CVRx Reports Third Quarter 2022 Financial and Operating Results

November 1, 2022

Third quarter 2022 revenue of $6.2 million, an 82% increase over prior year

MINNEAPOLIS, Nov. 01, 2022 (GLOBE NEWSWIRE) -- CVRx, Inc. (“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 2022.

Recent Highlights

- *Total revenue for the third quarter of 2022 was $6.2 million, an increase of 82% over the prior year quarter*
- *U.S. Heart Failure (HF) revenue for the third quarter of 2022 was $4.9 million, nearly doubling over the prior year quarter*
- *Active implanting centers in the U.S. grew to 91, an increase of 28% over the second quarter of 2022*
- *Reached the required 320th event of the BeAT-HF clinical trial; expect full unblinding of data in the first half of 2023*

“We are delighted with our performance during the third quarter as the adoption and utilization of Barostim continues to accelerate. The growth in our commercial organization as well as the early success of our marketing initiatives resulted in our U.S. Heart Failure revenue nearly doubling over the prior year quarter,” said Nadim Yared, President and Chief Executive Officer of CVRx. “Looking ahead, we will continue to build on our strategy to further drive the proliferation of Barostim to bring this novel treatment to more patients who are suffering from cardiovascular disease.”

Third Quarter 2022 Financial and Operating Results

Revenue was $6.2 million for the three months ended September 30, 2022, an increase of $2.8 million, or 82%, over the three months ended September 30, 2021.

Revenue generated in the U.S. was $5.0 million for the three months ended September 30, 2022, an increase of $2.5 million, or 96%, over the three months ended September 30, 2021. Total HF revenue units in the U.S. totaled 167 and 84 for the three months ended September 30, 2022 and 2021, respectively.

HF revenue in the U.S. totaled $4.9 million for the three months ended September 30, 2022, an increase of $2.4 million, or 99%, over the three months ended September 30, 2021. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

As of September 30, 2022, we had a total of 91 active implanting centers as compared to 38 as of September 30, 2021. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. As of September 30, 2022, the Company had a total of 23 sales territories as compared to 11 as of September 30, 2021.

Revenue generated in Europe was $1.1 million for the three months ended September 30, 2022, an increase of $0.3 million, or 39%, over the three months ended September 30, 2021. Total revenue units in Europe were 61 for the three months ended September 30, 2022 as compared to 38 in the prior year period. The revenue increase was primarily due to the lessening impact of the COVID-19 pandemic in Germany, partially offset by an unfavorable currency impact on net sales. As of September 30, 2022, we had a total of six sales territories in Europe.

Gross profit was $4.8 million for the three months ended September 30, 2022, an increase of $2.3 million, or 92%, over the three months ended September 30, 2021. Gross margin increased to 78% for the three months ended September 30, 2022, compared to 74% for the three months ended September 30, 2021. Gross margin for the three months ended September 30, 2022 was higher due to a decrease in the cost per unit. This was partially offset by a decrease in the average selling price and a larger percentage of our revenue units coming from full systems versus battery replacements. New patients receive a full system that includes an IPG and a stimulation lead, which has a lower gross margin than a stand-alone IPG used for a battery replacement.

R&D expenses increased $0.6 million, or 35%, to $2.3 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021. This change was primarily driven by a $0.5 million increase in compensation expenses, mainly as a result of increased headcount, and a $0.1 million increase in non-cash stock-based compensation expense, partially offset by a $0.1 million decrease in clinical study expenses.

SG&A expenses increased $4.6 million, or 56%, to $12.7 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021. This was primarily driven by a $3.2 million increase in compensation expenses, mainly as a result of increased headcount, a $0.5 million increase in travel expenses, a $0.4 million increase in non-cash stock-based compensation expense, a $0.3 million increase in marketing and advertising expenses associated with the commercialization of Barostim in the U.S., and a $0.2 million increase in professional fees.

Other income, net was $0.3 million for the three months ended September 30, 2022, compared to $1.8 million for the three months ended September 30, 2021. The income in the third quarter of 2021 reflects $1.5 million of income related to the change in the fair value of our convertible preferred stock warrants from June 30, 2021 to July 2, 2021, which is the date the warrants converted to common stock warrants. As these preferred stock warrants converted to common stock warrants upon the IPO, there is no longer a change in fair value recorded in other income, net.

Net loss was $9.8 million, or $0.48 per share, for the three months ended September 30, 2022, compared to a net loss of $6.1 million, or $0.30 per share, for the three months ended September 30, 2021. Net loss per share was based on 20.6 million and 20.1 million weighted average shares outstanding for the third quarter of 2022 and 2021, respectively.

At the end of the current quarter, cash and cash equivalents were $110.0 million. Net cash used in operating and investing activities was $11.4 million for the current quarter, compared to $9.4 million for the same period last year. We continue to prudently monitor our cash usage in support of our growth initiatives as we progress towards profitability.

BeAT-HF Clinical Trial Update

The Company recently reached the required 320th event of the BeAT-HF clinical trial, which is designed to demonstrate the mortality and morbidity benefit of Barostim in the heart failure patient population with reduced ejection fraction. The Company is still blinded to the results, and is working to ensure all event data is collected and analyzed. The Company expects to be able to share data during the first half of 2023.

Business Outlook

For the full year of 2022, the Company now expects:

- Total revenue between $21.8 million and $22.3 million as compared to prior guidance of $20.5 million and $23.0 million;
- Gross margin between 76% and 77% as compared to prior guidance of 75% and 76%;
- Operating expenses between $58 million and $60 million as compared to prior guidance of $58 million and $61 million;

For the fourth quarter of 2022, the Company expects to report total revenue between $6.5 million and $7.0 million.

Debt Facility

On October 31, 2022, the Company entered into a term loan agreement with Innovatus Capital Partners. The new term loan provides up to $50 million of non-dilutive capital with an interest rate equal to the greater of 8.15% or prime plus 2.65% and a final payment fee of 4.5% of the funded loan amount. The interest only period is 5 years followed by a 3-month repayment period. The facility is set up in three tranches. On October 31, the Company borrowed the minimum amount of $7.5 million. The Company has the option to draw down the remaining $7.5 million of Tranche A from the filing date of the 2022 10-K until September 30, 2023. Tranche B allows the Company to draw up to $30.0 million less the Tranche A funded amount between September 1, 2023 and December 15, 2023 if the Company achieves trailing three months revenue of $5.75 million prior to June 30, 2023. Tranche C allows the Company to draw up to $20.0 million between September 1, 2024 and December 15, 2024 if the Company achieves trailing three months revenue of $9.0 million prior to June 30, 2024. There is a performance covenant that will take effect at the earlier of September 30, 2025 or the Tranche C funding date. The covenant requires the Company to achieve 50% of the trailing 12-month revenue target set in the most recent Board approved plan. The term loans are secured by substantially all of the Company's assets.

Webcast and Conference Call Information

The Company will host a conference call at 5:30 pm Eastern Time on Tuesday, November 1st, 2022 to discuss results of the quarter as well as a question and answer session. The conference call will be broadcast live in listen-only mode via webcast at https://edge.media-server.com/mmc/p/8kfcmjvb. To listen to the conference call on your telephone, participants may register for the call **here**. While it is not required, it is recommended you join 10 minutes prior to the event start.

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 and fourth quarter 2022 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; our ability to establish and maintain sales and marketing capabilities; 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, 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 I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 109,985	$ 142,072
Accounts receivable, net	5,297	2,560
Inventory	6,064	3,880
Prepaid expenses and other current assets	3,066	2,585
Total current assets	124,412	151,097
Property and equipment, net	1,747	1,425
Operating lease right-of-use asset	391	—
Other non-current assets	26	26
Total assets	$ 126,576	$ 152,548
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,276	$ 510
Accrued expenses	6,120	5,398
Total current liabilities	7,396	5,908
Operating lease liability, non-current portion	175	—
Other long-term liabilities	761	681
Total liabilities	8,332	6,589
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 200,000,000 authorized as of September 30, 2022 and December 31, 2021; 20,578,963 and 20,399,337 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	206	204
Additional paid-in capital	543,903	540,707
Accumulated deficit	(425,646)	(394,754)
Accumulated other comprehensive loss	(219)	(198)
Total stockholders' equity	118,244	145,959
Total liabilities and stockholders' equity	$ 126,576	$ 152,548

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,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 6,186	$ 3,395	$ 15,293	$ 9,378
Cost of goods sold	1,340	876	3,490	2,656
Gross profit	4,846	2,519	11,803	6,722
Operating expenses:				
Research and development	2,293	1,699	6,906	5,704
Selling, general and administrative	12,679	8,111	35,945	18,198
Total operating expenses	14,972	9,810	42,851	23,902
Loss from operations	(10,126)	(7,291)	(31,048)	(17,180)
Interest expense	—	(614)	—	(1,823)
Other income (expense), net	328	1,795	237	(13,439)
Loss before income taxes	(9,798)	(6,110)	(30,811)	(32,442)
Provision for income taxes	(32)	(23)	(81)	(66)
Net loss	(9,830)	(6,133)	(30,892)	(32,508)
Cumulative translation adjustment	(8)	(3)	(21)	(8)
Comprehensive loss	$ (9,838)	$ (6,136)	$ (30,913)	$ (32,516)
Net loss per share, basic and diluted	$ (0.48)	$ (0.30)	$ (1.51)	$ (4.66)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,576,838	20,126,672	20,512,254	6,975,386