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 25, 2024**

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 2.02. Results of Operations and Financial Condition.

On January 25, 2024, CVRx, Inc. issued a press release announcing its financial results for the quarter and 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of CVRx, Inc., dated January 25, 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 25, 2024

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

Exhibit 99.1

CVRx Reports Fourth Quarter and Full Year 2023 Financial and Operating Results

MINNEAPOLIS, January 25, 2024 (GLOBE NEWSWIRE) -- CVRx, Inc. (“CVRx”), a commercial-stage medical device company focused on developing, manufacturing and commercializing innovative neuromodulation solutions for patients with cardiovascular diseases, today announced its financial and operating results for the fourth quarter and full year of 2023, and affirmed its 2024 business outlook.

Recent Highlights

- *Total revenue for the fourth quarter of 2023 was $11.3 million, an increase of 58% over the prior year quarter*
- *U.S. Heart Failure (HF) revenue for the fourth quarter of 2023 was $10.2 million compared to $6.0 million in the prior year quarter, an increase of 70% over the prior year quarter*
- *Total revenue for 2023 was $39.3 million, an increase of 75% over the prior year*
- *Active implanting centers for 2023 increased to 178, a 68% increase since December 31, 2022*
- *As previously announced, President and CEO Nadim Yared plans to retire upon the completion of a deliberate succession process and the appointment of a successor*

"As we reflect on the accomplishments of 2023, it has been a great year for CVRx. We are proud to have sustained the momentum in driving the adoption and utilization of Barostim, resulting in a 97% annual increase in U.S. heart failure revenue,” said Nadim Yared, President and CEO of CVRx. “Additionally, we achieved significant milestones, such as the expansion of Barostim labeling and CMS' OPPS ruling assigning Barostim to the New Technology payment code. We believe these changes will enhance access to our therapy.”

“Turning our focus to 2024, we're enthusiastic about CVRx's future and the ongoing commercial adoption of Barostim. With a strong foundation, an exceptional leadership team, and consistent execution of our strategy over the last two years, we are confident in our ability to attract a high-caliber CEO. This individual will play a crucial role in executing our strategic plans and driving future commercial growth. Serving as CEO of CVRx has been an incredible experience and privilege, and I look forward to continuing to contribute to the Company’s success through this transition."

Fourth Quarter 2023 Financial and Operating Results

Revenue was $11.3 million for the three months ended December 31, 2023, an increase of $4.1 million, or 58%, over the three months ended December 31, 2022.

Revenue generated in the U.S. was $10.3 million for the three months ended December 31, 2023, an increase of $4.3 million, or 72%, over the three months ended December 31, 2022. HF revenue units in the U.S. totaled 330 and 193 for the three months ended December 31, 2023 and 2022, respectively. HF revenue in the U.S. totaled $10.2 million and $6.0 million for the three months ended December 31, 2023 and 2022, respectively. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

As of December 31, 2023, the Company had a total of 178 active implanting centers, as compared to 159 as of September 30, 2023. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. 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. A sales territory is an established regional area held by an account manager, typically after at least six months of employment.

Revenue generated in Europe was $1.0 million for the three months ended December 31, 2023, a decrease of $0.2 million, or 15%, over the three months ended December 31, 2022. Total revenue units in Europe decreased to 52 for the three months ended December 31, 2023 from 68 in the prior year period. The number of sales territories in Europe remained consistent at six during the three months ended December 31, 2023.

Gross profit was $9.6 million for the three months ended December 31, 2023, an increase of $3.9 million, or 69%, over the three months ended December 31, 2022. Gross margin increased to 85% for the three months ended December 31, 2023 compared to 79% for the three months ended December 31, 2022. Gross margin for the three months ended December 31, 2023 was higher due to a decrease in the cost per unit and an increase in the average selling price.

R&D expenses decreased $0.8 million, or 26%, to $2.2 million for the three months ended December 31, 2023 compared to the three months ended December 31, 2022. This change was primarily driven by a $0.7 million decrease in clinical study expenses and a $0.6 million decrease in consulting expenses, partially offset by a $0.3 million increase in compensation expenses, mainly as a result of increased headcount and a $0.1 million increase in non-cash stock-based compensation expense.

SG&A expenses increased $2.9 million, or 21%, to $17.0 million for the three months ended December 31, 2023 compared to the three months ended December 31, 2022. This change was driven by a $1.7 million increase in compensation expenses, mainly as a result of increased headcount, a $0.7 million increase in marketing and advertising expenses, primarily related to the commercialization of Barostim in the U.S., a $0.4 million increase in non-cash stock-based compensation expense and a $0.4 million increase in consulting expenses, partially offset by a $0.1 million decrease related to D&O insurance costs and a $0.1 million decrease in professional fees.

Interest expense increased $0.4 million to $0.6 million for the three months ended December 31, 2023 compared to the three months ended December 31, 2022. This change was driven by the interest expense on borrowings under the loan agreement entered into on October 31, 2022.

Other income, net was $1.1 million for each of the three months ended December 31, 2023 and 2022. Other income, net consisted primarily of income on interest-bearing accounts.

Net loss was $9.2 million, or $0.44 per share, for the three months ended December 31, 2023, compared to a net loss of $10.5 million, or $0.51 per share, for the three months ended December 31, 2022. Net loss per share was based on 20,826,634 weighted average shares outstanding for three months ended December 31, 2023 and 20,593,312 weighted average shares outstanding for the three months ended December 31, 2022.

Full Year 2023 Financial and Operating Results

Revenue was $39.3 million for the year ended December 31, 2023, an increase of $16.8 million, or 75%, over the year ended December 31, 2022.

Revenue generated in the U.S. was $35.1 million for the year ended December 31, 2023, an increase of $17.1 million, or 95%, over the year ended December 31, 2022. Total HF revenue units in the U.S. totaled 1,123 and 587 for the years ended December 31, 2023 and 2022, respectively. HF revenue in the U.S. totaled $34.6 million and $17.6 million for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, the Company had a total of 178 active implanting centers, as compared to 106 as of December 31, 2022. The number of sales territories in the U.S. increased by 12 to a total of 38 during the year ended December 31, 2023.

Revenue generated in Europe was $4.2 million for the year ended December 31, 2023, a decrease of $0.3 million, or 6%, over the year ended December 31, 2022. Total revenue units in Europe decreased to 207 for the year ended December 31, 2023, from 231 for the prior year period. The number of sales territories in Europe remained consistent at six during the year ended December 31, 2023.

Gross profit was $33.0 million for the year ended December 31, 2023, an increase of $15.6 million, or 89%, over the year ended December 31, 2022. Gross margin increased to 84% for the year ended December 31, 2023, compared to 78% for the year ended December 31, 2022. Gross margin for the year ended December 31, 2023 was higher due to a decrease in the cost per unit and an increase in the average selling price.

R&D expenses increased $1.7 million, or 17%, to $11.6 million for the year ended December 31, 2023, compared to the year ended December 31, 2022. This change was primarily driven by a $1.7 million increase in compensation expenses, mainly as a result of increased headcount and a $0.6 million increase in non-cash stock-based compensation expense, partially offset by a $0.8 million decrease in clinical study expenses.

SG&A expenses increased $14.5 million, or 29%, to $64.5 million for the year ended December 31, 2023, compared to the year ended December 31, 2022. This change was driven by a $8.6 million increase in compensation expenses, mainly as a result of increased headcount, a $2.3 million increase in marketing and advertising expenses, primarily related to the commercialization of Barostim in the U.S., a $1.8 million increase in non-cash stock-based compensation expense, a $1.5 million increase in travel expenses and a $1.0 million increase in consulting expenses, partially offset by a $0.3 million decrease related to D&O insurance costs and a $0.2 million decrease in professional fees.

Interest expense increased $1.6 million to $1.8 million for the year ended December 31, 2023 compared to the year ended December 31, 2022.This change was driven by the interest expense on borrowings under the loan agreement entered into on October 31, 2022.

Other income, net was $3.9 million for the year ended December 31, 2023, compared to other income, net of $1.4 million for the year ended December 31, 2022. This increase was primarily driven by higher interest rates on interest-bearing accounts partially offset by a lower cash balance.

Net loss was $41.2 million, or $1.99 per share, for the year ended December 31, 2023, compared to a net loss of $41.4 million, or $2.02 per share, for the year ended December 31, 2022.

As of December 31, 2023, cash and cash equivalents were $90.6 million. Net cash used in operating and investing activities was $39.6 million for the year ended December 31, 2023, compared to $43.4 million for the year ended December 31, 2022.

Business Outlook

For the full year of 2024, the Company expects:

- Total revenue between $53.0 million and $57.0 million;
- Gross margin between 83.0% and 84.0%;
- 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.

Recent Developments

In the fourth quarter of 2023 and first quarter of 2024, the Company announced the following business developments:

- **CEO Retirement Plans -** In January 2024, current President and Chief Executive Officer, Nadim Yared, announced his plans to retire. Both he and the Board are committed to a measured and deliberate process to identify his successor, and Mr. Yared will remain in his current role until a new CEO is appointed.
- **FDA Approved Expanded Labeling for Barostim -** In December 2023, the U.S. Food and Drug Administration approved revised Instructions For Use for Barostim, incorporating key long-term clinical data from the BeAT-HF randomized clinical trial. For more information, please refer to the press release **HERE**.

- **Market Opportunity Updated -** In December 2023, the Company announced an updated U.S. annual market opportunity for Barostim. Based on the new long-term safety and efficacy data, the Company's commercial experience, and the new reimbursement assignment, the number of patients considered to be eligible for Barostim therapy by physicians was increased to 76,000 new patients or $2.2 billion annually, as compared to the earlier estimate of 55,000 new patients or $1.4 billion, representing increases of approximately 38% and 60%, respectively.

- **CMS Increased Outpatient Payment for Barostim Procedure -** In November 2023, the Centers for Medicare and Medicaid Services reassigned the Barostim implant procedure to New Technology APC 1580, which carries an average payment amount of $45,000 effective January 1, 2024, an increase from the prior average payment amount of $29,000, with a Transitional Pass-Through Payment. The move is expected to improve access to Barostim therapy for Medicare heart failure patients by ensuring facilities receive adequate reimbursement.

Webcast and Conference Call Information

The Company will host a conference call to review its results at 4:30 p.m. Eastern Time today. A live webcast of the investor conference call will be available online at the investor relations page of the Company's website at ir.cvrx.com. To listen to the conference call on your telephone, please dial 1-877-704-4453 for U.S. callers, or 1-201-389-0920 for international callers, approximately ten minutes prior to the start time.

About CVRx, Inc.

CVRx is a commercial-stage medical device company focused on 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. 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 (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.

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CVRx, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 90,569	$ 106,194
Accounts receivable, net of allowances of $508 and $679, respectively	7,551	5,504
Inventory	10,983	6,957
Prepaid expenses and other current assets	2,987	4,223
Total current assets	112,090	122,878
Property and equipment, net	1,763	1,698
Operating lease right-of-use asset	1,349	334
Other non-current assets	27	27
Total assets	$ 115,229	$ 124,937
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,884	$ 1,719
Accrued expenses	5,980	6,369
Total current liabilities	7,864	8,088
Long-term debt	29,222	6,747
Operating lease liability, non-current portion	1,160	117
Other long-term liabilities	1,036	805
Total liabilities	39,282	15,757
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 200,000,000 authorized as of December 31, 2023 and December 31, 2022; 20,879,199 and 20,663,736 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	209	207
Additional paid-in capital	553,326	545,362
Accumulated deficit	(477,381)	(436,182)
Accumulated other comprehensive loss	(207)	(207)
Total stockholders' equity	75,947	109,180
Total liabilities and stockholders' equity	$ 115,229	$ 124,937

CVRx, INC.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Three months ended December 31,		Year ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenue	$ 11,305	$ 7,176	$ 39,295	$ 22,469
Cost of goods sold	1,720	1,509	6,256	4,999
Gross profit	9,585	5,667	33,039	17,470
Operating expenses:				
Research and development	2,241	3,046	11,633	9,952
Selling, general and administrative	17,005	14,100	64,509	50,045
Total operating expenses	19,246	17,146	76,142	59,997
Loss from operations	(9,661)	(11,479)	(43,103)	(42,527)
Interest expense	(579)	(165)	(1,799)	(165)
Other income, net	1,116	1,136	3,850	1,373
Loss before income taxes	(9,124)	(10,508)	(41,052)	(41,319)
Provision for income taxes	(39)	(28)	(147)	(109)
Net loss	(9,163)	(10,536)	(41,199)	(41,428)
Cumulative translation adjustment	1	12	—	(9)
Comprehensive loss	$ (9,162)	$ (10,524)	$ (41,199)	$ (41,437)
Net loss per share, basic and diluted	$ (0.44)	$ (0.51)	$ (1.99)	$ (2.02)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,826,634	20,593,312	20,754,375	20,532,838