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): **August 4, 2021**

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):

o 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 August 4, 2021, CVRx, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2021. 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 August 4, 2021

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: August 4, 2021

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

Exhibit 99.1

CVRx Reports Second Quarter 2021 Financial and Operating Results

Second Quarter 2021 Revenue of $3.1 million, a 150% Increase Over Prior Year

MINNEAPOLIS, August 4, 2021 (GLOBE NEWSWIRE) -- CVRx, Inc. (NASDAQ: CVRX) ("CVRx"), a commercial-stage medical device company focused on developing, manufacturing and commercializing innovative and minimally invasive neuromodulation solutions for patients with cardiovascular diseases, today announced its financial and operating results for the second quarter of 2021.

Recent Highlights

- *Total revenue for the second quarter 2021 was $3.1 million, an increase of 150% over prior year quarter*
- *U.S. Heart Failure (HF) revenue for the second quarter of 2021 was $2.0 million compared to $0.07 million in the prior year quarter*
- *Closed Initial Public Offering (IPO) on July 2, 2021, raising net proceeds of approximately $133.3 million*
- *Martha Shadan appointed to the Company's Board of Directors*
- *Successfully completed the first clinical procedure with BATwire, a new ultrasound-guided implant toolkit*

"We are extremely pleased with our continued strong financial and operational performance during the quarter. We delivered topline growth of 150%, driven by a significant increase in the number of active implanting centers added in recent quarters, as well as the accelerated utilization of Barostim by existing customers. These results demonstrate the strong and growing adoption of Barostim by physicians and patients as a solution for heart failure," said Nadim Yared, President and Chief Executive Officer of CVRx. "Looking forward, we are focused on driving growth by increasing patient flow at existing implanting centers, as well as increasing the number of new active implanting centers. To accomplish this, we will continue to invest to expand our commercial infrastructure and increase awareness of this life changing technology among physicians and patients. The closing of our IPO in July provides us with incremental capital to fuel that expansion and accelerate the adoption of Barostim."

Second Quarter 2021 Financial and Operating Results

Revenue by Geography
Three months ended June 30,

	2021 Amount	2020 Amount	% Change
	(dollars in thousands)		
United States	$ 2,105	$ 197	969%
Europe	1,018	1,053	(3)%
Total Revenue	$ 3,123	$ 1,250	150%

United States Revenue by Product Category
Three months ended June 30,

	2021 Amount	2020 Amount	% Change
	(dollars in thousands)		
U.S. Heart Failure (HF)	$ 2,001	$ 65	NM
U.S. Legacy Hypertension	104	132	(21)%
Total U.S. Revenue	$ 2,105	$ 197	969%

NM – Not meaningful

Revenue increased by $1.9 million, or 150%, to $3.1 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020.

Revenue generated in the U.S. was $2.1 million for the three months ended June 30, 2021, an increase of $1.9 million, or 969%, over the three months ended June 30, 2020. HF revenue units in the U.S. totaled 67 and 2 for the three months ended June 30, 2021 and 2020, respectively. HF revenue in the U.S. totaled $2.0 million and $65,000 for the three months ended June 30, 2021 and 2020, respectively. The increase was primarily driven by continued growth following the commercial launch in 2020, which resulted in the expansion into new sales territories and increased physician and patient awareness of Barostim. As of June 30, 2021, the Company had a total of 31 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. The number of sales territories in the U.S. increased by two to a total of eight during the three months ended June 30, 2021.

Revenue generated in Europe was $1.0 million for the three months ended June 30, 2021, a decrease of $35,000, or 3.3%, over the three months ended June 30, 2020. Total revenue units in Europe decreased to 47 from 49 for the three months ended June 30, 2021 and 2020, respectively. The revenue decrease was primarily due to the impact of the COVID-19 pandemic. The number of sales territories in Europe remained consistent at six during the three months ended June 30, 2021.

Gross profit was $2.2 million for the three months ended June 30, 2021, an increase of $1.3 million, or 144%, over the three months ended June 30, 2020. Gross margin decreased to 70.8% for the three months ended June 30, 2021 compared to 72.4% for the three months ended June 30, 2020. Gross margin for the three months ended June 30, 2021 was lower due to a larger percentage of our revenue units coming from full systems, which require an IPG and a stimulation lead, as compared to individual IPG sales. This was partially offset by an increase in the average selling price.

R&D expenses increased $0.1 million, or 5.8%, to $2.3 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. This change was primarily due to an increase in stock-based compensation expense from $0.01 million to $0.19 million for the three months ended June 30, 2020 and 2021, respectively.

SG&A expenses increased $3.8 million, or 207%, to $5.6 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. The primary driver was an increase in compensation, including salaries and commissions, and other employee-related expenses, mainly as a result of increased headcount. In addition, stock-based compensation expense increased from $0.02 million to $0.43 million for the three months ended June 30, 2020 and 2021, respectively.

Other expense, net was $11.4 million for the three months ended June 30, 2021 compared to income of $0.03 for the three months ended June 30, 2020. This change was primarily driven by an $11.4 million increase in expense related to the increase in fair value of the Company’s convertible preferred stock warrants.

Net loss was $17.7 million, or $48.48 per share, for the three months ended June 30, 2021, compared to a net loss of $3.7 million, or $10.18 per share, for the three months ended June 30, 2020. Net loss per share was based on 366,066 and 360,238 weighted average shares outstanding for the second quarter of 2021 and 2020, respectively.

As of June 30, 2021, cash and cash equivalents were $47.1 million compared to $54.0 million as of March 31, 2021. Net cash used in operating and investing activities were $6.8 million for the three months ended June 30, 2021.

Business Outlook

For the full year of 2021, the Company expects:

- Total revenue between $13.3 million and $13.9 million;
- Gross margin between 72.0% and 74.0%;
- Operating expenses between $34.0 million and $36.0 million;

For the third quarter of 2021, the Company expects to report total revenue between $3.3 million and $3.6 million.

Initial Public Stock Offering

On July 2, 2021, the Company closed its IPO of 8,050,000 shares of its common stock at a public offering price of $18.00 per share, which included 1,050,000 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares, for net proceeds from the offering, after deducting the underwriting discount and other offering expenses payable by CVRx, of approximately $133.3 million.

In connection with the IPO, on June 22, 2021, the Company effected a 1-for-39.548 reverse stock split of the Company's common stock. Accordingly, all share and per-share amounts for all periods presented in this release, including the financial statements below, have been adjusted retroactively to reflect the reverse stock split.

The table below presents the Company's balance sheet data as of June 30, 2021 on an actual basis and on a pro forma as adjusted basis to give effect to:

- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 11,929,584 shares of common stock upon the closing of the IPO; and

- the sale of 8,050,000 shares of common stock in the IPO, after deducting the underwriting discount and estimated offering expenses.

	As of June 30, 2021	
	Actual	Pro forma as adjusted
	(in thousands, except share data)	
Cash and cash equivalents	$ 47,128	$ 180,385
Convertible preferred stock warrant liability	19,051	-
Redeemable convertible preferred stock	329,983	-
Total stockholders' equity (deficit)	$ (318,931)	$ 163,360
Shares of common stock outstanding	366,342	20,345,926

Board of Directors Appointment

On July 12, 2021, the Company announced the appointment of Martha Shadan to its Board of Directors. With more than three decades of experience as a business leader in the life science industry, Ms. Shadan brings a long track record of success in helping to commercialize medical technology innovations for both start-up and large companies. Ms. Shadan currently serves as the president and CEO of Miach Orthopaedics, a developer of bioengineered surgical implants for connective tissue repair.

First Clinical Procedure with BATwire

In June 2021, the first BATwire procedure was performed in the U.S. as part of a clinical trial. BATwire is a new implant toolkit which enables an ultrasound-guided implant procedure of Barostim. The Company believes BATwire could potentially expand the Company's addressable patient population by including those who are deemed clinically unfit for the current procedure. In addition, as a result of this simplified implantation process, the Company believes more physicians, including electrophysiologists, would be confident and comfortable implanting Barostim.

Webcast and Conference Call Information

The Company will host a conference call at 5:30 pm Eastern Time on August 4, 2021 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 1659235. To listen to a live webcast, please visit the Investors section of the CVRx website at: https://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 third quarter and full year 2021 results and expectations about 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 NEO; our ability to establish and maintain sales and marketing capabilities; our ability to demonstrate to physicians and patients the merits of our BAROSTIM NEO; any failure by third-party payors to provide adequate coverage and reimbursement for the use of BAROSTIM NEO; 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, 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 II, Item 1A. Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 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.

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 47,128	$ 59,112
Accounts receivable, net	2,243	1,281
Inventory	3,161	3,343
Prepaid expenses and other current assets	1,684	605
Total current assets	54,216	64,341
Property and equipment, net	820	410
Other non-current assets	26	26
Total assets	$ 55,062	$ 64,777
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 888	$ 483
Accrued expenses	3,772	3,583
Warrant liability	19,051	3,911
Current portion of long-term debt	1,333	—
Total current liabilities	25,044	7,977
Long-term debt	18,082	19,278
Other long-term liabilities	884	777
Total liabilities	44,010	28,032
Commitments and contingencies		
Convertible preferred stock, $0.01 par value, 237,370,645 authorized as of June 30, 2021 and December 31, 2020; 223,541,754 shares issued and outstanding as of June 30, 2021 and December 31, 2020	329,983	329,983
Stockholders' equity (deficit):		
Common stock, $0.01 par value, 625,217,795 authorized as of June 30, 2021 and December 31, 2020; 366,342 and 360,412 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	4	4
Additional paid-in capital, common stock	59,311	58,624
Accumulated deficit	(378,051)	(351,676)
Accumulated other comprehensive loss	(195)	(190)
Total stockholders' equity (deficit)	(318,931)	(293,238)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 55,062	$ 64,777

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

	Three months ended June 30,		Six months ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 3,123	$ 1,250	$ 5,983	$ 2,968
Cost of goods sold	913	345	1,780	777
Gross profit	2,210	905	4,203	2,191
Operating expenses:				
Research and development	2,255	2,131	4,005	4,400
Selling, general and administrative	5,627	1,834	10,087	4,128
Total operating expenses	7,882	3,965	14,092	8,528
Loss from operations	(5,672)	(3,060)	(9,889)	(6,337)
Interest expense	(608)	(618)	(1,209)	(1,235)
Other income (expense), net	(11,442)	33	(15,234)	137
Loss before income taxes	(17,722)	(3,645)	(26,332)	(7,435)
Provision for income taxes	(26)	(22)	(43)	(45)
Net loss	(17,748)	(3,667)	(26,375)	(7,480)
Cumulative translation adjustment	(1)	(11)	(5)	(21)
Comprehensive loss	$ (17,749)	$ (3,678)	$ (26,380)	$ (7,501)
Net loss per share, basic and diluted	$ (48.48)	$ (10.18)	$ (72.58)	$ (18.06)
Weighted-average common shares used to compute net loss per share, basic and diluted	366,066	360,238	363,397	414,225