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): **February 21, 2023**

CVRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-40545**	**41-1983744**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

9201 West Broadway Avenue, Suite 650
Minneapolis, MN 55445
(Address of principal executive offices) (Zip Code)

(763) 416-2840
(Registrant's telephone number, including area code)

N/A
(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, par value $0.01 per share	**CVRX**	**The Nasdaq Global Select Market**

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 February 21, 2023, CVRx, Inc. (the "Company") issued a press release announcing the preliminary results of the BeAT-HF post-market randomized clinical trial. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" with the Securities and Exchange Commission 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 and is not incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On February 21, 2023, the Company issued a press release announcing the preliminary results of the BeAT-HF post-market randomized clinical trial. The BeAT-HF post-market phase of the multi-center, prospective, randomized, controlled trial assessed 323 patients suffering from heart failure with reduced ejection fraction. The patients were randomized to two groups, treatment with Barostim and guideline directed medical therapy versus guideline directed medical therapy alone. The primary endpoint was a composite of cardiovascular mortality and heart failure morbidity (specifically, worsening heart failure events requiring treatment in the hospital or emergency department). The trial accrued 332 primary events and had a median follow-up of 3.7 years, corresponding to 1,037 patient-years.

While the trial did not reach statistical significance on the primary endpoint, it did contain additional clinically meaningful prespecified analyses that favored Barostim, including:

- all-cause survival, free from LVAD and heart transplant,
- a hierarchical composite ("Win Ratio") analysis of cardiovascular mortality, heart failure events and quality of life, and
- a clinical stability analysis.

In addition, the safety profile of Barostim and the symptomatic improvement at 6 months, that were the basis for the FDA pre-market approval, were shown to be durable through 24 months (where data collection was prespecified).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release of CVRx, Inc., dated February 21, 2023
104	Cover Page Interactive Data File (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.

CVRx, Inc.

Date: February 21, 2023

By: /s/ Nadim Yared
Name: Nadim Yared
Its: President and Chief Executive Officer

Exhibit 99.1

CVRx Reports Preliminary Results of the BeAT-HF Post-Market Randomized Clinical Trial

The trial did not meet its primary endpoint, however, the totality of data supports Barostim's use as an effective treatment for patients with heart failure

MINNEAPOLIS, February 21, 2023 (GLOBE NEWSWIRE) -- CVRx, Inc. ("CVRx"), a commercial-stage medical device company focused on developing, manufacturing and commercializing Barostim™, an innovative extravascular implantable neuromodulation device for patients with cardiovascular diseases, announced today the preliminary topline results of the BeAT-HF, Baroreflex Activation Therapy for Heart Failure, post-market randomized clinical trial.

The BeAT-HF post-market phase of the multi-center, prospective, randomized, controlled trial assessed 323 patients suffering from heart failure with reduced ejection fraction. The patients were randomized to two groups, treatment with Barostim and guideline directed medical therapy versus guideline directed medical therapy alone. The primary endpoint was a composite of cardiovascular mortality and heart failure morbidity (specifically, worsening heart failure events requiring treatment in the hospital or emergency department). The trial accrued 332 primary events and had a median follow-up of 3.7 years, corresponding to 1,037 patient-years.

While the trial did not reach statistical significance on the primary endpoint, it did contain additional clinically meaningful prespecified analyses that favored Barostim, including:

- all-cause survival, free from LVAD and heart transplant,
- a hierarchical composite ("Win Ratio") analysis of cardiovascular mortality, heart failure events and quality of life, and
- a clinical stability analysis.

In addition, the safety profile of Barostim and the symptomatic improvement at 6 months, that were the basis for the FDA pre-market approval, were shown to be durable through 24 months (where data collection was prespecified).

The Company will host a conference call at 9:00 am Eastern Time on Tuesday, February 21, 2023 to discuss the preliminary results of the BeAT-HF post-market phase clinical data and provide education about the prespecified analyses.

The BeAT-HF post-market phase clinical data will be presented at the Transcatheter Heart Failure Therapies Conference ("THT") on Tuesday, March 21, 2023 at 10:45 am Eastern Time in Boston.

“On behalf of the Executive Steering Committee of BeAT-HF, I congratulate CVRx for conducting a rigorous scientific randomized controlled study that spanned 7 years, to assess the benefits and risks of Barostim in patients with chronic heart failure with reduced ejection fraction,” said Michael R. Zile, M.D., Distinguished University Professor, Medical University of South Carolina. “The new results from the post-market phase of BeAT-HF confirm Barostim’s long-term symptomatic benefits and safety, and its use as an effective treatment for heart failure.”

“We are grateful to all the patients who enrolled in BeAT-HF, to the investigators in the 108 clinical sites and to the Executive Steering Committee for their dedicated effort over the years,” said Nadim Yared, President and CEO of CVRx. “This new evidence is welcome news for the many patients with heart failure, who remain symptomatic despite optimal medical therapy. We plan to submit the totality of evidence of BeAT-HF to FDA seeking an expansion of Barostim labeling.”

Webcast and Conference Call Information

The Company will host a conference call at 9:00 am Eastern Time on Tuesday, February 21, 2023 to discuss the preliminary results of the BeAT-HF post-market phase clinical data and provide education about the prespecified analyses. The conference call and related presentation materials will be broadcast live in listen-only mode via webcast at https://edge.media-server.com/mmc/p/i9jdqiw4. To listen to the conference call on your telephone, participants may register for the call at https://register.vevent.com/register/BIc19a03ffb45b44008562d6fc20e7db7c. While it is not required, it is recommended you join 10 minutes prior to the event start.

Upcoming Data Presentation

The long-term outcomes of the BeAT-HF trial will be presented as a featured presentation at the THT Conference on Tuesday, March 21, 2023 at 10:45 am Eastern Time in Boston. The Company will host a conference call following the presentation at THT. The Company’s conference call and related presentation materials will be broadcast live in listen-only mode via webcast. The conference call information will be made available on the investor relations page of the Company’s website at ir.cvrx.com.

About CVRx, Inc.

CVRx is a commercial-stage medical device company focused on the developing, manufacturing and commercializing innovative neuromodulation solutions for patients with cardiovascular diseases. Barostim™ is the first medical technology approved by FDA that uses neuromodulation to improve the symptoms of patients with heart failure. Barostim is an implantable device that delivers electrical pulses to baroreceptors located in the wall of the carotid artery. Baroreceptors activate the body’s baroreflex, which in turn triggers an autonomic response to the heart. The therapy is designed to restore balance to the autonomic nervous system and thereby reduce the symptoms of heart failure. Barostim received the FDA Breakthrough Device designation and is FDA-approved for use in heart failure patients in the U.S. It has also received the CE Mark for heart failure and resistant hypertension in the European Economic Area. To learn more about Barostim, visit www.cvrx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including statements regarding our future financial performance, our anticipated growth strategies, anticipated trends in our industry, our business prospects and our opportunities, including specifically those related to potential new indications, labelling or marketing opportunities, our continued review and analysis of trial data and future business and financial impacts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "outlook," "guidance," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

The forward-looking statements in this press release are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including, uncertainties related to obtaining regulatory approvals, further analysis and understanding of clinical trial data, physician and patient adoption, and other important factors that could cause actual results, performance or achievements to differ materially from those projected in the forward-looking statements that are found in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in our other filings with the Securities and Exchange Commission. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Investor Contact:
Mark Klausner or Mike Vallie
ICR Westwicke
443-213-0501
ir@cvrx.com

Media Contact:
Erich Sandoval
Finn Partners
212-867-1762
erich.sandoval@finnpartners.com