Shockwave Medical Announces Agreement to Acquire Neovasc

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Neovasc's Innovative Reducer System Will Target the Estimated $5 Billion Refractory Angina Market

Shockwave Medical Announces Preliminary Fourth Quarter and Full Year 2022 Revenues and Full Year 2023 Revenue Guidance

SANTA CLARA, Calif., Jan. 17, 2023 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, today announced it has entered into a definitive agreement to acquire Neovasc Inc. (NASDAQ,TSX:NVCN), a company focused on the minimally invasive treatment of refractory angina.

The Neovasc Reducer System is a first-of-its-kind technology to address refractory angina. Refractory angina is a chronic condition in which a patient suffers chest pain that cannot be controlled by conventional therapies. It is estimated that each year, in the U.S. and the E.U. alone, up to 300,000 new patients with obstructive coronary disease who are ineligible for conventional revascularization experience refractory angina, despite guideline-directed medical therapy. In addition, it is estimated that up to another 500,000 new patients present with angina and non-obstructive coronary artery disease (ANOCA) in the U.S. and the E.U. each year. The Neovasc Reducer System has been granted Breakthrough Device designation by the FDA, is CE-marked and is currently enrolling patients in the COSIRA-II study, a randomized clinical trial being conducted under an Investigation Device Exemption intended to support U.S. FDA approval for patients with coronary obstructive refractory angina.

"Refractory angina is a debilitating condition without an effective therapy that impacts millions of patients," said Gregg W. Stone, MD, FACC, MSCAI, Principal Investigator of COSIRA-II, Director of Academic Affairs for the Mount Sinai Heart Health System, and Professor of Medicine (Cardiology) and of Population Health Sciences and Policy. "The ongoing COSIRA-II randomized trial has been designed to definitively demonstrate that the Reducer is superior to a sham control for these patients, offering the potential to change the lives of these patients who are desperate for a solution for their refractory angina."

"Our team at Shockwave has proven that we excel at developing products and markets for large, underserved patient populations and commercializing innovative solutions for these patients. We believe the Reducer is an excellent fit for Shockwave as it enables us to apply our capabilities to address another large, unmet need within cardiology – refractory angina," said Doug Godshall, President and Chief Executive Officer of Shockwave. "The timing is ideal as there will be no distraction to our U.S. sales organization in the near term and, as we did with C^2, our coronary device, we expect to refine our commercialization approach and begin the development of international markets in advance of U.S. approval. This transaction supports our commitment to drive growth through innovation and we are excited for the potential to bring even more solutions to our customers and the patients they serve with the Reducer System."

Terms of the Neovasc Agreement
Upon the closing of the transaction, Shockwave Medical will acquire all outstanding Neovasc shares for an upfront cash payment of $27.25 per share, corresponding to an enterprise value of approximately $100 million, inclusive of certain deal-related costs. Neovasc shareholders will also receive a potential deferred payment in the form of a non-tradable contingent value right (CVR) entitling the holder to receive up to an additional $12 per share in cash if certain regulatory milestones are achieved. The upfront cash consideration represents a premium of 27% and 68% to the closing price and 30-day VWAP, respectively, of Neovasc's common shares on the Nasdaq Capital Market on January 13, 2023.

The transaction will be effected by way of a court-approved plan of arrangement pursuant to the *Canada Business Corporations Act*, and is subject to customary closing conditions, including requisite Neovasc shareholder approval. Shockwave expects to complete the transaction in the first half of 2023.

The Board of Directors of Neovasc, acting on the unanimous recommendation of a special committee comprised of independent directors and after having received an opinion from its financial advisor to the effect that the consideration to be received by Neovasc shareholders pursuant to the plan of arrangement is fair from a financial point of view, has unanimously approved the arrangement. Directors and executive officers of Neovasc and related parties, holding an aggregate of approximately 9.23% of the Neovasc shares currently outstanding (on a non-diluted basis) have entered into support and voting agreements with Shockwave.

Shockwave Medical Preliminary Fourth Quarter and Full Year 2022 Revenues and Full Year 2023 Revenue Guidance

- Preliminary unaudited revenue for the fourth quarter of 2022 is expected to be between $143 million and $144 million, an increase of 70% to 71% compared to the fourth quarter of 2021. Fourth quarter 2022 U.S. Coronary preliminary unaudited revenue is expected to be between $81 million and $82 million
- Preliminary unaudited revenue for the full year 2022 is expected to be between $489 million and $490 million, an increase of 106% to 107% compared to the full year 2021. Full year 2022 U.S. Coronary preliminary unaudited revenue is expected to be between $288 million and $289 million
- Shockwave Medical projects revenue for the full year 2023 to range from $660 million to $680 million, which represents growth of approximately 35% to 39% over 2022.

Shockwave will provide more detail and discuss full financial results on its fourth quarter 2022 earnings conference call on February 16, 2023.

Conference Call
Shockwave Medical management will host a conference call today at 8:30 a.m. ET to discuss its definitive agreement to acquire Neovasc.

Investors interested in listening to conference call may do so by dialing (877) 423-9813 for domestic callers or (201) 689-8573 for international callers, using conference ID: 13735529. Live and archived webcasts of all earnings events will also be made available at https://ir.shockwavemedical.com.

About Shockwave Medical, Inc.
Shockwave Medical is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave Medical aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which the company refers to as Intravascular Lithotripsy (IVL). IVL is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. To view an animation of the IVL procedure and for more information, visit www.shockwavemedical.com.

About Reducer
The Reducer is CE-marked in the European Union for the treatment of refractory angina, a painful and debilitating condition that occurs when the coronary arteries deliver an inadequate supply of blood to the heart muscle, despite treatment with standard revascularization or cardiac drug therapies. It affects millions of patients worldwide, who typically lead severely restricted lives as a result of their disabling symptoms, and its incidence is growing. The Reducer provides relief of angina symptoms by altering blood flow within the myocardium of the heart and increasing the perfusion of oxygenated blood to ischemic areas of the heart muscle. Placement of the Reducer is performed using a minimally invasive transvenous procedure. While the Reducer is not approved for commercial use in the United States, the FDA granted Breakthrough Device designation to the Reducer in October 2018, and it is being studied in the COSIRA-II clinical trial.

About Neovasc Inc.
Neovasc is a specialty medical device company that develops, manufactures, and markets products for the rapidly growing cardiovascular marketplace. Its products include Reducer, for the treatment of refractory angina, which is under clinical investigation in the United States and has been commercially available in Europe since 2015. For more information visit: www.neovasc.com.

Preliminary Financial Results
Shockwave Medical's audited financial statements for the year ended December 31, 2022 are not yet available. Accordingly, Shockwave Medical's preliminary financial results are an estimate and subject to the completion of Shockwave Medical's financial closing and other procedures and finalization of Shockwave Medical's consolidated financial statements for the year ended December 31, 2022, including the completion of the audit of Shockwave Medical's financial statements. Accordingly, actual financial results that will be reflected in Shockwave Medical's Annual Report on Form 10-K for the year ended December 31, 2022, including audited financial statements, when they are completed and publicly disclosed may differ from these preliminary results.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including, but not limited to, statements related to the expected date of closing of the proposed transaction and the potential benefits thereof; the potential advantages of the Reducer; Shockwave's preliminary unaudited financial results for the three months and year ended December 31, 2022; and Shockwave's outlook for the year ending December 31, 2023. All statements, other than statements of historical facts, are statements that could be deemed forward-looking. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue," and similar expressions, and the negative of these terms. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current plans, expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware.

Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: whether the acquisition of Neovasc is completed; whether the COSIRA-II clinical trial is completed and achieves its endpoints; whether the Reducer receives FDA approval for the treatment of angina; the completion of Shockwave's 2022 financial statements; Shockwave's 2023 operational and financial performance; and other risks and uncertainties discussed in our filings with the Securities and Exchange Commission (SEC), including in Part I, Item IA - Risk Factors in our most recent Annual Report on Form 10-K filed with the SEC, and in our other reports filed with the SEC. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations.

Additional Information and Where to Find It

This communication is being made in respect of a proposed arrangement involving Shockwave Medical, Inc. and Neovasc Inc. Further details of this transaction will be included in a management information circular to be mailed to Neovasc shareholders in accordance with applicable securities laws. Copies of the arrangement agreement and the information circular will be filed with Canadian securities regulators and will be accessible on SEDAR at www.sedar.com. The information circular and this communication are not offers to sell Neovasc securities, are not soliciting an offer to buy Neovasc securities in any state where the offer and sale is not permitted and are not a solicitation of any vote or approval.

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