

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 11, 2021

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 45040

(Address of Principal Executive Offices, and Zip Code)

(513) 755-4100

(Registrant's Telephone Number, Including Area Code)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Common Stock, \$0.01 par value

Trading Symbol(s)
ATRC

Name of each exchange on which registered
NASDAQ

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 11, 2021, 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, 2020. 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 11, 2021 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.

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 11, 2021](#)

[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 11, 2021

By: /s/ Angela L. Wirick
Angela L. Wirick
Chief Financial Officer

For immediate release
January 11, 2021

AtriCure Reports Preliminary Results for Fourth Quarter and Full Year 2020

*Fourth quarter 2020 worldwide revenue of \$57.7 million
(U.S. \$47.4 million, International \$10.3 million)*

MASON, Ohio, January 11, 2021 – AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage (LAA) management, announced preliminary financial results for the fourth quarter and full year 2020.

“We are pleased with our fourth quarter and full-year results which reflect the resiliency and strength of our team, as well as the overarching unmet need in our core markets. COVID-19 continues to impact our revenue as procedure volumes remain below pre-pandemic levels globally, and each resurgence of the virus is a reminder of the strain on healthcare resources,” said Michael Carrel, President and Chief Executive Officer of AtriCure. “That said, the unwavering commitment of our people in support of our patient-first mission has been inspiring throughout the year.”

Mr. Carrel continued, “We ended 2020 in a very strong position financially and strategically, having made remarkable progress on many key initiatives across our business. Additionally, we are in a unique position of igniting multiple catalysts in 2021, including the hybrid Convergent procedure, EnCompass® Clamp, Crvo Nerve Block therapy expansion, and aMAZE™ clinical trial data, leading to significant market expansion and accelerated and durable growth rates over the long-term.”

Preliminary and Unaudited 2020 Financial Results

Preliminary, unaudited revenue for fourth quarter 2020 is expected to be approximately \$57.7 million, reflecting a decrease of approximately 6% over the fourth quarter of 2019 (-7% on a constant currency basis). Preliminary revenue for full year 2020 is expected to be \$206.5 million, reflecting a decline of approximately 11% over full year 2019 (-11% on a constant currency basis). Fourth quarter and full year 2020 revenue was impacted by the global decline in surgical procedures as a result of the COVID-19 pandemic.

On a sequential quarter basis, worldwide revenue for fourth quarter 2020 increased approximately 5% over third quarter 2020. The increase in revenue from third quarter 2020 reflects stabilizing procedure volumes for the majority of the fourth quarter.

Constant currency revenue is a non-GAAP measure. AtriCure will provide a reconciliation of non-GAAP measures to the related GAAP measure in the release of final 2020 results.

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 left atrial appendage management devices worldwide. 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. Actual results could differ materially.

CONTACTS:

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AtriCure Investor Presentation

Creating a World Class Afib Platform



January 2021

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 AtriCure's actual results to be materially different than those expressed in its forward-looking statements, see its Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the SEC and available at <http://www.sec.gov>, which contain risk factors. Forward-looking statements address AtriCure's 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. These risks and uncertainties include, but are not limited to: whether CONVERGE will be approved by FDA and any other required regulatory authorities; whether any additional clinical trials will be initiated or required for CONVERGE prior to approval of FDA, or at all; whether AtriCure will be able to successfully implement its commercialization plans for CONVERGE, if approved; whether the market opportunity for CONVERGE is consistent with the Company's expectations and market research; AtriCure's ability to execute on the commercial launch of CONVERGE, if and when approved, on the timeline expected, or at all; whether AtriCure will be able to generate its projected net product revenue on the timeline expected, or at all; the effects of the COVID-19 outbreak on AtriCure's business and results of operations, including the effects of suspension or halting of elective surgeries; other matters that could affect the availability or commercial potential of CONVERGE and AtriCure's other products and product candidates; competition from new and existing products and procedures in the highly competitive medical device industry; and other important factors, including, AtriCure's expectations regarding its financial performance and capital requirements, any of which could cause AtriCure's actual results to differ from those contained in the forward-looking statements or otherwise discussed in AtriCure's reports filed with the SEC. With respect to the forward-looking statements, AtriCure claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. AtriCure undertakes no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise unless required by law.

We are passionately focused on reducing the global Afib epidemic and healing the lives of those affected



Large Markets

Addressing an underserved and growing patient population



Strong Portfolio

Existing products and solutions driving consistent growth



Bright Future

Novel therapies supported by growing body of clinical evidence

Afib: a Serious Problem



Atrial Fibrillation (Afib) is an irregular heartbeat (or arrhythmia) that affects more than 33 million people worldwide.¹

Approximately 1.2 million Afib diagnoses annually in the US.²

5x

Risk of **Stroke**³

>5x

Higher risk of **Heart Failure**⁴

46%

Greater risk of all cause **Mortality**⁵

US Market Opportunity

\$350M

Pain Management Procedures (Ablation)

Boosting Growth via adjacent new market

Estimated **140,000 thoracic patients** annually

\$700-800M

Concomitant Open Procedures (Ablation/LAAM)

Steady Growth in penetration of Cardiac Surgery Market

- Estimated **300,000 total patients** (Afib, non-Afib) annually with structural heart issue
- Only PMA product for the concomitant surgical treatment of Afib

\$2B+ and growing Standalone Hybrid Procedures (Ablation/LAAM)

Expansive Growth from development of Standalone Afib Market

Vastly underpenetrated market with 10-15% estimated annual market expansion

- **Addressable market is more than 3 million patients;** less than 1% treated today
 - 25,000 long-standing persistent patients treated by catheter ablation only today
- Multiple approaches to treatment
 - CONVERGENT + AtriClip®, DEEP, LARIAT®

Significant Global Market Opportunity

US Market Focus

- Continued build of dedicated sales and training expertise
- Clinical data supporting multiple label expansions
- New product development
- Enhance reimbursement

US market opportunity
\$3B+ annually



International market
opportunity \$2B+ annually

International Market Focus

- Penetration of large markets first
- Expand product availability
- Improve market access via reimbursement
- Continued build of dedicated sales and training expertise

History of Strong Financial Performance

Worldwide Revenue (\$ Millions)



Revenue Growth	20.8%	19.5%	12.6%	15.4%	14.5%
Gross Margin	71.6%	71.6%	72.2%	73.0%	73.8%

Historical Results

Consistent Revenue Growth

Strong history of double-digit YoY growth

Steady Improvement to Gross Margin

\$250 million Cash & Investments
as of September 30, 2020

Q4 2020 Results*

Revenue of \$57.7 million
+5% sequential quarter growth over Q3 2020

* Q4 2020 revenue is preliminary and unaudited

COVID-19 Response

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



Health & Safety

Provide a safe work environment for our employees

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



Maintaining Operations

Deliver products and support to our customers

- Maintaining manufacturing, assembly, fulfillment – modified to adhere to safety recommendations
- Continuing case coverage support
- Utilizing online and mobile training venues to educate our customers



Expense Management

Cost-reductions without sacrificing strategic initiatives

- Delayed certain capital investments
- Temporarily reduced executive and board compensation
- Limited other non-essential operating expenses where possible

While our plans will continue to evolve in response to changes caused by the COVID-19 pandemic, we remain committed to the AtriCure Team and to the execution of our strategic initiatives.

2021 Priorities: Building for the Future



Standalone Hybrid Procedures
Ablation and LAAM

- **CONVERGE PMA approval and launch**
 - Re-engaging sites and training new accounts
 - Addition of AtriClip to the Convergent procedure
 - Continued global expansion of commercial and training teams
- **aMAZE™ clinical trial**
 - PMA submission to FDA
 - Release of clinical trial data



Concomitant Open Ablation
Pain Management

- **EnCompass® Clamp clearance and launch**
- **Expansion of commercial team, training programs**



COVID Recovery

- **Supporting our people, patients and partners**

CONVERGE Overview

SUPERIORITY TRIAL designed to support FDA approval of the Epi-Sense device

STUDY DESIGN

Summary

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

Number of Subjects and Sites

153 subjects
27 sites (25 US and 2 OUS)

Study Duration

12 month and 18 month monitoring, then 3 and 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

Predetermined performance goal for the study is 12% freedom from MAE's as adjudicated by the CEC for the procedural to 30-day post procedure time period

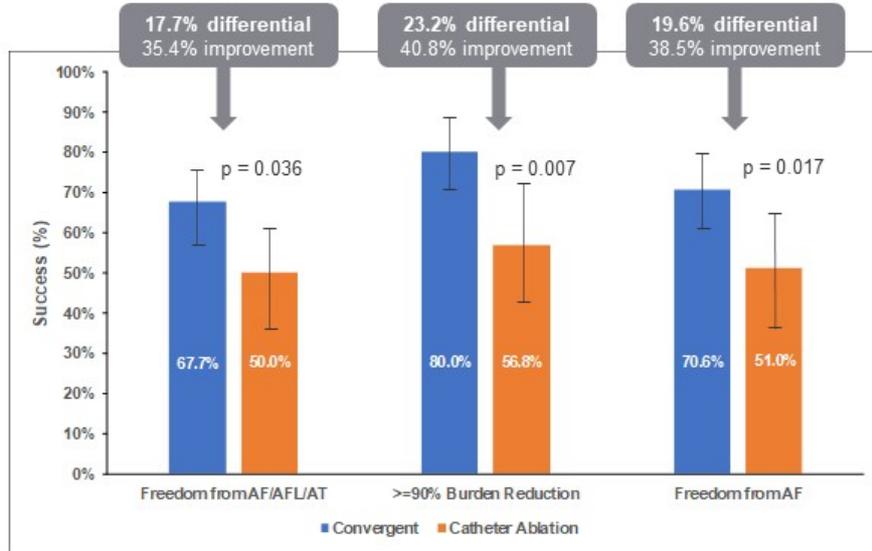


HIGHLIGHTS

- Completed enrollment August 2018
- Data released at virtual Heart Rhythm Society (HRS) conference May 2020
- PMA submission seeking approval for treatment of long-standing persistent Afib Q4 2020
- Trial results published in *Circulation: Arrhythmia and Electrophysiology* November 2020
- Convergent procedure featured in HRS conference in November 2020: *Hybrid Therapies for AF: Present and Future*

Achieved statistical superiority for primary endpoints

CONVERGE Trial Primary and Secondary Effectiveness

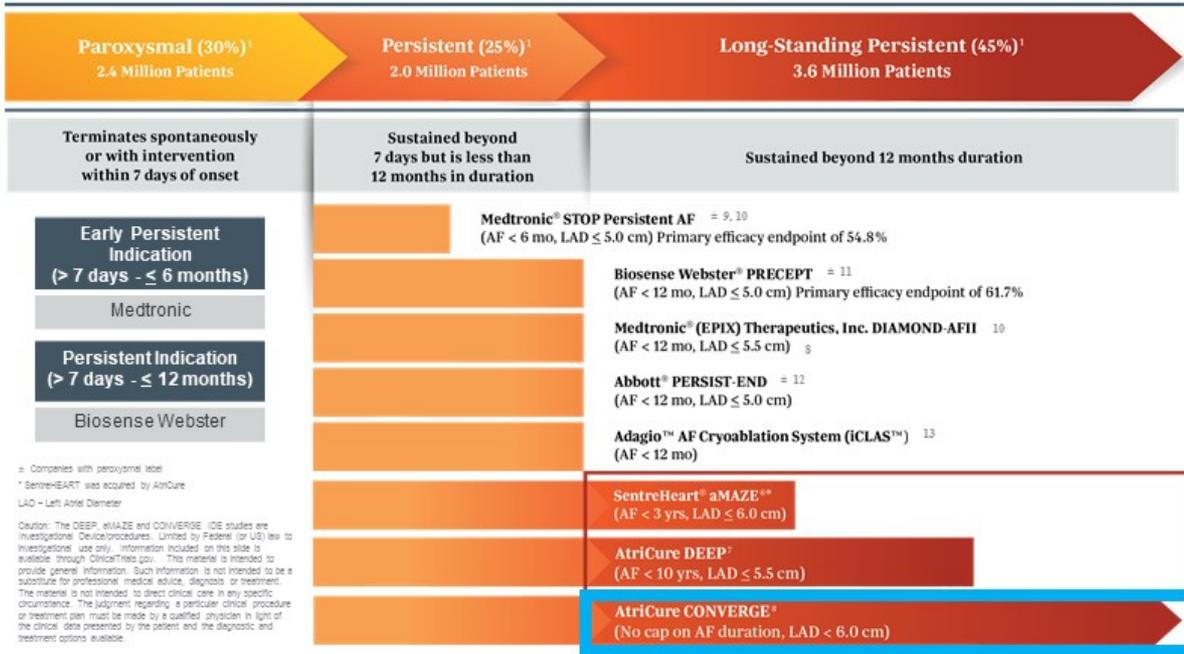


Superiority of the Hybrid Convergent procedure over Catheter ablation in all three primary and secondary endpoints was demonstrated; more than 35% improvement in each endpoint was shown.

Data for long-standing persistent patients in the trial demonstrated particularly compelling efficacy and durability – exceeding the overall trial results at left.

Chi-squared p values

Persistent / Long-Standing Persistent AF Clinical Trial Patient Landscape



⁸ = Compares with paroxysmal label
⁹ SentreHEART was acquired by AtriCure
 LAD = Left Atrial Diameter
 Caution: The DEEP, aMAZE and CONVERGE IDE studies are investigational. Device/procedures. Limited by Federal (or US) law to investigational use only. Information included on this slide is available through ClinicalTrials.gov. This material is intended to provide general information. Such information is not intended to be a substitute for professional medical advice, diagnosis or treatment. The material is not intended to direct clinical care in any specific circumstance. The judgment regarding a particular clinical procedure or treatment plan must be made by a qualified physician in light of the clinical data presented by the patient and the diagnostic and treatment options available.

¹ Percentages reflect the percentage of diagnosed AF patients in each disease stage in the AF Progression

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CONVERGE

Emphasizes value of **team-based approach** for advanced AF treatment

Additive to endocardial catheter ablation

AtriCure

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

- **Summary**
Multi-center, prospective, open label randomized 2:1
 - Control Arm – PVI
 - Treatment Arm – PVI + Ligation of LAA with Lariat System
- **Number of Subjects and Sites**
600 subjects; 65 sites, all U.S.
- **Study Duration**
12 month monitoring and then 5 year follow-up of all subjects

PRIMARY ENDPOINTS

- **Effectiveness** - Freedom from episodes of Afib >30 seconds at 12 months post index pulmonary vein isolation
- **Safety** - Primary safety endpoint for the study is 10% freedom from MAE's as adjudicated by the CEC for the period from the procedure through 30 days
- **Time Frame:** 12 months following pulmonary vein isolation catheter ablation procedure, measured by 24-hour Holter monitoring

amaze
LARIAT Clinical Trial

HIGHLIGHTS

- Acquired SentreHEART® August 2019
- Trial enrollment completed December 2019
- Final Patient follow-up expected 1H 2021
- Expect PMA submission to FDA in 2H 2021
- Anticipated PMA approval in 2022-2023

Innovative and Expanding Product Portfolio



Ablation ISOLATOR® SYNERGY™ CLAMP cryoICE® CRYOABLATION PROBE EPI-SENSE® DEVICE cryoSPHERE® CRYOABLATION PROBE **Future 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® FLEX DEVICE ATRICLIP PRO® DEVICE ATRICLIP PRO•V® 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 transmission of pain signals coming from the chest wall during surgery
- Nerve "scaffolds" remain intact allowing axons to regenerate and restore nerve function over time
- Applicability in a wide variety of thoracic surgical approaches (thoracotomy, video-assisted, robotic) and procedures (resection, transplant, thoracoabdominal, surgical rib fixation, pectus repair)



HIGHLIGHTS

- \$350M U.S. market opportunity*
- Dedicated commercial team established in 2019 and expanding
- Q1 2019 launch of cryoSPHERE probe
- **Q4 2020 label expansion includes adolescent patients as young as 12 years of age**
- Continuing to gather data to support evidence development for therapy
- Potential to contribute to combatting the opioid epidemic – 1 in 7 thoracic surgery patients become reliant upon opioids after their procedure¹⁴

* Market opportunity based on internal estimates and research, as well as from publicly available information.

15

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AtriCure

Aligning Expertise with Opportunity



Commercial Teams

54 U.S. Sales Managers
Covering 1,000+ accounts

64 U.S. Clinical Specialists
providing case support

30 U.S. Dedicated MIS+Lariat team members

14 U.S. Specialists
Cryo Nerve Block Team

33 U.S. Education Support
Physician + Field

39 International Sales and Clinical Support

AtriCure Pillars

Foundation of our past and strengthening our future



Innovation

Expanding pipeline to drive Open ablation penetration and build MIS market



Clinical Science

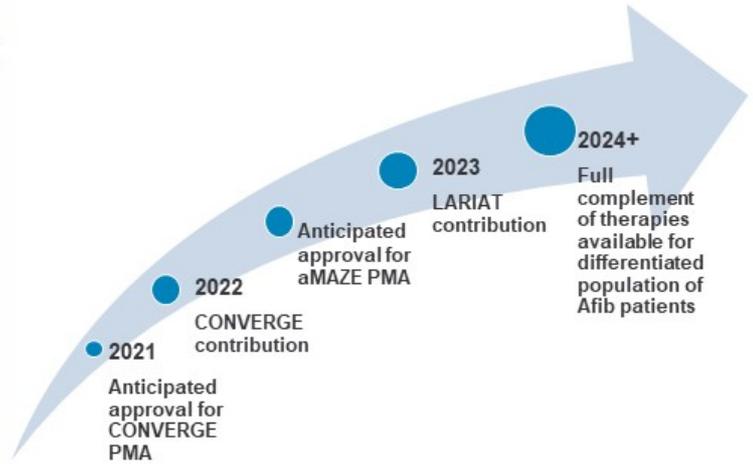
CONVERGE & aMAZE trials are complimentary and differentiated as the ONLY randomized control trials for advanced Afib



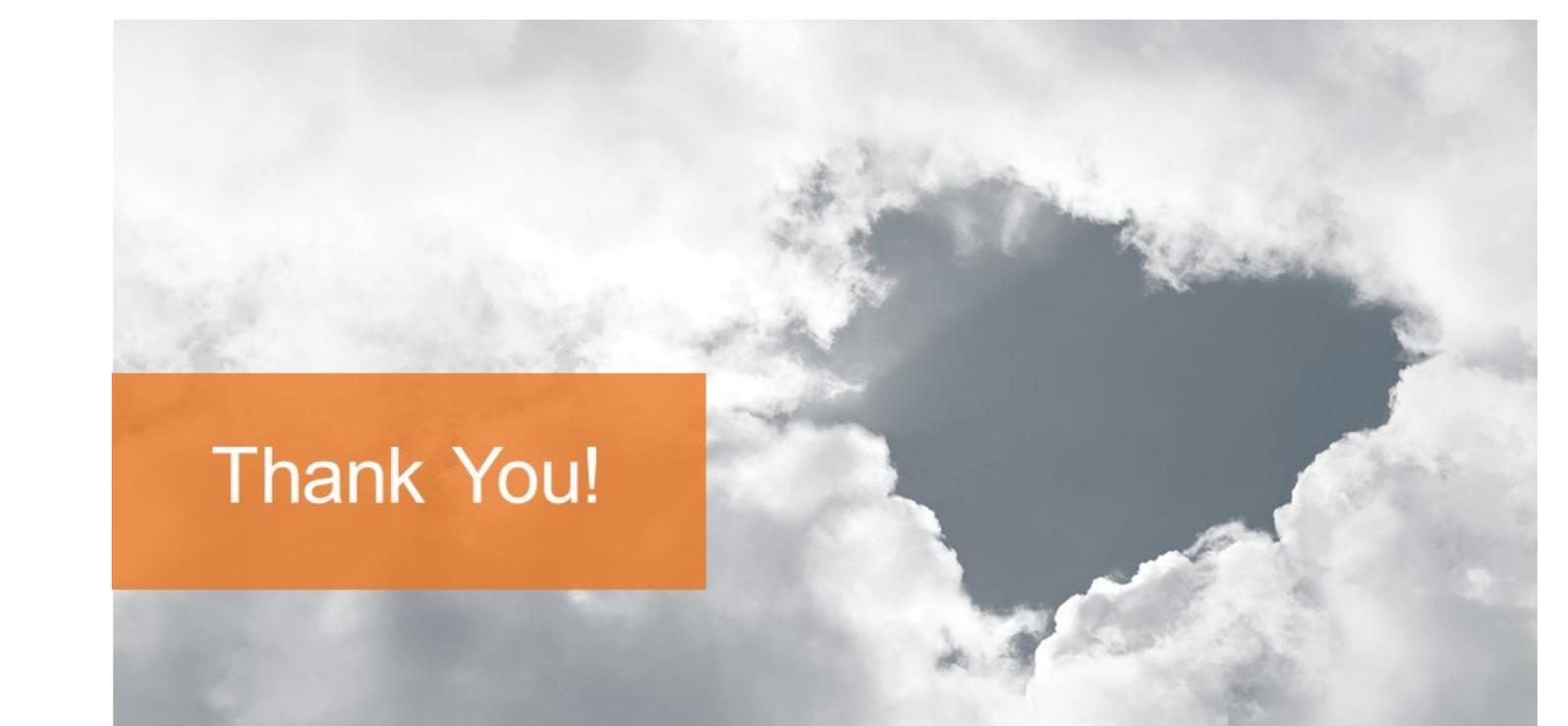
Education

Significant investment in physician education, providing multiple training options

Expecting An Exciting Future...



Core double-digit growth business with accelerators in EP landscape (Hybrid Convergent + aMAZE)



Thank You!

Supplemental Information

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

Key Investment Rationale



Large Markets
Addressing an underserved
and growing patient population

- Approximately 33 million Atrial Fibrillation patients globally, with majority having advanced forms of the disease¹
- Multibillion dollar annual market opportunity
- Current standard of care for intervention (catheter ablation) does not adequately address the most advanced forms of the disease



Strong Portfolio
Existing products and solutions
driving consistent growth

- Strong history of double-digit revenue growth, driven by great products, clinical evidence, commitment to education, and societal guideline support
- Only PMA product for the concomitant surgical treatment of Afib
- The AtriClip device is the most widely used Left Atrial Appendage device with approximately 275,000 sold to date
- Diverse and expanding product portfolio from internal development and acquisitions



Bright Future
Novel therapies supported by
growing body of clinical evidence

- PMA pivotal trials for hybrid approaches for Afib: CONVERGE, aMAZE
- 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 2022 and beyond

Two Distinct Patient Profiles



Referring Physician:
GP, Cardiologist



STRUCTURAL HEART ISSUE

Surgery required – Afib corrected at same time (Valve, CABG)

GUIDELINES¹⁵

Surgical Ablation is **RECOMMENDED**
LAA management is **REASONABLE**

Concomitant Open Procedures
(Ablation/LAAM)



NO STRUCTURAL ISSUE

Afib is primary concern

Intervention is better choice

Medicine is effective

Paroxysmal (occasional)

Non-Paroxysmal

Persistent

Long-Standing Persistent

*Type of Afib matters!
Afib is a progressive disease*

Standalone Hybrid Procedures
(Ablation/LAAM)

Catheter often first line of treatment



US Concomitant Market Opportunity

Estimated **Afib** Opportunity in Cardiac Surgery

Annual Cardiac Surgeries ¹⁹	300,000
Pre-Operative Afib Rate ¹⁷	~28%
Cardiac Opportunity – Pre-Op Afib	85,000
ASP Mix (Ablation and Appendage Management) ²⁰	\$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) ²⁰	\$1,750
Open Cardiac Surgery Opportunity – Non-Afib	\$376M



- US annual cardiac surgery volume steady over the past 5 years with shifts in procedure types¹⁶
- Pre-Op Afib occurs frequently in cardiac surgery patients¹⁷
- New onset Post-Op Afib is a well-documented complication of cardiac surgery, even if patients do not present with pre-op Afib¹⁸

US Standalone Market Opportunity



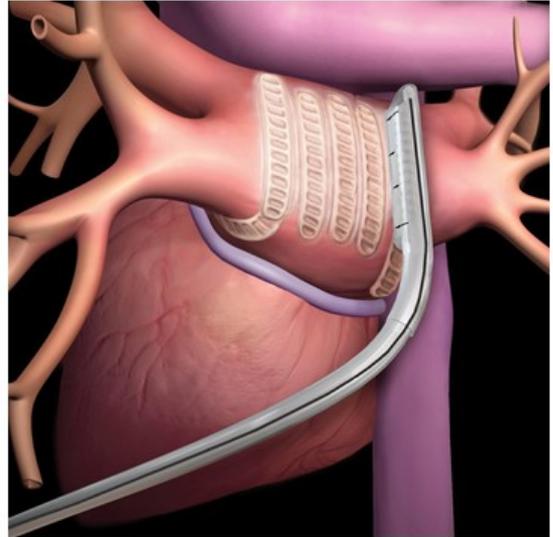
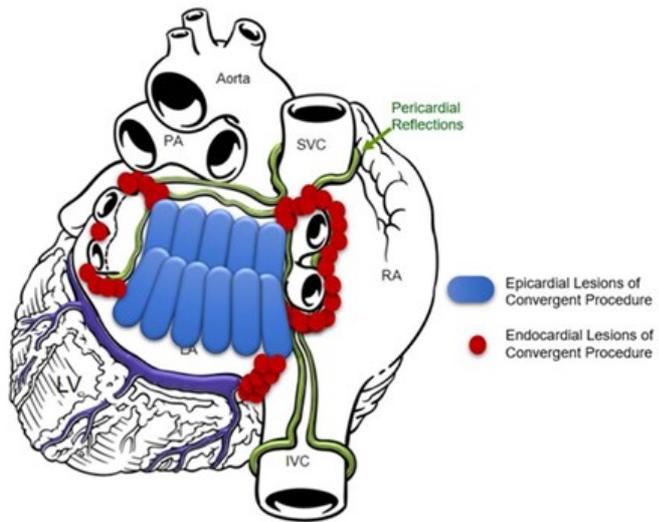
Estimated Standalone Afib Opportunity

	2020	Projected 2025
Long-standing Persistent Afib Catheter Ablation ²³	25,000	45,000
ASP Mix (Ablation + Appendage Management) ²⁰	\$15,000	\$15,000
Immediate Standalone Afib Opportunity	\$375M	\$675M
Additional penetration Long-standing Persistent Afib patients (estimated at 5% penetration)	150,000	175,000
ASP Mix (Ablation + Appendage Management) ²⁰	\$15,000	\$15,000
Incremental Standalone Afib Opportunity (estimated at 5% penetration)	\$2B+	\$3B+

Market opportunity in analysis at left considers:

- Addition of ablation and LAAM to existing catheter ablation procedures
 - Catheter ablation procedures have grown 10-15% annually²²
- Incremental penetration of advanced Afib patient population
 - Today, long-standing persistent Afib population represents more than 3 million patients in the United States, expected to grow to more than 4.4 million by 2025²¹
- ASP Mix reflects both ablation and AtriClip, with potential future uplift from Lariat

The CONVERGENT Approach



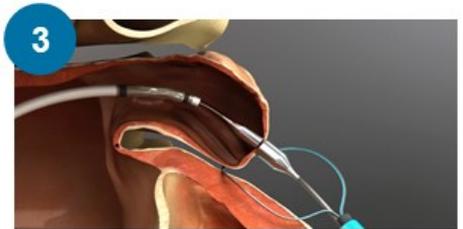
The LARIAT Procedure



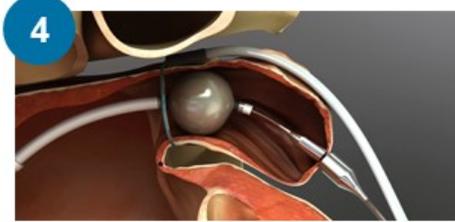
1
Access: Routine percutaneous techniques for pericardial and transseptal access are performed using fluoroscopy and transesophageal echocardiography.



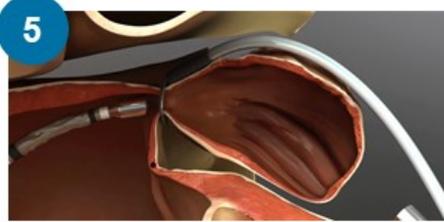
2
Delivery: Two magnet-tipped guidewires (FindrWIRZ®) are attached to stabilize the LAA with minimal trauma and manipulation for delivery of the LARIAT.



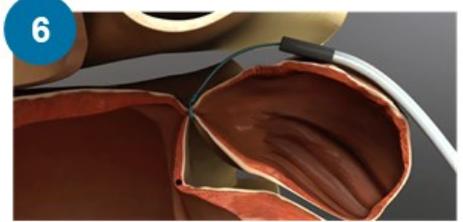
3
Delivery: The LARIAT snare is delivered over the epicardial FindrWIRZ to the apex of the LAA.



4
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.

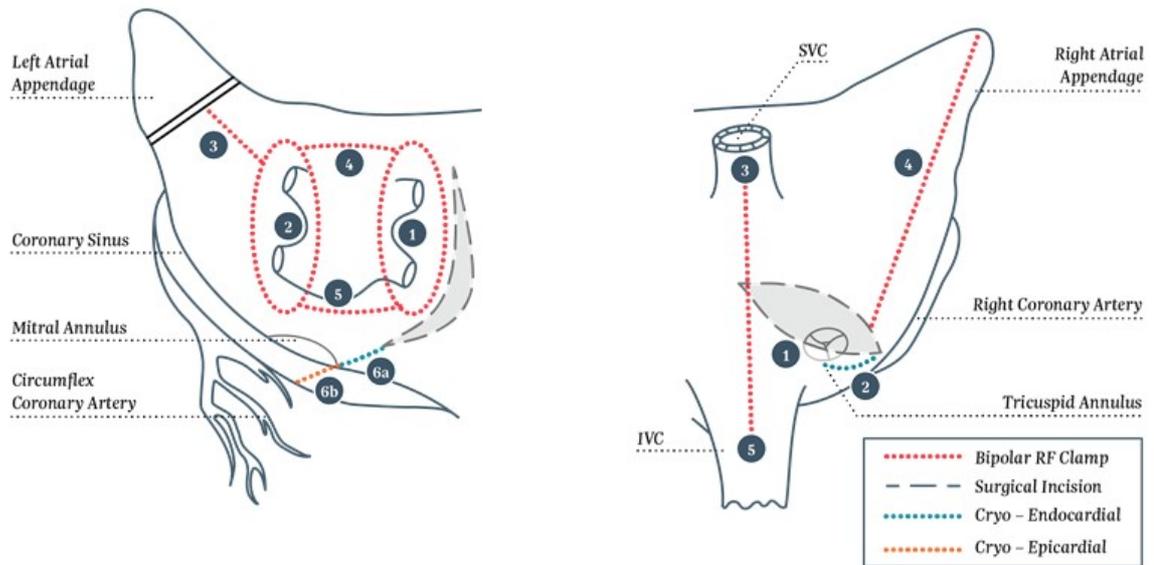


5
Closure: The LARIAT snare is closed and the FindrWIRZ and the EndoCATH are removed prior to release and tightening of the suture.



6
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



Endnotes and Abbreviations

Note	Reference
1	Worldwide Epidemiology of Atrial Fibrillation: A Global Burden of Disease 2010 Study
2	The American Journal of Cardiology (2013), 112: 1142-1147
3	J Geriatr Cardiol. 2016 Oct; 13(10): 880–882, doi: 10.11909/j.issn.1671-5411.2016.10.004
4	Santhanakrishnan R et al., "AF Begets Heart Failure and Vice Versa," Circulation, 133 (2016):484-492
5	Odutayo, A. et al. (2016). Atrial fibrillation and risks of cardiovascular disease, renal disease, and deaths systematic review and meta analysis. BMJ 2016; 354:i4482
6	Presented at AF Symposium 2018 by Lakkireddy et al.
7	ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29. Identifier: NCT02393885. Pivotal Study Of A Dual Epicardial & Endocardial Procedure (DEEP) Approach (DEEP Pivotal).
8	ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29. Identifier: NCT01984346. CONVERGE - Epi/Endo Ablation For Treatment of Persistent Atrial Fibrillation(AF) (CONVERGE).
9	ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29. Identifier NCT03012841. STOP Persistent AF; 2017 Jan 6 [cited 2018 Aug 22].
10	Mansour, M., Calkins, H., Osorio J. et al. Persistent atrial fibrillation ablation with contact force sensing catheter: The prospective multicenter PRECEPT Trial, JACC: Clinical Electrophysiology (2020)
11	ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29. Identifier NCT02817776. Review of the Safety and Effectiveness of the THERMOCOOL SMARTTOUCH® SF Catheter Evaluated for Treating Symptomatic Persistent AF (PRECEPT); 2016 Jun 29 [cited 2018 Aug 22]
12	ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29. Identifier: NCT03650556. Safety and Effectiveness of TactiCath™ Contact Force, Sensor Enabled™ (TactiCath SE) Catheter for Ablation of Drug Refractory, Symptomatic, Persistent Atrial Fibrillation (PERSIST-END IDE) 2018 Aug 28 [cited 2018 Aug 29]
13	ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT0406160. iCLAS™ for Persistent Atrial Fibrillation

Note	Reference
14	The Society of Thoracic Surgeons, Current News Release (1/30/2018): 1 in 7 Lung Surgery Patients at Risk for Opioid Dependence
15	The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation
16	STS Adult Cardiac Surgery Database, 2018/2019 Harvest Executive Summary
17	McCarthy, P.M. et al. (2019). Prevalence of atrial fibrillation before cardiac surgery and factors associated with concomitant ablation. J Thorac Cardiovasc Surg, PII: S0022-5223(19)31361-3, DOI: 10.1016/J.JTCVS.2019.06.062.
18	Lin et al, Stroke 2019 Jun; 50(6):1384-1371. doi: 10.1161/STROKEAHA.118.023921. Epub 2019 May 2.
19	Harvested from data previously available through the Society of Thoracic Surgeons
20	Average Selling Prices (ASPs) are management estimates based on a mix of products used for the various procedures
21	Medical management estimate: Colilla, et al. Estimates of Current and Future Incidence and Prevalence of Atrial Fibrillation in the U.S. Adult Population. Am Journal of Cardiology 2013, 112: 1142-1147 Persistent patient estimate: Berisso et al Epidemiology of atrial fibrillation: European perspective Clin Epidemiol. 2014; 6: 213–220
22	Estimated based on various catheter company presentations
23	Estimated based on Advisory Board data, along with various scientific presentations

Key Abbreviations

Afib or AF	Atrial Fibrillation	CEC	Clinical Events Committee
FDA	Food & Drug Administration	EP	Electrophysiologist
PMA	Pre-Market Approval	LAA	Left Atrial Appendage
AFL	Atrial Flutter	LAAM	LAA Management
AT	Atrial Tachycardia	MAE	Material Adverse Event
AAD	Anti-Arhythmic Drugs	PVI	Pulmonary Vein Isolation