
**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): **January 13, 2025**

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 2.02. Results of Operations and Financial Condition.

On January 13, 2025, CVRx, Inc. (the “Company”) issued a press release announcing certain preliminary financial results for the fourth quarter and fiscal year ended December 31, 2024. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 2.02, 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.

As disclosed above, on January 13, 2025, the Company issued a press release announcing preliminary financial results for the fourth quarter and fiscal year ended December 31, 2024.

Fourth Quarter 2024

Total revenue for the fourth quarter of 2024 is expected to be in the range of approximately \$15.2 million to \$15.3 million, representing an increase of approximately 35% over fourth quarter 2023 revenue of \$11.3 million. Total revenue generated in the fourth quarter of 2024 is expected to be comprised of approximately \$14.2 million to \$14.3 million in U.S. revenue and \$1.0 million in European revenue.

For the three months ended December 31, 2024, the Company issued 869,059 shares of common stock for gross proceeds of \$12.8 million under its at-the-market offering.

Full Year 2024

Total revenue for full year 2024 is expected to be in the range of approximately \$51.1 million to \$51.2 million, representing an increase of approximately 30% over full year 2023 revenue of \$39.3 million. Total revenue generated in 2024 is expected to be comprised of approximately \$47.0 to \$47.1 million in U.S. revenue and \$4.1 million in European revenue.

As of December 31, 2024, the Company had a total of 223 active implanting centers in the U.S., as compared to 208 as of September 30, 2024. The number of sales territories in the U.S. increased by three to a total of 48 during the three months ended December 31, 2024.

As of December 31, 2024, cash and cash equivalents were \$105.9 million.

The foregoing estimated financial results for the fourth quarter and full year 2024 are preliminary, unaudited and represent the most recent current information available to Company management. The Company’s actual results may differ from these estimated financial results, including due to the completion of its financial closing procedures and final adjustments. The Company expects to issue full financial results for the fourth quarter and full year 2024 in early February 2025.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of CVRx, Inc., dated January 13, 2025
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: January 13, 2025

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

CVRx Reports Preliminary Fourth Quarter and Fiscal Year 2024 Financial Results and Issues Fiscal 2025 Guidance

- *Fourth quarter revenue expected to be \$15.2 million to \$15.3 million, representing growth of 35%*
- *Full year revenue expected to be \$51.1 million to \$51.2 million, representing growth of 30%*
- *Fiscal 2025 revenue expected to be between \$63.0 million and \$65.0 million, representing growth of 23% to 27%*

MINNEAPOLIS, Jan. 13, 2025 (GLOBE NEWSWIRE) -- CVRx, Inc. (NASDAQ: CVRX) ("CVRx"), a commercial-stage medical device company, today announced certain preliminary unaudited fourth quarter and full year 2024 revenue results and provided its 2025 business outlook.

"We ended 2024 with a strong fourth quarter, highlighted by 41% growth in U.S. heart failure revenue, as we continued to see the benefits of the successful execution of our commercial strategy as well as our focus on increasing education and awareness, expanding our clinical evidence base, and improving patient access" said Kevin Hykes, President and Chief Executive Officer of CVRx. "Beyond the strength of our revenue performance, we continue to deliver increasing operating leverage as a result of our prudent capital deployment strategy."

"We are inspired by the exciting prospects of 2025. Having successfully navigated a number of critical reimbursement milestones during 2024, in combination with the positive utilization and adoption momentum we built throughout the year, we believe we are very well positioned to continue to drive strong, sustainable, cost-efficient topline growth in the coming year as Barostim advances toward the standard of care for patients suffering from the debilitating symptoms of heart failure."

Fourth Quarter 2024

Total revenue for the fourth quarter of 2024 is expected to be in the range of approximately \$15.2 million to \$15.3 million, representing an increase of approximately 35% over fourth quarter 2023 revenue of \$11.3 million. Total revenue generated in the fourth quarter of 2024 is expected to be comprised of approximately \$14.2 million to \$14.3 million in U.S. revenue and \$1.0 million in European revenue.

Full Year 2024

Total revenue for full year 2024 is expected to be in the range of approximately \$51.1 million to \$51.2 million, representing an increase of approximately 30% over full year 2023 revenue of \$39.3 million. Total revenue generated in 2024 is expected to be comprised of approximately \$47.0 million to \$47.1 million in U.S. revenue and \$4.1 million in European revenue.

As of December 31, 2024, the Company had a total of 223 active implanting centers in the U.S., as compared to 208 as of September 30, 2024. The number of sales territories in the U.S. increased by three to a total of 48 during the three months ended December 31, 2024.

As of December 31, 2024, cash and cash equivalents were \$105.9 million.

For the three months ended December 31, 2024, the Company issued 869,059 shares of common stock for gross proceeds of \$12.8 million under its at-the-market offering.

Business Outlook

For the full year of 2025, the Company expects:

- Total revenue between \$63.0 million and \$65.0 million;
- Gross margin between 83% and 84%; and
- Operating expenses between \$100.0 million and \$104.0 million.

For the first quarter of 2025, the Company expects to report total revenue between \$14.5 million and \$15.0 million.

Upcoming Investor Conference Presentation

The Company will be participating in the 43rd Annual J.P. Morgan Healthcare Conference, including a company presentation on Wednesday, January 15, 2025, at 2:15 pm Pacific Time. A live audio webcast of the conference presentation will be available online at the investor relations page of the Company's website at ir.cvr.com.

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 our future financial performance (including our financial guidance regarding full year and first quarter 2025 results), our anticipated growth strategies, anticipated trends in our industry, our business prospects and our opportunities. 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, but not limited to, our history of significant losses, which we expect to continue; our limited history operating as a commercial company and our dependence on a single product, Barostim; our limited commercial sales and experience marketing and selling Barostim; our ability to demonstrate to physicians and patients the merits of our Barostim; any failure by third-party payors to provide adequate coverage and reimbursement for the use of Barostim; our competitors’ success in developing and marketing products that are safer, more effective, less costly, easier to use or otherwise more attractive than Barostim; any failure to receive access to hospitals; our dependence upon third-party manufacturers and suppliers, and in some cases a limited number of suppliers; a pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide; product liability claims; future lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and ultimately unsuccessful; any failure to retain our key executives or recruit and hire new employees; impacts on adoption and regulatory approvals resulting from additional long-term clinical data about our product; 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, 2023 and in “Part 2, Item 1A. Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, 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.

Preliminary Fourth Quarter/Full Year 2024 Results

This press release includes estimated financial results for the fourth quarter and full year of 2024, which are preliminary, unaudited and represent the most recent current information available to Company management. The Company's actual results may differ from these estimated financial results, including due to the completion of its financial closing procedures and final adjustments. The Company expects to issue full financial results for the fourth quarter and full year 2024 in early February.

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