# 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): November 24, 2021**

# CARDIOVASCULAR SYSTEMS, INC.

**(Exact name of Registrant as Specified in its Charter)**

| **Delaware** | **000-52082** | **41-1698056** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**1225 Old Highway 8 Northwest**
**St. Paul, Minnesota 55112-6416**
**(Address of Principal Executive Offices and Zip Code)**

**651 259-1600**
**(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:

☐ 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 (CFR 17 §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR § 240.12b-2).
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. ☐

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

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| Common Stock, One-tenth of One Cent ($0.001) Par Value Per Share | CSII | The Nasdaq Stock Market LLC |

**Item 8.01. Other Events.**

On November 24, 2021, Cardiovascular Systems, Inc. (the "Company") issued a press release announcing a voluntary recall of its WIRION Embolic Protection System. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The Company expects to record a one-time charge of approximately $2.5 million to cost of goods sold in its second quarter of fiscal 2022 relating to the recall. This one-time charge was not factored into the Company's fiscal 2022 guidance issued on November 9, 2021. The Company's revenue guidance issued on that date is not affected by the recall.

*Forward-Looking Statements*
Statements in this report regarding the timing and amount of expenses associated with the recall, the effect of the recall and the issues with WIRION on the Company's anticipated financial results and guidance are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are provided under the protection of the safe harbor for forward-looking statements provided by that Act. These statements involve risks and uncertainties that could cause results to differ materially from those projected, including, but not limited to, future actions by the FDA and other regulatory bodies; the Company's failure to adequately assess the cause and effect of the issues with WIRION that led to the recall; FDA approval of future designs and versions of WIRION; the possibility that this recall could subject the Company to disputes, claims or proceedings that may adversely impact its business and financial condition; and other factors detailed from time to time in the Company's SEC reports, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. The Company encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this report. As a result of these matters, changes in facts, assumptions not being realized or other circumstances, the Company's actual results may differ materially from the expected results discussed in the forward-looking statements contained in this report. The forward-looking statements made in this report are made only as of the date of this report, and the Company undertakes no obligation to update them to reflect subsequent events or circumstances.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit Number | Description |
|---|---|
| **99.1** | Press Release dated November 24, 2021 |

**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.

Date: November 24, 2021

CARDIOVASCULAR SYSTEMS, INC.

By: /s/ Jeffrey S. Points

Jeffrey S. Points
Chief Financial Officer

**CARDIOVASCULAR SYSTEMS, INC. INITIATES VOLUNTARY RECALL OF WIRION® EMBOLIC PROTECTION SYSTEM**

**St. Paul, Minn.** – **November 24, 2021** – Cardiovascular Systems, Inc. (CSI®) (NASDAQ: CSII) has initiated a voluntary recall of unused WIRION Embolic Protection Systems (WIRION) due to complaints of filter breakage during retrieval.

CSI has informed all affected healthcare facilities to discontinue use of WIRION immediately and return unused product to CSI. The U.S. Food and Drug Administration (FDA) has also been notified. To date, CSI has received 9 complaints of filter breakage during retrieval. Filter breakage may result in device embolism and possible additional intervention.

The company plans to voluntarily recall all WIRION units currently in customer inventory. In total, 697 devices were distributed in the U.S. between March 22, 2021 and November 15, 2021. All lots of the following models are being recalled:

**Name:** WIRION Embolic Protection Device
**Model:** WRN-D6

Physicians and healthcare facilities can direct questions to their CSI representative or, call 651-259-2800. Adverse reactions or quality problems experienced with the use of the WIRION System may be reported to the FDA MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (http://www.fda.gov/MedWatch/getforms.htm)

**About Cardiovascular Systems, Inc.**
Cardiovascular Systems, Inc., based in St. Paul, Minn., is a medical device company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. The company's orbital atherectomy system treats calcified and fibrotic plaque in arterial vessels throughout the leg and heart and addresses many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. For additional information, please visit www.csi360.com and connect on Twitter @csi360.

## Contact:

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