

**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 5, 2025**

CVRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-40545
(Commission
File Number)

41-1983744
(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

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 November 5, 2025, CVRx, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2025. 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 5, 2025
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 5, 2025

By: /s/ Jared Oasheim

Name: Jared Oasheim

Its: Chief Financial Officer

CVRx Reports Third Quarter 2025 Financial and Operating Results

MINNEAPOLIS, November 5, 2025 (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 third quarter of 2025.

Recent Highlights

- Total revenue for the third quarter 2025 was \$14.7 million, an increase of 10% over the prior year quarter
- U.S. revenue for the third quarter of 2025 was \$13.5 million, an increase of 10% over the prior year quarter
- Active implanting centers in the U.S. grew to 250, an increase of 20% since September 30, 2024
- CMS published the final rule to assign favorable physician fee payment levels in connection with the Category I CPT codes set to take effect in 2026

"We're pleased with the solid progress we made in the third quarter as we continue to execute and build momentum across the organization," said Kevin Hykes, President and Chief Executive Officer of CVRx. "Our revised commercial strategy continues to show positive results. The development of our territories is progressing nicely as our newest reps are becoming increasingly more productive, resulting in both higher Barostim implant volumes and the expansion of our customer base. We're also pleased that CMS finalized our transition to Category I CPT codes, both improving patient access and removing key adoption barriers. Our focus remains on positively impacting the lives of patients who suffer from heart failure, and we are well positioned to drive deeper adoption going forward."

Third Quarter 2025 Financial and Operating Results

Revenue was \$14.7 million for the three months ended September 30, 2025, an increase of \$1.3 million, or 10%, over the three months ended September 30, 2024.

Revenue generated in the U.S. was \$13.5 million for the three months ended September 30, 2025, an increase of \$1.2 million, or 10%, over the three months ended September 30, 2024. Revenue units in the U.S. totaled 420 and 394 for the three months ended September 30, 2025 and 2024, 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 September 30, 2025, the Company had a total of 250 active implanting centers in the U.S., compared to 240 as of June 30, 2025. 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 50 during the three months ended September 30, 2025.

Revenue generated in Europe was \$1.2 million for the three months ended September 30, 2025, an increase of \$0.1 million, or 12%, over the three months ended September 30, 2024. Total revenue units in Europe decreased to 50 for the three months ended September 30, 2025, compared to 56 in the prior year period. The number of sales territories in Europe remained consistent at five for the three months ended September 30, 2025.

Gross profit was \$12.8 million for the three months ended September 30, 2025, an increase of \$1.6 million, or 15%, over the three months ended September 30, 2024. Gross margin increased to 87% for the three months ended September 30, 2025, compared to 83% for the three months ended September 30, 2024. Gross margin for the three months ended September 30, 2025 was higher due to an increase in the average selling price and a decrease in the cost per unit, primarily due to an increase in manufacturing efficiencies.

R&D expenses increased \$0.6 million, or 26%, to \$3.1 million for the three months ended September 30, 2025, compared to the three months ended September 30, 2024. This change was driven by a \$0.5 million increase in compensation expenses and a \$0.2 million increase in consulting expenses, partially offset by a \$0.2 million decrease in clinical trial expenses.

SG&A expenses increased \$0.2 million, or 1%, to \$21.9 million for the three months ended September 30, 2025, compared to the three months ended September 30, 2024. This change was primarily driven by a \$0.2 million increase in consulting expenses, a \$0.2 million increase in travel expenses, and a \$0.2 million increase in non-cash stock-based compensation expense, partially offset by a \$0.2 million decrease in advertising expenses and a \$0.2 million decrease in compensation expenses.

Interest expense increased \$0.5 million for the three months ended September 30, 2025, compared to the three months ended September 30, 2024. This increase was driven by the interest expense on higher levels of borrowings under the term loan agreement with Innovatus Capital Partners.

Other income, net was \$0.9 million for each of the three months ended September 30, 2025 and 2024. These balances consisted of interest income on our interest-bearing accounts.

Net loss was \$12.9 million, or \$0.49 per share, for the three months ended September 30, 2025, compared to a net loss of \$13.1 million, or \$0.57 per share, for the three months ended September 30, 2024. Net loss per share was based on 26.2 million weighted average shares outstanding for three months ended September 30, 2025 and 22.8 million weighted average shares outstanding for the three months ended September 30, 2024.

As of September 30, 2025, cash and cash equivalents were \$85.1 million. Net cash used in operating and investing activities was \$10.0 million for the three months ended September 30, 2025 compared to \$10.4 million for the three months ended September 30, 2024.

Business Outlook

For the full year of 2025, the Company updated its guidance ranges and now expects:

- Total revenue between \$55.6 million and \$56.6 million, compared to prior guidance of \$55.0 million to \$57.0 million;
- Gross margin between 85% and 86%, compared to prior guidance of 83% to 84%;
- Operating expenses between \$98.0 million and \$99.0 million, compared to prior guidance of \$96.0 million to \$98.0 million.

For the fourth quarter of 2025, the Company expects to report total revenue between \$15.0 million and \$16.0 million.

Webcast and Conference Call Information

The Company will host a conference call to review its results at 4:30 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.cvr.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. 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 been certified as compliant with the EU Medical Device Regulation (MDR) and holds CE Mark approval for heart failure and resistant hypertension in the European Economic Area. To learn more about Barostim, visit www.cvr.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 our financial guidance regarding full year and fourth quarter 2025 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 limited commercial sales experience marketing and selling Barostim; our ability to continue demonstrating 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; 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; impacts on adoption and regulatory approvals resulting from additional long-term clinical data about our product; 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, 2024 and “Part II, Item 1A. Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, 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, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 85,124	\$ 105,933
Accounts receivable, net of allowances of \$871 and \$780, respectively	8,209	9,268
Inventory	11,394	12,107
Prepaid expenses and other current assets	3,163	2,505
Total current assets	107,890	129,813
Property and equipment, net	2,446	2,505
Operating lease right-of-use asset	963	1,069
Other non-current assets	26	27
Total assets	<u>\$ 111,325</u>	<u>\$ 133,414</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,628	\$ 2,582
Accrued expenses	7,590	8,180
Total current liabilities	11,218	10,762
Long-term debt	49,453	49,273
Operating lease liability, non-current portion	730	877
Other long-term liabilities	1,870	1,447
Total liabilities	<u>63,271</u>	<u>62,359</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value, 200,000,000 authorized as of September 30, 2025 and December 31, 2024; 26,193,733 and 25,324,684 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	262	253
Additional paid-in capital	626,714	608,354
Accumulated deficit	(578,718)	(537,346)
Accumulated other comprehensive loss	(204)	(206)
Total stockholders' equity	48,054	71,055
Total liabilities and stockholders' equity	<u>\$ 111,325</u>	<u>\$ 133,414</u>

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,	
	2025	2024	2025	2024
Revenue	\$ 14,690	\$ 13,373	\$ 40,627	\$ 35,950
Cost of goods sold	1,937	2,248	6,112	5,763
Gross profit	12,753	11,125	34,515	30,187
Operating expenses:				
Research and development	3,146	2,504	8,132	8,326
Selling, general and administrative	21,875	21,632	66,464	71,077
Total operating expenses	25,021	24,136	74,596	79,403
Loss from operations	(12,268)	(13,011)	(40,081)	(49,216)
Interest expense	(1,480)	(958)	(4,410)	(2,877)
Other income, net	875	917	3,108	2,905
Loss before income taxes	(12,873)	(13,052)	(41,383)	(49,188)
Benefit (provision) for income taxes	3	(47)	11	(126)
Net loss	(12,870)	(13,099)	(41,372)	(49,314)
Cumulative translation adjustment	(1)	2	2	(1)
Comprehensive loss	\$ (12,871)	\$ (13,097)	\$ (41,370)	\$ (49,315)
Net loss per share, basic and diluted	\$ (0.49)	\$ (0.57)	\$ (1.59)	\$ (2.25)
Weighted-average common shares used to compute net loss per share, basic and diluted	26,168,562	22,783,337	26,039,718	21,884,588