



# **Neovasc Inc. Management's Discussion and Analysis**

Form 51-102F2

**For the Three and Nine Months ended  
September 30, 2009 and 2008**

**Q3  
2009**

## **FORM 51-102F1: MANAGEMENT'S DISCUSSION AND ANALYSIS**

This discussion and analysis covers the unaudited interim consolidated financial statements for the three and nine months ended September 30, 2009 and 2008.

The Management's Discussion and Analysis ("MD&A") of Financial Condition and Results of Operations should be read in conjunction with the unaudited interim consolidated financial statements and notes thereto for the three and nine months ended September 30, 2009 (included as part of Neovasc Inc.'s quarterly filing) as well as the audited consolidated financial statements and notes thereto and the MD&A for the fiscal year ended December 31, 2008 (collectively known as the "Financial Statements").

### **FORWARD-LOOKING STATEMENTS**

This discussion and analysis, contains forward-looking statements that are not based on historical fact, including without limitation statements containing the words "believes", "may", "plan", "will", "estimate", "continue", "anticipates", "intends", "expects", and similar expressions, including the negative of such expressions. These statements are only predictions.

Forward-looking statements and information should be considered carefully. Undue reliance should not be placed on forward-looking statements and information as there can be no assurance that the plans, intentions or expectations upon which they are based will occur. By their nature, forward-looking statements and information involve numerous assumptions, known and unknown risks and uncertainties, both general and specific, which contribute to the possibility that the predictions, forecasts, projections and other forward-looking statements and information will not occur and may cause actual results or events to differ materially from those anticipated in such forward-looking statements and information. The assumptions made by Neovasc include the ability of the Company to obtain and enforce timely patent protection for its technologies, the development of products; the timing of receipt of regulatory approvals; the sufficiency of budgeted capital expenditures in carrying out planned activities; and the availability and cost of labour and services (see 'Risks and Uncertainties').

More particularly and without limitation, this discussion and analysis contains forward-looking statements and information concerning the potential of Neovasc and the timing of market acceptance of the Company's technology products.

There are also other factors that may cause the actual results, events or developments to be materially different

from any future results, events or developments expressed or implied by such forward-looking statements and information. Such factors include, among others, the stage of development of Neovasc, additional capital requirements, the impact of the global economic downturn, the ability to develop, manufacture and commercialize its products in a cost-effective manner, the ability to integrate newly-acquired businesses and the ability to protect Neovasc's intellectual property.

A more complete discussion of the risks and uncertainties facing Neovasc appears in Neovasc's management information circular available at [www.sedar.com](http://www.sedar.com). Neovasc disclaims any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements or information contained herein to reflect future results, events or developments, except as required by law.

All financial information is prepared in accordance with Canadian generally accepted accounting principles ("GAAP") and is expressed in Canadian dollars.

Date: October 28, 2009

### **OVERVIEW**

#### **Description of the Business**

Neovasc Inc. is a specialty vascular device company that develops, manufactures and markets medical devices for the rapidly growing vascular and surgical marketplace. The company's current products include the Neovasc Reducer™, a novel product in development to treat refractory angina, as well as a line of advanced biological tissue products that are used as surgical patches for a variety of procedures and as key components in a range of third party medical products such as minimally invasive artificial heart valves.

Neovasc's business operations started in March 2002, with the acquisition of Neovasc Medical Inc. (formerly PM Devices Inc. ("PMD")). PMD manufactures a line of collagen based surgical patch products made for use in cardiac reconstruction and vascular repair procedures as well as other surgeries. The products are made from chemically treated bovine and equine pericardial tissue.

In May 2003, Neovasc acquired Angiometrx Inc. ("ANG"). ANG has developed a technology called the "Metricath® System," a catheter-based device that allows clinicians to measure artery and stent size and confirm stent deployment during interventional treatment of coronary and peripheral artery disease.

In July, 2008, Neovasc acquired two pre-commercial vascular device companies based in Israel: Neovasc Medical Ltd. ("Neovasc Medical") and B-Balloon Ltd. ("B-

Balloon”) (the “Acquisitions”). Neovasc Medical is developing a novel catheter-based treatment for refractory angina, a debilitating condition resulting from inadequate blood flow to the heart muscle. Refractory angina affects millions of patients and at present there is no effective cure. B-Balloon is developing a suite of vascular catheter products to solve problems physicians frequently encounter when attempting to place vascular stents at locations where an artery branches from the aorta (the “ostium”) or where an artery splits into multiple branches (a “bifurcation”).

## Product Portfolio

### Peripatch Products

Neovasc manufactures the *PeriPatch™* line of advanced biological tissue products that are manufactured from pericardium, which is the protective sac that surrounds the heart of an animal. Neovasc uses its proprietary processes to convert raw pericardial tissue from animal sources into sheets of implantable tissue that can be used as a reinforcement during surgery (for example to patch a hole in an artery or to help repair a hernia) or that can be incorporated into third party medical devices (for example for use as the material for artificial heart valve leaflets or as a covering on a vascular stent). Peripatch tissue retains the mechanical characteristics of natural tissue and is readily incorporated into the body without rejection. Neovasc’s Peripatch material was originally developed to fabricate artificial heart valves and has a 20-year history of successful implantation for heart valve and other surgical applications. Peripatch tissue can be manufactured to meet the mechanical and biological characteristics required for a wide variety of applications, such as surgical reinforcement patches or aortic heart valve leaflets.

The product line includes: the *PeriPatch™ Sheet*, and *PeriPatch™ EQ Sheet*, which are rectangular patches made from bovine (cow) or equine (horse) tissue, applied as internal bandages to repair weak or damaged organs or vessels. These are typically supplied sterile to customers who then use the sheets in surgical procedures.

The company also provides a range of custom Peripatch products to industry customers for incorporation into their own products. These include Peripatch tissues fabricated from bovine, equine and porcine sources and offered in a wide variety of shapes and sizes. Neovasc works closely with these industry customers to develop and supply tissue to meet their specific needs. This often includes providing tissue in custom shapes or molded to 3-D configurations. The company also provides product development and specialized manufacturing services related to PeriPatch tissue-based products.

### Regulatory Status

The Peripatch Sheets are cleared for sale in the United States, Canada and Mexico. The Peripatch EQ Sheet is approved for sale in the European Union and in Canada. A number of 3<sup>rd</sup> party products which incorporate Peripatch tissue are approved for sale or have pending approvals in various markets. There is no assurance that these approvals for 3<sup>rd</sup> party products will be obtained.

### Distribution

Certain sizes of sterile Peripatch and Peripatch EQ Sheets for surgical repair, specifically “strips” which are used primarily for vascular reconstruction procedures, are distributed exclusively by LeMaitre Vascular (Boston, MA) in the United States and Europe. Non-strip sizes of Peripatch Sheets for surgical repair are distributed by LeMaitre Vascular as well as a number of other independent distributors in Europe and elsewhere. The Company’s goal is to steadily increase its distribution reach in new target markets, while increasing market share in current markets and in particular in the United States.

Distribution of custom Peripatch tissue products to industry customers is handled directly by Neovasc through its business and product development group.

### Neovasc Reducer

The Neovasc Reducer™ is a treatment for patients with refractory angina. Refractory angina patients have severe, debilitating chest pain due to insufficient blood supply to the heart muscle, or myocardium, which is not amenable to revascularization. Using a simple catheter-based procedure, the Reducer is implanted in the coronary sinus, the major blood vessel that sends de-oxygenated blood from the heart back to the systemic circulation. The Reducer has been clinically demonstrated to provide significant relief of chest pain in refractory angina patients. There are approximately 1,000,000 new patients each year in the United States and Europe with recurrent angina who are potential candidates for the Neovasc Reducer, either because they cannot be revascularized or because they are otherwise poorly managed using conventional medical therapies. These patients represent an annual market opportunity of over \$3 billion for the Reducer product. The initial target market for the Reducer product is patients presenting with refractory angina with no other treatment options. Once physicians have adopted Reducer for use in these refractory patients, it is expected that there will be a natural spillover into the broader recurrent angina market, which represents a substantially larger patient population.

The Neovasc Reducer is an hourglass-shaped, balloon-expandable, stainless steel “stent-like” device, which is implanted in the coronary sinus, creating a restriction in venous outflow from the myocardium. It is implanted

using conventional percutaneous techniques. The Reducer is provided sterile and pre-loaded on a balloon catheter system. The system is 9F sheath compatible and operates over a .035" guidewire. The implantation procedure is quick and requires minimal training. Once guidewire access to the coronary sinus is achieved, implantation typically takes less than 10 minutes.

Following implantation, the bare metal Neovasc Reducer is incorporated into the endothelial tissue and creates a permanent (but reversible) narrowing in the coronary sinus. The coronary sinus is narrowed from a typical diameter of 10-12mm to approximately 3mm at the site of implantation. This narrowing slightly elevates the venous outflow pressure that restores a more normal ratio of epicardial/endocardial blood flow between the outer and inner layers of the ischemic areas of the heart muscle. This results in improved perfusion of the endocardium, which helps relieve ischemia. The physiological mechanism behind this effect is well documented in medical literature.

The clinical utility of this approach is demonstrated by a number of analogous approaches used in the past that achieved excellent clinical outcomes for angina patients by constricting or intermittently blocking the coronary sinus to improve perfusion to the heart muscle. However, these therapies required the use of highly invasive surgery or leaving a catheter in the heart for a prolonged period, making them impractical or clinically unacceptable for use in modern medical practice. Neovasc Reducer was developed to deliver this therapy in a safe, simple and effective manner via a catheter that is consistent with modern medical practice.

The Neovasc Reducer has demonstrated excellent results in multiple animal studies and in a clinical trial of 15 patients suffering from chronic refractory angina who were followed for three years after implantation. The six-month results from this clinical trial were published in the *Journal of the American College of Cardiology* and three-year data is now being compiled and submitted for publication. In this clinical trial, implantation of the Reducer resulted in significant clinical improvements in stress test and perfusion measurements, as well as an overall quality of life improvement in the majority of the patients.

#### *Regulatory Status*

The Neovasc Reducer is not yet approved for sale. Neovasc has completed development of the commercial-generation Reducer and the product has been transferred to pilot manufacture. The company expects CE mark regulatory approval for the Reducer within the next year, which will enable sales to begin in Europe. There is no assurance that the CE mark will be granted in the time frame anticipated by management, or granted at any time in the future. Neovasc is presently

developing a US regulatory approval strategy that will address the requirement for a larger randomized clinical trial that is mandatory in the US. US approval is expected in about four years. There is no assurance that US regulatory approval will be granted in the time frame anticipated by management, or granted at any time in the future.

#### **Metricath System**

The Metricath product line consists of a small, IV pole-mounted console unit and two distinct catheter models: the *Metricath Libra*<sup>®</sup> measure-only catheter, and the *Metricath Gemini*<sup>®</sup> measure-and-treat catheter.

Metricath catheters are used during angioplasty, a procedure used to open arteries where blood flow is restricted by arterial plaque (the accumulation of fats and cholesterol). Metricath provides the user with precise measurements of the artery by inflating the balloon at the catheter's tip and monitoring its volume and pressure as it comes up against the artery walls. These measurements allow doctors to quickly diagnose artery blockages and treat them with balloons and stents that are optimally sized for the artery.

The current generation of Metricath has been designed to measure the precise size of arteries to assist with arterial stent implantation and related procedures. The company is also exploring opportunities to use the existing platform to develop additional Metricath products which will measure the precise size of the aorta (the large artery which distributes oxygenated blood from the heart) to assist in the implantation of minimally invasive artificial aortic heart valves or to measure holes in the "septum" or wall that separates certain chambers of the heart to assist physicians in selecting devices which are implanted through catheters to close these defects.

#### *Regulatory Status*

The Metricath Libra is cleared for sale in the United States, Canada, the European Union, Australia, Brazil and Israel. The Metricath Gemini is cleared for sale for peripheral artery use in the United States, for coronary arteries in Canada, and for all vascular applications in the European Union.

#### *Distribution*

During 2008, the Metricath line was sold via direct sales force in the United States and Canada and via distributors in other countries. As part of a larger cost reduction exercise the Metricath direct sales force staff were terminated in the fourth quarter of 2008, and there is presently a limited sales channel for the Metricath product.

#### **Additional Products and Third Party Sales**

Neovasc provides consulting and original equipment manufacturing services to other medical device

companies when these services fall within the scope of its expertise and capabilities. These activities are substantially focused on providing specialized development and manufacturing services for industry customers who incorporate the company's Peripatch tissue materials into their vascular device products such as heart valves. The goal of these activities is to drive near term revenues as well as support development of a long term revenue stream through the ongoing provision of tissue and manufacturing services to customers with successful device products that incorporate Neovasc tissue. Revenue earned from various contract agreements varies throughout the year depending on customer needs.

### **Regulatory Affairs and Clinical Trials**

In the second quarter of 2009, the company submitted a CE mark application for the Neovasc Reducer product. Review of this application is ongoing.

During the second quarter of 2009 the company completed the 3-year follow-up on the 15 patients enrolled in the clinical study for the Neovasc Reducer. These results have been analyzed and prepared for presentation. The Company is currently seeking publication of the data through a suitable medical forum.

The company is presently planning two additional trials for the Reducer product, one in Europe which will be focused on building the volume of safety and efficacy data to support use of the product, and a second trial in the US which will be the pilot study for a larger randomized trial required to obtain FDA approval to market the Neovasc Reducer product in the US. Key investigators for these trials have already been identified and have agreed to participate.

In the second quarter of 2009 the company received a number of additional questions from the FDA related to its PMA application for the Metricath Gemini product for use in measuring coronary arteries for stent procedures. The company is presently evaluating these questions and determining how to respond. The Company will consider factors such as the cost of responding to the questions from the FDA and the expected likelihood of receiving a PMA approval in comparison to the potential revenues expected from the product line. There is a possibility that the Company may abandon its PMA application for the Metricath Gemini.

### **Product Development**

Product development at the Company is presently focused on completing the development and commercialization of the Neovasc Reducer product. All other internal development projects are on hold to conserve cash. The company is also undertaking a substantial volume of product development work under contract for third parties. These third party projects are typically focused on supporting the development of

products that incorporate Neovasc's PeriPatch tissue. These activities both generate near term revenues from consulting activities for Neovasc and also are expected to drive longer term growth as a result of the revenues that will result from future sales of new PeriPatch tissue products as well as the related manufacturing services we will provide for these customers once their products reach the market.

### **Sales & Marketing**

The Company's sales and marketing activities are currently focused on reaching tissue product customers and distributors and contract manufacturing clients.

In preparation for CE mark approval of the Neovasc Reducer, the company is also developing a strategy for pilot launch of the product into the European marketplace.

### **TRENDS, RISKS AND UNCERTAINTIES**

The Company has incurred operating losses of \$802,448 and \$3,879,139 for the three and nine months ended September 30, 2009, respectively (2008: \$4,004,023 and \$7,661,271) and has a deficit of \$63,769,102 at September 30, 2009 (September 30, 2008: \$33,291,669). The Company's ability to continue as a going concern is dependent on the profitable commercialization of its products or obtaining additional debt or equity financing to fund ongoing operations until profitability is achieved. The current economic crisis which has significantly tightened the credit and equity markets may result in required funds not being available to the Company at the time required or on terms acceptable to the Company and may also reduce demand for the Company's products.

Neovasc has a limited operating history which makes it difficult to predict how its business will develop or its future operating results. The Company has a history of fiscal losses since its inception and will need to generate significantly greater revenues than it has to date to achieve and maintain profitability. There is no certainty of future profitability, and results of operations in future periods cannot be predicted based on results of operations in past periods. Generally, the securities of the Company should be considered a highly speculative investment.

Neovasc is subject to risks and uncertainties associated with operating in the life sciences industry and as a company engaged in significant development, regulatory, production and commercialization activity. Neovasc cannot anticipate or prevent all of the potential risks to its success, nor predict the impact of any such risk. To the extent possible, management implements strategies aimed at reducing or mitigating risks and uncertainties associated with its business.

Operating risks include but are not limited to: market acceptance of the Company's technology and products; the Company's ability to obtain and enforce timely patent protection of its technology and products; the Company's ability to develop, manufacture and commercialize its products cost-effectively and according to regulatory standards of numerous governments; the competitive environment and impact of technological change and/or product obsolescence; the continued availability of capital to finance the Company's activities; the Company's ability to conduct and complete successful clinical trials; the Company's ability to garner regulatory approvals for its products in a timely fashion; the Company's ability to attract and retain key personnel, effectively manage growth, and smoothly integrate newly acquired businesses or technologies; limitations on third-party reimbursement; instances of product or third-party liability; dependence on a single supplier for some products; animal disease or other factors affecting the quality and availability of raw materials; conflicts of interest among the Company's directors, officers, promoters and members of management; fluctuations in the values of relative foreign currencies; volatility of the Company's share price; fluctuations in quarterly financial results; unanticipated expenses; changes in business strategy; impact of any negative publicity; general political and economic conditions; and Acts of God and other unforeseeable events, natural or human-caused.

## **FOREIGN OPERATIONS**

The majority of the Company's revenues are derived from product sales in the United States and Europe, primarily denominated in United States dollars and Euros. The Company expects that international sales will continue to account for a significant portion of its revenues that are denominated in foreign currencies. Consequently, a decrease in the value of a relevant foreign currency in relation to the Canadian dollar, occurring after establishment of prices and before receipt of payment by Neovasc, has an adverse effect on the Company's results of operations. The fluctuation of foreign exchange may impose an adverse effect on the Company's results of operations and cash flows in the future. Additionally, Neovasc may be materially and adversely affected by increases in duty rates, exchange or price controls, repatriation restrictions, or other restrictions on foreign currencies. The Company's international operations are subject to certain other risks common to international operations, including, without limitation: government regulations; import restrictions and, in certain jurisdictions, reduced protection for the Company's intellectual property rights.

Foreign currency translation gains and losses arising from normal business operations are credited to or charged to operations in the period incurred. To date, Neovasc has not entered into any foreign exchange forward contracts.

## **SELECTED ANNUAL FINANCIAL INFORMATION**

The following discussion should be read in conjunction with the unaudited interim consolidated financial statements for the three and nine months ended September 30, 2009 and 2008.

## **DISCUSSION OF OPERATIONS AND FINANCIAL CONDITION**

This section analyzes the significant changes in the unaudited interim consolidated financial statements of operations and deficit and cash flows for the three and nine months ended September 30, 2009, compared to those for the same periods ended September 30, 2008 and compares the financial condition at September 30, 2009 to that at December 31, 2008.

The statements of operations include the results of Neovasc, PMD, ANG, B-Balloon and Neovasc Medical for the three and nine months ended September 30, 2009. Comparatively, the results of operations for the nine months ended September 30, 2008 only reflected the results of Neovasc, ANG and PMD for the nine months ended September 30, 2008 and those of Neovasc Medical and B-Balloon for the three months from July 1 to September 30, 2008.

### **Results of Operations**

Results for the three and nine months ended September 30, 2009 and 2008 follow:

#### **Net Losses**

The consolidated net loss for the three and nine months ended September 30, 2009 was \$802,448 and \$3,879,139 or \$0.03 and \$0.16 basic loss per share, as compared with a net loss of \$4,004,023 and \$7,661,271, or \$0.23 and \$0.80 basic loss per share, for the comparable periods in 2008.

#### **Revenues**

Revenues increased 70% year-over-year to \$1,000,367 for the quarter ended September 30, 2009 from \$587,884 for the same period in 2008. For the nine months ended September 30, 2009, revenues increased 34% to \$1,956,175 from \$1,454,430 for the same period in 2008. These increases primarily reflect increased revenues from our tissue products and services business.

Sales of tissue and surgical products and services for the three months ended September 30, 2009 were \$992,839, compared to \$534,197 in the same period in 2008, an increase of 86%. Sales of tissue products and services for the nine months ended September 30, 2009 were \$1,928,903, as compared to sales of \$1,274,603 for the same period of 2008, representing an increase of 51%. These revenues include sales of Neovasc's

Peripatch products, as well as consulting services and contract manufacturing revenues for tissue and surgical products. The company is continuing to develop additional consulting services and contract manufacturing clients.

Sales of catheter products for the nine months ended September 30, 2009 were \$27,272, an 85% decrease over sales of \$179,827 in the comparable period in 2008. The termination of our direct sales force for Metricath products at the end of 2008, a strategic decision to allow the company to focus on its most promising growth opportunities, contributed to this decrease in sales.

#### **Cost of Sales**

The cost of sales for the three and nine months ended September 30, 2009 was \$465,565 and \$892,590, respectively, as compared to \$283,070 and \$711,674 in the comparable periods in 2008. The overall gross margin for the first three quarters of 2009 rose to 54%, as compared to 51% in 2008. The improvement in gross margin reflects the company's strategic shift to certain contract and specialty tissue patch products with higher margins.

#### **Expenses**

Total expenses for the three and nine months ended September 30, 2009 were \$1,188,672 and \$4,806,555, respectively, as compared to \$3,201,046 and \$7,184,796 for the same periods in 2008. Total expenses declined by 63% year-over-year for the three-month period and 33% for the nine-month period.

Sales and marketing expenses declined 88% to \$94,412 for the three months ended September 30, 2009, from \$816,421 for the same period in 2008, and they declined 76% to \$560,980 for the nine months ended September 30, 2009 from \$2,351,416 for the same period in 2008. The Company terminated its direct sales force for its catheter products in the fourth quarter of 2008 and will continue to minimize sales and marketing costs while it focuses on growing its business-to-business revenue streams.

General and administrative expenses were \$576,804 and \$1,986,637 for the three and nine months ended September 30, 2009 as compared to \$1,297,333 and \$2,614,981 for the three and nine months ended September 30, 2008, representing a decrease of 56% and 24% over the same periods of 2008. These

decreases reflect the Company's tighter business focus and the implementation of rigorous cost-cutting measures.

In the third quarter of 2009 the Company booked an additional accrual of \$98,212, increasing its Medsurge settlement provision to \$400,000. Medsurge was the former distributor of the Company's Peripatch biologic products. The distribution agreement was terminated in the fourth quarter of 2008. As part of the termination, Neovasc was required to partially reverse revenue reported in 2008 and also to receive back into inventory all product returned by Medsurge, the value of which was disputed. In an agreed settlement, Neovasc will pay 12 monthly installments of US\$30,000 each to Medsurge for the returned inventory. The payments began in September 2009.

Despite this one-time expense, the Company has been able to streamline its administrative expenses by minimizing administrative staff and curtailing its US listing and investor relations activities to achieve significant year-over-year reductions in administrative expenses.

Product development and clinical trial expenses were \$517,456 and \$2,258,938 for the three and nine months ended September 30, 2009 as compared to \$1,087,292 and \$2,123,995 for the same periods of 2008, representing a decrease of 52% for the three months and an increase of 6% for the nine months over the same periods in 2008. In the first nine months of 2009, product development expenditures were focused on activities supporting the CE mark submission for the Neovasc Reducer device. Also included in product development and clinical trial expenses in the third quarter was an accrual of \$65,000 for the costs associated with the suspension of certain research and development activities at the Israeli facility.

#### **Amortization and Other expenses**

Amortization and other expenses for the three and nine months ended September 30, 2009 were \$148,578 and \$136,169 as compared to amortization and other expenses of \$1,107,791 and \$1,219,231 for the same periods in 2008. The decrease for the three and nine months ended September 30, 2009 as compared to the prior year period in 2008 is attributable to an amortization charge of \$1,064,785 for intangible assets incurred in the third quarter of 2008, and \$nil in the same period of 2009.

## Quarterly Information

The following is a summary of selected unaudited financial information for the eight fiscal quarters to September 30, 2009:

	Quarter Ended - Unaudited			
	September 30 2009	June 30, 2009	March 31, 2009	December 31, 2008
<b>Sales</b>				
Catheter products	\$ 7,528	\$ 3,537	\$ 16,207	\$ 75,920
Tissue and surgical products and services	992,839	596,787	339,277	15,889
	<u>1,000,367</u>	<u>600,324</u>	<u>355,484</u>	<u>91,809</u>
Cost of sales	<u>465,565</u>	<u>277,265</u>	<u>149,760</u>	<u>(3,374)</u>
<b>Expenses</b>				
Selling	94,412	163,683	302,885	894,470
General and administration	576,804	659,004	750,829	844,819
Product development and clinical trials	517,456	864,702	876,780	977,874
Impairment of intangible assets	-	-	-	23,061,012
Inventory Write Down	-	-	-	532,521
Repayable contribution write back	-	-	-	(320,445)
	<u>1,188,672</u>	<u>1,687,389</u>	<u>1,930,494</u>	<u>25,990,251</u>
EBITDA	<u>(653,870)</u>	<u>(1,364,330)</u>	<u>(1,724,770)</u>	<u>(25,895,068)</u>
Amortization/Other expenses	<u>148,578</u>	<u>(33,879)</u>	<u>21,470</u>	<u>703,225</u>
<b>Net loss</b>	<u>\$ (802,448)</u>	<u>\$ (1,330,451)</u>	<u>\$ (1,746,240)</u>	<u>\$ (26,598,294)</u>
Basic loss per share	<u>\$ (0.03)</u>	<u>\$ (0.05)</u>	<u>\$ (0.10)</u>	<u>\$ (1.50)</u>

	Quarter Ended - Unaudited			
	September 30, 2,008	June 30, 2008	March 31, 2008	December 31, 2007
<b>Sales</b>				
Catheter products	\$ 53,687	\$ 45,904	\$ 80,236	\$ 81,004
Tissue/surgical products	534,197	387,157	353,249	545,970
	<u>587,884</u>	<u>433,061</u>	<u>433,485</u>	<u>626,974</u>
Cost of sales	<u>283,070</u>	<u>220,344</u>	<u>208,260</u>	<u>372,956</u>
<b>Expenses</b>				
Selling	816,421	785,491	749,504	785,773
General and administration	1,297,333	779,363	538,285	483,681
Product development and clinical trials	1,087,292	414,958	621,745	683,379
Inventory Write Down	-	94,404	-	434,961
	<u>3,201,046</u>	<u>2,074,216</u>	<u>1,909,534</u>	<u>2,387,794</u>
EBITDA	<u>(2,896,232)</u>	<u>(1,861,499)</u>	<u>(1,684,309)</u>	<u>(2,133,776)</u>
Amortization/Other expenses	<u>1,107,791</u>	<u>54,174</u>	<u>57,266</u>	<u>166,453</u>
<b>Net loss</b>	<u>\$ (4,004,023)</u>	<u>\$ (1,915,673)</u>	<u>\$ (1,741,575)</u>	<u>\$ (2,300,229)</u>
Basic loss per share	<u>\$ (0.23)</u>	<u>\$ (0.34)</u>	<u>\$ (0.32)</u>	<u>\$ (0.47)</u>

## **LIQUIDITY AND CAPITAL RESOURCES**

The Company finances its operations and capital expenditures with cash generated from operations, lines of credit, long-term debt and equity financings. At September 30, 2009, the Company had cash and cash equivalents of \$564,724, as compared to cash and cash equivalents of \$2,498,439 at December 31, 2008. In addition, at September 30, 2009 the Company had restricted cash related to a security on long-term debt of \$50,000 included in long-term assets.

At September 30, 2009 the Company had working capital of \$462,044 as compared to working capital of \$2,123,519 at December 31, 2008. The decrease in working capital during the nine months ended September 30, 2009 was predominantly due to a decline in cash, an increase in accounts receivable and inventory, and a decrease in accounts payable. The growth in accounts receivable and inventory are in line with revenue growth while the decrease in accounts payable reflects the decline in product development and other departmental expenditures.

Cash used in operations was \$721,230 and \$3,829,576 for the three and nine months ended September 30, 2009, as compared to \$2,796,298 and \$6,124,091 for the same periods of 2008. The decrease in cash usage for the nine months ended September 30, 2009 as compared to same period of 2008 is primarily the result of the Company's increased sales and decreased operating expenses in 2009.

Net cash used in investing activities was \$44,689 and \$53,234 on capital assets for the three and nine months ended September 30, 2009 compared to net cash generated of \$149,638 and \$135,946 in 2008. On July 1, 2008, the Company completed acquisition of B-Balloon and Neovasc Medical. The cash spent to acquire the companies was \$845,241, of which \$273,046 was unpaid and in accounts payable at September 30, 2008. On completing the transaction Neovasc acquired \$781,008 of cash and cash equivalents. During the three months ended September 30, 2008 the transaction generated net cash of \$208,813 while \$59,175 was spent on capital additions.

Net cash used by financing activities was \$9,828 for the three months ended September 30, 2009, compared to cash provided of \$7,868,681 in the same period of 2008. Net cash provided by financing activities was \$1,949,095 for the nine months ended September 30, 2009, compared to cash provided of \$7,852,263 in the same periods of 2008.

Concurrent with the acquisition completed on July 1, 2008, the Company issued 2,081,251 units of common shares at a price of \$4.00 per unit for gross proceeds of \$8,325,004 less issue costs of \$93,916, net \$8,231,088.

Each unit consists of one common share of the Company and 0.62 of a warrant. Each whole warrant is exercisable to purchase one additional common share of the Company at a price of \$5.00 for a period of 18 months from July 1, 2008. From the proceeds of the financing the Company repaid \$356,440 in loans from parties related to B-Balloon.

On April 23, 2009, the Company completed a non-brokered private placement of 9,523,810 units at the price of \$0.21 per unit for aggregate gross proceeds of \$2,000,000. Each unit consisted of one common share of Neovasc stock and one-half of one common share purchase warrants of Neovasc stock. Each whole warrant entitles the holder to purchase one common share of Neovasc stock at the exercise price of \$0.30 per share for a period of one year after the closing date of the offering. Share issue costs were \$20,314.

## **CONTINGENCIES**

On November 14, 2008, the Company received a claim from an ex-employee claiming wrongful dismissal. The employee was made redundant as part of the rationalization process undertaken subsequent to the period end. On September 22, 2009, the claim was settled for \$1,760.

## **SUBSEQUENT EVENTS**

There are no material events subsequent to September 30, 2009 to the date of this report.

## **OUTSTANDING SHARE DATA**

As at September 30, 2009, the Company had 27,384,365 common voting shares issued and outstanding. Further, the following securities are convertible into exercisable or exchangeable for common shares of the Company: 2,408,201 stock options with a weighted average price of \$0.51, and 6,827,671 share purchase warrants with exercise prices ranging from \$0.30 to \$5.00. The fully diluted share capital of the Company at September 30, 2009 is 36,620,237.

## **OFF BALANCE SHEET ARRANGEMENTS**

The Company has no off balance sheet arrangements.

## **RELATED PARTY TRANSACTIONS**

Related party transactions are disclosed in Note 12 of the unaudited interim consolidated financial statements. Neovasc has a contract with a corporation owned by its Chairman for his services that are invoiced monthly. All other related party transactions are invoiced to Neovasc on a month-to-month basis for services rendered. There

are no potential material termination clauses in any of the related party agreements.

### **PROPOSED TRANSACTIONS**

The Company is not party to any transaction requiring additional disclosure.

### **CONTROLS AND PROCEDURES**

The Chief Executive Officer (CEO) and Chief Financial Officer (CFO), in cooperation with the other members of senior management and Directors, are responsible for the Company's disclosure policy. The effectiveness of the Company's internal disclosure controls have been evaluated by the CEO and the CFO, and they have concluded that the Company's control procedure provides reasonable assurance that (i) information required to be disclosed by the Company in its annual and interim reports or other reports filed or submitted by it under applicable securities legislation is recorded, processed, summarized and reported within the prescribed time periods, and (ii) material information regarding the Company is accumulated and communicated to the Company's management, including its CEO and CFO, in a timely manner.

The CEO and CFO are responsible for the design of internal controls over financial reporting in order to provide reasonable assurance that the Company's financial reporting is reliable and that financial statements prepared for external purposes are prepared in accordance with Canadian GAAP and for the safeguarding of Company assets. The CEO and CFO are aware that internal controls relating to the accounting function could be strengthened by adhering to a strict policy of segregating the duties of accounting staff to reduce the risk of unauthorized journal entries being made or a misappropriation of cash. At the Company's current size, adoption of such a policy is impractical. To reduce these risks, the CFO reviews bank reconciliation statements and performs periodic reviews of non-standard entries after they have been recorded; all cheque payments require two signing authorities. The CEO periodically reviews recorded financial information. The CEO and CFO believe that these reviews are an adequate compensating control; accordingly, there are no plans to remediate this internal control weakness.

No material changes were made to the Company's system of internal controls relating to financial reporting during the three months ended March 31, 2009.

### **INTERNATIONAL FINANCIAL REPORTING STANDARDS ("IFRS")**

In February 2008, the Canadian Accounting Standards Board confirmed that the use of International Financial Reporting Standards ("IFRS") would be required for

Canadian publicly accountable enterprises for fiscal years beginning on or after January 1, 2011. In preparation for the conversion to IFRS, the Company has developed an IFRS changeover plan. We are currently in the process of reviewing the differences between current Canadian GAAP and IFRS and assessing the impacts on the other key elements of our conversion plan in this phase. These key elements include: accounting policy changes, information technology changes, education and training requirements, internal control over financial reporting, and impacts on business activities. While the Company has begun assessing the adoption of IFRS for 2011, the financial reporting impact of the transition to IFRS cannot be reasonably estimated at this time.