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): **February 15, 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 February 15, 2022, CVRx, Inc. issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 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 February 15, 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: February 15, 2022

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

Exhibit 99.1

CVRx Reports Fourth Quarter and Full Year 2021 Financial and Operating Results

Fourth Quarter 2021 Revenue of $3.7 million, a 75% Increase Over Prior Year

MINNEAPOLIS, February 15, 2022 (GLOBE NEWSWIRE) -- CVRx, Inc. (NASDAQ: 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 2021.

Recent Highlights

- *Total revenue for the fourth quarter of 2021 was $3.7 million, an increase of 75% over the prior year quarter*
- *U.S. Heart Failure (HF) revenue for the fourth quarter of 2021 was $2.7 million, an increase of 345% over the prior year quarter*
- *Total revenue for 2021 was $13.0 million, an increase of 115% over the prior year*
- *Received FDA Implantable Pulse Generator ("IPG") approval in December 2021*
- *Fully repaid $20 million loan on November 3, 2021*

"We are very proud of everything we accomplished in 2021 despite the challenging global environment. We more than doubled our revenue as a result of the successful launch of Barostim for heart failure in the United States and we also made significant progress advancing our product innovation pipeline," said Nadim Yared, President and Chief Executive Officer of CVRx. "We are excited about the position we are in as we move into 2022. Throughout the year we will be focused on driving accelerated adoption by executing on our commercial strategy, which includes the continued expansion of our salesforce and the efforts to educate healthcare providers and consumers on the benefits of Barostim."

Fourth Quarter 2021 Financial and Operating Results

	Revenue by Product Category/Geography Three months ended December 31,		
	2021	2020	
	Amount	Amount	% Change
	(dollars in thousands)		
U.S. Heart Failure (HF)	$ 2,702	$ 607	345%
U.S. Legacy Hypertension	$ 156	$ 224	(30)%
United States	$ 2,858	$ 831	244%
Europe	$ 800	$ 1,257	(36)%
Total Revenue	$ 3,658	$ 2,088	75%

Revenue was $3.7 million for the three months ended December 31, 2021, an increase of $1.6 million, or 75%, over the three months ended December 31, 2020.

Revenue generated in the U.S. was $2.9 million for the three months ended December 31, 2021, an increase of $2.0 million, or 244%, over the three months ended December 31, 2020. HF revenue units in the U.S. totaled 95 and 21 for the three months ended December 31, 2021 and 2020, respectively. HF revenue in the U.S. totaled $2.7 million and $0.6 million for the three months ended December 31, 2021 and 2020, respectively. The increase was primarily driven by continued growth in the U.S. heart failure business as a result of the expansion into new sales territories, new accounts and increased physician and patient awareness of Barostim.

As of December 31, 2021, the Company had a total of 46 active implanting centers, as compared to 38 as of September 30, 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 three to a total of 14 during the three months ended December 31, 2021.

Revenue generated in Europe was $0.8 million for the three months ended December 31, 2021, a decrease of $0.5 million, or 36%, over the three months ended December 31, 2020. Total revenue units in Europe decreased to 39 for the three months ended December 31, 2021 from 55 in the prior year period. The decrease is due to the reduced procedure volumes in Germany in December 2021 due to COVID-related headwinds. The number of sales territories in Europe remained consistent at six during three months ended December 31, 2021.

Gross profit was $2.7 million for the three months ended December 31, 2021, an increase of $1.0 million, or 63%, over the three months ended December 31, 2020. Gross margin decreased to 73% for the three months ended December 31, 2021 compared to 78% for the three months ended December 31, 2020. Gross margin for the three months ended December 31, 2021 was lower due to a larger percentage of our revenue units coming from full systems versus battery replacements for existing patients. 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. This was partially offset by an increase in our average selling price.

R&D expenses increased $1.3 million, or 252%, to $1.8 million for the three months ended December 31, 2021 compared to the three months ended December 31, 2020. This change was primarily due to an increase in clinical study expenses due to a $1 million non-recurring reduction in a clinical accrual in the fourth quarter of 2020. Additionally, this increase was driven by a $0.2 million increase in compensation expenses as a result of increased headcount and a $0.1 million increase in non-cash stock-based compensation expense.

SG&A expenses increased $6.4 million, or 196%, to $9.7 million for the three months ended December 31, 2021 compared to the three months ended December 31, 2020. This change was driven by an increase of $3.0 million in compensation expenses as a result of increased headcount, a $1.2 million increase in marketing and advertising expenses, primarily related to the commercialization of Barostim in the U.S., a $0.6 million increase in non-cash stock-based compensation expense, a $0.7 million increase related to D&O insurance costs incurred as a result of becoming a public company and a $0.5 million increase in travel expenses.

Other expense, net was $1.4 million for the three months ended December 31, 2021 compared to $0.6 million for the three months ended December 31, 2020. The expense in the fourth quarter of 2021 was primarily driven by a $1.3 million loss on debt extinguishment in connection with the repayment of the outstanding debt under the Horizon loan agreement. The expense in the fourth quarter of 2020 was primarily driven by the increase in the fair value of the convertible preferred stock warrant liability from September 30, 2020 to December 31, 2020.

Net loss was $10.6 million, or $0.52 per share, for the three months ended December 31, 2021, compared to a net loss of $3.4 million, or $10.04 per share, for the three months ended December 31, 2020. Net loss per share was based on 20,367,064 weighted average shares outstanding for three months ended December 31, 2021 and 360,412 weighted average shares outstanding for the fourth quarter of 2020.

Full Year 2021 Financial and Operating Results

	Revenue by Product Category/Geography Full year ended December 31,		
	2021	2020	
	Amount	Amount	% Change
	(dollars in thousands)		
U.S. Heart Failure (HF)	$ 8,429	$ 987	754%
U.S. Legacy Hypertension	$ 718	$ 746	(4)%
United States	$ 9,147	$ 1,733	428%
Europe	$ 3,889	$ 4,320	(10)%
Total Revenue	$ 13,036	$ 6,053	115%

Revenue was $13.0 million for the full year ended December 31, 2021, an increase of $7.0 million, or 115%, over the full year ended December 31, 2020.

Revenue generated in the U.S. was $9.1 million for the full year ended December 31, 2021, an increase of $7.4 million, or 428%, over the full year ended December 31, 2020. HF revenue units in the U.S. totaled 290 and 32 for the full years ended December 31, 2021 and 2020, respectively. HF revenue in the U.S. totaled $8.4 million and $1.0 million for the full years ended December 31, 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, new accounts and increased physician and patient awareness of Barostim.

As of December 31, 2021, the Company had a total of 46 active implanting centers, as compared to 11 as of December 31, 2020. The number of sales territories in the U.S. increased by eight to a total of 14 during the full year ended December 31, 2021.

Revenue generated in Europe was $3.9 million for the full year ended December 31, 2021, a decrease of $0.4 million, or 10%, over the full year ended December 31, 2020. Total revenue units in Europe decreased to 176 for the full year ended December 31, 2021 from 193 for the prior year period. The decrease is due to reduced procedure volumes resulting from the Delta and Omicron variants of COVID-19 in 2021.

Gross profit was $9.4 million for the full year ended December 31, 2021, an increase of $4.8 million, or 104%, over the full year ended December 31, 2020. Gross margin decreased to 72% for the full year ended December 31, 2021 compared to 76% for the full year ended December 31, 2020. Gross margin for the year ended December 31, 2021 was lower due to a larger percentage of our revenue units coming from full systems versus battery replacements for existing patients. This was partially offset by an increase in the average selling price.

R&D expenses increased $1.1 million, or 17%, to $7.5 million for the full year ended December 31, 2021 compared to the full year ended December 31, 2020. This change was primarily driven by a $0.4 million increase in clinical study expenses, a $0.4 million increase in compensation expenses as a result of increased headcount and a $0.4 million increase in non-cash stock-based compensation expense.

SG&A expenses increased $18.1 million, or 187%, to $27.9 million for the full year ended December 31, 2021 compared to the full year ended December 31, 2020. This change was driven by an increase of $9.0 million in compensation expenses as a result of increased headcount, a $3.1 million increase in marketing and advertising expenses, primarily related to the commercialization of Barostim in the U.S., a $1.4 million increase in non-cash stock-based compensation expense, a $1.3 million increase related to D&O insurance costs incurred as a result of becoming a public company, a $1.2 million increase in travel expenses and a $1.0 million increase in consulting expenses.

Other expense, net was $14.8 million for the full year ended December 31, 2021 compared to $40,000 for the full year ended December 31, 2020. The expense in 2021 was primarily driven by a $13.7 million increase in expense related to the increase in the fair value of our convertible preferred stock warrants due to the change in the value of our common stock from December 31, 2020 to July 2, 2021, which is the date the warrants converted to common stock warrants. The expense in 2021 was also due to a $1.3 million loss on debt extinguishment in connection with the November 2021 repayment of the outstanding debt under the Horizon loan agreement.

Net loss was $43.1 million, or $4.16 per share, for the full year ended December 31, 2021, compared to a net loss of $14.1 million, or $37.01 per share, for the full year ended December 31, 2020.

As of December 31, 2021, cash and cash equivalents were $142.1 million. Net cash used in operating and investing activities was $28.9 million for the year ended December 31, 2021, compared to $16.4 million for the year ended December 31, 2020.

Business Outlook

For the full year of 2022, the Company expects:

- 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 first quarter of 2022, the Company expects to report total revenue between $3.6 million and $4.0 million.

Regulatory Update

In 2021, the Company filed three separate PMA Supplement submissions with the U.S. Food and Drug Administration ("FDA"), all of which relate to the development of its Barostim platform, for the following:

- MRI Conditional labeling, which would allow MRI scanning with specific instructions for patients implanted with Barostim
- New IPG, which would deliver 20% longer battery life on average and is smaller in volume when compared to the current IPG
- New Programmer, which would provide even simpler programming software in a tablet form factor

The company received FDA approval for the new IPG in December of 2021. Approval for the two additional PMA Supplement submissions is expected in the first half of 2022.

Debt Repayment

On November 3, 2021, the Company fully repaid its $20 million loan with Horizon Technology Finance Corporation. The total repayment cost was $21.3 million, inclusive of prepayment and other fees.

Webcast and Conference Call Information

The Company will host a conference call at 5:30 pm Eastern Time on Tuesday, February 15, 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 2879175. To listen to a live webcast, please visit the Investors section of the CVRx website at: ir.cvrx.com/investor-relations. 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 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 II, Item 1A. Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 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.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 142,072	$ 59,112
Accounts receivable, net	2,560	1,281
Inventory	3,880	3,343
Prepaid expenses and other current assets	2,585	605
Total current assets	151,097	64,341
Property and equipment, net	1,425	410
Other non-current assets	26	26
Total assets	$ 152,548	$ 64,777
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 510	$ 483
Accrued expenses	5,398	3,583
Warrant liability	—	3,911
Total current liabilities	5,908	7,977
Long-term debt	—	19,278
Other long-term liabilities	681	777
Total liabilities	6,589	28,032
Commitments and contingencies		
Convertible preferred stock, $0.01 par value, 10,000,000 and 237,370,645 authorized as of December 31, 2021 and December 31, 2020, respectively; 0 and 223,541,754 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	—	329,983
Stockholders' equity (deficit):		
Common stock, $0.01 par value, 200,000,000 and 625,217,795 authorized as of December 31, 2021 and December 31, 2020, respectively; 20,399,337 and 360,412 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	204	4
Additional paid-in capital	540,707	58,624
Accumulated deficit	(394,754)	(351,676)
Accumulated other comprehensive loss	(198)	(190)
Total stockholders' equity (deficit)	145,959	(293,238)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 152,548	$ 64,777

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

	Three months ended December 31,		Year ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 3,658	$ 2,088	$ 13,036	$ 6,053
Cost of goods sold	984	451	3,640	1,440
Gross profit	2,674	1,637	9,396	4,613
Operating expenses:				
Research and development	1,797	510	7,501	6,410
Selling, general and administrative	9,665	3,262	27,863	9,717
Total operating expenses	11,462	3,772	35,364	16,127
Loss from operations	(8,788)	(2,135)	(25,968)	(11,514)
Interest expense	(396)	(614)	(2,219)	(2,470)
Other expense, net	(1,361)	(632)	(14,800)	(40)
Loss before income taxes	(10,545)	(3,381)	(42,987)	(14,024)
Provision for income taxes	(25)	(21)	(91)	(85)
Net loss	(10,570)	(3,402)	(43,078)	(14,109)
Cumulative translation adjustment	—	6	(8)	(1)
Comprehensive loss	$ (10,570)	$ (3,396)	$ (43,086)	$ (14,110)
Net loss per share, basic and diluted	$ (0.52)	$ (10.04)	$ (4.16)	$ (37.01)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,367,064	360,412	10,360,054	387,083