



NASDAQ, TSX: NVCN

## Neovasc Announces Third Quarter 2019 Financial Results

### ***Recent Highlights***

- *Delivered continued revenue growth for Neovasc Reducer™ (“Reducer”)*
- *Reducer added to the European Society of Cardiology Practice Guidelines for the treatment of refractory angina*
- *Reducer featured at the 40<sup>th</sup> Annual National Congress of the Italian Society of Interventional Cardiology*
- *Announced Norman Radow joined the board of directors*
- *Granted a US patent covering Tiara™ (“Tiara”) mitral valve replacement device*

**VANCOUVER, November 7, 2019** – [Neovasc, Inc.](#) (“Neovasc” or the “Company”) ([NASDAQ, TSX: NVCN](#)), a leader in the development of minimally invasive transcatheter mitral valve replacement technologies and in the development of minimally invasive devices for the treatment of refractory angina, today reported financial results for the third quarter ended September 30, 2019.

“The third quarter of 2019 was another one of significant progress for the Company as we build the clinical data around Tiara and expand our Reducer commercial presence” said Fred Colen, President and Chief Executive Officer of Neovasc. “We continued to add to our sales team, and reached an important milestone with close to 200 patients being implanted with Reducer in Germany just after the end of the quarter. Additionally, we have taken concrete steps on the path to approval in the U.S. market. To that end, we decided to submit a full PMA application to the FDA before the year is out. We believe that the totality of clinical data available now, from the COSIRA study, REDUCER-I European Post-Market study (with over 200 of 400 patients enrolled), and multiple independent published studies, should provide reasonable assurance of safety and effectiveness to support a PMA.” Continued Mr. Colen, “Moving on to Tiara, at quarter end there were 79 patients who have been treated in our two clinical trials or through compassionate use cases and in October we received approval from FDA to close enrollment in the TIARA-I Early Feasibility trial in the United States on November 15, 2019. Study patients will continue to be followed out to 5 years per protocol. We believe to have accomplished the objectives of the study; primarily, to demonstrate the safety of the Tiara, while gathering preliminary information on device performance and clinical outcomes. This decision is in-line with the Company’s goal to focus on Tiara TF/TS approval in the U.S. market, while continuing to pursue the CE mark for Tiara TA in Europe. Enrollment is ongoing in the TIARA-II CE Mark Clinical Study.”

### **The Tiara Mitral Valve**



As of November 5, 2019, 79 patients have been treated with Tiara in either the TIARA-I Early Feasibility Clinical Study, compassionate use cases, or in our TIARA-II CE Mark Clinical Study. Neovasc believes that early results have been encouraging as the 30-day survival rate for the patients treated with the Tiara is 89% with one patient now having survived over five and a half years post implant. The Tiara has successfully treated both functional and degenerative Mitral Regurgitation patients, as well as patients with pre-existing prosthetic aortic valves and mitral surgical annuloplasty rings.

### **The Transfemoral Trans-septal ("TF/TS") Tiara system**

The TF/TS development program is based on our extensive clinical experience with the transapical Tiara system, enabling a very controlled and predictable implantation procedure. The team has narrowed the TF/TS Tiara system down to a system design concept, that has shown strong potential and was most recently successfully deployed in animals using the TF/TS access with great seating, sealing and rotational alignment. The Company is benefitting from a real understanding of the anatomical and technical challenges, due to our clinical experience and our extensive clinical data base. We intend to move rapidly now to reach system design freeze by the end of 2019, as planned and to initiate an early, small clinical feasibility study in humans before the end of 2020. The TF/TS Tiara is being designed to allow for full retrievability of the device, even after the trigonal tabs have been released, up to the final point of connection with the delivery system.

### **The Reducer**

The REDUCER-I post-market observational study has enrolled 224 of 400 patients across Europe at 23 active centers. Data from this study, the COSIRA study, as well as published data from several physician-initiated studies, continues to reflect the very positive safety profile and improvements in a patient's refractory angina, therefore improving the patient's quality of life following Reducer implantation.

### **Neovasc Board of Directors**

On September 16, the Company announced that Norman Radow, a Managing Partner at Strul Medical Group ("Strul"), a leading investment firm that participated in Neovasc's \$11.5 million financing in May 2019 (the "May 2019 Financing"), has been appointed to the Company's Board of Directors, effective immediately. Concurrently, Dr. Jane Hsiao has stepped down from Neovasc's Board in order to increase her focus on other business interests.

### **Subsequent Developments**

On October 15, 2019, the United States Patent and Trademark Office ([USPTO](#)) issued to Neovasc US Patent No. 10,433,952, titled: "PROSTHETIC VALVE FOR AVOIDING OBSTRUCTION OF OUTFLOW". The granted claims are directed to a prosthetic valve that helps reduce LVOT obstruction and improve unobstructed blood flow through the Tiara and the native ventricle. The Company believes this issuance marks an important step in the protection of Tiara's intellectual property for its next generation Tiara prosthesis, and is the first patent granted in the U.S. covering new Tiara technologies.



Separately, Neovasc received approval from the FDA on October 16, 2019 to close enrollment in the Tiara Early Feasibility Trial protocol. Enrollment will close on November 15, 2019, however study patients will continue to be followed out to 5 years per protocol. We believe to have accomplished the objectives of the study; primarily, to demonstrate the safety of the Tiara, while gathering preliminary information on device performance and clinical outcomes.

## **Results for the three-month periods ended September 30, 2019 and 2018**

### **Revenues**

Revenues increased 4% to \$500,498 for the third quarter of 2019, compared to revenues of \$480,540 for the same period in 2018 as the Company continues its commercialization strategies. The limited sales growth versus same period last year is mostly due to a large purchase of inventory from our new distributor in Italy in the third quarter of 2018 that skewed the comparative period.

### **Cost of Goods Sold**

The cost of goods sold for the quarter was \$137,999 compared to \$96,743 for the same period in 2018. The overall gross margin for the quarter was 72%, compared to 80% gross margin for the same period in 2018. During the three months ended September 30, 2019, the Company voluntarily replaced certain expired inventory of Reducers with newly sterilized product, which reduced the gross margin in the third quarter of 2019.

### **Expenses**

Total expenses for the third quarter of 2019 were \$7,355,531 compared to \$10,034,390 for the third quarter of 2018, representing a decrease of \$2,678,859 or 27%. The decrease in total expenses from a year ago was primarily caused by a \$2,311,677 decrease in non-cash charges for a collaboration, license and settlement agreements provision, an \$868,118 decrease in non-cash stock-based compensation charges and offset by a \$476,523 increase in other expenses.

Selling expenses for third quarter 2019 were \$380,412, compared to \$202,947 in the third quarter of 2018, representing an increase of \$177,465 or 87%. The increase in selling expenses from the year ago quarter reflects an increase in costs incurred for commercialization activities related to the Reducer, including hiring additional sales representatives.

General and administrative expenses for the third quarter of 2019 were \$2,197,922, compared to \$6,340,747 for the same period in 2018, representing a decrease of \$4,142,825. The decrease in general and administrative compared to the year ago quarter was driven by a decrease in certain non-cash charges: lower collaboration, license and settlement agreement expenses, lower stock-based incentive awards, as well as, lower severance expenses.

Product development and clinical trial expenses were \$4,777,197 compared to \$3,490,696 for 2018, representing an increase of \$1,286,501 or 37%, substantially



explained by an increase in non-cash stock-based compensation charges, an increase in cash-based employee expenses as additional staff have been hired in 2019 and an increase in other product development and clinical trial expenses as the Company continues to incur development and clinical costs related to Tiara and regulatory costs related to Tiara and Reducer.

### **Other Income and Loss**

The other income for the third quarter of 2019 was \$775,550 compared to other losses of \$4,932,151 for the same period in 2018, a difference of \$5,707,701. The main cause of the decrease in the other loss was the accounting treatment of the May 2019 Financing resulting in a decrease of \$5,759,228 compared to the prior year.

### **Losses**

The comprehensive losses for the three months ended September 30, 2019 were \$6,555,186 compared to \$14,290,417 for the same period in 2018.

The \$7,735,231 decrease in the comprehensive loss incurred for the three months ended September 30, 2019 compared to the same period in 2018 can be substantially explained by a \$5,707,701 decrease in other losses and a \$2,657,561 decrease in operating losses, offset by a \$699,536 increase in other comprehensive loss.

### **Discussion of Liquidity and Capital Resources**

Neovasc finances its operations and capital expenditures with cash generated from operations and through equity and debt financings. As at September 30, 2019 the Company had cash and cash equivalents of \$11,396,063 compared to cash and cash equivalents of \$9,242,809 as at December 31, 2018. The Company will require significant additional financing in order to continue to operate its business. Given the current nature of the Company's capital structure, there can be no assurance that such financing will be available on favorable terms, or at all. These circumstances indicate the existence of material uncertainty and cast substantial doubt about the Company's ability to continue as a going concern.

The Company is in a negative working capital position of \$1,455,733, with current assets of \$12,982,569 and current liabilities of \$14,438,302. The Company will require additional working capital in order to continue to operate its business and there can be no assurance that such additional working capital will be available on favorable terms, or at all.

Net cash applied to operating activities for the nine months ended September 30, 2019 was \$18,089,177, compared to \$16,822,109, for the same period in 2018. For the nine months ended September 30, 2019, cash operating expenses were \$17,093,583, compared to \$17,729,515 for the same period in 2018, a decrease of \$635,932 as the Company continues to manage its cash flows while still advancing the commercialization and development of its products. Net cash outflow from the net change in non-cash working capital items for the nine months ended September 30, 2019 was \$1,185,872, compared to net cash inflow of \$938,010 in the same period in 2018, a \$2,123,882 increase due to the payment of \$2,150,000 collaboration and licensing expenses.



Net cash applied to investing activities for the nine months ended September 30, 2019 was \$176,941 compared to net cash received from investing activities of \$715,848 for the same period in 2018, primarily due to the \$865,610 cash inflow from the sale of a manufacturing building in 2018.

During the nine months ended September 30, 2019, the Company received net proceeds of \$19,601,526 from the 2019 Financings (being the February 2019 underwritten public offering of Common Shares, the March 2019 underwritten public offering of Common Shares and the May 2019 Financing) and \$1,200,400 from the exercise of warrants (the "2017 Warrants") issued pursuant to the 2017 underwritten public offering and November 2017 private placement, compared to \$13,086,587 proceeds from the exercise of 2017 Warrants in the comparative period in 2018.

### **Subsequent events**

On November 7, 2019, the Company announced that it has appointed Bill Little, former Global Head of Customer and New Market Insights at Abbott/St Jude as Chief Operating Officer of Neovasc.

### **Outstanding Share Data**

As of November 5, 2019, subsequent to the effect of the share consolidations, the Company had 7,647,823 Common Shares issued and outstanding. The following securities are convertible into Common Shares: 1,052,767 stock options with a weighted average exercise price of \$20.92, 144,444 broker warrants with an exercise price of \$5.625, \$11,500,000 principal amount of notes issued pursuant to the May 2019 Financing which could convert into 1,533,333 common shares and \$6,874,000 principal amount of notes issued pursuant to the November 2017 private placement (the "2017 Notes") which could convert into 1,740,253 Common Shares (not taking into account the alternate conversion price or anti-dilution mechanisms). Our fully diluted share capital as of the same date is 12,118,620. Our fully diluted share capital, adjusted on the assumption that all of the outstanding 2017 Notes are converted using the alternate conversion price at the closing price on November 5, 2019, is 12,561,109.

### **Conference Call and Webcast information**

Neovasc will be hosting a conference call and audio webcast today at 4:30 pm ET to discuss these results.

Domestic: 888-220-8474  
International: 323-794-2588  
Conference ID: 5350680  
Webcast: <http://public.viavid.com/index.php?id=136842>

### **About Tiara**

Tiara is a self-expanding mitral bioprosthesis specifically designed to treat mitral valve regurgitation ("MR") by replacing the diseased valve. Conventional surgical treatments are only appropriate for about half of MR patients, who number an estimated four million



in the U.S. with a similar number of patients affected throughout Europe. Tiara is implanted in the heart using a minimally invasive, transapical transcatheter approach without the need for open-heart surgery or use of a cardiac bypass machine.

The Tiara valve is not currently commercially available in the United States and is currently being evaluated in TIARA-I – an early feasibility study in the United States, Canada and Belgium, in TIARA-II – a European Conformité Européenne Mark Trial in Germany, Italy, Spain, and the United Kingdom and patients have also been treated and under compassionate programs in Canada, Italy, Germany, Israel, and Switzerland.

### **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 in the heart's circulatory system, thereby 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 that is similar to implanting a coronary stent and is completed in approximately 20 minutes.

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. This designation is granted by the FDA in order to expedite the development and review of a device that demonstrates compelling potential to provide a more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases. In addition, there must be no FDA approved treatments presently available, or the technology must offer significant advantages over existing approved alternatives.

Refractory angina, resulting in continued symptoms despite maximal medical therapy and without revascularization options, is estimated to affect 600,000 to 1.8 million Americans, with 50,000 to 100,000 new cases per year. <sup>1</sup>

<sup>1</sup>T. J. Povsic, S. Broderick, K. J. Anstrom et al., "Predictors of long-term clinical endpoints in patients with refractory angina," *Journal of the American Heart Association*, vol. 4, no. 2, article e001287, 2015.

### **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 not currently commercially available in the United States (though two U.S. patients have been treated under compassionate use) and has been commercially available in Europe since 2015, and Tiara, for the transcatheter treatment of mitral valve disease, which is currently under



clinical investigation in the United States, Canada, Israel and Europe. For more information, visit: [www.neovasc.com](http://www.neovasc.com).

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### **Forward-Looking Statement Disclaimer**

Certain statements in this news release contain forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and applicable Canadian securities laws that may not be based on historical fact, including without limitation statements containing the words "believe", "may", "plan", "will", "estimate", "continue", "anticipate", "intend", "expect" and similar expressions. Forward-looking statements may involve, but are not limited to, beliefs and expectations as to the totality of the clinical data and multiple independent studies providing reasonable grounds of safety and effectiveness to support a PMA for the Reducer, the Company's discussions with the FDA and potential pathways to the U.S. market for the Reducer, early results of the Tiara clinical studies being encouraging, the objectives of the Tiara Early Feasibility Trial protocol being accomplished, plans for the design freeze and feasibility study of the Tiara by the end of 2019 and 2020 respectively, the issuance of the new Tiara patent marking an important step in protection of Tiara's intellectual property, the growing incidence of refractory angina and the growing cardiovascular marketplace. Many factors and assumptions could cause the Company's actual results, performance or achievements to differ materially from those expressed or implied by its forward-looking statements. In particular, as noted above, any pathway to U.S. market approval by the FDA carries considerable risk, and there can be no assurance that the PMA will be approved by the FDA in a timely manner or at all. For example, the FDA may not agree with the Company's belief that the totality of existing clinical evidence will provide reasonable assurance of safety and effectiveness to support a PMA. There could be unforeseen developments that cause a delay in the filing of the PMA beyond 2019. In addition, the Company's expectations regarding the PMA pathway bringing the best chance of success within reasonable cost and time constraints compared to the other options the Company had been considering could prove to be incorrect. In the event that the PMA is approved by the FDA, there can be no assurance that Neovasc will be successful in commencing commercialization of Reducer in the United States on a timely basis or at all, or of the total addressable market size for Reducer. Other risks that could cause the Company's actual results, performance or achievements to differ materially from those expressed or implied by its forward looking statements include, without limitation, risks relating to the possibility that the Company's common shares may be delisted from the Nasdaq Capital Market or the Toronto Stock Exchange, including Nasdaq's discretionary public interest authority to apply more stringent criteria for continued listing or suspend or delist securities, which could affect their market price and liquidity; the substantial doubt about the Company's ability to continue as a going concern; risks relating to the 2017 Notes, resulting in significant dilution to the Company's shareholders; risks relating to the Company's need for significant additional future capital and the Company's ability to raise additional funding; risks relating to cashless exercise and adjustment provisions in the 2017 Notes, which could make it more difficult and expensive for the Company to raise additional capital in the future and result in further dilution to investors; risks relating to the sale of a significant number of common shares of the Company; risks relating to the conversion of the 2017 Notes, which may encourage short sales by third parties; risks relating to the Company's conclusion that it did not have effective internal control over financial reporting as at December 31, 2018; risks relating to the Company's Common Share price being volatile; risks relating to the influence of significant shareholders of the Company over the Company's business operations and share price; risks relating to the Company's significant indebtedness, and its effect on the Company's financial condition; risks relating to claims by third parties alleging infringement of their intellectual property rights; risks relating to lawsuits that the Company is subject to, which could divert the Company's resources and result in the payment of significant damages and other remedies; the Company's ability to establish, maintain and defend intellectual property rights in the Company's products; risks relating to results from clinical trials of the Company's products, which may be unfavorable or perceived as unfavorable; the Company's history of losses and significant accumulated deficit; risks associated with product liability claims, insurance and recalls; risks relating to use of the Company's products in unapproved circumstances, which could expose the Company to liabilities; risks relating to competition in the medical device industry, including the risk that one or more of the Company's competitors may develop more effective or more affordable products; risks relating to the Company's ability to achieve or maintain expected levels of market acceptance for the Company's products, as well as the Company's ability to successfully build its in-house sales capabilities or secure third-party marketing or distribution partners; the Company's ability to convince public payors and hospitals to include the Company's products on their approved products lists; risks relating to new legislation, new regulatory requirements and the efforts of governmental and third-party payors to contain or reduce the costs of healthcare; risks relating to increased regulation, enforcement and inspections



of participants in the medical device industry, including frequent government investigations into marketing and other business practices; risks associated with the extensive regulation of the Company's products and trials by governmental authorities, as well as the cost and time delays associated therewith; risks associated with post-market regulation of the Company's products; health and safety risks associated with the Company's products and industry; risks associated with the Company's manufacturing operations, including the regulation of the Company's manufacturing processes by governmental authorities and the availability of two critical components of the Reducer; risk of animal disease associated with the use of the Company's products; risks relating to the manufacturing capacity of third-party manufacturers for the Company's products, including risks of supply interruptions impacting the Company's ability to manufacture its own products; risks relating to the Company's dependence on limited products for substantially all of the Company's current revenues; risks relating to the Company's exposure to adverse movements in foreign currency exchange rates; risks relating to the possibility that the Company could lose its foreign private issuer status under U.S. federal securities laws; risks relating to breaches of anti-bribery laws by the Company's employees or agents; risks associated with future changes in financial accounting standards and new accounting pronouncements; risks relating to the Company's dependence upon key personnel to achieve its business objectives; the Company's ability to maintain strong relationships with physicians; risks relating to the sufficiency of the Company's management systems and resources in periods of significant growth; risks associated with consolidation in the health care industry, including the downward pressure on product pricing and the growing need to be selected by larger customers in order to make sales to their members or participants; risks relating to the Company's ability to successfully identify and complete corporate transactions on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances; risks relating to the Company's ability to successfully enter into fundamental transactions as defined in the 2017 Notes; anti-takeover provisions in the Company's constating documents which could discourage a third party from making a takeover bid beneficial to the Company's shareholders; and risks relating to conflicts of interests among the Company's officers and directors as a result of their involvement with other issuers. These risk factors and others relating to the Company are discussed in greater detail in the "Risk Factors" section of the Company's Annual Report on Form 20-F and in the Management's Discussion and Analysis for the three and nine months ended September 30, 2019 (copies of which may be obtained at [www.sedar.com](http://www.sedar.com) or [www.sec.gov](http://www.sec.gov)). The Company has no intention and undertakes no obligation to update or revise any forward-looking statements beyond required periodic filings with securities regulators, whether as a result of new information, future events or otherwise, except as required by law.