p>
OPEN	MIS				
 <p>ATRICLIP LONG ATRICLIP FLEX</p>	 <p>ATRICLIP PRO ATRICLIP PRO2</p>				

U.S. Market - \$1 Billion Opportunity

6 million Afib patients in the U.S.



ADDRESSABLE MARKET OPPORTUNITY



OPEN ABLATION

\$260M

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



LAA CLOSURE

\$290M

Market applies to both open chest and minimally-invasive procedures

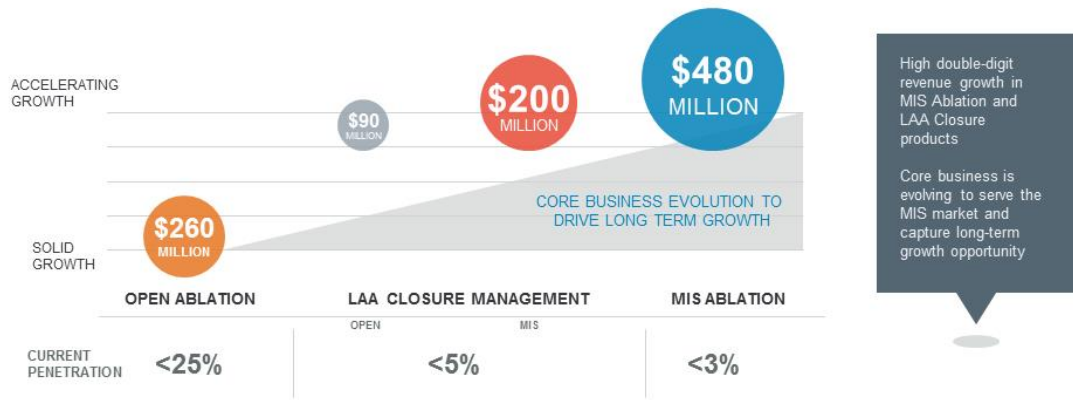


MIS ABLATION

\$480M

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

Business Evolution to Drive Long Term Growth



U.S. Open Ablation

Competitive Advantages

- Labeling advantage in the U.S.
- Robust portfolio across two technology platforms
- Solid gross margins
- Leader in market development via physician education



OPEN ABLATION

*AtriCure has the only ON-LABEL product (FDA approved)
Growth will be driven by increased market penetration*

90K

Cardiac surgeries on patients with pre-existing Afib

\$260M

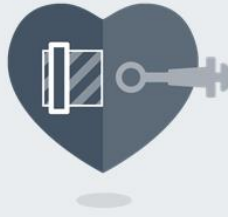
Market size

Growth Drivers

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

U.S. LAA Closure Management

OPEN & MIS



Open LAA Growth Drivers

- Broadening awareness of benefits of LAA management (science and society endorsement)
- Technology-driven benefits (ease of use and closure)
- ATLAS trial studying prophylactic treatment for non-Afib patients

MIS LAA Growth Drivers

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



LAA CLOSURE MANAGEMENT

*Highest growing franchise – over 30% CAGR for past three years
Over 110K AtriClip Systems implanted worldwide*

U.S. MIS Ablation

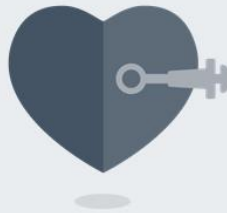
\$480M

US 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



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

MIS ABLATION

Upcoming clinical data will drive sustained market growth

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**
- **Clip business complementing growth** of Open / MIS segments

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 of current team is a top priority
- Each Area Includes:
 - 5-6 Regional Sales Managers
 - 4-6 Clinical Specialists
 - 1-2 Minimally Invasive Manager(s)



Key Sales Positions	2013	2016	2017
Area Directors	8	11	11
Regional Sales Managers	37	53	53
Ablation/Clinical Specialists	22	44	51
Minimally Invasive Managers	0	10	13

International Market = \$2B

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



Current International Sales (\$mm)



■ Open Ablation ■ MIS Ablation ■ Atriclip



\$525 M
OPEN ABLATION



\$600 M
LAA CLOSURE



\$985 M
MIS ABLATION

Financial Performance

Revenue growth expectations fueled by stability in OPEN ablation and high growth in MIS and LAA Closure



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- Cash, cash equivalents, and investments position of \$34M as of December 31, 2017
- Sufficient capital to operate the business to cash flow generation
- Historical **gross margins 70 – 72%** with expansion opportunity
- Expect top line constant currency growth of ~13% for 2017, or ~\$174.7 million
- Expect \$4M - \$6M EBITDA loss for the year
- On the cusp of profitability and committed to **positive full year EBITDA profit for 2018**

AtriCure

Investor Highlights

Leader in \$1B US 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 with improving profitability
- Commitment to innovation, education, and clinical science
- On the cusp of EBITDA profitability and positive cash flow



GROWTH DRIVERS

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



Thank You!

Supplemental Information

Franchise / Business Overview

Focus Areas	Products	Global Market Potential	Keys to Success	Trials/Data
OPEN Ablation (Concomitant)		\$770M Annually	<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 Synergy II 	<ul style="list-style-type: none"> ABLATE IDE = PMA PMA Post Approval Study (365 Patients) STS/Medicare retrospective studies Guidelines key – supporting many grants
OPEN Clip		\$1B+ Annually (Open & MIS)	<ul style="list-style-type: none"> EXCLUDE trial (510k data) Continued education and awareness Tie to ablation growth New Clip in 2018 ATLAS and other data 	<ul style="list-style-type: none"> EXCLUDE – Complete ATLAS – Enrolling
MIS Ablation		\$2B+ Annually	<ul style="list-style-type: none"> Trials – DEEP and CONVERGE Collaborative care Convergent growth 	<ul style="list-style-type: none"> CONVERGE IDE DEEP IDE
MIS Clip			<ul style="list-style-type: none"> Awareness Trial Product expansion (Pro2, Pro-V) 	<ul style="list-style-type: none"> Stroke Safety Feasibility Complete No trial planned
International		Included above	<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 Clip registries

AtriCure Portfolio Designed to Treat Afib

2016 U.S. REVENUE BY PRODUCT CATEGORY



OPEN ABLATION

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



LAA CLOSURE MANAGEMENT

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

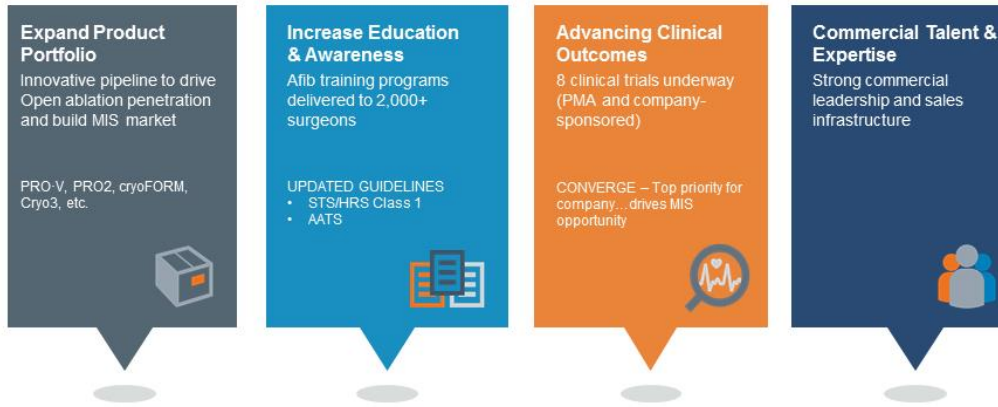
MIS
Strong product line with new product innovations continuing to drive the shift to MIS procedures



MIS ABLATION

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

Keys to Market Development



Expanding Product Portfolio

- Launched 8 products in last three years (2 from acquisitions)
- Defined track record of organic and inorganic execution
- Pipeline focus across all franchises
- Innovation toward less invasive, simpler, easier to use, and more efficient products
- Strong commercial pricing discipline for new product introductions



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Long-term Goal

Continued expansion of products in both core and new markets

AtriCure

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+
physicians worldwide

Helping physicians address
the growing Afib epidemic

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
ATLAS	Trial designed to compare impact of surgical LAA closure using AtriClip LAA Exclusion Systems on postoperative Afib patients
CEASE AF	Randomized trial of hybrid bi-lateral approach (same as DEEP) versus catheter ablation in persistent and longstanding persistent Afib

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 US and 3 OUS)

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

- Principal Investigator announced in Q1 2017
- Total of **25** sites enrolling
- **100** patients enrolled (Q4 2017)
- Enrollment completion target: **mid-2018**

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; LAAM 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 LS 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.

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WHAT'S NEXT?

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

AtriCure

Society Guidelines for Treatment of AF

SOCIETY

RECOMMENDATION

STS (2016)¹

Surgical ablation for AF 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 AF 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 AF surgical ablation procedure is reasonable for selected patients with AF undergoing cardiac surgery for other indications.

A stand-alone AF surgical ablation procedure may be reasonable for selected patients with highly symptomatic AF not well managed with other approaches.

HRS/ACC/AHA/STS/EHRA/ECAS (2012)³

"It is advisable that all patients with documented AF referred for other cardiac surgeries undergo a left or biatrial procedure for AF 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 AF should be considered in patients with persistent AF, or with symptomatic AF undergoing cardi thoracic surgery.

ESC (2010)⁶

Surgical ablation of AF should be considered in patients with symptomatic or asymptomatic AF undergoing cardiac surgery.

Minimally invasive surgical ablation of AF without concomitant cardiac surgery is feasible and may be performed in patients with symptomatic AF after failure of catheter ablation

1. Badiwari 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 64, no 21, 2014
 3. Callans et al. HRS/ACC/AHA/STS/EHRA/ECAS Catheter and Surgical Ablation. Heart Rhythm. vol. 9, no. 4, April 2012.
 4. Aylward et al. Surgical ablation for atrial fibrillation in cardiac surgery: Innovations. Vol 8, no 3, 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 LAAM

SOCIETY	RECOMMENDATION
STS (2016) ¹	It is reasonable to perform left atrial appendage excision or exclusion in conjunction with surgical ablation for AF 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 LAAO 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 ^{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 AF 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 WW Procedures 900,000

Total Open U.S. Procedures 300,000

30% with Afib

U.S. Procedures with Afib 90,000

~ U.S. Annual Opportunity¹ \$260M

~Current U.S. OPEN Ablation penetration, 25%

2016 U.S. OPEN Ablation Sales **\$60M**

- ~40K CABG... <10% Penetrated
- ~20K Aortic... < 20% Penetrated
- ~30K Mitral... < 50% Penetrated



1. Assumes annual pricing of \$2,900

U.S. LAA Closure Market Work-Up

OPEN LAA

Total OPEN WW Procedures	900,000
Total OPEN U.S. Procedures	300,000
30% with Afib	
U.S. Procedures with Afib	90,000
~U.S. Annual Opportunity ²	\$90M

MIS LAA

Non-paroxysmal Pts Annually Treated w 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



1. Assumes annual pricing of \$3,600 for MIS
 2. Assumes annual pricing of \$1,019 for Open

U.S. MIS Market Work-Up

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

~Unsuccessful Outcomes with Cath Ablation, 70%

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

~ Annual U.S. MIS Ablation Opportunity¹ \$480M

~Current MIS OPEN Ablation penetration, 5%

2016 U.S. MIS Ablation Sales **\$30M**



1: Assumes annual pricing of \$8,600

Additional Growth Drivers with AtriClip

Prophylactic treatment for OPEN LAA

Additional \$500M global market

Total OPEN WW Procedures	900,000
Total OPEN U.S. Procedures	300,000
70% without A fib	
~U.S. Procedures with A fib	210,000
~U.S. LAA Prophylactic Annual Opportunity ²	\$215M

Sole Therapy LAAM Market

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

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

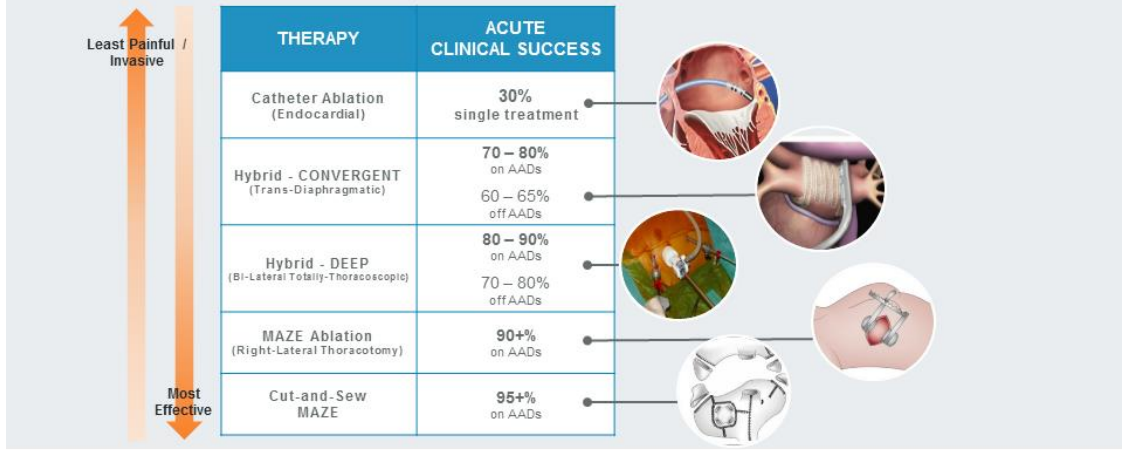
MIS Clip with Heart Procedures

- 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 annual pricing of \$3,600 for MIS
² Assumes annual pricing of \$1,019 for Open

Non-Drug Options of Care For Non-Paroxysmal Afib



Maze IV Procedure

