CVRx Reports Fourth Quarter and Full Year 2022 Financial and Operating Results

January 26, 2023

Fourth Quarter 2022 Revenue of $7.2 million, a 96% Increase Over Prior Year

MINNEAPOLIS, Jan. 26, 2023 (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 fourth quarter and full year of 2022, and provided a 2023 business outlook.

Recent Highlights

- *Total revenue for the fourth quarter 2022 was $7.2 million, an increase of 96% over prior year quarter*
- *U.S. Heart Failure (HF) revenue for the fourth quarter of 2022 was $6.0 million, an increase of 121% over the prior year quarter*
- *Total revenue for 2022 was $22.5 million, an increase of 72% over the prior year*
- *Active implanting centers increased from 46 to 106 in 2022, an increase of 130%*
- *Announcement of BeAT-HF clinical trial results is now expected later in the first quarter of 2023*

“The growth of our commercial organization combined with the success of our marketing efforts have continued to deliver increased adoption of Barostim, resulting in the more than doubling of our U.S. heart failure business as compared to 2021. Importantly, patients continued to report a positive and meaningful impact from the therapy,” said Nadim Yared, President and Chief Executive Officer of CVRx. “This has been a fantastic final quarter to a strong year and we are very excited to see these trends continue heading into 2023 as we work to promote further awareness among physicians, hospitals and patients in order to accelerate the adoption of Barostim.”

Fourth Quarter 2022 Financial and Operating Results

Revenue was $7.2 million for the three months ended December 31, 2022, an increase of $3.5 million, or 96%, over the three months ended December 31, 2021.

Revenue generated in the U.S. was $6.0 million for the three months ended December 31, 2022, an increase of $3.1 million, or 109%, over the three months ended December 31, 2021. HF revenue units in the U.S. totaled 193 and 95 for the three months ended December 31, 2022 and 2021, respectively. HF revenue in the U.S. totaled $6.0 million and $2.7 million for the three months ended December 31, 2022 and 2021, respectively. The increase was primarily driven by continued growth in the U.S. heart failure business as a result of the expansion into new sales territories, new accounts and increased physician and patient awareness of Barostim.

As of December 31, 2022, the Company had a total of 106 active implanting centers, as compared to 91 as of September 30, 2022. 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 26 during the three months ended December 31, 2022.

Revenue generated in Europe was $1.2 million for the three months ended December 31, 2022, an increase of $0.4 million, or 49%, over the three months ended December 31, 2021. Total revenue units in Europe increased to 68 for the three months ended December 31, 2022 from 39 in the prior year period. The revenue increase was primarily due to the lessening impact of the COVID-19 pandemic in Europe. The number of sales territories in Europe remained consistent at six during three months ended December 31, 2022.

Gross profit was $5.7 million for the three months ended December 31, 2022, an increase of $3.0 million, or 112%, over the three months ended December 31, 2021. Gross margin increased to 79% for the three months ended December 31, 2022 compared to 73% for the three months ended December 31, 2021. Gross margin for the three months ended December 31, 2022 was higher due to a decrease in the cost per unit and an increase in the average selling price. This was partially offset by a larger percentage of our revenue units coming from full systems versus battery replacements.

R&D expenses increased $1.2 million, or 70%, to $3.0 million for the three months ended December 31, 2022 compared to the three months ended December 31, 2021. This change was driven by a $0.8 million increase in consulting fees and a $0.5 million increase in compensation expenses as a result of increased headcount.

SG&A expenses increased $4.4 million, or 46%, to $14.1 million for the three months ended December 31, 2022 compared to the three months ended December 31, 2021. This change was driven by a $2.4 million increase in compensation expenses, mainly as a result of increased headcount, a $0.6 million increase in travel expenses, a $0.3 million increase in non-cash stock-based compensation expense, a $0.2 million increase in marketing and advertising expenses, primarily related to the commercialization of Barostim in the U.S., a $0.2 million increase in professional fees, and a $0.1 million increase in consulting expenses.

Other income, net was $1.1 million for the three months ended December 31, 2022 compared to other expense, net of $1.4 million for the three months ended December 31, 2021. Other income, net in the fourth quarter of 2022 was primarily driven by $0.9 million in interest income on our interest-bearing account. Other expense, net in the fourth quarter of 2021 was primarily driven by a $1.3 million loss on debt extinguishment in connection with the repayment of the outstanding debt under the Horizon loan agreement.

Net loss was $10.5 million, or $0.51 per share, for the three months ended December 31, 2022, compared to a net loss of $10.6 million, or $0.52 per share, for the three months ended December 31, 2021. Net loss per share was based on 20,593,312 weighted average shares outstanding for the three months ended December 31, 2022 and 20,367,064 weighted average shares outstanding for the fourth quarter of 2021.

Full Year 2022 Financial and Operating Results

Revenue was $22.5 million for the year ended December 31, 2022, an increase of $9.4 million, or 72%, over the year ended December 31, 2021.

Revenue generated in the U.S. was $18.0 million for the year ended December 31, 2022, an increase of $8.9 million, or 97%, over the year ended December 31, 2021. Total HF revenue units in the U.S. totaled 587 and 290 for the years ended December 31, 2022 and 2021, respectively. HF revenue in the U.S. totaled $17.6 million and $8.4 million for the years ended December 31, 2022 and 2021, respectively. 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 December 31, 2022, the Company had a total of 106 active implanting centers, as compared to 46 as of December 31, 2021. The number of sales territories in the U.S. increased by 12 to a total of 26 during the year ended December 31, 2022.

Legacy hypertension revenue in the U.S. totaled $0.5 million and $0.7 million for each of the years ended December 31, 2022 and 2021, respectively.

Revenue generated in Europe was $4.4 million for the year ended December 31, 2022, an increase of $0.6 million, or 14%, over the year ended December 31, 2021. Total revenue units in Europe increased to 231 for the year ended December 31, 2022, from 176 for the prior year period. The revenue increase was primarily due to the lessening impact of the COVID-19 pandemic in Europe. The number of sales territories in Europe remained consistent at six during the year ended December 31, 2022.

Gross profit was $17.5 million for the year ended December 31, 2022, an increase of $8.1 million, or 86%, over the year ended December 31, 2021. Gross margin increased to 78% for the year ended December 31, 2022, compared to 72% for the year ended December 31, 2021. Gross margin for the year ended December 31, 2022 was higher due to a decrease in the cost per unit and an increase in the average selling price. This was partially offset by a larger percentage of our revenue units coming from full systems versus battery replacements.

R&D expenses increased $2.5 million, or 33%, to $10.0 million for the year ended December 31, 2022, compared to the year ended December 31, 2021. This change was primarily driven by a $1.8 million increase in compensation expenses, mainly as a result of increased headcount, a $0.4 million increase in consulting fees, a $0.2 million increase in clinical study expenses and a $0.1 million increase in non-cash stock-based compensation expense.

SG&A expenses increased $22.2 million, or 80%, to $50.0 million for the year ended December 31, 2022, compared to the year ended December 31, 2021. This change was driven by a $12.3 million increase in compensation expenses, mainly as a result of increased headcount, a $2.4 million increase in travel expenses, a $1.8 million increase in non-cash stock-based compensation expense, a $1.7 million increase in marketing and advertising expenses, primarily related to the commercialization of Barostim in the U.S., a $1.2 million increase related to D&O insurance costs incurred as a result of becoming a public company, a $0.9 million increase in professional fees, and a $0.6 million increase in consulting expenses.

Other income, net was $1.4 million for the year ended December 31, 2022, compared to other expense, net of $14.8 million for the year ended December 31, 2021. Other income, net in 2022 was primarily driven by $1.5 million in interest income on our interest-bearing account. Other expense, net in 2021 was primarily driven by a $13.7 million increase in expense related to the increase in fair value of our convertible preferred stock warrants due to the change in the value of our common stock from December 31, 2021 to July 2, 2021, which is the date the warrants converted to common stock warrants. The expense in 2021 was also due to a $1.3 million loss on debt extinguishment in connection with the November 2021 repayment of the outstanding debt under the Horizon loan agreement.

Net loss was $41.4 million, or $2.02 per share, for the full year ended December 31, 2022, compared to a net loss of $43.1 million, or $4.16 per share, for the full year ended December 31, 2021.

As of December 31, 2022, cash and cash equivalents were $106.2 million. Net cash used in operating and investing activities was $43.4 million for the year ended December 31, 2022, compared to $28.9 million for the year ended December 31, 2021.

Business Outlook

For the full year of 2023, the Company expects:

- Total revenue between $35.0 million and $38.0 million;
- Gross margin between 78.0% and 79.0%;
- Operating expenses between $76.0 million and $80.0 million.

For the first quarter of 2023, the Company expects to report total revenue between $7.1 million and $7.5 million.

BeAT-HF Clinical Trial Update

In the third quarter of 2022, the Company accrued the required 320th event to unblind the data from the BeAT-HF clinical trial. This trial is designed to demonstrate that Barostim provides a mortality and morbidity benefit in addition to the reduction of symptoms of heart failure in patients 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 unblind and announce data later in the first quarter of 2023.

Webcast and Conference Call Information

The Company will host a conference call at 5:30 pm Eastern Time on Thursday, January 26, 2023 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/d5cu7e7x.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 a commercial-stage medical device company focused on the 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. 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 future financial performance (including, specifically, our 2023 expected operating and financial 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 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)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 106,194	$ 142,072
Accounts receivable, net of allowances of $679 and $0, respectively	5,504	2,560
Inventory	6,957	3,880
Prepaid expenses and other current assets	4,223	2,585

Total current assets	122,878	151,097
Property and equipment, net	1,698	1,425
Operating lease right-of-use asset	334	—
Other non-current assets	27	26
Total assets	$ 124,937	$ 152,548
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,719	$ 510
Accrued expenses	6,369	5,398
Total current liabilities	8,088	5,908
Long-term debt	6,747	—
Operating lease liability, non-current portion	117	—
Other long-term liabilities	805	681
Total liabilities	15,757	6,589
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 200,000,000 authorized as of December 31, 2022 and December 31, 2021; 20,633,736 and 20,399,337 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	207	204
Additional paid-in capital	545,362	540,707
Accumulated deficit	(436,182)	(394,754)
Accumulated other comprehensive loss	(207)	(198)
Total stockholders' equity	109,180	145,959
Total liabilities, convertible preferred stock, and stockholders' equity	$ 124,937	$ 152,548

CVRx, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three months ended December 31,		Year ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 7,176	$ 3,658	$ 22,469	$ 13,036
Cost of goods sold	1,509	984	4,999	3,640
Gross profit	5,667	2,674	17,470	9,396
Operating expenses:				
Research and development	3,046	1,797	9,952	7,501
Selling, general and administrative	14,100	9,665	50,045	27,863
Total operating expenses	17,146	11,462	59,997	35,364
Loss from operations	(11,479)	(8,788)	(42,527)	(25,968)
Interest expense	(165)	(396)	(165)	(2,219)
Other expense, net	1,136	(1,361)	1,373	(14,800)
Loss before income taxes	(10,508)	(10,545)	(41,319)	(42,987)
Provision for income taxes	(28)	(25)	(109)	(91)
Net loss	(10,536)	(10,570)	(41,428)	(43,078)
Cumulative translation adjustment	12	—	(9)	(8)
Comprehensive loss	$ (10,524)	$ (10,570)	$ (41,437)	$ (43,086)
Net loss per share, basic and diluted	$ (0.51)	$ (0.52)	$ (2.02)	$ (4.16)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,593,312	20,367,064	20,532,838	10,360,054