



NASDAQ, TSX: NVCN

Neovasc Announces Third Quarter 2021 Financial Results and Provides Corporate Update

VANCOUVER and MINNEAPOLIS – November 9, 2021 – [Neovasc, Inc.](#) ("Neovasc" or the "Company") ([NASDAQ](#), [TSX](#): NVCN), today reported financial results for the third quarter ended September 30, 2021.

Third Quarter Highlights

- Strong progress against all three value creation strategies.
- Generated record revenue of approximately \$703,000 in the quarter, up 12% from the same period in 2020.
- Advanced strategic focus to obtain additional reimbursement for the Neovasc Reducer™ in multiple EU countries and the United States.
- Continued preparations for COSIRA II US trial for Reducer, and received FDA approval for the investigational Device Exemption ("IDE") for the trial in September.
- Experienced a reduction in expenditures and cash burn from cost-cutting decisions in the first half of the year, extending the expected cash runway into 2024.

“Neovasc continued to make good progress with its value creation strategies during the third quarter. The first of these three strategic initiatives is to expand the use of Reducer in Europe, which we did as we generated record revenues during the quarter. Additionally, we continue to have productive dialogue with payers in multiple countries, including the United Kingdom, France, Germany and the United States, to secure reimbursement status for the Reducer. We believe that this novel device’s efficacy will ultimately be widely recognized by the medical industry,” said Fred Colen, President and Chief Executive Officer of Neovasc. “We recently received FDA approval for the IDE for the COSIRA-II pivotal trial and expect to enroll the first patients in late 2021. With respect to Tiara TA, we continue to work with our notified body in Europe to pursue the CE mark for the Tiara TA device and expect to have a decision in late 2022. We recognize that there is much more work to do, but we are confident that we have the team in place and that we are steadily advancing our value creation strategies.”

Progress on COSIRA-II Clinical Study

Neovasc’s key initiative for the remainder of this year is to advance toward the first patient enrollment in its new US IDE clinical study, COSIRA-II, with the aim of supporting a future PMA submission to the FDA. The Company remains on track to enroll the first patient in the trial in Q4 of 2021. It is engaged with several top clinical trial sites and continues to progress on site qualifications, contracting, and



Institutional Review Board (“IRB”) approvals. Earlier this month, Neovasc received its first IRB approval for the Trial from WCG IRB (formerly Western IRB), the largest independent review board in the United States, with over 3,000 partner hospitals. The Company is also working on a potential path towards US reimbursement for coverage and device payment by CMS during the COSIRA II clinical trial. This is a complex undertaking, and the outcome is not certain at all, but we have initiated our request.

Mechanism of action research

Recently, European physicians demonstrated a very meaningful improvement in the absolute coronary blood flow into the heart muscle upon implantation of the Reducer in two consecutive patients. This is the first time this procedure could be demonstrated in humans using the most advanced diagnostic tools and leading science. The physicians, both world-renowned experts in coronary physiology, were emphatic about the positive results. For the first time, the physicians were able to demonstrate, in real time, that implantation of the coronary sinus Reducer resulted in an immediate increase in blood flow to the heart muscle.

Nasdaq \$1 minimum bid price breach

Neovasc is currently in breach of Nasdaq’s \$1 minimum bid price rule and has been granted an initial grace period to cure this breach. The Company can cure this breach by closing 10 consecutive trading days above \$1, before November 22, 2021. However, it remains unlikely that the Company can achieve this in the time remaining. Neovasc believes that according to the Nasdaq rules and guidelines it could be eligible for a second 180-day grace period until May 21, 2022, providing the Company with additional time to cure the breach. The Company will make an application for a second grace period in the coming weeks, but Nasdaq will only be able to decide on eligibility for this additional grace period on or after the last day of the initial grace period, on November 22, 2021.

In addition, since the Company’s shareholders equity remains greater than \$2.5 million, satisfying the shareholders equity requirement, the Nasdaq \$35 million market capitalization requirement is not applicable for Neovasc.

Cost-reduction program

“We are pleased to note that our third quarter results demonstrate the benefits of the difficult cost cutting decisions we made in the first half of 2021, as Neovasc experienced significant expense reduction in the quarter and helped extend our projected cash runway into mid-2024,” Chris Clark, Neovasc’s Chief Financial Officer, commented. “We now have the financial security to continue our work for years not months, and that includes conducting the upcoming pivotal COSIRA II trial.”



Financial results for the third quarter ended September 30, 2021

Revenues increased by 12% to \$703,420 for the three months ended September 30, 2021, compared to revenues of \$626,418 for the same period in 2020.

The cost of goods sold for the three months ended September 30, 2021 was \$164,843 compared to \$150,503 for the same period in 2020. The overall gross margin for the three months ended September 30, 2021 was 77%, compared to 76% gross margin for the same period in 2020.

Total expenses for the three months ended September 30, 2021 were \$7,263,253 compared to \$10,644,367 for 2020, representing a decrease of \$3,381,114 or 32%.

The operating losses and comprehensive losses for the three months ended September 30, 2021 were \$6,724,676 and \$6,915,962, respectively, or \$0.11 basic and diluted loss per share, as compared with \$10,168,452 operating losses and \$10,392,921, comprehensive loss, or \$0.51 basic and diluted loss per share, for the same period in 2020.

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: 1-877-407-9208
International: 1-201-493-6784
Reference ID Code: 13723809

Parties wishing to access the call via webcast should use the link in the Investors section of the Neovasc website at <https://www.neovasc.com/investors/>. A replay of the webcast will be available in the Investors sections of the website approximately 30 minutes after the conclusion of the call.

About Neovasc Inc.

Neovasc is a specialty medical device company that develops, manufactures and markets products for the rapidly growing cardiovascular marketplace. The Company is a leader in the development of minimally invasive transcatheter mitral valve replacement technologies, and minimally invasive devices for the treatment of refractory angina. Its products include the Neovasc Reducer™, for the treatment of refractory angina, which is not currently commercially available in the United States 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.



NEOVASC INC.

Condensed Interim Consolidated Statements of Financial Position

(Expressed in U.S. dollars) (Unaudited)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 55,827,026	\$ 12,935,860
Accounts receivable	1,787,257	987,057
Finance lease receivable	68,815	95,849
Inventory	1,601,815	839,472
Research and development supplies	20,934	167,378
Prepaid expenses and other assets	912,160	705,471
Total current assets	60,218,007	15,731,087
Non-current assets		
Restricted cash	484,010	470,460
Right-of-use asset	549,892	830,551
Finance lease receivable	-	42,841
Property and equipment	190,272	803,280
Deferred loss on 2021 derivative warrant liabilities	10,730,698	-
Total non-current assets	11,954,872	2,147,132
Total assets	\$ 72,172,879	\$ 17,878,219
LIABILITIES AND EQUITY		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	\$ 4,812,486	\$ 7,243,500
Lease liabilities	282,051	342,910
2019 Convertible notes	154,531	38,633
2020 Convertible notes, warrants and derivative warrant liabilities	145,688	37,525
Total current liabilities	5,394,756	7,662,568
Non-current Liabilities		
Lease liabilities	349,676	596,881
2019 Convertible notes	6,410,532	6,156,724
2020 Convertible notes, warrants and derivative warrant liabilities	1,694,237	1,484,529
2021 Derivative warrant liabilities	722,293	-
Total non-current liabilities	9,176,738	8,238,134
Total liabilities	\$ 14,571,494	\$ 15,900,702
Equity		
Share capital	\$ 439,685,360	\$ 369,775,383
Contributed surplus	39,860,975	35,045,056
Accumulated other comprehensive loss	(7,981,719)	(7,615,717)
Deficit	(413,963,231)	(395,227,205)
Total equity	\$ 57,601,385	\$ 1,977,517
Total liabilities and equity	\$ 72,172,879	\$ 17,878,219



NEOVASC INC.

Condensed Interim Consolidated Statements of Loss and Comprehensive Loss

For the three and nine months ended September 30, 2021 and 2020

(Expressed in U.S. dollars) (Unaudited)

	For the three months ended September 30		For the nine months ended September 30	
	2021	2020	2021	2020
REVENUE	\$ 703,420	\$ 626,418	\$ 1,788,282	\$ 1,443,360
COST OF GOODS SOLD	164,843	150,503	346,342	349,735
GROSS PROFIT	538,577	475,915	1,441,940	1,093,625
EXPENSES				
Selling expenses	786,366	498,671	2,257,157	1,504,714
General and administrative expenses	2,999,003	4,642,979	13,334,376	10,955,991
Product development and clinical trials expenses	3,477,884	5,502,717	11,840,199	14,615,847
	7,263,253	10,644,367	27,431,732	27,076,552
OPERATING LOSS	(6,724,676)	(10,168,452)	(25,989,792)	(25,982,927)
OTHER INCOME/(EXPENSE)				
Interest and other income	507,775	495,628	557,529	554,278
Interest and other expense	(33,551)	(191,989)	(352,114)	(729,539)
Loss on foreign exchange	(8,162)	(65,983)	(28,400)	(191,636)
Unrealized gain on warrants, derivative liability warrants and convertible notes	1,738,258	730,242	16,997,651	4,233,073
Realized (loss)/gain on exercise or conversion of warrants, derivative liability warrants and convertible notes	(223,747)	1,567,127	(2,119,091)	587,497
Amortization of deferred loss	(2,791,494)	(2,601,250)	(7,817,937)	(2,736,332)
	(810,921)	(66,225)	7,237,638	1,717,341
LOSS BEFORE TAX	(7,535,597)	(10,234,677)	(18,752,154)	(24,265,586)
Tax refund/(expense)	-	-	16,128	(5,997)
LOSS FOR THE PERIOD	\$ (7,535,597)	\$ (10,234,677)	\$ (18,736,026)	\$ (24,271,583)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD				
Fair market value changes in convertible notes due to changes in own credit risk	619,635	(158,244)	(366,002)	(1,029,200)
LOSS AND OTHER COMPREHENSIVE LOSS FOR THE PERIOD	\$ (6,915,962)	\$ (10,392,921)	\$ (19,102,028)	\$ (25,300,783)
LOSS PER SHARE				
Basic and diluted loss per share	\$ (0.11)	\$ (0.51)	\$ (0.31)	\$ (1.69)



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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. 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, expectations as to the future growth of the Company, the Company making good progress with its value creation strategies, the expansion of the use of the Reducer in Europe, securing reimbursement status for the Reducer, taking the recently received FDA approval for the Investigational Device Exemption for the COSIRA-II pivotal trial and enrolling patients in late 2021 and the perusal of a CE mark decision for the Tiara TA. 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, the doubt about the Company's ability to continue as a going concern; risks related to the recent 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 (the "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, 2020 but not at December 31, 2019 and 2018; risks relating to the Common Share price being volatile; risks relating to the possibility that the 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 significant indebtedness, and its effect on the Company's financial condition; 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; 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 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; and risks relating to antitakeover 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 Information Form and in the Management's Discussion and Analysis for the three and nine months ended September 30, 2021 (copies of which may be obtained at www.sedar.com or 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. 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.