

**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): **April 25, 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 April 30, 2024, CVRx, Inc. issued a press release announcing its financial results for the quarter ended March 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On April 25, 2024, the Compensation Committee of the Board of Directors approved a \$50,000 bonus for Paul Verrastro in recognition of his efforts related to the Company’s management transition in the first quarter of 2024.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of CVRx, Inc., dated April 30, 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: April 30, 2024

By: /s/ Jared Oasheim

Name: Jared Oasheim

Its: Chief Financial Officer

CVRx Reports First Quarter 2024 Financial and Operating Results

MINNEAPOLIS, April 30, 2024 (GLOBE NEWSWIRE) -- CVRx, Inc. (NASDAQ: CVRX) (“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 first quarter of 2024.

Recent Highlights

- *Total revenue for the first quarter 2024 was \$10.8 million, an increase of 35% over the prior year quarter*
- *U.S. Heart Failure (HF) revenue for the first quarter of 2024 was \$9.7 million, an increase of 43% over the prior year quarter*
- *Active implanting centers in the U.S. grew to 190, an increase of 56% over the first quarter of 2023*
- *Kevin Hykes was appointed as Chief Executive Officer on February 12, 2024*
- *BeAT-HF post-market data was published in the European Journal of Heart Failure in April 2024*

“We had a solid first quarter, which was offset by some commercial execution challenges in our U.S. Heart Failure business during our recent management transition in February. We are taking steps to address these challenges, including a change in sales leadership, which we are announcing today. I’ve also begun the process of broadening our leadership team and intensifying our efforts on therapy awareness, clinical evidence, and patient access, which will be important in order to scale the business to address the tremendous opportunity in front of us,” said Kevin Hykes, President and Chief Executive Officer of CVRx. “In my first two months, I have seen first-hand that Barostim is a highly impactful therapy, which has been proven to significantly improve the lives of patients suffering from heart failure. Based on my prior industry experience, I appreciate the remarkable opportunity that Barostim represents and am convinced that we can successfully advance this therapy towards standard of care.”

First Quarter 2024 Financial and Operating Results

Revenue was \$10.8 million for the three months ended March 31, 2024, an increase of \$2.8 million, or 35%, over the three months ended March 31, 2023.

Revenue generated in the U.S. was \$9.8 million for the three months ended March 31, 2024, an increase of \$2.9 million, or 42%, over the three months ended March 31, 2023. HF revenue units in the U.S. totaled 319 and 225 for the three months ended March 31, 2024 and 2023, respectively. HF revenue in the U.S. totaled \$9.7 million and \$6.8 million for the three months ended March 31, 2024 and 2023, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

As of March 31, 2024, the Company had a total of 190 active implanting centers, as compared to 178 as of December 31, 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 one to a total of 39 during the three months ended March 31, 2024.

Revenue generated in Europe was \$0.9 million for the three months ended March 31, 2024, an increase of \$0.1 million, or 10%, over the three months ended March 31, 2023. Total revenue units in Europe decreased to 44 for the three months ended March 31, 2024 from 52 in the prior year period. The number of sales territories in Europe remained consistent at six for the three months ended March 31, 2024.

Gross profit was \$9.2 million for the three months ended March 31, 2024, an increase of \$2.5 million, or 38%, over the three months ended March 31, 2023. Gross margin increased to 85% for the three months ended March 31, 2024, compared to 83% for the three months ended March 31, 2023. This increase was due primarily to a decrease in the cost per unit driven by an increase in the production volume.

R&D expenses decreased \$0.4 million, or 11%, to \$3.1 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. This change was driven by a \$0.2 million decrease in non-cash stock-based compensation expense, and a \$0.2 million decrease in consulting expenses.

SG&A expenses increased \$12.9 million, or 84%, to \$28.3 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. This change was primarily driven by a \$9.6 million increase in non-cash stock-based compensation expense, a \$2.0 million increase in compensation expense and a \$0.6 million increase in travel expenses. Approximately \$8.4 million of the increase in non-cash stock-based compensation expense is related to the previously disclosed modification of stock options held by the former CEO in connection with his retirement in the first quarter of 2024.

Other income, net decreased \$18,000 for the three months ended March 31, 2024, compared to the three months ended March 31, 2023. This decrease was primarily driven a lower cash balance in our interest-bearing accounts.

Net loss was \$22.2 million, or \$1.04 per share, for the three months ended March 31, 2024, compared to a net loss of \$11.4 million, or \$0.55 per share, for the three months ended March 31, 2023. Net loss per share was based on 21.2 million weighted average shares outstanding for three months ended March 31, 2024 and 20.7 million weighted average shares outstanding for the three months ended March 31, 2023.

As of March 31, 2024, cash and cash equivalents were \$80.1 million. Net cash used in operating and investing activities was \$11.8 million for the quarter ended March 31, 2024. This is compared to net cash used in operating and investing activities of \$8.0 million for the three months ended December 31, 2023.

Business Outlook

For the full year of 2024, the Company now expects:

- Total revenue between \$50.0 million and \$53.0 million;
- Gross margin between 83.0% and 85.0%; and
- Operating expenses between \$92.0 million and \$98.0 million.

For the second quarter of 2024, the Company expects to report total revenue between \$11.3 million and \$12.3 million.

Webcast and Conference Call Information

The Company will host a conference call to review its results at 5:00 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.cvr.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.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 second 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 limited commercial sales 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 NEO; 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, 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@cvr.com

Media Contact:

Laura O’Neill
Finn Partners
402-499-8203
laura.oneill@finnpartners.com

CVRx, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	March 31,	December 31,
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 80,115	\$ 90,569
Accounts receivable, net of allowances of \$647 and \$508, respectively	8,495	7,551
Inventory	11,056	10,983
Prepaid expenses and other current assets	2,656	2,987
Total current assets	102,322	112,090
Property and equipment, net	2,549	1,763
Operating lease right-of-use asset	1,274	1,349
Other non-current assets	26	27
Total assets	\$ 106,171	\$ 115,229
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,608	\$ 1,884
Accrued expenses	5,790	5,980
Total current liabilities	8,398	7,864
Long-term debt	29,270	29,222
Operating lease liability, non-current portion	1,092	1,160
Other long-term liabilities	1,150	1,036
Total liabilities	39,910	39,282
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value, 200,000,000 authorized as of March 31, 2024 and December 31, 2023; 21,593,173 and 20,879,199 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	216	209
Additional paid-in capital	565,822	553,326
Accumulated deficit	(499,567)	(477,381)
Accumulated other comprehensive loss	(210)	(207)
Total stockholders' equity	66,261	75,947
Total liabilities and stockholders' equity	\$ 106,171	\$ 115,229

CVRx, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three months ended	
	March 31,	
	2024	2023
Revenue	\$ 10,770	\$ 7,979
Cost of goods sold	1,615	1,328
Gross profit	<u>9,155</u>	<u>6,651</u>
Operating expenses:		
Research and development	3,057	3,416
Selling, general and administrative	28,330	15,397
Total operating expenses	<u>31,387</u>	<u>18,813</u>
Loss from operations	(22,232)	(12,162)
Interest expense	(960)	(240)
Other income, net	1,044	1,062
Loss before income taxes	<u>(22,148)</u>	<u>(11,340)</u>
Provision for income taxes	(38)	(34)
Net loss	<u>(22,186)</u>	<u>(11,374)</u>
Cumulative translation adjustment	(3)	3
Comprehensive loss	<u>\$ (22,189)</u>	<u>\$ (11,371)</u>
Net loss per share, basic and diluted	\$ (1.04)	\$ (0.55)
Weighted-average common shares used to compute net loss per share, basic and diluted	21,232,009	20,693,224