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, 2022**

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 25, 2022, CVRx, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 25, 2022
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 25, 2022

By: /s/ Nadim Yared
Name: Nadim Yared
Its: President and Chief Executive Officer

Exhibit 99.1

CVRx Reports First Quarter 2022 Financial and Operating Results

First Quarter 2022 Revenue of $4.1 million, a 43% Increase Over Prior Year

MINNEAPOLIS, April 25, 2022 (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 2022.

Recent Highlights

- *Total revenue for the first quarter of 2022 was $4.1 million, an increase of 43% over prior year quarter*
- *U.S. Heart Failure (HF) revenue for the first quarter of 2022 was $2.9 million, an increase of 133% over the prior year quarter*
- *Received FDA approval for a new programmer in April 2022*

"I am very pleased with the progress we have made in the first quarter as we continued to drive the adoption of Barostim - growing U.S. heart failure revenue by 133% year over year, expanding our U.S. active implanting centers and delivering a record number of revenue units - despite a highly challenging macro environment early in the year," said Nadim Yared, President and Chief Executive Officer of CVRx. "With the expansion of our U.S. commercial organization, increased awareness among physicians and patients of the benefits of Barostim, and recent regulatory progress within our product portfolio, we believe we are in a strong position to continue to drive adoption of Barostim and provide a solution to individuals suffering from cardiovascular disease."

First Quarter 2022 Financial and Operating Results

	Revenue by Product Category/Geography Three months ended March 31,		
	2022	2021	
	Amount	Amount	% Change
	(dollars in thousands)		
U.S. Heart Failure (HF)	$ 2,928	$ 1,257	133%
U.S. Legacy Hypertension	130	354	(63)%
United States	3,058	1,612	90%
Europe	1,018	1,248	(18)%
Total Revenue	$ 4,076	$ 2,860	43%

Revenue was $4.1 million for the three months ended March 31, 2022, an increase of $1.2 million, or 43%, over the three months ended March 31, 2021.

Revenue generated in the U.S. was $3.1 million for the three months ended March 31, 2022, an increase of $1.4 million, or 90%, over the three months ended March 31, 2021. HF revenue units in the U.S. totaled 99 and 44 for the three months ended March 31, 2022 and 2021, respectively. HF revenue in the U.S. totaled $2.9 million for the three months ended March 31, 2022, an increase of $1.6 million, or 133% over the three months ended March 31, 2021. The increase was 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, 2022, the Company had a total of 56 active implanting centers as compared to 19 as of March 31, 2021. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. As of March 31, 2022, the Company had a total of 17 sales territories as compared to 6 as of March 31, 2021.

Revenue generated in Europe was $1.0 million for the three months ended March 31, 2022, a decrease of $0.2 million, or 18%, over the three months ended March 31, 2021. Total revenue units in Europe were 50 for the three months ended March 31, 2022 as compared to 52 in the prior year period. The decrease is due to reduced procedure volumes due to COVID-related headwinds. As of March 31, 2022, the Company had a total of six sales territories in Europe.

Gross profit was $3.1 million for the three months ended March 31, 2022, an increase of $1.1 million, or 57%, over the three months ended March 31, 2021. Gross margin increased to 77% for the three months ended March 31, 2022, compared to 70% for the three months ended March 31, 2021. Gross margin for the three months ended March 31, 2022 was higher due to a decrease in the cost per unit and an increase in the average selling price. This was partially offset by a larger percentage of our revenue units coming from full systems versus battery replacements. New patients receive a full system that includes an IPG and a stimulation lead and have a lower gross margin than a stand-alone IPG used for a battery replacement.

R&D expenses increased $0.5 million, or 29%, to $2.3 million for the three months ended March 31, 2022 compared to the three months ended March 31, 2021. This change was primarily driven by an increase in compensation expenses, mainly as a result of increased headcount, an increase in clinical study expenses and an increase in non-cash stock-based compensation expense.

SG&A expenses increased $6.3 million, or 142%, to $10.8 million for the three months ended March 31, 2022 compared to the three months ended March 31, 2021. This was primarily driven by an increase in compensation expenses, mainly as a result of increased headcount, and an increase in marketing and advertising expenses associated with the commercialization of Barostim in the U.S.

Other expense, net was $0.1 million for the three months ended March 31, 2022 compared to $3.8 million for the three months ended March 31, 2021. The expense in the first quarter of 2021 was primarily driven by the increase in fair value of the convertible preferred stock warrant liability from December 31, 2020 to March 31, 2021. As these preferred stock warrants converted to common stock warrants upon the IPO, there is no longer a change in fair value recorded into other expense, net.

Net loss was $10.0 million, or $0.49 per share, for the three months ended March 31, 2022, compared to a net loss of $8.6 million, or $23.92 per share, for the three months ended March 31, 2021. Net loss per share was based on 20,453,341 and 360,675 weighted average shares outstanding for the three months ended March 31, 2022 and 2021, respectively.

Cash and cash equivalents were $131.2 million as of March 31, 2022, compared to $142.1 million as of December 31, 2021.

Business Outlook

For the full year of 2022, the Company continues to expect:

- Total revenue between $20.0 million and $23.0 million;
- Gross margin between 74.0% and 76.0%;
- Operating expenses between $55.0 million and $61.0 million;

For the second quarter of 2022, the Company expects to report total revenue between $4.5 million and $5.0 million.

Regulatory Update

Subsequent to the end of the first quarter, the Company received FDA approval for a new programmer, which provides even simpler programming software in a tablet form factor.

Webcast and Conference Call Information

The Company will host a conference call at 4:30 pm Eastern Time on April 25, 2022 to discuss results of the quarter as well as a question and answer session. To listen to the conference call on your telephone, please dial (833) 730-3980 for U.S. callers, or +1 (720) 405-2140 for international callers, approximately ten minutes prior to the start time and reference conference code 8433167. To listen to a live webcast, please visit the Investors section of the CVRx website at: ir.cvrx.com/news-events/events. The webcast replay will be available on the CVRx website for 12 months following completion of the call.

About CVRx, Inc.

CVRx is focused on the development and commercialization of Barostim™, 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 financial guidance regarding full year 2022 results and expectations about regulatory approvals, liquidity and cash resources and adoption of our Barostim therapy. 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, 2021, 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@cvrx.com

Media Contact:

Erich Sandoval
Finn Partners
212.867.1762
erich.sandoval@finnpartners.com

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 131,177	$ 142,072
Accounts receivable, net	3,673	2,560
Inventory	5,261	3,880
Prepaid expenses and other current assets	2,090	2,585
Total current assets	142,201	151,097
Property and equipment, net	1,656	1,425
Operating lease right-of-use asset	522	—
Other non-current assets	26	26
Total assets	$ 144,405	$ 152,548
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,607	$ 510
Accrued expenses	4,985	5,398
Total current liabilities	6,592	5,908
Operating lease liability, non-current portion	304	—
Other long-term liabilities	706	681
Total liabilities	7,602	6,589
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.01 par value, 200,000,000 authorized as of March 31, 2022 and December 31, 2021; 20,486,971 and 20,399,337 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	205	204
Additional paid-in capital	541,547	540,707
Accumulated deficit	(404,745)	(394,754)
Accumulated other comprehensive loss	(204)	(198)
Total stockholders' equity	136,803	145,959
Total liabilities and stockholders' equity	$ 144,405	$ 152,548

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

	Three months ended March 31,	
	2022	**2021**
Revenue	$ 4,076	$ 2,860
Cost of goods sold	949	867
Gross profit	3,127	1,993
Operating expenses:		
Research and development	2,258	1,750
Selling, general and administrative	10,777	4,460
Total operating expenses	13,035	6,210
Loss from operations	(9,908)	(4,217)
Interest expense	—	(601)
Other expense, net	(57)	(3,792)
Loss before income taxes	(9,965)	(8,610)
Provision for income taxes	(26)	(17)
Net loss	(9,991)	(8,627)
Cumulative translation adjustment	(6)	(4)
Comprehensive loss	$ (9,997)	$ (8,631)
Net loss per share, basic and diluted	$ (0.49)	$ (23.92)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,453,341	360,675