CVRx Reports Preliminary Fourth Quarter and Fiscal Year 2021 Financial Results

January 10, 2022

MINNEAPOLIS, Jan. 10, 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 certain preliminary unaudited fourth quarter and full year 2021 revenue results, and provided a 2022 business outlook.

Fourth Quarter 2021

Total revenue for the fourth quarter of 2021 is expected to be in the range of approximately $3.6 million to $3.7 million, representing an increase of approximately 71% to 77% over fourth quarter 2020 revenue of $2.1 million. Total revenue generated in the fourth quarter of 2021 is expected to be made up of approximately $2.7 million in U.S. heart failure revenue, $0.8 million in European revenue and $0.16 million in U.S. legacy revenue.

Full Year 2021

Total revenue for full year 2021 is expected to be in the range of approximately $13.0 million to $13.1 million, representing an increase of approximately 113% to 116% over full year 2020 revenue of $6.1 million. Total revenue generated in full year 2021 is expected to be made up of approximately $8.4 million in U.S. heart failure revenue, $3.9 million in European revenue and $0.7 million in U.S. legacy revenue.

As of December 31, 2021, the Company had a total of 46 active implanting centers, as compared to 38 as of September 30, 2021. The number of sales territories in the U.S. increased by three to a total of fourteen during the three months ended December 31, 2021.

As of December 31, 2021, cash and cash equivalents were $142 million. Net cash used in operating and investing activities was $29 million for the twelve months ended December 31, 2021.

“We are very proud of our accomplishments during 2021 considering the material pandemic headwinds that our entire global organization faced. We more than doubled our revenue as a result of the launch of Barostim for heart failure in the U.S. and the expansion of our commercial organization, and we progressed our product innovation roadmap that includes product enhancements as well as our new ultrasound-guided implant toolkit,” said Nadim Yared, President and Chief Executive Officer of CVRx. “While our fourth quarter results were below our expectations due to material challenges in our international business as a result of widespread lockdowns in Europe , we continued to see resilience in our U.S. heart failure business.”

“We are highly confident in our ability to continue to grow the business in the future despite the overhang of COVID-19 that persists into 2022. We will execute on our commercial strategy with the continued expansion of our salesforce and the efforts to grow the utilization of Barostim,” continued Mr. Yared. “We are very excited about the position we are in to take advantage of the large opportunity that exists to accelerate the adoption of Barostim and bring relief to as many patients suffering with cardiovascular illness as possible.”

Business Outlook

For the full year of 2022, the Company expects:

- Total revenue between $20.0 million and $23.0 million;
- Gross margin between 74.0% and 76.0%;
- Operating expenses between $55.0 million and $61.0 million

For the first quarter of 2022, the Company expects to report total revenue between $3.6 million and $4.0 million.

Upcoming Investor Conference Presentation

The Company will be participating in the 40th Annual J.P. Morgan Healthcare Conference, including a company presentation on Tuesday, January 11, 2022 at 3:45 pm Eastern Time. Webcasts of the presentation and panel discussion will be available online at the investor relations page of the Company’s website at ir.cvrx.com/news-events/events.

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 future financial performance (including, specifically, our 2022 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 NEO; our ability to establish and maintain sales and marketing capabilities; our ability to demonstrate to physicians and patients the merits of our BAROSTIM NEO; any failure by third-party payors to provide adequate coverage and reimbursement for the use of BAROSTIM NEO; our competitors’ success in developing and marketing products that are safer, more effective, less costly, easier to use or otherwise more attractive than BAROSTIM NEO; 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 II, Item 1A. Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Preliminary Fourth Quarter/Full Year 2021 Results

This press release includes estimated financial results for the fourth quarter and full year of 2021, which are preliminary, unaudited and represent the most recent current information available to Company management. The Company’s actual results may differ from these estimated financial results, including due to the completion of its financial closing procedures and final adjustments. The Company expects to issue full financial results for the fourth quarter and full year 2021 in February.

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