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 27, 2023**

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 x

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 27, 2023, CVRx, Inc. issued a press release announcing its financial results for the quarter ended March 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 April 27, 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: April 27, 2023

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

Exhibit 99.1

CVRx Reports First Quarter 2023 Financial and Operating Results

MINNEAPOLIS, April 27, 2023 (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 2023.

Recent Highlights

- *Totality of evidence from BeAT-HF post-market study shows long-term benefits for patients with heart failure*
- *U.S. Heart Failure (HF) revenue for the first quarter of 2023 was $6.8 million compared to $2.9 million in the prior year quarter, an increase of 132% over prior year quarter*
- *Active implanting centers in the U.S. grew to 122, an increase of 118% over the first quarter of 2022*
- *Worldwide revenue for the first quarter of 2023 was $8.0 million, an increase of 96% over prior year quarter*

"I am thrilled with our first quarter performance, which demonstrated solid execution on multiple fronts. We were able to share the preliminary data from BeAT-HF during the first quarter and grow our US heart failure business. This is a testament to our team's ability to accelerate adoption of Barostim through the increased capabilities of our commercial organization and our marketing and awareness efforts," said Nadim Yared, President and Chief Executive Officer of CVRx. "As we look ahead to the rest of 2023, we are excited about the opportunities that lie ahead and confident that we will bring relief to patients suffering from heart failure."

First Quarter 2023 Financial and Operating Results

Revenue was $8.0 million for the three months ended March 31, 2023, an increase of $3.9 million, or 96%, over the three months ended March 31, 2022.

Revenue generated in the U.S. was $6.9 million for the three months ended March 31, 2023, an increase of $3.9 million, or 127%, over the three months ended March 31, 2022. HF revenue units in the U.S. totaled 225 and 99 for the three months ended March 31, 2023 and 2022, respectively. HF revenue in the U.S. totaled $6.8 million and $2.9 million for the three months ended March 31, 2023 and 2022, 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, 2023, the Company had a total of 122 active implanting centers, as compared to 106 as of December 31, 2022. 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 29 during the three months ended March 31, 2023.

Revenue generated in Europe was $1.0 million for the three months ended March 31, 2023, an increase of $0.02 million, or 2%, over the three months ended March 31, 2022. Total revenue units in Europe increased to 52 for the three months ended March 31, 2023 from 50 in the prior year period. The number of sales territories in Europe remained consistent at six for the three months ended March 31, 2023.

Gross profit was $6.7 million for the three months ended March 31, 2023, an increase of $3.5 million, or 113%, over the three months ended March 31, 2022. Gross margin increased to 83% for the three months ended March 31, 2023 compared to 77% for the three months ended March 31, 2022. Gross margin for the three months ended March 31, 2023 improved due primarily to a decrease in the cost per unit driven by an increase in the production volume.

R&D expenses increased $1.2 million, or 51%, to $3.4 million for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. This change was driven by a $0.5 million increase in compensation expenses as a result of increased headcount, a $0.4 million increase in non-cash stock-based compensation expense and a $0.4 million increase in consulting fees.

SG&A expenses increased $4.6 million, or 43%, to $15.4 million for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. This change was primarily driven by a $2.6 million increase in compensation expenses, mainly as a result of increased headcount, a $0.8 million increase in travel expenses, a $0.6 million increase in marketing and advertising expenses associated with the commercialization of Barostim in the U.S., and a $0.5 million increase in non-cash stock-based compensation expense.

Other income, net was $1.1 million for the three months ended March 31, 2023 compared to other expense, net of $57,000 for the three months ended March 31, 2022. The income in the first quarter of 2023 was primarily driven by interest income on our interest-bearing account.

Net loss was $11.4 million, or $0.55 per share, for the three months ended March 31, 2023, compared to a net loss of $10.0 million, or $0.49 per share, for the three months ended March 31, 2022. Net loss per share was based on 20,693,224 weighted average shares outstanding for the first quarter of 2023 and 20,453,341 weighted average shares outstanding for the first quarter of 2022.

As of March 31, 2023, cash and cash equivalents were $103.3 million. Net cash used in operating and investing activities was $10.5 million for the quarter ended March 31, 2023, compared to $10.9 million for the quarter ended March 31, 2022.

Business Outlook

For the full year of 2023, the Company expects:

- Total revenue between $35.5 million and $38.0 million, compared to prior guidance of between $35.0 million and $38.0 million;
- Gross margin between 80.0% and 83.0%, compared to prior guidance of between 78% and 79%;
- Operating expenses between $76.0 million and $80.0 million.

For the second quarter of 2023, the Company expects to report total revenue between $8.2 million and $8.8 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.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. 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.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, specifically, our 2023 expected operating and financial 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, 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.

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 103,276	$ 106,194
Accounts receivable, net of allowances of $641 and $679, respectively	6,434	5,504
Inventory	8,241	6,957
Prepaid expenses and other current assets	2,631	4,223
Total current assets	120,582	122,878
Property and equipment, net	1,805	1,698
Operating lease right-of-use asset	277	334
Other non-current assets	27	27
Total assets	$ 122,691	$ 124,937
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,996	$ 1,719
Accrued expenses	5,961	6,369
Total current liabilities	7,957	8,088
Long-term debt	14,218	6,747
Operating lease liability, non-current portion	59	117
Other long-term liabilities	815	805
Total liabilities	23,049	15,757
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 200,000,000 authorized as of March 31, 2023 and December 31, 2022; 20,708,940 and 20,633,736 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	207	207
Additional paid-in capital	547,195	545,362
Accumulated deficit	(447,556)	(436,182)
Accumulated other comprehensive loss	(204)	(207)
Total stockholders' equity	99,642	109,180
Total liabilities and stockholders' equity	$ 122,691	$ 124,937

CVRx, INC.

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

	Three months ended March 31,	
	2023	**2022**
Revenue	$ 7,979	$ 4,076
Cost of goods sold	1,328	949
Gross profit	6,651	3,127
Operating expenses:		
Research and development	3,416	2,258
Selling, general and administrative	15,397	10,777
Total operating expenses	18,813	13,035
Loss from operations	(12,162)	(9,908)
Interest expense	(240)	—
Other income (expense), net	1,062	(57)
Loss before income taxes	(11,340)	(9,965)
Provision for income taxes	(34)	(26)
Net loss	(11,374)	(9,991)
Cumulative translation adjustment	3	(6)
Comprehensive loss	$ (11,371)	$ (9,997)
Net loss per share, basic and diluted	$ (0.55)	$ (0.49)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,693,224	20,453,341