UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

| | CURRENT REPORT | | | | |
|--|--|--|--|--|--|
| Pursuant to S | Section 13 or 15(d) of the Securities Exchange | Act of 1934 | | | |
| Date of | report (Date of earliest event reported): July 29, | 2024 | | | |
| | CVRx, Inc. | | | | |
| (E | xact name of registrant as specified in its charter |) | | | |
| | - | | | | |
| Delaware (State or other jurisdiction of | 001-40545 41-1983744 (Commission (I.R.S. Employer | | | | |
| incorporation) | File Number) | Identification No.) | | | |
| | 9201 West Broadway Avenue, Suite 650 Minneapolis, MN 55445 | | | | |
| (A | address of principal executive offices) (Zip Code |) | | | |
| | (763) 416-2840 | | | | |
| (Re | egistrant's telephone number, including area code | e) | | | |
| (Forms | N/A r name or former address, if changed since last r | an out) | | | |
| (Forme | iname of former address, it changed since last in | eport) | | | |
| Check the appropriate box below if the Form 8-K filing collowing provisions (see General Instruction A.2. below | - | obligation of the registrant under any of the | | | |
| Written communications pursuant to Rule 425 und Soliciting material pursuant to Rule 14a-12 under Pre-commencement communications pursuant to Rule 425 und Pre-commencement communications | the Exchange Act (17 CFR 240.14a-12) Rule 14d-2(b) under the Exchange Act (17 CFR | | | | |
| Securities registered pursuant to Section 12(b) of the A | act: | | | | |
| | | Name of each analysis | | | |
| 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 | | | |
| ndicate by check mark whether the registrant is an emchapter) or Rule 12b-2 of the Securities Exchange Act | | of the Securities Act of 1933 (§ 230.405 of this | | | |
| Emerging growth company ⊠ | | | | | |
| f an emerging growth company, indicate by check ma | rk if the registrant has elected not to use the exte | nded transition period for complying with any new | | | |
| or revised financial accounting standards provided pur | | and the second s | | | |
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Item 2.02. Results of Operations and Financial Condition.

On July 29, 2024, CVRx, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2024. 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 |
| <u>99.1</u> | Press release of CVRx, Inc., dated July 29, 2024 |
| 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: July 29, 2024 By: /s/ Jared Oasheim

Name: Jared Oasheim Its: Chief Financial Officer

CVRx Reports Second Quarter 2024 Financial and Operating Results

MINNEAPOLIS, July 29, 2024 (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 2024.

Recent Highlights

- Total revenue for the second quarter 2024 was \$11.8 million, an increase of 24% over the prior year quarter
- U.S. Heart Failure (HF) revenue for the second quarter of 2024 was \$10.5 million, an increase of 27% over the prior year quarter
- Active implanting centers in the U.S. were 189, an increase of 35% over the second quarter of 2023
- · Hired new Chief Revenue Officer and completed expansion of executive leadership team

"We are pleased with our solid second quarter results, driven by another record quarter in our U.S. Heart Failure business. We remain extremely optimistic about the Barostim technology and our market opportunity. Our recent leadership appointments have significantly bolstered our executive team, positioning us well to address key market development priorities," said Kevin Hykes, President and Chief Executive Officer of CVRx. "Our focus is on continuing to broaden therapy awareness, strengthen our clinical evidence, and improve patient access. With our innovative technology, expanding market presence, and the depth of expertise on our expanded leadership team, we're well-positioned to drive Barostim towards becoming standard of care, making a meaningful difference in the lives of those suffering from heart failure and other cardiovascular diseases."

Second Quarter 2024 Financial and Operating Results

Revenue was \$11.8 million for the three months ended June 30, 2024, an increase of \$2.3 million, or 24%, over the three months ended June 30, 2023.

Revenue generated in the U.S. was \$10.7 million for the three months ended June 30, 2024, an increase of \$2.4 million, or 29%, over the three months ended June 30, 2023. HF revenue units in the U.S. totaled 339 and 265 for the three months ended June 30, 2024 and 2023, respectively. HF revenue in the U.S. totaled \$10.5 million and \$8.3 million for the three months ended June 30, 2024 and 2023, 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, 2024, the Company had a total of 189 active implanting centers, as compared to 190 as of March 31, 2024. 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 42 during the three months ended June 30, 2024.

Revenue generated in Europe was \$1.1 million for the three months ended June 30, 2024, a decrease of \$0.1 million, or 6%, over the three months ended June 30, 2023. Total revenue units in Europe increased to 63 for the three months ended June 30, 2024 from 56 in the prior year period. The number of sales territories in Europe remained consistent at six for the three months ended June 30, 2024.

Gross profit was \$9.9 million for the three months ended June 30, 2024, an increase of \$1.9 million, or 24%, over the three months ended June 30, 2023. Gross margin was 84% for each of the three months ended June 30, 2024 and June 30, 2023.

R&D expenses decreased \$0.5 million, or 16%, to \$2.8 million for the three months ended June 30, 2024 compared to the three months ended June 30, 2023. This change was driven by a \$0.4 million decrease in consulting expenses and a \$0.1 million decrease in compensation expenses.

SG&A expenses increased \$4.7 million, or 28%, to \$21.1 million for the three months ended June 30, 2024 compared to the three months ended June 30, 2023. This change was primarily driven by a \$2.6 million increase in compensation expenses, mainly as a result of increased headcount, a \$1.0 million increase in non-cash stock-based compensation expense, a \$0.4 million increase in advertising expenses, a \$0.2 million increase in travel expenses, and a \$0.2 million increase in consulting expenses.

Other income, net increased \$0.3 million for the three months ended June 30, 2024, compared to the three months ended June 30, 2023. This increase was primarily driven by greater interest income on our interest-bearing accounts.

Net loss was \$14.0 million, or \$0.65 per share, for the three months ended June 30, 2024, compared to a net loss of \$11.6 million, or \$0.56 per share, for the three months ended June 30, 2023. Net loss per share was based on 21.6 million weighted average shares outstanding for three months ended June 30, 2024 and 20.7 million weighted average shares outstanding for the three months ended June 30, 2023.

As of June 30, 2024, cash and cash equivalents were \$70.4 million. Net cash used in operating and investing activities was \$10.2 million for the quarter ended June 30, 2024. This is compared to net cash used in operating and investing activities of \$11.8 million for the three months ended March 31, 2024.

Leadership Team Expansion

During the quarter, the Company strengthened its executive team to drive market development priorities. Key appointments include Robert John as Chief Revenue Officer, bringing over 25 years of sales leadership experience in the medical device industry; Dr. Philip Adamson as Chief Medical Officer; Bonnie Handke as SVP of Patient Access, Reimbursement, and Healthcare Economics; Jennifer Englund as SVP of Global Clinical Research to enhance clinical evidence; and Tonya Austin as Chief Human Resources Officer. These strategic hires position CVRx to effectively address awareness, clinical, and patient access barriers as it drives Barostim towards becoming standard of care for heart failure.

Business Outlook

For the full year of 2024, the Company now expects:

- · Total revenue between \$50.0 million and \$53.0 million;
- · Gross margin between 83.0% and 85.0%; and
- Operating expenses between \$95.0 million and \$98.0 million, up from previously issued guidance of \$92.0 million and \$98.0 million

For the third quarter of 2024, the Company expects to report total revenue between \$12.7 million and \$13.7 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.cvrx.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 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 future financial performance (including our financial guidance regarding full year and third quarter 2024 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 demonstrate 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, 2023, 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,

Investor Contact:

Mark Klausner or Mike Vallie ICR Westwicke 443-213-0501 ir@cvrx.com

Media Contact:

Laura O'Neill Finn Partners 402-499-8203 laura.oneill@finnpartners.com

CVRx, INC.

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

| | | June 30, 2024 | | ecember 31, 2023 |
|--|----|------------------|----|---------------------|
| Assets | | | | |
| Current assets: | | | | |
| Cash and cash equivalents | \$ | 70,400 | \$ | 90,569 |
| Accounts receivable, net of allowances of \$656 and \$508, respectively | | 8,606 | | 7,551 |
| Inventory | | 11,224 | | 10,983 |
| Prepaid expenses and other current assets | | 1,762 | | 2,987 |
| Total current assets | | 91,992 | | 112,090 |
| Property and equipment, net | | 2,763 | | 1,763 |
| Operating lease right-of-use asset | | 1,200 | | 1,349 |
| Other non-current assets | | 26 | | 27 |
| Total assets | \$ | 95,981 | \$ | 115,229 |
| Liabilities and Stockholders' Equity | | | | |
| Current liabilities: | | | | |
| Accounts payable | \$ | 3,516 | \$ | 1,884 |
| Accrued expenses | | 5,610 | | 5,980 |
| Total current liabilities | | 9,126 | | 7,864 |
| Long-term debt | | 29,319 | | 29,222 |
| Operating lease liability, non-current portion | | 1,023 | | 1,160 |
| Other long-term liabilities | | 1,265 | | 1,036 |
| Total liabilities | | 40,733 | | 39,282 |
| Commitments and contingencies | | | - | |
| Stockholders' equity: | | | | |
| Common stock, \$0.01 par value, 200,000,000 authorized as of June 30, 2024 and December 31, 2023; 21,712,357 | | | | |
| and 20,879,199 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively | | 217 | | 209 |
| Additional paid-in capital | | 568,837 | | 553,326 |
| Accumulated deficit | | (513,596) | | (477,381) |
| Accumulated other comprehensive loss | | (210) | | (207) |
| Total stockholders' equity | | 55,248 | | 75,947 |
| Total liabilities and stockholders' equity | \$ | 95,981 | \$ | 115,229 |

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, | | | | |
|--|-----------------------------|------------|----|---------------------------|----|------------|----|------------|
| | | 2024 | | 2023 | | 2024 | | 2023 |
| Revenue | \$ | 11,807 | \$ | 9,500 | \$ | 22,577 | \$ | 17,479 |
| Cost of goods sold | | 1,900 | | 1,517 | | 3,515 | | 2,845 |
| Gross profit | | 9,907 | | 7,983 | | 19,062 | | 14,634 |
| Operating expenses: | | | | | | | | |
| Research and development | | 2,765 | | 3,280 | | 5,822 | | 6,696 |
| Selling, general and administrative | | 21,115 | | 16,455 | | 49,445 | | 31,852 |
| Total operating expenses | | 23,880 | | 19,735 | | 55,267 | | 38,548 |
| Loss from operations | | (13,973) | | (11,752) | | (36,205) | | (23,914) |
| Interest expense | | (959) | | (481) | | (1,919) | | (721) |
| Other income, net | | 944 | | 616 | | 1,988 | | 1,678 |
| Loss before income taxes | | (13,988) | | (11,617) | | (36,136) | | (22,957) |
| Provision for income taxes | | (41) | | (34) | | (79) | | (68) |
| Net loss | | (14,029) | | (11,651) | | (36,215) | | (23,025) |
| Cumulative translation adjustment | | _ | | 17 | | (3) | | 20 |
| Comprehensive loss | \$ | (14,029) | \$ | (11,634) | \$ | (36,218) | \$ | (23,005) |
| Net loss per share, basic and diluted | \$ | (0.65) | \$ | (0.56) | \$ | (1.69) | \$ | (1.11) |
| Weighted-average common shares used to compute net loss per share, basic and diluted | | 21,628,542 | | 20,711,850 | | 21,430,276 | | 20,702,589 |