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): September 23, 2022

ARTIVION, INC.

(Exact name of registrant as specified in its charter)

Delaware	**1-13165**	**59-2417093**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1655 Roberts Boulevard, N.W., Kennesaw, Georgia 30144
(Address of principal executive office) (zip code)

Registrant's telephone number, including area code: (770) 419-3355

(Former name or former address, if changed since last report)

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value	AORT	NYSE

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 7.01 Regulation FD Disclosure

On September 23, 2022, Artivion, Inc. issued a press release announcing that it has stopped the PROACT Xa clinical trial on the recommendation of the independent Data and Safety Monitoring Board of the trial. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01(d) Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1*	Press Release dated September 23, 2022.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Furnished herewith, not filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, Artivion, Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 23, 2022

ARTIVION, INC.

By: /s/ D. Ashley Lee
Name: D. Ashley Lee
Title: Executive Vice President and Chief Financial Officer

ARTIVION
Formerly CryoLife | Jotec
NEWS RELEASE

FOR IMMEDIATE RELEASE

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Artivion Follows Recommendation to Stop PROACT Xa Clinical Trial

Study Was Evaluating the Use of Apixaban in Patients Treated with Mechanical Aortic Valves

ATLANTA, GA - (September 23, 2022) - Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, announced today that it has stopped the PROACT Xa clinical trial, a prospective, randomized, trial designed to determine if patients with an On-X mechanical aortic valve can be maintained safely and effectively on apixaban rather than on warfarin. The decision was based on the recommendation of the independent Data and Safety Monitoring Board (DSMB) of the trial due to lack of evidence supporting non-inferiority of apixaban to warfarin for valve thrombosis and thromboembolism.

The PROACT Xa trial randomized patients having an On-X aortic valve replacement to receive either warfarin or apixaban as their anticoagulant to prevent blood clots. The trial began enrolling in April 2020. The DSMB found that blood clots, resulting in stroke, occurred more frequently in patients receiving apixaban and that continuing the trial was unlikely to achieve the primary endpoint while possibly exposing patients to increased risk. Physician investigators at the trial's sites are being notified to change patients who are in the apixaban arm of the trial back to warfarin.

Dr. John Alexander, Chair of the PROACT Xa trial and Professor of Medicine/Cardiology at Duke University School of Medicine, said, "The PROACT Xa trial was designed to determine whether apixaban would yield equivalent safety to the standard anticoagulant, warfarin. Unfortunately, it appears that it does not. On behalf of all of the investigators, we appreciate the research effort into the science of managing patients with artificial heart valves."

Pat Mackin, Chairman, President and Chief Executive Officer of Artivion said, "The On-X aortic valve has a long track record of safe and efficacious outcomes and is the leading mechanical aortic valve in the United States and in other markets around the globe. Despite this setback, the On-X aortic

valve provides significant clinical benefits to patients and remains the only mechanical aortic valve for which patients can be safely managed with reduced blood thinners, leading to a 60 percent reduction in bleeding."

Mr. Mackin continued, "We are disappointed to stop the PROACT Xa trial as a successful trial would have significantly benefited patients and significantly increased our addressable market opportunity beginning in 2025. Despite stopping the trial, we are reiterating our 2022 outlook of delivering double-digit top-line growth and we remain committed to delivering the financial expectations we communicated in our March investor meeting: Double digit top-line growth, expanding gross margins, and accelerated adjusted EBITDA growth through 2024. We had committed approximately $10 million in annual funding to this study through 2024 and will now redirect these funds to other development opportunities and to incremental EBITDA and cash flow in 2023 and 2024."

Webcast and Conference Call Information
The Company will hold a teleconference call and live webcast later today, September 23, 2022, at 8:30 a.m. ET. To participate in the conference call dial 201-689-8261 a few minutes prior to 8:30 a.m. ET. The teleconference replay will be available approximately one hour following the completion of the event and can be accessed by calling (toll free) 877-660-6853 or 201-612-7415. The conference number for the replay is 13733128.

The live webcast and replay can be accessed by going to the Investors section of the Artivion website at www.Artivion.com and selecting the heading Webcasts & Presentations.

About Artivion
Headquartered in suburban Atlanta, Georgia, Artivion, Inc. is a medical device company focused on developing simple, elegant solutions that address cardiac and vascular surgeons' most difficult challenges in treating patients with aortic diseases. This multinational company's four major groups of products include: aortic stents and stent grafts, prosthetic heart valves, cryopreserved cardiac and vascular allografts, and surgical sealants. Artivion markets and sells products in more than 100 countries worldwide. For additional information about Artivion, visit our website, www.artivion.com.

Forward Looking Statements
Statements made in this press release that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect the views of management at the time such statements are made. These statements include our beliefs that the On-X aortic valve is the leading mechanical aortic valve in the United States and in other markets around the globe; that the On-X aortic valve provides significant clinical benefits to patients and remains the only mechanical aortic valve for which patients can be safely managed with reduced blood thinners, leading to a 60 percent reduction in bleeding; and our expectations that we will achieve our 2022 outlook of delivering double-digit top line growth; will deliver on the financial expectations we communicated in our March investor meeting: Double digit top-line growth, expanding gross margins, and accelerated adjusted EBITDA growth through 2022; and will redirect the funds we planned to invest in the PROACT Xa clinical trial into other development opportunities and to incremental EBITDA and cash flow in 2023 and 2024. These forward-looking statements are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for year ended December 31, 2021. Artivion does not undertake to update its forward-looking statements, whether as a result of new information, future events, or otherwise.