

**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 3, 2024**

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 8, 2024, CVRx, Inc. (the “Company”) issued a press release announcing certain preliminary financial results for the fourth quarter and fiscal year ended December 31, 2023. 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 8, 2024, the Company announced that its President and Chief Executive Officer, Nadim Yared, provided notice to the Company’s Board of Directors (the “Board”) of his plans to retire upon the completion of a deliberate succession process and the appointment of a successor. Both Mr. Yared and the Board are committed to a planful and deliberate process to identify his successor, and Mr. Yared will remain in his current role until a new Chief Executive Officer is appointed. The Board is currently conducting a search to identify a new Chief Executive Officer with the assistance of a leading executive search firm.

Item 8.01. Other Events.

As disclosed above, on January 8, 2024, the Company issued a press release announcing preliminary financial results for the fourth quarter and fiscal year ended December 31, 2023.

Fourth Quarter 2023

Total revenue for the fourth quarter of 2023 is expected to be in the range of approximately \$11.2 million to \$11.3 million, representing an increase of approximately 56% to 58% over fourth quarter 2022 revenue of \$7.2 million. Total revenue generated in the fourth quarter of 2023 is expected to be comprised of approximately \$10.2 million in U.S. heart failure revenue, \$1.0 million in European revenue and \$0.1 million in U.S. legacy revenue.

Full Year 2023

Total revenue for full year 2023 is expected to be in the range of approximately \$39.2 million to \$39.3 million, representing an increase of approximately 74% to 75% over full year 2022 revenue of \$22.5 million. Total revenue generated in 2023 is expected to be comprised of approximately \$34.6 million in U.S. heart failure revenue, \$4.2 million in European revenue and \$0.5 million in U.S. legacy revenue.

As of December 31, 2023, the Company had a total of 178 active implanting centers, as compared to 159 as of September 30, 2023. The number of sales territories in the U.S. increased by three to a total of 38 during the three months ended December 31, 2023.

As of December 31, 2023, cash and cash equivalents were \$91 million.

The foregoing estimated financial results for the fourth quarter and full year 2023 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 2023 in late January 2024.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of CVRx, Inc., dated January 8, 2024
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 8, 2024

By: /s/ Jared Oasheim

Name: Jared Oasheim

Its: Chief Financial Officer

CVRx Reports Preliminary Fourth Quarter and Fiscal Year 2023 Financial Results and Announces Nadim Yared Retirement Plans

- *Fourth quarter revenue expected to be \$11.2 million to \$11.3 million, representing growth of 56% to 58%*
- *Full year revenue expected to be \$39.2 million to \$39.3 million, representing growth of 74% to 75%*
- *President and CEO Nadim Yared plans to retire upon the completion of a deliberate succession process and the appointment of a successor*

MINNEAPOLIS, Jan 8, 2024 – CVRx, Inc. (NASDAQ: CVRX) (“CVRx”), a commercial-stage medical device company, announced today certain preliminary unaudited fourth quarter and full year 2023 revenue results as well as its 2024 business outlook. The Company also announced that President and Chief Executive Officer, Nadim Yared, has informed the Board of Directors of his plans to retire following the selection and appointment of his successor.

Fourth Quarter 2023

Total revenue for the fourth quarter of 2023 is expected to be in the range of approximately \$11.2 million to \$11.3 million, representing an increase of approximately 56% to 58% over fourth quarter 2022 revenue of \$7.2 million. Total revenue generated in the fourth quarter of 2023 is expected to be comprised of approximately \$10.2 million in U.S. heart failure revenue, \$1.0 million in European revenue and \$0.1 million in U.S. legacy revenue.

Full Year 2023

Total revenue for full year 2023 is expected to be in the range of approximately \$39.2 million to \$39.3 million, representing an increase of approximately 74% to 75% over full year 2022 revenue of \$22.5 million. Total revenue generated in 2023 is expected to be comprised of approximately \$34.6 million in U.S. heart failure revenue, \$4.2 million in European revenue and \$0.5 million in U.S. legacy revenue.

As of December 31, 2023, the Company had a total of 178 active implanting centers, as compared to 159 as of September 30, 2023. The number of sales territories in the U.S. increased by three to a total of 38 during the three months ended December 31, 2023.

As of December 31, 2023, cash and cash equivalents were \$91 million.

“2023 was another fantastic year for CVRx,” said Nadim Yared, President and Chief Executive Officer of CVRx. “We continued to drive the adoption and utilization of Barostim, evidenced by the 97% increase in U.S. heart failure revenue. In addition, we announced several positive catalysts during the year, including the recently announced expansion of Barostim labeling as well as CMS’ OPPS ruling to reassign Barostim to a new APC code, which we believe will facilitate increased access to the therapy for Medicare patients with heart failure by offering facilities sufficient reimbursement for the procedure.”

Business Outlook

For the full year of 2024, the Company expects:

- Total revenue between \$53.0 million and \$57.0 million;
- Gross margin between 83% and 84%;
- Operating expenses between \$86.0 million and \$90.0 million.

For the first quarter of 2024, the Company expects to report total revenue between \$11.0 million and \$12.0 million.

CEO Retirement Plans and Initiation of Search Process

The Company's current President and Chief Executive Officer, Yared, has informed the Board of Directors of his plans to retire. Both he and the Board are committed to a planful and deliberate process to identify his successor, and Yared will remain in his current role until a new CEO is appointed. The Board is currently conducting a search to identify a new CEO with the assistance of a leading executive search firm.

"As we look to 2024, we are very excited about the prospects for the Company and the expanded penetration of Barostim. Based on the Company's strong position, excellent leadership team, consistent execution of our strategy over the last two years, and the opportunity that lies in front of us, the Company is well-positioned to attract a high-caliber CEO who can continue to execute on our strategic plans and drive future commercial growth," Yared said. "My 17 years as CEO of CVRx have been an incredible experience and honor, and I look forward to continuing to serve the Company and support the Board throughout this transition."

"The Board of Directors is grateful to Nadim for his extraordinary leadership and his commitment since his arrival at CVRx in 2006. He has worked tirelessly to transform Barostim from an intriguing concept into a commercially successful FDA-approved therapy, and CVRx into a thriving public company," said Kirk Nielsen, lead independent director. "Nadim has contributed tremendously to the success of CVRx, and we look forward to working closely with him to identify his successor and support a seamless transition."

Upcoming Investor Conference Presentation

The Company will be participating in the 42nd Annual J.P. Morgan Healthcare Conference, including a company presentation on Wednesday, January 10, 2024 at 3:45 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 2024 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 ability to establish and maintain sales and marketing capabilities; 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, including the outbreak of the novel strain of coronavirus, COVID-19; any failure of clinical studies for future indications to produce results necessary to support regulatory clearance or approval in the U.S. or elsewhere; 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; 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 and in "Part 2, Item 1A. Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, 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 2023 Results

This press release includes estimated financial results for the fourth quarter and full year of 2023, 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 2023 in late January.

Media Contact:

Laura O'Neill

Finn Partners

402-499-8203

laura.oneill@finnpartners.com

Investor Contact:

Mark Klausner or Mike Vallie

ICR Westwicke

443.213.0501

ir@cvr.com
