

Neovasc Announces Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Corporate Update

VANCOUVER and MINNEAPOLIS – ([NewMediaWire](#)) – March 30, 2023 – Neovasc Inc. (“Neovasc” or the “Company”) (NASDAQ, TSX: NVCN) today reported financial results for the fourth quarter and year ended December 31, 2022.

Recent Highlights

- Generated revenue of \$1.45 million in the fourth quarter of 2022 (91% growth against the fourth quarter of 2021), and \$3.8 million for the full year 2022 (49% growth against fiscal 2021).
- On March 13, 2023, following the conclusion of oral arguments on March 9, 2023, the U.S. Court of Appeals for the Federal Circuit issued a summary order affirming the judgment of the District Court for the Southern District of New York (the “District Court”). On February 1, 2022, the District Court had dismissed the class action litigation against the Company and certain of its officers, with prejudice and without leave to amend.
- Acquisition by Shockwave Medical, Inc., which was announced on January 17, 2023 is expected to close early in Q2 2023 (the “Arrangement”).

“Earlier this month we were pleased to announce the shareholder approval of the acquisition of Neovasc by Shockwave Medical,” said Fred Colen, President and Chief Executive Officer. “We are working diligently with the Shockwave Medical team to ensure a quick and seamless transaction, and look forward to announcing the close of transaction in the near term.”

Financial Results for the Fiscal Year Ended December 31, 2022

Revenues increased by 49% to \$3,805,017 for the year ended December 31, 2022, compared to revenues of \$2,547,406 for the same period in 2021.

The cost of goods sold for the year ended December 31, 2022 was \$773,834 compared to \$555,697 for the same period in 2021. The overall gross margin for the year ended December 31, 2022 was 80%, compared to 78% gross margin for the same period in 2021.

Total expenses for the year ended December 31, 2022 were \$37,177,906 compared to \$33,101,250 for 2021, representing an increase of \$4,076,656.

The operating losses and comprehensive losses for the year ended December 31, 2022 were \$34,146,723 and \$41,421,356, respectively, or \$15.07 basic and diluted loss per share, as compared with \$31,109,541 operating losses and \$25,158,376 comprehensive losses, or \$9.88 basic and diluted loss per common share in the capital of the Company (each, a “Share”), for the same period in 2021.

ABOUT NEOVASC

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™, for the transcatheter treatment of mitral valve disease, which is under clinical investigation in the United States, Canada, Israel, and Europe and for which activity has been indefinitely paused. 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.

Consolidated Statements of Financial Position

As at December 31,
(Expressed in U.S. dollars)

	2022	2021	2020
ASSETS			
Current assets			
Cash and cash equivalents	\$ 25,791,598	\$ 51,537,367	\$ 12,935,860
Accounts receivable	2,503,956	1,369,455	987,057
Finance lease receivable	-	43,543	95,849
Inventory	1,086,038	1,480,077	1,006,850
Prepaid expenses and other assets	403,249	787,734	705,471
Total current assets	29,784,841	55,218,176	15,731,087
Non-current assets			
Restricted cash	443,595	469,808	470,460
Right-of-use asset	341,609	456,339	830,551
Finance lease receivable	-	-	42,841
Property and equipment	161,236	182,041	803,280
Deferred loss on 2020 derivative warrant liabilities	1,401,110	4,300,484	7,595,093
Deferred loss on 2021 derivative warrant liabilities	6,596,721	9,898,475	-
Total non-current assets	8,944,271	15,307,147	9,742,225
Total assets	\$ 38,729,112	\$ 70,525,323	\$ 25,473,312
LIABILITIES AND EQUITY			
Liabilities			
Current liabilities			
Accounts payable and accrued liabilities	\$ 9,850,077	\$ 4,629,163	\$ 7,243,500
Lease liabilities	219,522	273,145	342,910
2019 Convertible notes	-	38,633	38,633
2020 Convertible notes, warrants and derivative warrant liabilities	-	40,587	37,525
Total current liabilities	10,069,599	4,981,528	7,662,568
Non-Current Liabilities			
Lease liabilities	143,881	272,652	596,881
2019 Convertible notes	-	6,548,796	6,156,724
2020 Convertible notes, warrants and derivative warrant liabilities	357,924	6,088,728	\$9,079,622
2021 Derivative warrant liabilities	43,616	405,508	-
2022 Convertible Note	12,275,067	-	-
Total non-current liabilities	12,820,488	13,315,684	15,833,227
Total liabilities	\$ 22,890,087	\$ 18,297,212	\$ 23,495,795
Equity			
Share capital	\$ 441,369,134	\$ 439,873,457	\$ 369,775,383
Contributed surplus	43,892,545	40,355,952	35,045,056
Accumulated other comprehensive loss	(6,229,804)	(7,885,024)	(7,615,717)
Deficit	(463,192,850)	(420,116,274)	(395,227,205)
Total equity	15,839,025	52,228,111	1,977,517
Total liabilities and equity	\$ 38,729,112	\$ 70,525,323	\$ 25,473,312

NEOVASC INC.

Consolidated Statements of Loss and Comprehensive Loss

For the years ended December 31,
(Expressed in U.S. dollars)

	2022	2021	2020
REVENUE	\$ 3,805,017	\$ 2,547,406	\$ 1,957,362
COST OF GOODS SOLD	773,834	555,697	446,239
GROSS PROFIT	3,031,183	1,991,709	1,511,123
EXPENSES			
Selling expenses	4,848,906	2,996,292	2,196,803
General and administrative expenses	14,785,424	14,655,957	14,081,153
Product development and clinical trials expenses	17,543,576	15,449,001	20,401,595
TOTAL EXPENSES	37,177,906	33,101,250	36,679,551
OPERATING LOSS	(34,146,723)	(31,109,541)	(35,168,428)
OTHER (EXPENSE)/ INCOME			
Interest and other income	472,902	551,940	1,394,035
Interest and other expense	(1,518,055)	(631,199)	(1,035,957)
Loss on foreign exchange	(56,634)	(50,798)	(256,585)
Unrealized gain on warrants, derivative liability warrants and convertible notes	215,438	17,404,002	8,528,255
Realized (loss)/gain on exercise or conversion of warrants, derivative liability warrants and convertible notes	(1,845,822)	(1,898,092)	814,083
Amortization of deferred loss	(4,300,786)	(9,068,689)	(3,494,501)
TOTAL OTHER (EXPENSE)/ INCOME	(7,032,957)	6,307,164	5,949,330
LOSS BEFORE TAX	(41,179,680)	(24,802,377)	(29,219,098)
Tax (expense)/recovery	(24,738)	(86,692)	524,057
LOSS FOR THE YEAR	\$ (41,204,418)	\$ (24,889,069)	\$ (28,695,041)
OTHER COMPREHENSIVE LOSS FOR THE YEAR			
Fair market value changes in convertible notes due to changes in own credit risk	(216,938)	(269,307)	(1,475,210)
	(216,938)	(269,307)	(1,475,210)
LOSS AND OTHER COMPREHENSIVE LOSS FOR THE YEAR	\$ (41,421,356)	\$ (25,158,376)	\$ (30,170,251)
LOSS PER SHARE			
Basic and diluted loss per share	\$ (15.07)	\$ (9.88)	\$ (43.04)

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 proposed timing and completion of the Arrangement; the satisfaction of the conditions precedent to the Arrangement and timing. 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 that a condition to closing of the Arrangement may not be satisfied; 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; if the Arrangement is not completed, 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 the Company’s Shares; risks relating to the possibility that the Company’s Shares may be delisted from the Nasdaq Capital Market or the Toronto Stock Exchange, which could affect their market price and liquidity; risks relating to the 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 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 most recent Annual Information Form and Management’s Discussion and Analysis for the year ended December 31, 2022, which are available on SEDAR at www.sedar.com and on Form 6-K filed with the Securities and Exchange Commission at 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.

Contacts

Investors:

Mike Cavanaugh

ICR Westwicke

Phone: +1.617.877.9641

Email: Mike.Cavanaugh@westwicke.com

Media:

Sean Leous

ICR Westwicke

Phone: +1.646.866.4012

Email: Sean.Leous@westwicke.com