

**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, 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 August 4, 2025, CVRx, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 4, 2025, the Company announced that its Board of Directors (the “Board”) appointed Brent Binkowski as Chief Operating Officer, effective August 11, 2025.

Mr. Binkowski, age 56, previously served as Vice President of Operations – Interventional Urology of Coloplast Corp., a healthcare products company, from June 2020 to August 2025. Prior to Coloplast, Mr. Binkowski held positions of increasing responsibility in engineering, manufacturing and operations at Teleflex Incorporated, Vascular Solutions, Inc. (which was acquired by Teleflex), CeloNova BioSciences, Inc., and American Medical Systems – Ireland. The Compensation Committee of the Board approved the following compensation for Mr. Binkowski: (i) an initial annual base salary of \$405,000, (ii) a target cash incentive award of 50% of base salary (which will be pro-rated for fiscal 2025), (iii) initial equity awards consisting of 74,900 stock options and 16,600 restricted stock units, which will have terms consistent with the Company’s current forms of equity awards, and (iv) a sign-on bonus in recognition of the annual incentive opportunity he will forfeit from his current employer in the amount of \$50,000 that is subject to repayment if Mr. Binkowski resigns or is terminated for cause prior to the first anniversary of his hire date. Mr. Binkowski will receive the Company’s standard form of severance agreement for executive officers.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit**No.****Description**

99.1	Press release of CVRx, Inc., dated August 4, 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: August 4, 2025

By: /s/ Jared Oasheim

Name: Jared Oasheim

Its: Chief Financial Officer

CVRx Reports Second Quarter 2025 Financial and Operating Results

MINNEAPOLIS, August 4, 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 second quarter of 2025.

Recent Highlights

- Total revenue for the second quarter 2025 was \$13.6 million, an increase of 15% over the prior year quarter
- U.S. Heart Failure (HF) revenue for the second quarter of 2025 was \$12.1 million, an increase of 15% over the prior year quarter
- Active implanting centers in the U.S. grew to 240, an increase of 27% since June 30, 2024
- CMS proposed to keep Barostim implant procedure in New Technology APC 1580 for 2026 with a payment of approximately \$45,000 for outpatient procedures
- CMS proposed favorable physician fee payment levels in connection with the Category I CPT codes set to take effect in 2026
- Brent Binkowski appointed to newly created Chief Operating Officer role

"We delivered solid second quarter results and continued to build momentum across our business," said Kevin Hykes, President and Chief Executive Officer of CVRx. "Our sales force transformation is gaining traction, and we're building sustainable Barostim programs with high potential centers. We continue to make progress on multiple fronts by advancing our clinical evidence strategy and strengthening our reimbursement position, including CMS' proposal to keep Barostim in APC 1580 with appropriate payment for the implant procedure. The fundamentals of our business remain strong, and our maturing commercial organization positions us well for continued growth."

Second Quarter 2025 Financial and Operating Results

Revenue was \$13.6 million for the three months ended June 30, 2025, an increase of \$1.8 million, or 15%, over the three months ended June 30, 2024.

Revenue generated in the U.S. was \$12.2 million for the three months ended June 30, 2025, an increase of \$1.6 million, or 15%, over the three months ended June 30, 2024. HF revenue in the U.S. totaled \$12.1 million and \$10.5 million for the three months ended June 30, 2025 and 2024, respectively. HF revenue units in the U.S. totaled 387 and 339 for the three months ended June 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 June 30, 2025, the Company had a total of 240 active implanting centers in the U.S., compared to 227 as of March 31, 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 two to a total of 47 during the three months ended June 30, 2025.

Revenue generated in Europe was \$1.3 million for the three months ended June 30, 2025, an increase of \$0.2 million, or 19%, over the three months ended June 30, 2024. Total revenue units in Europe decreased to 61 for the three months ended June 30, 2025, compared to 63 in the prior year period. The number of sales territories in Europe remained consistent at five for the three months ended June 30, 2025.

Gross profit was \$11.5 million for the three months ended June 30, 2025, an increase of \$1.5 million, or 16%, over the three months ended June 30, 2024. Gross margin was 84% for each of the three months ended June 30, 2025 and 2024.

R&D expenses decreased \$0.3 million, or 11%, to \$2.5 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. This change was driven by a \$0.3 million decrease in compensation expenses.

SG&A expenses increased \$2.2 million, or 11%, to \$23.4 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. This change was primarily driven by a \$1.4 million increase in compensation expenses, a \$0.8 million increase in travel expenses, and a \$0.4 million increase in non-cash stock-based compensation expense, partially offset by a \$0.5 million decrease in advertising expenses.

Interest expense increased \$0.5 million for the three months ended June 30, 2025, compared to the three months ended June 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 increased \$0.2 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. This increase was primarily driven by more interest income on our interest-bearing accounts.

Net loss was \$14.7 million, or \$0.57 per share, for the three months ended June 30, 2025, compared to a net loss of \$14.0 million, or \$0.65 per share, for the three months ended June 30, 2024. Net loss per share was based on 26.1 million weighted average shares outstanding for three months ended June 30, 2025 and 21.6 million weighted average shares outstanding for the three months ended June 30, 2024.

As of June 30, 2025, cash and cash equivalents were \$95.0 million. Net cash used in operating and investing activities was \$8.0 million for the three months ended June 30, 2025 compared to \$10.2 million for the three months ended June 30, 2024.

Reimbursement Updates

2026 OPSS Rule Progress: CMS has proposed to keep the Barostim implant procedure as part of the New Technology Ambulatory Payment Classification (APC) 1580 for 2026, with an associated payment of approximately \$45,000 for procedures performed in the outpatient setting. CMS is also soliciting comments about the need for a Level 6 Neurostimulator APC. CVRx expects CMS to publish the 2026 Medicare Hospital Outpatient Prospective Payment System (OPSS) final rule in November, which is expected to take effect on January 1, 2026.

Category I CPT Codes: The transition to Category I CPT codes in January 2026 represents a significant milestone that will directly benefit commercial efforts. The proposed Medicare Physician Fee Schedule, released July 15, specified 11 relative value units (RVUs) for the implant procedure, translating to a national average physician payment of approximately \$550, consistent with the Company's expectations. Overall, the transition to Category I will eliminate the automatic denials regularly seen with Category III codes and improve prior authorization predictability to fairly pay physicians for the procedure. This proposal is also expected to be finalized in November.

Chief Operating Officer Appointment

CVRx is pleased to announce that Brent Binkowski will join as Chief Operating Officer in August, and will be responsible for the research and development, operations, regulatory affairs and quality functions. Binkowski brings over 20 years of leadership experience in medical devices, with expertise in implantable devices covering interventional cardiology, radiology, and urology. His experience building world-class teams and scaling businesses will be of great value to the Company.

Business Outlook

For the full year of 2025, the Company narrowed its revenue and operating expense guidance ranges and now expects:

- Total revenue between \$55.0 million and \$57.0 million, compared to prior guidance of \$55.0 million and \$58.0 million;
- Gross margin between 83% and 84%;
- Operating expenses between \$96.0 million and \$98.0 million, compared to prior guidance of \$95.0 million and \$98.0 million.

For the third quarter of 2025, the Company expects to report total revenue between \$13.7 million and \$14.7 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 1-800-445-7795 for U.S. callers, or 1-785-424-1699 for international callers, approximately ten minutes prior to the start time. Please reference the following conference ID to access the call: CVRXQ225.

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 third quarter 2025 results), our anticipated growth strategies (including statements about the proposal to maintain the APC for the Barostim implant procedure and progress toward expanded access to Barostim), 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; the final OPPS rule, which could differ from the proposed rule, following the public comment period; the actual impact of the APC on actual reimbursement and patient access; 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, 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, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 95,025	\$ 105,933
Accounts receivable, net of allowances of \$871 and \$780, respectively	7,153	9,268
Inventory	11,720	12,107
Prepaid expenses and other current assets	2,247	2,505
Total current assets	116,145	129,813
Property and equipment, net	2,345	2,505
Operating lease right-of-use asset	1,048	1,069
Other non-current assets	26	27
Total assets	\$ 119,564	\$ 133,414
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,032	\$ 2,582
Accrued expenses	6,657	8,180
Total current liabilities	9,689	10,762
Long-term debt	49,392	49,273
Operating lease liability, non-current portion	819	877
Other long-term liabilities	1,730	1,447
Total liabilities	61,630	62,359
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value, 200,000,000 authorized as of June 30, 2025 and December 31, 2024; 26,145,951 and 25,324,684 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	261	253
Additional paid-in capital	623,724	608,354
Accumulated deficit	(565,848)	(537,346)
Accumulated other comprehensive loss	(203)	(206)
Total stockholders' equity	57,934	71,055
Total liabilities and stockholders' equity	\$ 119,564	\$ 133,414

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,	
	2025	2024	2025	2024
Revenue	\$ 13,589	\$ 11,807	\$ 25,937	\$ 22,577
Cost of goods sold	2,139	1,900	4,175	3,515
Gross profit	11,450	9,907	21,762	19,062
Operating expenses:				
Research and development	2,469	2,765	4,986	5,822
Selling, general and administrative	23,357	21,115	44,589	49,445
Total operating expenses	25,826	23,880	49,575	55,267
Loss from operations	(14,376)	(13,973)	(27,813)	(36,205)
Interest expense	(1,473)	(959)	(2,930)	(1,919)
Other income, net	1,110	944	2,233	1,988
Loss before income taxes	(14,739)	(13,988)	(28,510)	(36,136)
Benefit (provision) for income taxes	3	(41)	8	(79)
Net loss	(14,736)	(14,029)	(28,502)	(36,215)
Cumulative translation adjustment	3	—	3	(3)
Comprehensive loss	\$ (14,733)	\$ (14,029)	\$ (28,499)	\$ (36,218)
Net loss per share, basic and diluted	\$ (0.57)	\$ (0.65)	\$ (1.10)	\$ (1.69)
Weighted-average common shares used to compute net loss per share, basic and diluted	26,071,316	21,628,542	25,974,229	21,430,276