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): April 29, 2021

AtriCure, Inc.
(Exact name of registrant as specified in charter)

Delaware	**000-51470**	**34-1940305**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $.001 par value	ATRC	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 7.01 Regulation FD

On April 29, 2021 AtriCure issued a press release announcing the U.S. Food and Drug Administration approval of the EPi-Sense® System to treat patients diagnosed with long-standing persistent atrial fibrillation. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and also is incorporated by reference into this Item 7.01.

The information contained in Item 7.01 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing or other document under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), regardless of any general incorporation language in any such filing or document, except as shall be expressly set forth by specific reference in any such filing or document. The furnishing of the information contained in Item 7.01 (including Exhibit 99.1) is not intended to, and does not, constitute a determination or admission by the Company that this information is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Press Release dated April 29, 2021
104	Cover Page Interactive Data File--the cover page XBRL tags are embedded within the Inline XBRL document.

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: April 29, 2021

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

Exhibit 99.1

For immediate release
April 29, 2021

AtriCure's EPi-Sense System Approved by FDA for Treatment of Long-Standing Persistent Afib Patients

FDA approval results in the only label of its kind for more than 3 million patients in the United States, significantly expanding AtriCure's addressable market
Superiority trial showed a 29% difference in effectiveness at 12 months and a 35% difference in effectiveness at 18 months for long-standing persistent Afib patients.
Study also showed improved Electrophysiology Lab efficiency

MASON, Ohio – (BUSINESS WIRE) –April 29, 2021 – AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage (LAA) management, today announced U.S. Food and Drug Administration (FDA) approval of the EPi-Sense® System to treat patients diagnosed with long-standing persistent Afib. The CONVERGE™ trial demonstrated superiority in the hybrid AF™ therapy arm compared to endocardial catheter ablation alone. In patients diagnosed with long-standing persistent Afib, the hybrid therapy arm showed a 29% absolute difference in efficacy at 12-months (78% relative improvement) and an absolute difference of 35% at 18 months (110% relative improvement). There was also a 33% absolute difference in Afib burden reduction in favor of the hybrid AF therapy at 12 months, which increased to 37% at 18 months.

"FDA approval is a monumental step forward in the market focused on patients with the most advanced and difficult to treat Afib," said Michael Carrel, President and Chief Executive Officer at AtriCure. "The long-standing persistent Afib population represents over three million patients in the United States alone, or nearly half of all diagnosed Afib patients. This approval will enable us to educate and train physicians across the country on the benefits of hybrid AF therapy in treating long-standing persistent Afib patients. In addition to superior clinical results, the procedure significantly improves electrophysiology lab efficiency by reducing endocardial ablation times by over 40 minutes, improving throughput and enabling more patients to be treated."

"This therapy should help change the standard of care and improve the lives of millions of patients. Due to less than optimal outcomes with endocardial ablation alone, many patients in whom Afib has progressed are not even considered for ablation treatment today. The high-quality evidence from the CONVERGE trial should encourage cardiologists, electrophysiologists and surgeons, as a team, to consider this procedure for these patients," said David DeLurgio, M.D., Director of Electrophysiology at Emory St. Joseph's Hospital, and the trial's global principal investigator. "The improvement using the EPi-Sense System for posterior left atrial wall and pulmonary vein ablation, in combination with an endocardial catheter to address lesion gaps, is truly remarkable. Additionally, Afib burden reduction results are especially encouraging as they mirror our experience as well as peer reviewed published data outside of the trial."

Afib affects over 33 million people worldwide and approximately 45% of those people have long-standing persistent Afib.[1] Afib increases the risk of stroke and is linked with increased risk of mortality. The number of people with Afib is expected to increase significantly over the next decade.

“Hybrid AF therapy is the only FDA-approved minimally invasive ablation procedure to treat patients who have been in continuous Afib for more than one year, which is a large number of my patients,” said Hugh Calkins, M.D., Director of the Arrhythmia Service and the Clinical Electrophysiology Lab at Johns Hopkins University. “These patients with advanced Afib are very difficult to treat with catheter ablation alone. The data from the CONVERGE trial is compelling, and patients will benefit greatly from having this treatment.”

18-Month Data Shows Durability

Data from the CONVERGE trial at 18 months has shown that hybrid AF therapy provides durable, sustained efficacy. In the treatment arm, freedom from all arrhythmias in the long-standing persistent population was 61%, versus 26% for endocardial catheter ablation alone. Freedom from Afib alone at 18-months was 68% for hybrid AF therapy, versus 30% in the catheter ablation arm for the same group of patients.

“These 18-month results are incredible and demonstrate the durability of the procedure,” said Dr. DeLurgio. “This is a key finding from the trial and shows that patients who undergo a hybrid procedure should expect continued freedom from Afib. I’m really looking forward to seeing this therapy expand and impact more patients who have no other effective treatment options.”

Table 1: Effectiveness endpoints for long-standing persistent AF sub-group (12-month follow up)

Parameter	Hybrid ablation arm (N=38)	Endocardial catheter ablation arm (N=27)	Difference (Hybrid – Endocardial catheter ablation)
Freedom from AF/AFL/AT from 3-month blanking period through the 12-months* *n%, (95% Confidence Interval)*	65.8% (50.7%, 80.9%)	37.0% (18.8%, 55.3%)	28.8% in favor of Hybrid
≥90% AF burden reduction at 12 months* *n%, (95% Confidence Interval)*	78.9% (66.0%, 91.9%)	46.2% (27.0%, 65.3%)	32.7% in favor of Hybrid
Freedom from AF through 12 months * *n%, (95% Confidence Interval)*	71.1% (56.6%, 85.5%)	37.0% (18.8%, 55.3%)	34.1% in favor of Hybrid

*Without new/ increased dosage of previously failed class I/III AADs
AADs: anti-arrhythmic drugs; AF: atrial fibrillation; AFL: atrial flutter; AT: atrial tachycardia.

Table 2: Effectiveness endpoints for long-standing persistent AF sub-group (18-month follow up)			
Parameter	**Hybrid ablation arm (N=38)**	**Endocardial catheter ablation arm (N=27)**	**Difference (Hybrid – Endocardial catheter ablation)**
Freedom from AF/AFL/AT from 3-month blanking period through the 18-months* *n%, (95% Confidence Interval)*	60.5% (45.0%, 76.1%)	25.9% (9.4%, 42.5%)	34.6% in favor of Hybrid
≥90% AF burden reduction at 18 months* *n%, (95% Confidence Interval)*	73.0% (58.7%, 87.3%)	36.0% (17.2%, 54.8%)	37.0% in favor of Hybrid
Freedom from AF through 18 months * *n%, (95% Confidence Interval)*	68.4% (53.6%, 83.2%)	29.6% (12.4%, 46.9%)	38.8% in favor of Hybrid
*Without new/increased dosage of previously failed class I/III anti-arrhythmic drugs AF: atrial fibrillation; AFL: atrial flutter; AT: atrial tachycardia			

About the CONVERGE Trial

The CONVERGE trial was a landmark prospective, superiority, randomized controlled pivotal trial to evaluate the overall success of hybrid ablation compared to endocardial catheter ablation alone for patients with persistent or long-standing persistent Afib. The procedure combines a minimally invasive, closed chest epicardial ablation performed by a surgeon using the AtriCure EPi-Sense System with endocardial radiofrequency catheter ablation performed by an electrophysiologist. The trial enrolled 153 patients at 27 locations (25 in the United States and 2 in the United Kingdom). Patients were randomized at a rate of 2:1 and received either the hybrid procedure or an endocardial catheter ablation alone.

About AtriCure, Inc.

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 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. AtriCure's Hybrid AF™ Therapy is a minimally invasive procedure that provides a lasting solution for long-standing persistent Afib patients. AtriCure's cryoICE cryoSPHERE® probe is cleared for temporary ablation of peripheral nerves to block pain, providing pain relief in cardiac and thoracic procedures. For more information, visit AtriCure.com or follow us on Twitter @AtriCure.

Forward-Looking Statements

This press release 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, clinical trials, 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. These risks and uncertainties include, but are not limited to: whether AtriCure will be able to successfully execute its commercialization plans for or otherwise expand the development of CONVERGE; whether the market opportunity for CONVERGE is consistent with the Company’s expectations and market research; whether AtriCure will be able to generate its projected net product revenue in the timeline expected, or at all; whether AtriCure’s cash resources or other financing sources will be sufficient to fund AtriCure’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of CONVERGE and AtriCure’s other product candidates; risks associated with market acceptance of CONVERGE; costs associated with defending intellectual property infringement, product liability and other claims; regulatory developments in the United States, Europe and other jurisdictions; and other important factors, including, without limitation, the effects of the coronavirus COVID-19 pandemic on the market and AtriCure’s financial condition and results of operations, 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 U.S. Securities and Exchange Commission. 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.

[1] Berisso et al. Epidemiology of atrial fibrillation: European perspective. Clin Epidemiol. 2014; 6: 213–220.

CONTACTS:

Angie Wirick
Investor Relations
Chief Financial Officer
(513) 755-5334
awirick@atricure.com

Valerie Storch-Willhaus
Media Relations
Vice President, Corporate Marketing and Communications
(612) 605-3311
vstorch-willhaus@atricure.com