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): **November 3, 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):

☐ 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 1.02. Termination of a Material Definitive Agreement.

On November 3, 2021, CVRx, Inc. (the "Company") fully repaid all amounts outstanding under that certain Venture Loan and Security Agreement, by and among Horizon Technology Finance Corporation ("Horizon"), as a lender and collateral agent, and the Company, as borrower (the "Horizon Loan Agreement"). Under the Horizon Loan Agreement, the Company could borrow up to a total of $20.0 million at a floating per annum rate equal to 10% plus the amount by which the 30-day U.S. dollar London Interbank Offered Rate on the first business day of the month exceeded 2.2%. Notes with an aggregate principal amount of $20.0 million were outstanding under the Horizon Loan Agreement at the time of repayment. Pursuant to the Horizon Loan Agreement, upon the prepayment of the amounts outstanding, the Company paid a prepayment fee in an amount equal to 3% of the then outstanding principal balance and a final payment equal to 3.5% of the original principal, resulting in a total payment by the Company to Horizon of $21.3 million.

The borrowings were collateralized by substantially all of the assets of the Company, including its intellectual property portfolio. The security interests and liens granted in connection with the Horizon Loan Agreement were terminated in connection with the Company's discharge of indebtedness thereunder.

Item 2.02. Results of Operations and Financial Condition.

On November 4, 2021, the Company issued a press release announcing its financial results for the quarter ended September 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 November 4, 2021
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: November 4, 2021

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

Exhibit 99.1

CVRx Reports Third Quarter 2021 Financial and Operating Results

Third Quarter 2021 Revenue of $3.4 million, a 241% Increase Over Prior Year

MINNEAPOLIS, November 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 third quarter of 2021.

Recent Highlights

- *Total revenue for the third quarter 2021 was $3.4 million, an increase of 241% over prior year quarter*
- *U.S. Heart Failure (HF) revenue for the third quarter of 2021 was $2.5 million compared to $0.1 million in the prior year quarter*
- *Closed Initial Public Offering (IPO) on July 2, 2021, raising net proceeds of approximately $133.2 million*
- *Filed three PMA Supplement applications related to the innovation of the Company's product portfolio*
- *Fully repaid $20 million loan subsequent to quarter end*

"We are very encouraged by our performance in the quarter. Like other procedure-based companies, we experienced COVID-19 Delta variant related headwinds in the quarter, but were able to navigate through those challenges to deliver for our customers. We are particularly encouraged by the performance of our U.S. heart failure business, which continues to show strong early adoption trends," said Nadim Yared, President and Chief Executive Officer of CVRx. "Looking ahead, we remain focused on the expansion of our U.S. commercial organization in an effort to drive wide-spread adoption. We will continue to engage with new customers, train surgeons, and onboard new active implanting facilities, in addition to supporting existing customers to grow their utilization of Barostim to bring relief to patients suffering from cardiovascular diseases."

Third Quarter 2021 Financial and Operating Results

	Revenue by Geography Three months ended September 30,		
	2021 Amount	2020 Amount	% Change
	(dollars in thousands)		
United States	$ 2,572	$ 296	769%
Europe	823	701	17%
Total Revenue	$ 3,395	$ 997	241%

	United States Revenue by Product Category Three months ended September 30,		
	2021 Amount	2020 Amount	% Change
	(dollars in thousands)		
U.S. Heart Failure (HF)	$ 2,468	$ 140	NM
U.S. Legacy Hypertension	104	156	(33)%
Total U.S. Revenue	$ 2,572	$ 296	769%

NM – Not meaningful

Revenue was $3.4 million for the three months ended September 30, 2021, an increase of $2.4 million, or 241%, over the three months ended September 30, 2020.

Revenue generated in the U.S. was $2.6 million for the three months ended September 30, 2021, an increase of $2.3 million, or 769%, over the three months ended September 30, 2020. HF revenue units in the U.S. totaled 84 and four for the three months ended September 30, 2021 and 2020, respectively. HF revenue in the U.S. totaled $2.5 million and $140,000 for the three months ended September 30, 2021 and 2020, respectively. The increase was primarily driven by continued growth following the U.S. HF commercial launch in 2020, which resulted in the expansion into new sales territories and increased physician and patient awareness of Barostim.

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

Revenue generated in Europe was $0.8 million for the three months ended September 30, 2021, an increase of $0.1 million, or 17%, over the three months ended September 30, 2020. Total revenue units in Europe increased to 38 from 32 for the three months ended September 30, 2021 and 2020, respectively. The slight revenue increase was primarily due the lessening impact of the COVID-19 pandemic in Germany. The number of sales territories in Europe remained consistent at six during the three months ended September 30, 2021.

Gross profit was $2.5 million for the three months ended September 30, 2021, an increase of $1.7 million, or 221%, over the three months ended September 30, 2020. Gross margin decreased to 74% for the three months ended September 30, 2021 compared to 79% for the three months ended September 30, 2020. Gross margin for the three months ended September 30, 2021 was lower due to a larger percentage of our revenue units coming from full systems, which require an Implantable Pulse Generator (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 $0.2 million, or 13%, to $1.7 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020. This change was primarily due to an increase of $0.1 million in non-cash stock-based compensation expense, and an increase of $0.1 million in compensation expenses, including salaries and other employee-related expenses, mainly as a result of increased headcount.

SG&A expenses increased $5.8 million, or 249%, to $8.1 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020. This change was driven by an increase of $2.8 million in compensation expenses, including salaries and commissions, and other employee-related expenses, mainly as a result of increased headcount, a $0.8 million increase in marketing and advertising expenses primarily related to the commercial launch of Barostim in the U.S., a $0.7 million increase in insurance costs incurred as a result of the IPO, $0.4 million of additional travel expenses, a $0.3 million increase in non-cash stock-based compensation expense, and a $0.3 million increase in consulting expenses.

Other income, net was $1.8 million for the three months ended September 30, 2021 compared to $0.5 million for the three months ended September 30, 2020, driven by a $1.5 million decrease in fair value of the convertible preferred stock warrant liability due to the change in the common stock price from June 30, 2021 to July 2, 2021, which is the date the warrants converted to common stock warrants.

Net loss was $6.1 million, or $0.30 per share, for the three months ended September 30, 2021, compared to a net loss of $3.2 million, or $9.56 per share, for the three months ended September 30, 2020. Net loss per share was based on 20,126,672 and 360,356 weighted average shares outstanding for the third quarter of 2021 and 2020, respectively.

As of September 30, 2021, cash and cash equivalents were $170.9 million compared to $47.1 million as of June 30, 2021. Net cash used in operating and investing activities was $9.4 million for the three months ended September 30, 2021.

Business Outlook

For the full year of 2021, the Company continues to expect:

- 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 fourth quarter of 2021, the Company expects to report total revenue between $3.9 million and $4.5 million.

Regulatory Update

In the last two months 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 relative to prior generations
- New Programmer, which would provide even simpler programming software in a tablet form factor

Approval for the three 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 of $21.3 million, inclusive of prepayment and other fees, will be reflected in the fourth quarter.

Following the repayment, the Company believes it has more than three years of cash on hand to fund operations.

Webcast and Conference Call Information

The Company will host a conference call at 5:30 pm Eastern Time on November 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 6038756. 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 2021 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 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 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.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 170,913	$ 59,112
Accounts receivable, net	3,421	1,281
Inventory	3,440	3,343
Prepaid expenses and other current assets	2,923	605
Total current assets	180,697	64,341
Property and equipment, net	943	410
Other non-current assets	67	26
Total assets	$ 181,707	$ 64,777
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 541	$ 483
Accrued expenses	4,977	3,583
Warrant liability	—	3,911
Current portion of long-term debt	3,333	—
Total current liabilities	8,851	7,977
Long-term debt	16,151	19,278
Other long-term liabilities	941	777
Total liabilities	25,943	28,032
Commitments and contingencies		
Convertible preferred stock, $0.01 par value, 10,000,000 and 237,370,645 authorized as of September 30, 2021 and December 31, 2020, respectively; 0 and 223,541,754 shares issued and outstanding as of September 30, 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 September 30, 2021 and December 31, 2020, respectively; 20,351,779 and 360,412 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	204	4
Additional paid-in capital	539,941	58,624
Accumulated deficit	(384,184)	(351,676)
Accumulated other comprehensive loss	(197)	(190)
Total stockholders' equity (deficit)	155,764	(293,238)
Total liabilities, convertible preferred stock, and stockholders' equity	$ 181,707	$ 64,777

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 3,395	$ 997	$ 9,378	$ 3,965
Cost of goods sold	876	212	2,656	989
Gross profit	2,519	785	6,722	2,976
Operating expenses:				
Research and development	1,699	1,500	5,704	5,900
Selling, general and administrative	8,111	2,327	18,198	6,455
Total operating expenses	9,810	3,827	23,902	12,355
Loss from operations	(7,291)	(3,042)	(17,180)	(9,379)
Interest expense	(614)	(621)	(1,823)	(1,856)
Other income (expense), net	1,795	455	(13,439)	592
Loss before income taxes	(6,110)	(3,208)	(32,442)	(10,643)
Provision for income taxes	(23)	(19)	(66)	(64)
Net loss	(6,133)	(3,227)	(32,508)	(10,707)
Cumulative translation adjustment	(3)	14	(8)	(7)
Comprehensive loss	$ (6,136)	$ (3,213)	$ (32,516)	$ (10,714)
Net loss per share, basic and diluted	$ (0.30)	$ (9.56)	$ (4.66)	$ (27.58)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,126,672	360,356	6,975,386	396,071