CVRx Reports Third Quarter 2024 Financial and Operating Results

October 29, 2024

MINNEAPOLIS, Oct. 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 third quarter of 2024.

Recent Highlights

- *Total revenue for the third quarter 2024 was $13.4 million, an increase of 27% over the prior year quarter*
- *U.S. Heart Failure (HF) revenue for the third quarter of 2024 was $12.2 million, an increase of 30% over the prior year quarter*
- *Active implanting centers in the U.S. were 208, an increase of 31% over the prior year quarter*
- *Final Inpatient Prospective Payment System rule confirmed the reassignment of Barostim to MS-DRG 276, increasing payment to hospitals from approximately $17,000-$23,000 to approximately $43,000 effective October 1, 2024*
- *The American Medical Association CPT® Editorial Panel accepted new Current Procedural Terminology (CPT) Category I codes for Barostim to treat the symptoms of heart failure, expected to take effect January 1, 2026*
- *New data published in JACC: Heart Failure demonstrated durable quality of life benefits of Barostim in heart failure patients with reduced ejection fraction*

“We're thrilled with our continued strong performance in the third quarter, which reflects the growing adoption of Barostim therapy and the dedication of our team,” said Kevin Hykes, President and Chief Executive Officer of CVRx. "The recent favorable news regarding inpatient reimbursement and the Category 1 code, coupled with new long-term data demonstrating Barostim’s durable quality of life benefits, strengthens our position in the market. We remain focused on improving patient access, increasing education and awareness, and expanding our clinical evidence base. These developments, along with our strengthened leadership team and stabilized sales force reinforce our confidence in Barostim's potential to become standard of care for patients suffering from the debilitating symptoms of heart failure."

Third Quarter 2024 Financial and Operating Results

Revenue was $13.4 million for the three months ended September 30, 2024, an increase of $2.9 million, or 27%, over the three months ended September 30, 2023.

Revenue generated in the U.S. was $12.3 million for the three months ended September 30, 2024, an increase of $2.7 million, or 28%, over the three months ended September 30, 2023. HF revenue units in the U.S. totaled 391 and 303 for the three months ended September 30, 2024 and 2023, respectively. HF revenue in the U.S. totaled $12.2 million and $9.4 million for the three months ended September 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 September 30, 2024, the Company had a total of 208 active implanting centers in the U.S., as compared to 189 as of June 30, 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 45 during the three months ended September 30, 2024.

Revenue generated in Europe was $1.1 million for the three months ended September 30, 2024, a nominal increase compared to the three months ended September 30, 2023. Total revenue units in Europe increased to 56 for the three months ended September 30, 2024 from 47 in the prior year period. The number of sales territories in Europe remained consistent at six for the three months ended September 30, 2024.

Gross profit was $11.1 million for the three months ended September 30, 2024, an increase of $2.3 million, or 26%, over the three months ended September 30, 2023. Gross margin was 83% and 84% for the three months ended September 30, 2024 and September 30, 2023, respectively.

R&D expenses decreased $0.2 million, or 7%, to $2.5 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, driven by a decrease in consulting expenses.

SG&A expenses increased $6.0 million, or 38%, to $21.6 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. This change was primarily driven by a $3.7 million increase in compensation expenses, mainly as a result of increased headcount, a $1.1 million increase in non-cash stock-based compensation expense, a $0.5 million increase in travel expenses, and a $0.4 million increase in advertising expenses.

Interest expense increased $0.5 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, driven by the increased borrowings under the term loan agreement with Innovatus Capital Partners.

Other income, net decreased $0.1 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023. This decrease was primarily driven by less interest income on our interest-bearing accounts.

Net loss was $13.1 million, or $0.57 per share, for the three months ended September 30, 2024, compared to a net loss of $9.0 million, or $0.43 per

share, for the three months ended September 30, 2023. Net loss per share was based on 22.8 million weighted average shares outstanding for three months ended September 30, 2024 and 20.8 million weighted average shares outstanding for the three months ended September 30, 2023.

As of September 30, 2024, cash and cash equivalents were $100.2 million. Net cash used in operating and investing activities was $10.4 million for the three months ended September 30, 2024 as compared to $10.2 million for the three months ended June 30, 2024.

On September 30, 2024, the Company borrowed the remaining $20.0 million under the third and final tranche of the Innovatus loan agreement, such that the outstanding principal balance is $50.0 million.

For the three months ended September 30, 2024, the Company issued 2,358,775 shares of common stock for gross proceeds of $20.3 million under its at-the-market offering.

Final Inpatient Prospective Payment System Rule

In August 2024, the Company announced that the Centers for Medicare and Medicaid Services (CMS) has reassigned the Barostim implant procedure for the inpatient setting as part of the Medicare Hospital Inpatient Prospective Payment System (IPPS) final rule for CMS' Fiscal Year 2025, which began on October 1, 2024. On that date, Barostim was reassigned to MS-DRG 276, which carries a national average payment of approximately $43,000, a significant increase from the previous payment range of $17,000-$23,000, which is expected to facilitate increased access to the therapy for patients with heart failure.

AMA Approves Category I CPT Codes for Barostim Therapy

The American Medical Association's CPT Editorial Panel approved new Category I codes for Barostim therapy, effective January 1, 2026. Led by the Society for Vascular Surgery with support from the American College of Cardiology, this advancement from Category III to Category I status reflects Barostim's growing adoption and established clinical evidence in treating heart failure symptoms. The new designation is expected to streamline reimbursement processes and expand access to this important therapy for heart failure patients.

Long-term Quality of Life Benefits of Barostim

In September 2024, the Company announced the publication of new data in the Journal of the American College of Cardiology: Heart Failure, detailing the durable improvements in Barostim patients out to 24-months in quality of life measures. The data demonstrated that patients receiving Barostim plus guideline-directed medical therapy reported feeling significantly better in a variety of physical and psychosocial measures compared to patients who received guideline-directed medical therapy alone. This publication builds on the data from the BeAT-HF trial published in 2024 in the European Journal of Heart Failure demonstrating the long-term sustained symptomatic benefits of Barostim in heart failure patients with reduced ejection fraction.

Business Outlook

For the full year of 2024, the Company expects:

- Total revenue between $50.5 million and $51.5 million, narrowed from previously issued guidance of $50.0 million to $53.0 million;
- Gross margin between 83% and 85%, unchanged from previously issued guidance; and
- Operating expenses of approximately $100 million, up from previously issued guidance of $95 million to $98 million.

For the fourth quarter of 2024, the Company expects to report total revenue between $14.5 million and $15.5 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 fourth 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, 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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 100,161	$ 90,569
Accounts receivable, net of allowances of $522 and $508, respectively	9,033	7,551
Inventory	11,892	10,983
Prepaid expenses and other current assets	2,786	2,987
Total current assets	123,872	112,090
Property and equipment, net	2,631	1,763
Operating lease right-of-use asset	1,144	1,349
Other non-current assets	26	27
Total assets	$ 127,673	$ 115,229
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,276	$ 1,884
Accrued expenses	7,671	5,980
Total current liabilities	10,947	7,864
Long-term debt	49,214	29,222
Operating lease liability, non-current portion	951	1,160
Other long-term liabilities	1,378	1,036
Total liabilities	62,490	39,282
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 200,000,000 authorized as of September 30, 2024 and December 31, 2023; 24,203,658 and 20,879,199 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	242	209
Additional paid-in capital	591,844	553,326
Accumulated deficit	(526,695)	(477,381)
Accumulated other comprehensive loss	(208)	(207)
Total stockholders' equity	65,183	75,947
Total liabilities and stockholders' equity	$ 127,673	$ 115,229

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,	
	2024	**2023**	**2024**	**2023**
Revenue	$ 13,373	$ 10,511	$ 35,950	$ 27,990
Cost of goods sold	2,248	1,691	5,763	4,536
Gross profit	11,125	8,820	30,187	23,454
Operating expenses:				
Research and development	2,504	2,696	8,326	9,392
Selling, general and administrative	21,632	15,652	71,077	47,504
Total operating expenses	24,136	18,348	79,403	56,896
Loss from operations	(13,011)	(9,528)	(49,216)	(33,442)
Interest expense	(958)	(499)	(2,877)	(1,220)
Other income, net	917	1,056	2,905	2,734
Loss before income taxes	(13,052)	(8,971)	(49,188)	(31,928)
Provision for income taxes	(47)	(40)	(126)	(108)
Net loss	(13,099)	(9,011)	(49,314)	(32,036)
Cumulative translation adjustment	2	(21)	(1)	(1)
Comprehensive loss	$ (13,097)	$ (9,032)	$ (49,315)	$ (32,037)
Net loss per share, basic and diluted	$ (0.57)	$ (0.43)	$ (2.25)	$ (1.55)
Weighted-average common shares used to compute net loss per share, basic and diluted	22,783,337	20,801,350	21,884,588	20,730,024