# **AtriCure Investor Presentation**

**April 2020** 



## **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," "could," "target," "guidance," "forecast," "goal," "objective," "aim," 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, including, without limitation, statements about AtriCure's anticipated future operating and financial performance, business plans, and prospects and expectations for our product pipeline. 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 substantial 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.



## **AtriCure Overview**



# Large Markets Addressing an underserved and growing patient population

- Approximately 33 million Afib patients globally, with majority having advanced forms of the disease
- Current standard of care does not adequately address this population



#### **Strong Portfolio**

Existing products and solutions driving consistent growth

- Strong history of double-digit revenue growth, driven by great products, commitment to education, and societal guideline support
- Only PMA product for the surgical treatment of Afib
- The AtriClip® device is the most widely used Left Atrial Appendage (LAA) device with over 235,000 sold to date
- Expanding product portfolio from internal development and acquisitions



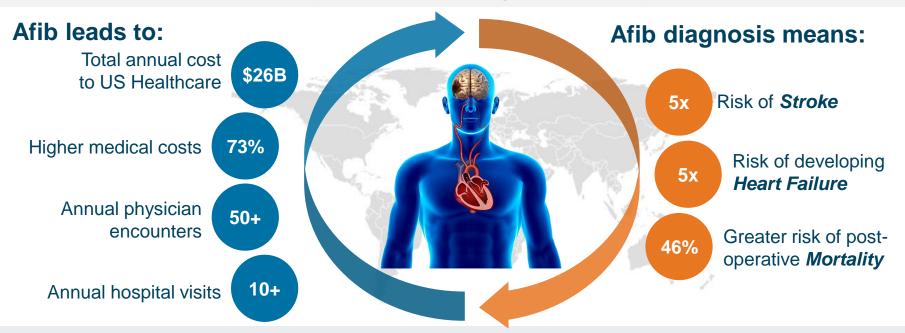
- PMA pivotal trials underway for hybrid approaches for Afib: CONVERGE, aMAZE, DEEP
- Launched pain management business to address pain associated with surgery
- Early in market development process Evolution to minimally invasive therapies will drive growth, diversifying and accelerating in 2021 and beyond



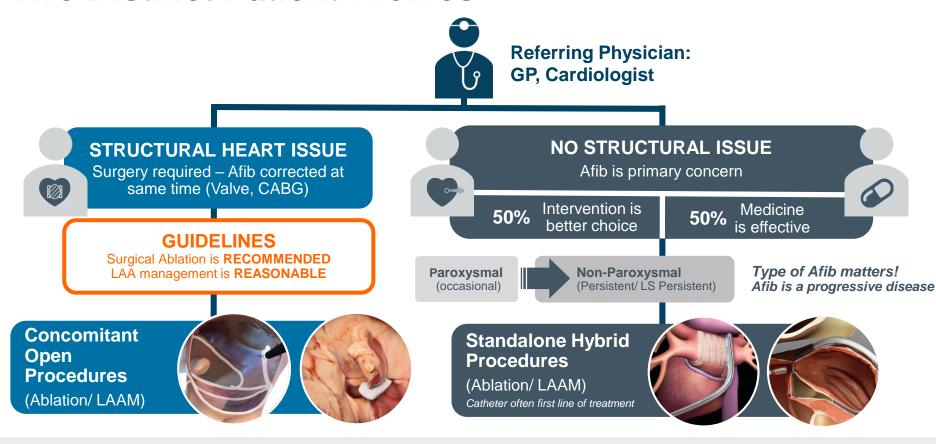
## Afib: a Serious and Costly Problem

Atrial Fibrillation (Afib) is an irregular heartbeat (or arrhythmia) that affects more than 33 million people worldwide.

Approximately 1.2 million Afib diagnoses annually in the US.



## **Two Distinct Patient Profiles**





# Atrial Fibrillation

\$1.0-1.6B

US Ablation + Appendage Management

## **Significant Market Opportunity**

## **US Standalone Market: Expanding Growth**

- More than 150k Afib patients annually
- Vastly underpenetrated and increasing market (estimating 10-15% market expansion)
- Multiple approaches to treatment
  - CONVERGENT + AtriClip, DEEP, LARIAT®

\$3B+ Worldwide

Total US market opportunity \$2B+ annually

International
Afib market
\$1B+ annually

## \$700-800M





\$350M

**US** Ablation

## **US Concomitant Markets: Steady Growth**

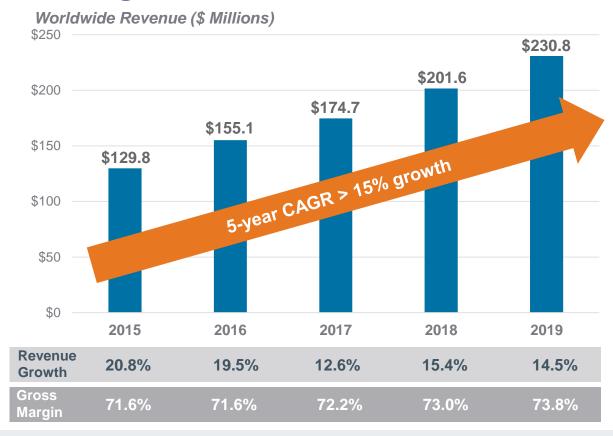
Cardiac Surgery ("Open")

- Estimated 300k total patients annually (Afib, non-Afib)
- Surgical market opportunity is steady

#### **Pain Management**

- Estimated 140k thoracic patients annually
- Boosting growth via new, adjacent market

# **Strong Financial Performance**



#### **Consistent Revenue Growth**

Strong history of double-digit YoY growth

\$68.5M Cash & Investments at March 31, 2020

Steady Improvement to Gross Margin
Future pathway to 75%+

#### 2020 Guidance

Given the uncertainty created during the COVID-19 pandemic, we have withdrawn our previously announced 2020 financial guidance.

# **Innovative and Expanding Product Portfolio**



**Ablation** 

ISOLATOR® SYNERGY™ CLAMP cryoICE® CRYOABLATION PROBE

EPI-SENSE® DEVICE cryoSPHERE® CRYOABLATION PROBE **2020 Product Launch:** ISOLATOR SYNERGY ENCOMPASS™ CLAMP

**2000 to 2015:** Foundation in surgical Afib tools *Future pipeline expansion across franchises* 

**2015 and Beyond:** Building the future in minimally invasive therapies *Innovation toward less invasive, simpler, and more efficient products* 

Appendage Management

ATRICLIP PRO® DEVICE

ATRICLIP FLEX.V® DEVICE

LARIAT® DEVICE



## **SPOTLIGHT: Cryo Nerve Block for Pain Management**

#### **Therapy Overview**

- Long-lasting pain management therapy, designed for use in thoracic surgical procedures
- · Temporarily stops the transmission of pain signals coming from the chest wall during surgery
- Nerve "scaffolds" remain intact allowing axons to regenerate and restore nerve function over the course of 1-3 months
- Applicability in a wide variety of thoracic surgical approaches (thoracotomy, video-assisted, robotic) and procedures (resection, transplant, thoracoabdominal, surgical rib fixation, pectus repair)



#### **Growth Drivers**

- Q1 2019 launch of cryoSPHERE probe
- Building a small team to begin market development
- Continuing to gather data to support evidence development the therapy
- Potential to contribute to combatting the opioid epidemic 1 in 7 thoracic surgery patients become reliant upon opioids after their procedure<sup>1</sup>



## **Advancing Clinical Outcomes**

Multiple studies to generate clinical evidence and expand indications



Trial/Study	Description	Status
CONVERGE Pivotal	Designed to support FDA approval of EPi-Sense device specifically for the treatment of persistent Afib through an abdominal approach	Final PMA module submitted; continued access protocol approved
aMAZE Pivotal	Designed to support FDA approval of LARIAT System to percutaneously isolate and ligate the Left Atrial Appendage, adjunct to pulmonary vein isolation (PVI) catheter ablation, for persistent or longstanding persistent Afib	Enrolled and in follow up; continued access protocol approved
DEEP Pivotal	Designed to support FDA approval of various devices specifically for the treatment of persistent Afib through a bi-lateral totally thoracoscopic approach	Enrolling
FROST Study	Designed to demonstrate that intraoperative intercostal cryoanalgesia in conjunction with standard of care (SOC) provides improved analgesic efficacy in patients undergoing unilateral thoracotomy cardiac procedures as compared to current SOC	Complete; presented at STS in January 2020
ICE-AFIB Pivotal	Designed to support FDA approval of CryolCE Ablation System for the treatment of persistent and long-standing persistent Afib during concomitant open chest cardiac surgery	Enrolling
ABLATE Pivotal	Designed to demonstrate the safety and effectiveness of the AtriCure Bipolar System for treating permanent atrial fibrillation during concomitant on-pump cardiac surgery	Complete – PMA obtained in 2011



## **CONVERGE Overview**

**SUPERIORITY 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**

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

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



#### **HIGHLIGHTS**

- Completed enrollment in August 2018
- Final PMA module submitted in late 2019
- Continued Access
   Protocol approved

Accepted for late-breaker for HRS meeting in May 2020



## aMAZE Overview

**SUPERIORITY TRIAL** designed to evaluate safety and effectiveness of the LARIAT System to percutaneously isolate and ligate the Left Atrial Appendage for the treatment of persistent or longstanding persistent Afib

#### STUDY DESIGN

Study is conducted in two stages:

- Limited Early Stage (Stage 1): up to 250 subjects at up to 65 sites – COMPLETE
- Pivotal Stage/ Phase III (Stage 2): up to 600 subjects at up to 65 sites – ONGOING
- All subjects from both stages will be included in the primary analysis

#### **PRIMARY ENDPOINTS**

- Freedom from episodes of atrial fibrillation > 30 seconds at 12 months post index pulmonary vein isolation
- Time Frame: 12 months following pulmonary vein isolation catheter ablation procedure, measured by 24-hour Holter monitoring



#### **HIGHLIGHTS**

- Acquired SentreHEART® August 2019
- Trial enrollment completed December 2019
- Continued Access Protocol recently approved; enrollment begins in 2020
- Expect PMA in 2022; will update with more specific timing as trial progresses



# Aligning Expertise with Opportunity

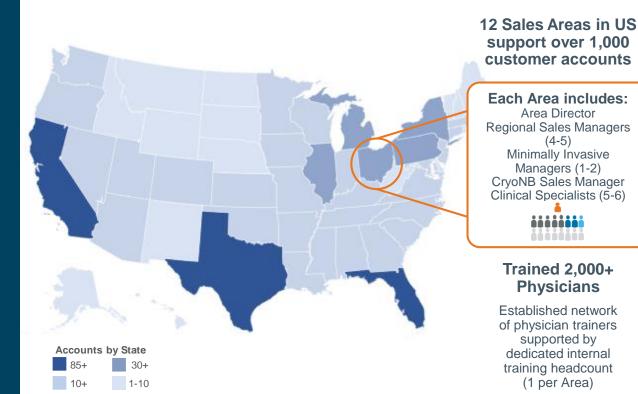
#### **Commercial Headcount**

- Shifting headcount growth from Sales Managers to Clinical Specialists
  - Managers build relationships, broaden adoption
  - Specialists provide case coverage
  - Improving productivity and leverage
- Dedicated MIS and cryoNB teams for market development

#### **Education Support**

- Significant investment in physician education
- Multiple training options including didactic, hands-on, proctoring, and case observations
- AATS Fellowships, STS and EACTs endorsed training program

# **US Commercial Organization**





#### ATRICURE PILLARS

Foundation of our past and strengthening our future



#### **Innovation**

Significant growth from AtriClip devices and cryoSPHERE probe

Expanding pipeline to drive Open ablation penetration and build MIS market



#### **Clinical Science**

First and only PMA approved device for surgical treatment of Afib

Multiple trials underway; priorities are CONVERGE & aMAZE

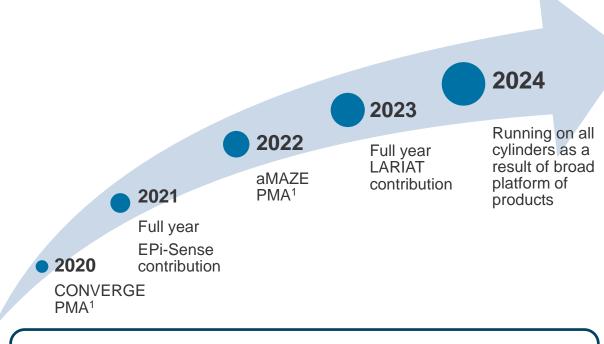


#### **Education and Awareness**

Afib training programs delivered to 3,000+ professionals worldwide

Updated Guidelines: STS/HRS Class I for surgical ablation

## **An Exciting Future**



Core double-digit growth business with improvement to profitability and continued margin expansion



<sup>&</sup>lt;sup>1</sup> Reflects estimated approval dates

# **AtriCure Highlights**

Creating a world class Afib platform





Addressing an underserved and growing patient population

- Large, vastly underpenetrated markets: over \$3B annually
  - US market opportunity in excess of \$2B
  - International market opportunity in excess of \$1B
- Current standard of care is not adequate for this population



## **Strong Portfolio**

Existing products and solutions driving consistent growth

- Diverse and growing portfolio Broad offering of products/solutions
- Commitment to innovation, education, and clinical science
  - Multiple product launches in last decade
  - Trained over 3,000 professionals
- Improving profitability profile



## **Bright Future**

Novel therapies supported by growing body of clinical evidence

- Evolution to minimally invasive therapies will drive growth
- Clinical evidence to support
   Multiple clinical trials readout out over next few years
- Launched pain management business

Adjacent use of technology adds to growth prospects





# Supplemental Information

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



## **COVID-19 Response**

Operationally, financially, and strategically positioning AtriCure for long-term growth



### **Health & Safety**

Taking precautions to provide a safe work environment for our employees

- Enabling employees to work from home as appropriate
- Implementing personal protection measures and extra cleaning to ensure the safety of those working in our offices
- Limiting non-essential travel



## **Maintaining Operations**

Continuing to provide products and support to our customers

- Running streamlined manufacturing, assembly, fulfillment and other related processes
- Providing continued case coverage support
- Utilizing online, interactive training to educate our customers



Executing cost-cutting measures without sacrificing strategic initiatives

- Delaying certain capital investments and hiring
- Reducing executive and board compensation
- Limiting other non-essential operating expenses where possible



# **US Concomitant Market Opportunity**

Estimated Afib Opportunity in Cardiac Surgery			
Annual Cardiac Surgeries	300,000		
Pre-Operative Afib Rate	~28%		
Cardiac Opportunity – Pre-Op Afib	85,000		
ASP Mix (Ablation and Appendage Management)	\$4,500		
Open Cardiac Surgery Opportunity – Afib	\$382M		

Estimated Non-Afib Opportunity in Cardiac Surgery			
Annual Cardiac Surgeries	300,000		
Pre-Operative Non-Afib Rate	~72%		
Cardiac Opportunity – Pre-Op Afib	215,000		
ASP Mix (Appendage Management ONLY)	\$1,750		
Open Cardiac Surgery Opportunity – Non-Afib	\$376M		



- US annual cardiac surgery volume steady over the past 5 years with shifts in procedure types<sup>1</sup>
- Pre-Op Afib occurs frequently in cardiac surgery patients<sup>2</sup>
- New onset Post-Op Afib is a well-documented complication of cardiac surgery, even if patients do not present with pre-op Afib<sup>3</sup>

<sup>1.</sup> STS Adult Cardiac Surgery Database, 2018/2019 Harvest Executive Summary

<sup>19 2.</sup> McCarthy, Davidson et al, JIVCS 2019

<sup>3.</sup> Lin et al. Stroke 2019

## **US Standalone Market Opportunity**

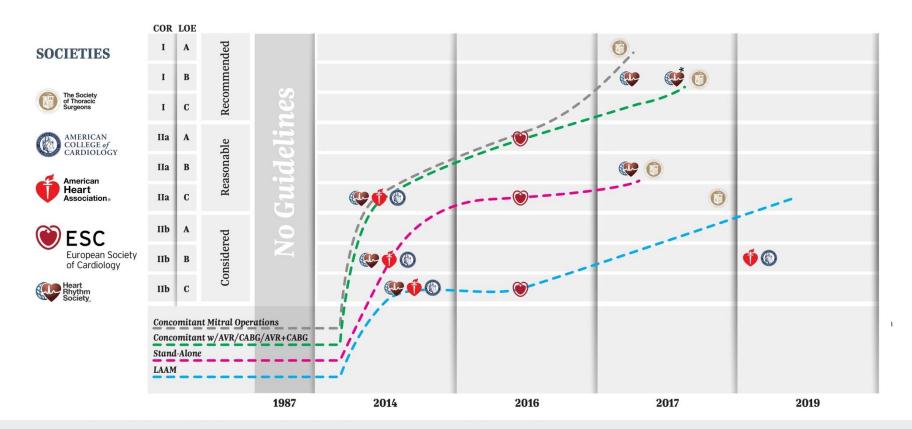
Estimated <b>Standalone</b> Afib Opportunity			
Paroxysmal Afib Catheter Ablation	100,000		
Failed Paroxysmal Afib Catheter Ablation (30%)	30,000		
Persistent/Longstanding Persistent Afib Catheter Ablation	56,000		
ASP Mix (Ablation + Appendage Management)	\$18,500		
Standalone Afib Opportunity (Persistent Only)	\$1.0B		
Standalone Afib Opportunity (Failed Paroxysmal & Persistent)	\$1.6B		



- Prevalence of Afib in the US is 6M patients with ~50% resistant to medical management. ~50% of these patient are classified as persistent Afib, or roughly 1.5M patients.<sup>1</sup>
- However, the US healthcare system lacks sufficient capacity to treat the true prevalence of Afib; market opportunity in analysis at left only considers catheter ablation patients.
- Catheter ablation procedures have grown 10-15% annually.<sup>2</sup>

Am Journal of Cardiology 2013, 112: 1142-1147, Clinical Epidemiology 2014, American Col of Card 2013. Circulation. 2006:114:119-125.

# **Advancing Surgical Ablation Guidelines**





## **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
- Standalone / 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

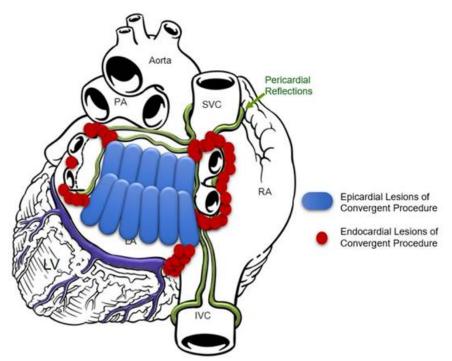


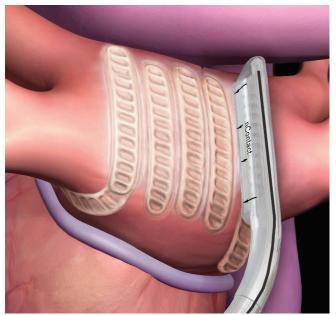
#### WHAT'S NEXT?

- Educate the market
   Continue investments in physician training across therapies
- Generate evidence
   Numerous clinical trials and studies underway
- Drive deep understanding of the benefits of hybrid ablation

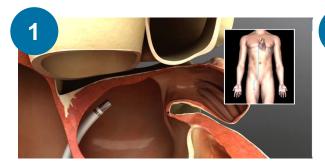


# The CONVERGENT Approach





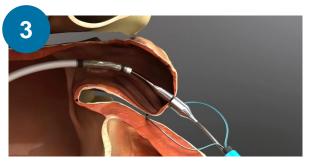
## The LARIAT Procedure



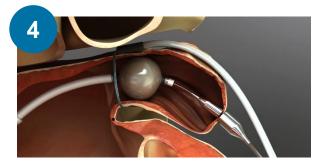
**Access:** Routine percutaneous techniques for pericardial and transseptal access are performed using fluoroscopy and transesophageal echocardiography.



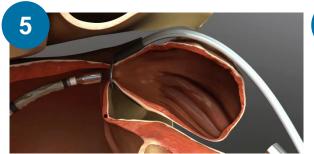
**Delivery:** Two magnet-tipped guidewires (FindrWIRZ®) are attached to stabilize the LAA with minimal trauma and manipulation for delivery of the LARIAT.



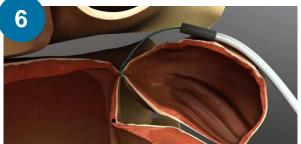
**Delivery:** The LARIAT snare is delivered over the epicardial FindrWIRZ to the apex of the LAA.



**Capture:** The LARIAT snare is positioned to the base of the LAA using the EndoCATH® balloon for anatomic land marking of the optimal closure site.



**Closure:** The LARIAT snare is closed and the FindrWIRZ and the EndoCATH are removed prior to release and tightening of the suture.



**Removal:** The suture is released and tightened at the base of the LAA and the LARIAT is removed. The SureCUT® suture cutter is used to remotely cut the excess suture.



## The Cox-Maze IV Procedure

