



**Neovasc Inc.**  
**Management's Discussion**  
**and Analysis**  
Form 51-102F1

**For the Years ended**  
**December 31, 2009 and 2008**

**Year End**  
**2009**

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

This discussion and analysis covers the audited consolidated financial statements of Neovasc Inc. (the "Company" or "Neovasc") for the years ended December 31, 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 audited consolidated financial statements and notes thereto for the year ended December 31, 2009 (included as part of Neovasc Inc.'s annual 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.

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: April 13, 2010

## 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™, an innovative 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. ("NMI")), NMI 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<sup>®</sup> 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 had developed and owned IP related to 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 had developed certain products intended to solve problems encounter by physicians 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™* (“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 made from bovine tissue are cleared for sale in the United States, Canada and Mexico. The Peripatch EQ Sheets made from equine tissue are approved for sale in the European Union and in Canada. A number of third-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 third-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™ (the “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 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 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 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. 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 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 was presented at the ACC annual scientific meeting in March 2010. 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 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 is presently initiating a clinical trial named “COSIRA” (Coronary Sinus Reducer for Treatment of Refractory Angina) which will provide data to support CE mark of the product. CE mark will enable the Company to begin marketing Reducer for use in Europe. COSIRA is expected to be a randomized, controlled multicentre trial with three to five investigation sites (two in Europe and one in Montreal Canada) and will commence in mid 2010. 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 to five 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.

## **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 Reducer product. This application was based on a small amount of clinical data from the initial Reducer trial and while this data was very positive, due to the small number of patients, the reviewers determined that additional clinical data is required to enable granting of the CE mark. The Company is presently initiating the COSIRA trial for this purpose.

During the year the Company moved to eliminate its Metricath product line and as a result abandoned the associated regulatory application for the Metricath Gemini product which was under review by the FDA.

### **Product Development**

Product development at the Company is presently focused on completing the development and commercialization of the Reducer product. 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 generate both 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 the Company 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.

## **TRENDS, RISKS AND UNCERTAINTIES**

The Company has incurred operating losses of \$4,476,284 for the year ended December 31, 2009 (2008: \$34,259,565) and has a deficit of \$64,366,247 at December 31, 2009 (2008: \$59,889,963). 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 audited consolidated financial statements for the years ended December 31, 2009 and 2008.

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

This section analyzes the significant changes in the audited consolidated financial statements of operations and deficit and cash flows for the year ended December 31, 2009, compared to those for the same period ended December 31, 2008 and compares the financial condition at December 31, 2009 to that at December 31, 2008.

The statements of operations include the results of Neovasc, NMI, ANG, B-Balloon and Neovasc Medical for the year ended December 31, 2009. Comparatively, the results of operations for year ended December 31, 2008 only reflect the results of Neovasc, ANG and NMI for the year ended December 31, 2008 and those of Neovasc Medical and B-Balloon from July 1 to December 31, 2008.

### **Results of Operations**

Results for the year ended December 31, 2009 and 2008 follow:

#### **Net Losses**

The consolidated net loss for the year ended December 31, 2009 was \$4,476,284 or \$0.18 basic loss per share, as compared with a net loss of \$34,259,565 or \$2.95 basic loss per share for the comparable period in 2008.

#### **Revenues**

Revenues increased 94% year-over-year to \$3,000,047 for the year ended December 31, 2009 from \$1,546,239 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 year ended December 31, 2009 were \$2,972,399, compared to \$1,284,121 in the same period in 2008, representing an increase of 131%. These revenues include sales of Neovasc's Peripatch products, as well as consulting services and contract manufacturing revenues for our other tissue and surgical products. The Company is continuing to develop additional consulting services and to add to its contract manufacturing clients.

Sales of catheter products for the year ended December 31, 2009 were \$27,648, an 89% decrease over sales of \$262,118 in the comparable period in 2008. The termination of our direct sales force for Metricath products at the end of 2008, a strategic decision intended 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 year ended December 31, 2009 was \$1,404,507, as compared to \$708,300 in the comparable period in 2008. The overall gross margin for 2009 was 53%, comparable to the 54% gross margin reported in 2008.

## Expenses

Total expenses for the year ended December 31, 2009 were \$5,848,916, as compared to \$33,175,047 for the same periods in 2008, representing a decrease of \$27,326,131. The decrease in expenses from 2008 to 2009 is attributable to the elimination of operating expenses incurred at our Israeli facility of \$1,003,516 and to non-recurring charges that included an impairment of intangible assets of \$23,061,012 and inventory write down of \$626,925 in 2008.

Sales and marketing expenses declined 79% to \$666,323 for the year ended December 31, 2009, from \$3,245,886 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 \$2,494,661 for the year ended December 31, 2009 as compared to \$3,459,800 for the same period of 2008, representing a decrease of 28%. 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 Medsurg settlement provision to \$400,000. Medsurg 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 Medsurg, the value of which was disputed. In an agreed settlement, Neovasc is paying 12 monthly installments of US\$30,000 each to Medsurg 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 \$2,687,932 for the year ended December 31, 2009 as compared to \$3,101,869 for the same period of 2008, representing a decrease of 13% over the same period in 2008. In 2009, product development expenditures were focused activities supporting the CE mark submission for the Reducer device. Also included in product development and clinical trial expenses 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 year ended December 31, 2009 were \$222,908 as compared to amortization and other expenses of \$1,922,457 for the same period in 2008. The decrease is largely attributable to an amortization charge of \$2,129,570 for intangible assets incurred in 2008.

Results for the quarter ended December 31, 2009 and 2008 follow:

## Net Losses

The consolidated net loss for the quarter ended December 31, 2009 was \$597,145 or \$0.02 basic loss per share as compared with a net loss of \$26,598,294 or \$1.50 basic loss per share for the comparative period in 2008.

## Revenues

Revenues for the quarter ended December 31, 2009 were \$1,043,872 compared to \$91,809 for the comparative period in 2008.

In the fourth quarter of 2008 the Company reduced revenues by \$516,601 associated with the repurchase of inventory from a terminated distribution agreement in accordance with EIC 156 *Accounting by a vendor for consideration given to a Customer*.

## Cost of Sales

The cost of sales for the quarter ended December 31, 2009 was \$511,917. The cost of sales for the quarter ended December 31, 2008 were positively impacted by termination of the distribution agreement (as discussed above as described in the annual results analysis) resulting in a net income from cost of sales of \$3,374.

## Expenses

Total expenses for the quarter ended December 31, 2009 and 2008 were \$1,042,361 and \$25,990,251 respectively. The decrease in expenses between the fourth quarters of 2008 to 2009 can be explained by a decrease in operating expenses incurred in Israel of \$617,811, an impairment of intangible assets of \$23,061,012 and inventory write down of \$532,521 in fourth quarter of 2008.

Sales and marketing expenses were \$105,343 for the quarter ended December 31, 2009 as compared to \$894,470 for the same periods in 2008, a decrease of 88%. The Company terminated its direct sales force for its catheter products in the fourth quarter of 2008.

General and administrative expenses for the quarter ended December 31, 2009 were \$508,024 as compared to \$844,819 in 2008, a decrease of 40%. The Company's tighter business focus and the implementation of rigorous cost-cutting measures contributed to the decrease.

Product development and clinical trial expenses of \$428,994 for the quarter ended December 31, 2009 as compared to \$977,874 for the quarter ended December 31, 2008, a decrease of 56%. There were no material development and clinical trial expenses incurred in Israel in 2009.

## Amortization and Other expenses

Amortization and other expenses for the quarter ended December 31, 2009 were \$86,739 as compared to other expense of \$703,225 for the same period in 2008. The decrease is attributable to an amortization charge of \$1,064,785 for intangible assets incurred in fourth quarter of 2008.

## Annual Information

The following is a summary of selected financial information for the three fiscal years to December 31, 2009:

	Years ended December 31		
	2009	2008	2007
Sales	\$ 3,000,047	\$ 1,546,239	\$ 1,517,873
Net loss	(4,476,284)	(34,259,565)	(7,830,954)
Basic and diluted loss per share	(0.18)	(2.95)	(0.08)
Total assets	2,273,314	4,820,523	5,689,800
Total long term liabilities	357,097	427,576	725,499

## Quarterly Information

The following is a summary of selected unaudited financial information for the eight fiscal quarters to December 31, 2009:

	Quarter Ended - Unaudited			
	December 31, 2009	September 30, 2009	June 30, 2009	March 31, 2009
<b>Sales</b>				
Catheter products	\$ 376	\$ 7,528	\$ 3,537	\$ 16,207
Tissue and surgical products and services	1,043,496	992,839	596,787	339,277
	<u>1,043,872</u>	<u>1,000,367</u>	<u>600,324</u>	<u>355,484</u>
Cost of sales	<u>511,917</u>	<u>465,565</u>	<u>277,265</u>	<u>149,760</u>
<b>Expenses</b>				
Selling	105,343	94,412	163,683	302,885
General and administration	508,024	576,804	659,004	750,829
Product development and clinical trials	428,994	517,456	864,702	876,780
	<u>1,042,361</u>	<u>1,188,672</u>	<u>1,687,389</u>	<u>1,930,494</u>
EBITDA	<u>(510,406)</u>	<u>(653,870)</u>	<u>(1,364,330)</u>	<u>(1,724,770)</u>
Amortization/Other expenses	86,739	148,578	(33,879)	21,470
<b>Net loss</b>	<u>\$ (597,145)</u>	<u>\$ (802,448)</u>	<u>\$ (1,330,451)</u>	<u>\$ (1,746,240)</u>
Basic loss per share	<u>\$ (0.02)</u>	<u>\$ (0.03)</u>	<u>\$ (0.05)</u>	<u>\$ (0.10)</u>

	Quarter Ended - Unaudited			
	December 31, 2008	September 30, 2008	June 30, 2008	March 31, 2008
<b>Sales</b>				
Catheter products	\$ 75,920	\$ 53,687	\$ 45,904	\$ 80,236
Tissue/surgical products	15,889	534,197	387,157	353,249
	<u>91,809</u>	<u>587,884</u>	<u>433,061</u>	<u>433,485</u>
Cost of sales	<u>(3,374)</u>	<u>283,070</u>	<u>220,344</u>	<u>208,260</u>
<b>Expenses</b>				
Selling	894,470	816,421	785,491	749,504
General and administration	844,819	1,297,333	779,363	538,285
Product development and clinical trials	977,874	1,087,292	414,958	621,745
Impairment of intangible assets	23,061,012			
Inventory Write Down	532,521	-	94,404	-
Repayable contribution write back	(320,445)			
	<u>25,990,251</u>	<u>3,201,046</u>	<u>2,074,216</u>	<u>1,909,534</u>
EBITDA	<u>(25,895,068)</u>	<u>(2,896,232)</u>	<u>(1,861,499)</u>	<u>(1,684,309)</u>
Amortization/Other expenses	703,225	1,107,791	54,174	57,266
<b>Net loss</b>	<u>\$ (26,598,294)</u>	<u>\$ (4,004,023)</u>	<u>\$ (1,915,673)</u>	<u>\$ (1,741,575)</u>
Basic loss per share	<u>\$ (1.50)</u>	<u>\$ (0.23)</u>	<u>\$ (0.34)</u>	<u>\$ (0.32)</u>

Revenues from tissue and surgical products and services have increased quarter over quarter during 2009 as the Company focused on its business-to-business sales strategy. Incremental revenue was generated each quarter as new customers were added and existing customers increased their demand. Since the termination of the Metricath sales force Catheter product revenues have declined quarter over quarter during 2009.

Selling expenses have fallen quarter over quarter and in comparison to 2008 as the Company has dismantled its external sales and marketing force and reduced selling expenses to meet the minimal needs of the business

development strategy now being pursued by the Company. General and administrative expense have been reduced quarter over quarter since the high point in the third quarter of 2008 immediately following the Acquisition of B-Balloon and Neovasc Medical on July 1, 2009 as the Company has pursued a vigorous cost reduction program. Product development and clinical trial costs have also been substantially reduced quarter over quarter in 2009 and in comparison to 2008 as the Company has focused its efforts on the development of the Reducer and has moth balled other development projects in order to preserve cash.

## **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 December 31, 2009, the Company had cash and cash equivalents of \$111,368, as compared to cash and cash equivalents of \$2,498,439 at December 31, 2008. In addition, at December 31, 2009 the Company had restricted cash related to a security on long-term debt of \$50,000 (December 31, 2008 - \$50,000) included in long-term assets.

At December 31, 2009 the Company had a negative working capital of \$28,502 as compared to working capital of \$2,123,519 at December 31, 2008. The decrease in working capital during 2009 was predominantly due to the net impact of a decline in cash, an increase in inventory, and a decrease in accounts payable. The growth in inventory is in line with revenue growth while the decrease in accounts payable reflects the decline in product development and other departmental expenditures. Since the year end and as disclosed in "Subsequent Events" the Company has raised additional equity financing to ensure that it meets its obligations as they fall due and to remedy the working capital deficiency present at the year end.

Cash used in operations was \$4,275,925 for the year ended December 31, 2009, as compared to \$8,477,808 for the same period in 2008. The decrease in cash usage for the year ended December 31, 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 \$51,281 on capital assets for the year ended December 31, 2009 compared to net cash used of \$111,998 in 2008. On July 1, 2008, the Company completed acquisition of B-Balloon and Neovasc Medical. On the completion of the Acquisitions Neovasc acquired \$781,008 of cash and cash equivalents. During the year ended December 31, 2008, \$47,765 was spent on capital additions.

Net cash provided by financing activities was \$1,940,135 for the year ended December 31, 2009, compared to cash provided of \$7,845,841 in the same period of 2008.

Concurrent with the Acquisition completed on July 1, 2008, the Company issued 2,081,251 units 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 consisted 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 warrant 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.

The Company has identified a number of factors that will negatively impact the Company's future working capital. They include but are not limited to: the anticipated increase of its accounts receivable and inventory balances in line with expected revenue growth and the repayment of certain liabilities, including US\$240,000 owed to Medsurg and an estimated \$60,000 owed to the Israeli tax authorities.

## **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**

On February 19, 2010, the Company completed a non-brokered private placement of 5,691,658 units at the price of \$0.27 per unit for aggregate gross proceeds of \$1,536,748. Each unit consisted of one common share of Neovasc stock and one-half of one common share purchase warrant of Neovasc stock. Each whole warrant will entitle the holder thereof to purchase one common share of Neovasc stock at the exercise price of \$0.40 per share for a period of one year after the closing date of the offering.

On February 19, 2010 the Company issued 1,527,715 incentive options to its board of directors, senior management and all other employees. The options have an exercise price of \$0.355 and expire five years after the grant date. Some options vested immediately, other vest over a four year period.

## **OUTSTANDING SHARE DATA**

As at December 31, 2009, the Company had 27,389,693 common voting shares issued and outstanding. Further, the following securities are convertible into exercisable or exchangeable for common shares of the Company: 2,329,671 stock options with a weighted average price of \$0.49, and 4,761,902 share purchase warrants with exercise prices of \$0.30. The fully diluted share capital of the Company at December 31, 2009 is 34,481,266.

## **OFF BALANCE SHEET ARRANGEMENTS**

The Company has no off balance sheet arrangements.

## **RELATED PARTY TRANSACTIONS**

Related party transactions are disclosed in Note 19 of the annual audited consolidated financial statements for the years ended December 31, 2009 and 2008. Neovasc had a contract with a corporation owned by its former CEO for his services that are invoiced monthly. The contract was terminated in January 2009.

## **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 year ended December 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 2008, in preparation for the conversion to IFRS, the Company has developed an IFRS changeover plan.

In 2009, the Company performed a diagnostic analysis of the key difference between Canadian GAAP, as currently applied by the Company, and IFRS for each significant accounting component to identify the areas that may be impacted by the transition. Based on the preliminary analysis, the Company assessed key areas that potential issues may arise during the transition, and ranked the potential impacts on the Company's financial statements as high, medium or low.

The key areas where significant changes in accounting policies are being assessed are as follows:

### **IFRS 2 – Share-based Payments:**

Areas impacted by applying IFRS 2 are method to account for graded-vesting features and forfeiture rate estimation. The Company uses straight-line method to account for graded-vesting features, and accounts for actual forfeitures as they occur under Canadian GAAP. Under IFRS 2, the Company is required to use the attribution method to account for graded-vesting features, and estimate a forfeiture rate at the date of grant on the basis of historical data and then revise it annually when circumstance indicates the changes of forfeiture rates. The adoption of IFRS 2 will likely result in a lower compensation expense being recorded in the income statement each period.

### **International Accounting Standards ("IAS") 16 – Property, Plant and Equipment ("PP&E"):**

IAS 16 allows an entity to use either the cost model or the revaluation model - all items of a class of PP&E carried at fair value rather than historical cost, for the subsequent measurement of cost. The Company elected to carry the fair value of the land and building starting from January 1, 2010 as the cost. The Company engaged a qualified appraiser to evaluate the fair value of our land and building. As a result of the appraisal, the fair value of the land and building will appreciate which will result in an increase in retained earnings as at the transition date.

### **IAS 21 – The Effects of Changes in Foreign Exchange Rates:**

The key difference between Canadian GAAP and IFRS is the requirement of determining the functional currency. Under IAS 21, the reporting entity must determine its functional currency in conjunction with the currency of the primary economic environment in which the entity operates. Based on the Company's current operations, the Company may be required to declare the U.S. dollar or European euro as our functional currency. However, the Company will still have the option under IFRS to report our financial results and position in Canadian dollars.

### **IAS 36 – Impairment of Assets:**

Under IAS 16, an impairment loss recognized in prior periods for an asset shall be reversed if there has been a change in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized, which is not allowed in the Canadian GAAP. As at December 31, 2008, the Company recognized an impairment charge of \$19,503,930 and wrote down its acquired technology and other intangible assets to \$nil. After applying IAS 16, if the circumstance indicates that the estimates and judgments regarding forecasts on the success and lifecycle of the technologies and future cash flows generated by the acquired technologies change, the impairment loss may be reversed.

### **IAS 12 – Income Taxes:**

The adoption of IAS 12 will change the measurement of some income tax amounts and require more extensive disclosure than under Canadian GAAP. However, the convergence project which is currently on-going between the IASB and the FASB will result in the elimination of the majority difference between Canadian GAAP and IFRS.

The other areas that will be impacted by the adoption of IFRS:

### **IAS 1 – Presentation of Financial Statements:**

IFRS introduces a number of changes to the format of the financial statements. Some of these are mandatory changes and will have a significant impact on the presentation of the Company's financial statements. IAS 1 requires a separate statement of retained earnings. However, Neovasc has the option of retaining its current financial statement presentation, subject to certain mandatory changes under IFRS, or making more significant changes to adopt IFRS presentation across its financial statements.

### **IFRS 1 – First-time Adoption of IFRS:**

IFRS generally has more extensive disclosure requirements than Canadian GAAP. To comply with the disclosure requirements, the Company will include the following reconciliations in its first IFRS financial statements: 1) a reconciliation of its total shareholders' equity reported under Canadian GAAP to its total shareholders' equity reported under IFRS for January 1, 2011 and December 31, 2011, and 2) a reconciliation of the earnings or loss reported under Canadian GAAP for the year ending December 31, 2011 to its earnings or loss under IFRS for the same period.

Our assessment to date of the implications of implementing IFRS has not revealed any requirements to significantly alter current information technology and data systems.

The Company will need to review and enhance internal controls over financial reporting to ensure that those controls accommodate the increased requirements of financial reporting and disclosure within an IFRS environment.