
**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): **December 26, 2023**

CVRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-40545
(Commission
File Number)

41-1983744
(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 8.01. Other Events.

On December 26, 2023, CVRx, Inc. (the “Company”) issued a press release announcing FDA approval for expanded labeling of the Company’s Barostim system and an increased U.S. annual market opportunity for Barostim based on real-world adoption and strength of long-term BeAT-HF data. The press release is attached as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of CVRx, Inc., dated December 26, 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: December 26, 2023

By: /s/ Jared Oasheim
Name: Jared Oasheim
Its: Chief Financial Officer

CVRx receives FDA approval for expanded labeling of Barostim

U.S. annual market opportunity increases based on real world adoption and strength of long-term BeAT-HF data

MINNEAPOLIS, Dec 26, 2023 – **CVRx, Inc.** (NASDAQ: CVRX) (“CVRx”), a commercial-stage medical device company, announced today that the U.S. Food and Drug Administration (FDA) has approved revised Instructions For Use (IFU) for Barostim incorporating key long-term clinical data from the BeAT-HF randomized clinical trial.

“We are very pleased to receive this important validation from FDA of the long-term results of the post-market phase of the BeAT-HF clinical trial and excited we can now share this data with physicians and patients,” said Nadim Yared, President and CEO of CVRx. “We remain grateful to all patients, investigators, research teams, the executive steering committee and FDA personnel, for supporting our efforts to conduct this landmark study over seven years, including the difficulties encountered during the COVID-19 pandemic.”

Labeling Update

The updated Indications statement for Barostim in the IFU now reads:

Barostim is indicated for patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a left ventricular ejection fraction of $\leq 35\%$, and a NT-proBNP <1600 pg/ml.

Barostim delivers Baroreflex Activation Therapy to improve patients’ heart failure functional status, six-minute hall walk, and quality of life.

The revised Clinical Summary section of the IFU now includes the primary endpoint results, the 6, 12 and 24 month symptomatic data, the win ratio, and the all-cause mortality data. The Clinical Summary concludes:

In summary, the primary safety endpoint in the Pre-Market Phase was previously met and confirmed in the Post-Market Phase. In the Pre-Market Phase, all effectiveness endpoints were previously met, demonstrating 6-months improvements in 6MHW, quality of life, NYHA Class and NT-proBNP. The Post-Market Phase effectiveness primary endpoint of CV death and HF hospitalization was not met. Additional Post-Market Phase effectiveness analyses (Win Ratio, freedom from all-cause mortality) suggested a favorable effect of Barostim therapy. The totality of the 6, 12 and 24-month data demonstrated symptomatic improvements for heart failure patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed therapies and have a left ventricular ejection fraction $\leq 35\%$ and a NT-proBNP <1600 pg/ml.

The revised IFU document can be found at www.cvr.com/ifu, and the Clinical Summary section of that IFU can be found at pages 24 to 39.

Annual Market Opportunity Update

Our estimate of the U.S. annual market opportunity for Barostim has been revised to increase the number of patients considered by physicians based on this new long-term safety and efficacy data as well as our commercial experience, and to account for the new reimbursement assignment for Barostim. We believe the U.S. annual market opportunity is now \$2.2 billion, or 76,000 new patients, as compared to our earlier estimate of \$1.4 billion, or 55,000 new patients, representing increases of approximately 60% and 38%, respectively.

About CVRx, Inc.

CVRx is focused on the development and commercialization of the Barostim™ System, the first medical technology approved by FDA that uses neuromodulation to improve the symptoms of 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.cvr.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 the expected market for Barostim. 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, but not limited to, our ability to demonstrate to physicians and patients the merits of our Barostim and other important factors that could cause actual results, performance or achievements to differ materially from those 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.

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