



NASDAQ, TSX: NVCN

Neovasc Announces Second Quarter 2021 Financial Results

VANCOUVER and MINNEAPOLIS – August 10, 2021 – [Neovasc, Inc.](#) ("Neovasc" or the "Company") ([NASDAQ](#), [TSX](#): NVCN), today reported financial results for the second quarter ended June 30, 2021.

Second Quarter Highlights

- Generated revenue of approximately \$633,000 in the quarter, up 123% from the same period in 2020, and a sequential 40% increase from Q1 2021.
- Streamlined strategic focus to pursue three value-creation strategies around Reducer and Tiara TA, suspending Tiara TF activity and reducing headcount by 40%. These moves are expected to extend the Company's cash runway into 2024.
- Continued to execute a strategic focus of additional reimbursement agreements, announcing in June that Reducer had been granted the first national reimbursement from the National Health Service England.
- Continued to pursue clinical studies supporting Reducer:
 - Advanced preparations for COSIRA II, the pivotal US trial for Reducer. The Company expects to file an Investigational Device Exemption (IDE) Supplement with the FDA in the third quarter.
 - Announced the first enrollment in the COSIMA trial in Germany, studying Reducer as a treatment for microvascular angina.

"Neovasc enjoyed a strong second quarter and continued to make good progress on its value creation strategies. During the quarter we made a strategic decision to streamline our focus on three value creation strategies, coupled with a significant corporate headcount reduction, which is expected to extend our cash runway for three years. We followed up on these moves in July, adding a new VP of Clinical Affairs and a VP of Regulatory Affairs, Global Angina Therapies to strengthen our expertise in these important areas. We are placing a heavy emphasis on expanding the market penetration of our CE-marked Reducer device in Europe, working directly with hospitals, cardiologists, and medical associations to raise awareness of the Reducer's safety, efficacy, and ease of use," said Fred Colen, President and Chief Executive Officer of Neovasc. Mr. Colen continued, "Our team is also working diligently to expand reimbursement for the Reducer device. Those efforts were rewarded when Reducer was granted full reimbursement by the National Health Service (NHS) England, and we look forward to sharing news of more reimbursement decisions in the second half of the year. In the United States, we continue to prepare for our pivotal U.S. trial for Reducer and expect to file an IDE Supplement in the third quarter. With respect to Tiara, we are working with our notified body in Europe to understand all specific requirements and leverage of work already performed, to pursue a CE mark decision for the Tiara TA device



under MDR. There is much more work to do, but we are confident that we now have the team in place and the financial security to successfully execute on our value creation strategies.”

Financial results for the second quarter ended June 30, 2021

Revenues increased 123% to approximately \$633,000 for the quarter ended June 30, 2021, compared to revenues of approximately \$284,000 for the same period in 2020.

The cost of goods sold for the three months ended June 30, 2021, was approximately \$109,000, compared to \$75,000 for the same period in 2020. The overall gross margin for the quarter ended June 30, 2021, was 83%, compared to 74% gross margin for the same period in 2020.

Total expenses for the quarter ended June 30, 2021, were \$9.6 million compared to \$8.9 million for the same period in 2020, representing an increase of approximately \$748,000 or 8%. The increase in total expenses can be substantially explained by the following non-cash charges; a \$1.0 million increase in non-cash share-based payments and an approximate \$903,000 charge related to the decision to pause the development of the Tiara TF device (\$594,000 impairment charge due to fixed assets obsolescence, and \$309,000 charge for employee termination expenses). This increase in non-cash charges was offset by a \$1.1 million decrease in cash-based employee expenses due to the Company’s reductions in force in December 2020 and June 2021.

Operating losses and comprehensive losses for the quarter ended June 30, 2021, were \$9.1 million and \$9.3 million, respectively, or \$0.13 basic and diluted loss per share, as compared with \$8.7 million operating losses and \$12.2 million comprehensive losses, or \$0.81 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: 13721306

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 (6 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.



NEOVASC INC.

Condensed Interim Consolidated Statements of Financial Position

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 63,294,878	\$ 12,935,860
Accounts receivable	1,213,450	987,057
Finance lease receivable	93,466	95,849
Inventory	1,387,718	839,472
Research and development supplies	11,852	167,378
Prepaid expenses and other assets	969,740	705,471
Total current assets	66,971,104	15,731,087
Non-current assets		
Restricted cash	483,714	470,460
Right-of-use asset	643,445	830,551
Finance lease receivable	-	42,841
Property and equipment	215,024	803,280
Deferred loss on 2021 derivative warrant liabilities	12,705,147	-
Total non-current assets	14,047,330	2,147,132
Total assets	\$ 81,018,434	\$ 17,878,219
LIABILITIES AND EQUITY		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	\$ 6,422,130	\$ 7,243,500
Lease liabilities	290,957	342,910
2019 Convertible notes	38,633	38,633
2020 Convertible notes, warrants and derivative warrant liabilities	37,839	37,525
Total current liabilities	6,789,559	7,662,568
Non-current Liabilities		
Lease liabilities	426,699	596,881
2019 Convertible notes	6,544,895	6,156,724
2020 Convertible notes, warrants and derivative warrant liabilities	2,077,415	1,484,529
2021 Derivative warrant liabilities	1,745,600	-
Total non-current liabilities	10,794,609	8,238,134
Total liabilities	\$ 17,584,168	\$ 15,900,702
Equity		
Share capital	\$ 439,679,546	\$ 369,775,383
Contributed surplus	38,783,708	35,045,056
Accumulated other comprehensive loss	(8,601,354)	(7,615,717)
Deficit	(406,427,634)	(395,227,205)
Total equity	\$ 63,434,266	\$ 1,977,517
Total liabilities and equity	\$ 81,018,434	\$ 17,878,219



NEOVASC INC.

Condensed Interim Consolidated Statements of Loss and Comprehensive Loss

For the three and six months ended June 30, 2021 and 2020

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

	For the three months ended June 30		For the six months ended June 30	
	2021	2020	2021	2020
REVENUE	\$ 633,068	\$ 284,047	\$ 1,084,862	\$ 816,942
COST OF GOODS SOLD	109,106	74,669	181,499	199,232
GROSS PROFIT	523,962	209,378	903,363	617,710
EXPENSES				
Selling expenses	832,812	452,514	1,470,791	1,006,043
General and administrative expenses	5,042,804	3,825,510	10,335,373	6,313,012
Product development and clinical trials expenses	3,740,887	4,589,724	8,362,315	9,113,130
	9,616,503	8,867,748	20,168,479	16,432,185
OPERATING LOSS	(9,092,541)	(8,658,370)	(19,265,116)	(15,814,475)
OTHER INCOME/(EXPENSE)				
Interest and other income	39,733	24,981	49,753	58,650
Interest and other expense	(278,154)	(566,886)	(318,563)	(537,550)
Gain/(loss) on foreign exchange	15,057	(125,002)	(20,238)	(125,653)
Unrealized gain on warrants, derivative liability warrants and convertible notes	2,809,340	369,849	15,259,393	3,502,831
Realized gain/(loss) on exercise or conversion of warrants, derivative liability warrants and convertible notes	219,307	(835,880)	(1,895,344)	(979,630)
Amortization of deferred loss	(2,761,152)	(135,082)	(5,026,442)	(135,082)
	44,131	(1,268,020)	8,048,559	1,783,566
LOSS BEFORE TAX	(9,048,410)	(9,926,390)	(11,216,557)	(14,030,909)
Tax refund/(expense)	15,396	1,075	16,128	(5,997)
LOSS FOR THE PERIOD	\$ (9,033,014)	\$ (9,925,315)	\$ (11,200,429)	\$ (14,036,906)
OTHER COMPREHENSIVE INCOME FOR THE PERIOD				
Fair market value changes in convertible notes due to changes in own credit risk	(280,051)	(2,309,141)	(985,637)	(870,956)
LOSS AND OTHER COMPREHENSIVE LOSS FOR THE PERIOD	\$ (9,313,065)	\$ (12,234,456)	\$ (12,186,066)	\$ (14,907,862)
LOSS PER SHARE				
Basic and diluted loss per share	\$ (0.13)	\$ (0.81)	\$ (0.19)	\$ (1.21)



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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 expansion of reimbursement for the Reducer, the continued preparation for the US trial of the Reducer, the expectation to file an IDE Supplement in the third quarter, the pursuit of a CE mark decision for the Tiara TA device under MDR 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 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 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 Information Form and in the Management's Discussion and Analysis for the three and six months ended June 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.