

Neovasc Announces Third Quarter Financial Results and Provides Corporate Update

VANCOUVER and MINNEAPOLIS – (NewMediaWire) – Nov 10, 2022 – Neovasc Inc. (“Neovasc” or the “Company”) (NASDAQ, TSX: NVCN) today reported financial results for the third quarter ended September 30, 2022.

Recent Highlights

- Generated revenues of \$923,000, a quarterly record and a year-over-year increase of 31% compared to the third quarter of 2021.
- Accelerating acceptance of Reducer in the UK and French markets, with France the largest volume market in the quarter.
- Continued enrollment in the COSIRA II pivotal trial, with enrollment expected to be complete in the first half of 2024 and initial data readout in the second half of 2024.
- In July, 2022, the Company received approval to expand the scope of the COSIRA II trial with a registry to include patients suffering from angina with non-obstructed coronary artery disease, so-called ANOCA patients.
- Released preliminary data at the Transcatheter Cardiovascular Therapeutics conference in September, showing the Reducer’s benefits to ANOCA patients.
- Received US outpatient reimbursement by CMS for the Reducer Therapy, effective January 1, ‘23.

“I am pleased to report on the tremendous progress the Neovasc team has made in the third quarter towards advancing our value creation strategies, despite a COVID surge that impacted procedure volumes and currency exchange fluctuations that impacted revenues in the quarter,” said Fred Colen, President and Chief Executive Officer. “Despite these headwinds, Neovasc nevertheless achieved another quarter of record revenues as we continue to benefit from the successes in getting the Reducer reimbursed in the UK, France, and in the US as part of the COSIRA II trial. We now have adequate coding, coverage and payment to support full reimbursement for the Reducer, in the CMS population, for both inpatient and outpatient procedures (effective January 1, 2023), both during the COSIRA-II Clinical Trial, and upon potential commercialization in the United States. Additionally, we have developed the new ICD-10 diagnosis code that became effective October 1, that established “refractory angina” as a condition distinct from other, less severe, forms of angina. Furthermore, we continue to provide leading clinical data, this time demonstrating benefits of the Reducer therapy in yet another refractory angina patient population, currently without good treatment options; in September 2022, we announced preliminary data supporting the benefits of the Reducer therapy to patients with angina and non-obstructive coronary artery disease, so-called ANOCA patients. I look forward to sharing further exciting updates in future quarters.”

Financial Results for the Third Quarter Ended September 30, 2022

Revenues increased by 31% to \$923,000 for the three months ended September 30, 2022, compared to revenues of \$703,000 for the same period in 2021. The overall gross margin for the three months ended September 30, 2022 was 76%, compared to 77% gross margin for the same period in 2021.

Total expenses for the three months ended September 30, 2022 were approximately \$7.4 million compared to approximately \$7.3 million for the third quarter of 2021, representing an increase of approximately \$181,000 or 2%, substantially due to an increase in employee expenses as we accrued for a portion of

annual bonuses that were previously not accrued, but were incurred, in the prior period and an increase in other operating expenses related to the COSIRA-II study, offset by a decrease in non-cash share-based payments, a decrease in director and officer insurance expenses and a decrease in litigation expenses.

Operating losses and comprehensive losses for the three months ended September 30, 2022 were \$6.7 million and \$8.2 million respectively, or \$3.00 basic and diluted loss per share, as compared with \$6.7 million operating losses and \$6.9 million comprehensive loss, or \$2.79 basic and diluted loss per share, for the same period in 2021. The increase of \$16,000 in operating losses can be explained by a \$181,000 increase in operating expenses offset by a \$165,000 increase in gross profit.

As of September 30, 2022, the company had \$31.3 million in cash and cash equivalents.

As of November 8, 2022, subsequent to the effect of the share consolidations, the Company had 2,746,625 common shares (“Common Shares”) issued and outstanding.

Conference Call and Webcast Information

Interested parties may access the conference call by dialing (800) 458-4121 or (856) 344-9290 (International) and reference Conference ID 7304031. Participants wishing to join the call via webcast should use the link posted on the investor relations section of the Neovasc website at neovasc.com/investors/. A replay of the webcast will be available approximately 30 minutes after the conclusion of the call using the link on the Neovasc website.

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 Neovasc 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, and Tiara™, a product under clinical investigation for the transcatheter treatment of mitral valve disease. The Company remains committed to the ongoing follow-up of patients in Tiara clinical trials and has paused all other Tiara activities. For more information, visit: www.neovasc.com.

NEOVASC INC.

Unaudited Condensed Interim Consolidated Statements of Financial Position

(Expressed in U.S. dollars)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	\$ 31,254,368	\$ 51,537,367
Accounts receivable	1,689,596	1,369,455
Finance lease receivable	-	43,543
Inventory	1,285,263	1,480,077
Prepaid expenses and other assets	368,766	787,734
Total current assets	34,597,993	55,218,176
Non-current assets		
Restricted cash	436,498	469,808
Right-of-use asset	333,708	456,339
Property and equipment	181,219	182,041
Deferred loss on 2020 derivative warrant liabilities	1,598,357	4,300,484
Deferred loss on 2021 derivative warrant liabilities	7,428,944	9,898,475
Total non-current assets	9,978,726	15,307,147
Total assets	\$ 44,576,719	\$ 70,525,323
LIABILITIES AND EQUITY		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	\$ 3,739,429	\$ 4,629,163
Lease liabilities	224,195	273,145
2019 Convertible notes	-	38,633
2020 Convertible notes	-	40,587
2022 Convertible notes	135,863	-
Total current liabilities	4,099,487	4,981,528
Non-Current Liabilities		
Lease liabilities	200,725	272,652
2019 Convertible notes	-	6,548,796
2020 Convertible notes, warrants and derivative warrant liabilities	126,355	6,088,728
2021 Derivative warrant liabilities	57,609	405,508
2022 Convertible notes	12,029,305	-
Total non-current liabilities	12,413,994	13,315,684
Total liabilities	\$ 16,513,481	\$ 18,297,212
Equity		
Share capital	\$ 441,153,987	\$ 439,873,457
Contributed surplus	42,491,190	40,355,952
Accumulated other comprehensive loss	(6,229,804)	(7,885,024)
Deficit	(449,352,135)	(420,116,274)
Total equity	28,063,238	52,228,111
Total liabilities and equity	\$ 44,576,719	\$ 70,525,323

NEOVASC INC.

Unaudited Condensed Interim Consolidated Statements of Loss and Comprehensive Loss

For the three and nine months ended September 30, 2022 and 2021

(Expressed in U.S. dollars)

	For the Three Months Ended September 30		For the Nine Months Ended September 30	
	2022	2021	2022	2021
REVENUE	\$ 923,311	\$ 703,420	\$ 2,352,118	\$ 1,788,282
COST OF GOODS SOLD	220,030	164,843	514,249	346,342
GROSS PROFIT	703,281	538,577	1,837,869	1,441,940
EXPENSES				
Selling expenses	1,062,454	786,366	3,276,625	2,257,157
General and administrative expenses	2,336,874	2,999,003	8,477,598	13,334,376
Product development and clinical trials expenses	4,044,443	3,477,884	11,655,659	11,840,199
	7,443,771	7,263,253	23,409,882	27,431,732
OPERATING LOSS	(6,740,490)	(6,724,676)	(21,572,013)	(25,989,792)
OTHER (EXPENSE)/INCOME				
Interest and other income	105,412	507,775	175,030	557,529
Interest and other expense	(427,207)	(33,551)	(1,166,472)	(352,114)
Loss on foreign exchange	(106,316)	(8,162)	(116,124)	(28,400)
Unrealized (loss)/gain on warrants, derivative liability warrants and convertible notes	(28,624)	1,738,258	433,014	16,997,651
Realized loss on exercise or conversion and extinguishment of warrants, derivative liability warrants and convertible notes	-	(223,747)	(1,845,822)	(2,119,091)
Amortization of deferred loss	(1,029,470)	(2,791,494)	(3,271,316)	(7,817,937)
	(1,486,205)	(810,921)	(5,791,690)	7,237,638
LOSS BEFORE TAX	(8,226,695)	(7,535,597)	(27,363,703)	(18,752,154)
Tax recovery	-	-	-	16,128
LOSS FOR THE PERIOD	\$ (8,226,695)	\$ (7,535,597)	\$ (27,363,703)	\$ (18,736,026)
OTHER COMPREHENSIVE LOSS FOR THE PERIOD				
Fair market value changes in convertible notes due to changes in own credit risk	-	619,635	(216,938)	(366,002)
LOSS AND OTHER COMPREHENSIVE LOSS FOR THE PERIOD	\$ (8,226,695)	\$ (6,915,962)	\$ (27,580,641)	\$ (19,102,028)
LOSS PER SHARE				
Basic and diluted loss per share	\$ (3.00)	\$ (2.79)	\$ (10.03)	\$ (7.63)

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. When used herein, the words “expect”, “anticipate”, “estimate”, “may”, “will”, “should”, “intend”, “believe”, and similar expressions, are intended to identify forward-looking statements. Forward-looking statements may involve, but are not limited to, the enrollment timeline for the COSIRA II pivotal trial, the expectation that the Company’s direct sales team will advance Reducer as a viable treatment for refractory angina in the UK, the expectation that the Company will have an equally strong performance in the fourth quarter of 2022, the expectation that the pause of all activity on the Tiara TA device will not affect ongoing business, the expected benefits of the Reducer therapy, the commitment to the ongoing follow-up of patients in Tiara clinical trials and the growing cardiovascular marketplace. Forward-looking statements are based on estimates and assumptions made by the Company in light of its experience and its perception of historical trends, current conditions and expected future developments, as well as other factors that the Company believes are appropriate in the circumstances. Many factors and assumptions could cause the Company’s actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements, including, without limitation, risks around the Company’s ability to continue as a going concern; risks around the Company’s history of losses and significant accumulated deficit; risks related to the COVID-19 coronavirus outbreak or other health epidemics, which could significantly impact the Company’s operations, sales or ability to raise capital or enroll patients in clinical trials and complete certain Tiara development milestones on the Company’s expected schedule; risks relating to the Company’s need for significant additional future capital and the Company’s ability to raise additional funding; risks relating to the sale of a significant number of Common Shares; risks relating to the possibility that the Company’s Common Shares may be delisted from the Nasdaq or the TSX, which could affect their market price and liquidity; risks relating to the Company’s conclusion that it did have effective internal control over financial reporting as of December 31, 2021 and 2020 but not at December 31, 2019; risks relating to the Common Share price being volatile; risks relating to the Company’s significant indebtedness, and its effect on the Company’s financial condition; risks relating to the influence of significant shareholders of the Company over our business operations and share price; 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; risks relating to claims by third-parties alleging infringement of their intellectual property rights; risks relating to 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; 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 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; risks relating to 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 relating to the extensive regulation of the Company’s products and trials by governmental authorities, as well as the cost and time delays associated therewith; risks relating to post-market regulation of the Company’s products; risks relating to health and safety concerns associated with the Company’s products and industry; risks relating to 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; risks relating to the possibility 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 the possibility that the Company could be treated as a “passive foreign investment company”; risks relating to breaches of anti-bribery laws by the Company’s employees or agents; risks relating to 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; risks relating to 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 relating to 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 conflicts of interests among the Company’s officers and directors as a result of their involvement with other issuers; risks relating to future issuances of equity securities by the Company, or sales of Common Shares or conversions of convertible notes, and exercise of warrants, options and restricted stock units by existing security holders, causing the price of the Company’s securities to fall; and risks relating to 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. 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 for the year ended December 31, 2021 and in the Management’s Discussion and Analysis for the three and nine months ended September 30, 2022 (copies of which may be obtained at www.sedar.com or www.sec.gov). These factors should be considered carefully, and readers should not place undue reliance on the Company’s forward-looking statements. The Company has no intention and undertakes no obligation to update or revise any forward-looking statements beyond required periodic filings with securities regulators (copies of which may be obtained at www.sedar.com or www.sec.gov), whether because of new information, future events or otherwise, except as required by law.

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