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): May 8, 2020

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 May 8, 2020 AtriCure issued a press release announcing the CONVERGE IDE clinical trial results. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	**Description**
99.1	Press Release dated May 8, 2020 announcing CONVERGE IDE Clinical Trial Results
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: May 8, 2020

By: /s/ M. Andrew Wade
M. Andrew Wade
Chief Financial Officer

Exhibit 99.1

For immediate release
May 8, 2020

AtriCure Announces Results from CONVERGE IDE Clinical Trial

Results presented virtually via Heart Rhythm 365 Platform; shows primary effectiveness superiority in favor of the hybrid Convergent procedure

MASON, Ohio – (BUSINESS WIRE) – May 8, 2020 – AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage (LAA) management, today announced the results from the CONVERGE IDE clinical trial. This first-of-its-kind trial, designed to demonstrate superiority, showed an 18% difference in favor of the hybrid Convergent procedure as compared to endocardial catheter ablation alone. Currently, the Food and Drug Administration (FDA) is reviewing the Premarket Application (PMA). The results of the trial were presented as part of the late-breaking clinical trials at the Heart Rhythm Society's (HRS) Annual Scientific Session and were broadcasted virtually via the Heart Rhythm 365 digital platform.

"The CONVERGE study is a monumental step forward in the market focused on the most difficult to treat Afib patients, those with persistent or long-standing persistent forms of the disease," said Michael Carrel, President and Chief Executive Officer at AtriCure. "This patient population represents many millions of patients and more than two-thirds of all diagnosed Afib patients. The study results presented at HRS mark a major milestone for the CONVERGE study and we look forward to working with the FDA moving forward."

The CONVERGE IDE trial's primary effectiveness endpoint is freedom from Afib, atrial tachycardia (AT), and atrial flutter (AFL), absent class I and III anti-arrhythmic drugs (AADs) except for a previously failed or demonstrated intolerance to class I or III AADs, with no increase in dosage following the 3-month blanking period through the 12-months post procedure follow-up visit. The primary safety endpoint is the incidence of protocol-defined major adverse events (MAEs) for subjects undergoing the Convergent procedure from the time of the intervention through 30-days post intervention. There were no deaths, cardiac perforations or atrio-esophageal fistulas reported in the trial. Dr. DeLurgio presented the MAE rate of 7.8% in treatment arm, which was lower than the protocol pre-specified performance goal of 12%. There were also no long-lasting safety events observed in the trial. More detail can be found in Table 1 below.

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 Convergent procedure or an endocardial catheter ablation alone. Dr. David DeLurgio, MD, of Emory St. Joseph's Hospital in Atlanta, Georgia, was the trial's national principal investigator.

"This is one of the most highly anticipated trials in the Afib space in many years because of the potential to effectively treat patients who are difficult to treat. I'm very pleased about the results of the trial, which showed an 18% difference between the Convergent arm and the control arm in evaluable patients at 12 months," said Dr. DeLurgio. "Additionally, the measure of Afib burden reduction of greater than 90% was remarkable and much better than expected. The data presented showed a greater than 23% advantage for the Convergent arm over the control arm. Based on these findings, epicardial and endocardial ablation using the hybrid Convergent procedure could prove to be a preferred therapy for patients with advanced forms of Afib."

Afib affects over 33 million people worldwide and approximately 70% have persistent and longstanding persistent Afib.[1] Afib increases the risk of stroke and is linked with increased risk of mortality.

“Most importantly, in keeping with the AtriCure mission, we look forward to working interactively with the FDA towards the approval of the therapy, which will facilitate targeted training and a more informed physician-patient discussion,” said Mr. Carrel.

Table 1: Effectiveness endpoints
Note: FDA is currently reviewing the results of the CONVERGE IDE Trial

Parameter	Convergent ablation arm	Endocardial catheter ablation arm	Difference (Convergent – Control)	p-value
Freedom from AFib/AFL/AT from 3-month blanking period through the 12-months* without imputation of missing data as failure *n%, (95% Confidence Interval)*	67.7% (67/99) *(58.5%-76.9%)*	50.0% (25/50) *(36.1%- 63.9%)*	17.7% *in favor of Convergent*	**0.036**
Freedom from AFib/AFL/AT from 3-month blanking period through the 12-months* with imputation of missing data as failure *n%, (95% Confidence Interval)*	65.7% (67/102) *(56.5%- 74.9%)*	49.0% (25/51) *(35.3% – 62.7%)*	16.7% *in favor of Convergent*	**0.047**
≥90% burden reduction at 12 months* *n%, (95% Confidence Interval)*	80% (60/75) *(70.9% – 89.1%)*	56.8% (25/44) *(42.2% – 71.5%)*	23.2% *in favor of Convergent*	**0.007**
Freedom from AF through 12 months * *n%, (95% Confidence Interval)*	71% (72/102) *(61.7% – 79.4%)*	51% (26/51) *(37.3% – 64.7%)*	20.0% *in favor of Convergent*	**0.017**
*Without new/ increased dosage of previously failed class I/III AADs AADs: anti-arrhythmic drugs; AF: atrial fibrillation; AFL: atrial flutter; AT: atrial tachycardia;				

Virtual Broadcast from Heart Rhythm 365 and Conference Call to Discuss Trial Results

The results were broadcast on the Heart Rhythm 365 digital platform. AtriCure will host a virtual meeting at HRS at 1:00 p.m. Eastern U.S. time to discuss the results from the trial. A live audio and slide presentation webcast of the meeting may be accessed by visiting the Investors page of AtriCure’s corporate website at ir.atricure.com. The live audio only feed of the call may be access through an operator by calling 844-884-9951 for domestic callers and 661-378-9661 for international callers using conference ID number 1978277. A replay of the presentation will be available on the website following the meeting.

About the CONVERGE IDE Trial

The CONVERGE IDE trial is a landmark prospective, superiority, randomized controlled pivotal trial to evaluate the overall success of the hybrid Convergent ablation to endocardial catheter ablation for patients with persistent or long-standing persistent Afib. The procedure combines a minimally invasive, closed chest epicardial ablation performed by a surgeon with endocardial catheter ablation performed by an electrophysiologist.

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 and only medical device to receive FDA approval for the treatment of persistent Afib. AtriCure's AtriClip Left Atrial Appendage (LAA) Exclusion System products are the most widely sold LAA 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," 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. These risks and uncertainties include, but are not limited to: 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; whether any additional clinical trials will be initiated or required for CONVERGE prior to approval of FDA, or at all, and whether CONVERGE will be approved by FDA and any other required regulatory authorities; AtriCure's ability 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; whether AtriCure's cash resources will be sufficient to fund AtriCure's foreseeable and unforeseeable operating expenses and capital expenditure requirements for AtriCure's expected timeline; other matters that could affect the availability or commercial potential of CONVERGE and AtriCure's product candidates, including CONVERGE; 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.

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