



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

Form 51-102F2

**For the Years ended  
December 31, 2008 and 2007**

**Year End  
2008**

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

This discussion and analysis covers the audited consolidated financial statements for the years ended December 31, 2008 and 2007.

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 year ended December 31, 2008 (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, 2007 (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: April 24, 2009

## OVERVIEW

### Description of the Business

Neovasc Inc. (formerly Medical Ventures Corp.) ("Neovasc" or the "Company") develops, manufactures and commercializes medical devices, focusing on products that address clinical needs in the vascular and surgical marketplace.

Neovasc was established to develop and commercialize a portfolio of medical devices from which the Company generates revenue from the distribution, licensing or sale of each of these products.

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<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.

### New Acquisitions

On January 30, 2008, Neovasc announced its intent to acquire 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”). Neovasc Medical and B-Balloon offer a potential pipeline of technologies that complement Neovasc’s existing products and sales call points.

The Acquisitions were completed on July 1, 2008. Neovasc issued 4,610,091 and 5,273,800 (post-consolidation) common shares for each of Neovasc Medical and B-Balloon.

Concurrently with the Acquisitions, the Company undertook:

- a) a private placement of units, each unit consisting of one common share priced at \$4.00 per share and a warrant to purchase 0.62 of a common share at price of \$5.00 per share for a period of 18 months from the date of closing. This price represented a significant premium to the market for Neovasc shares from the day prior to the announcement of the proposed transaction. The Frost Group, a shareholder of Neovasc Medical and B-Balloon, acted as lead investor for the private placement financing and, together with other investors, invested an aggregate of \$8,325,004 for approximately 11.76 per cent of Neovasc’s common shares (post-Acquisitions). The Frost Group is led by Dr. Phillip Frost, MD, a prominent U.S. pharmaceutical entrepreneur and managing director of the Frost Group, a Miami, Florida based private equity firm.
- b) a consolidation of its outstanding 111 million shares (136 million fully diluted), at 20 old shares for one new share.

Completing the Acquisitions significantly broadened the Company’s vascular device product and IP portfolio.

In conjunction with the completion of the Acquisitions, the Company changed its name to Neovasc Inc. to better reflect the focus of its ongoing operations as a specialty vascular device company.

### **Valuation of Goodwill and Technology**

Subsequent to the completion of the Acquisitions, an independent valuation of the fair value of the acquired tangible assets and identifiable intangible assets was conducted. The purchase price was allocated among acquired tangible assets, identifiable intangible assets and goodwill in accordance with Canadian GAAP. As a

result of the valuation and related purchase price allocation, \$448,475, \$10,907,300, and \$2,668,079 was initially allocated to liabilities, proprietary technologies and goodwill for B-Balloon, and \$716,688, \$10,726,200, and \$889,003 was initially allocated to tangible assets, proprietary technology and goodwill for Neovasc Medical.

### **Amortization of Technology**

The Company’s policy is to amortize the acquired technologies over the shorter of the life of the major patents for the technologies and the expected period of technological obsolescence. All the significant patents have at least 10 years to expiration and therefore the technologies are being amortized over the term until estimated technological obsolescence: 4 years for the B-Balloon technology and 7 years for the Neovasc technology. The ostial and bifurcation technologies acquired from B-Balloon are competing against other products to improve the treatment of disease at ostial and bifurcation sites. Management is aware of several competitive companies developing products for these types of disease and there is an increased risk that our technologies will be made obsolete by a competitor. The technology acquired from Neovasc Medical is a unique technology that is targeting a treatment for an end stage disease when other currently available procedures and/or medications having limited incremental impact on the patient. We are unaware of any direct competitors to the Neovasc product at this time.

An amortization charge of \$2,129,570 has been incurred in the year ended December 31, 2008. As at December 31, 2008, the net book value of the acquired technologies, before any impairment charges was \$9,543,887 for technology acquired from B-Balloon and \$9,960,043 for technology acquired from Neovasc Medical.

### **Impairment of Goodwill and Technology**

Goodwill is tested for impairment annually or more frequently if circumstances suggest impairment may exist. Definite-lived intangibles such as the acquired technologies are tested for recoverability whenever facts or circumstances suggest the possibility of impairment. During the fourth quarter of 2008, the Company’s market capitalization remained below the value of the shareholders equity for a significant period of time, indicating potential impairment of the Company’s goodwill and other intangible assets.

As a result of these market indicators and the Company’s impairment testing, the Company recorded an impairment charge of \$3,557,082 to write down goodwill to \$nil.

During the fourth quarter of 2008, the company reviewed its estimates and judgments regarding forecasts on the

success and lifecycle of the technologies and future cash flows generated by acquired the technologies.

Neovasc has been through a significant cost rationalization process, including a 40% reduction in personnel, a reduction in the scale of the Israeli operations and the suspension of development on three of the four technologies acquired from B-Balloon: the Ostial Stent, the Ballerina and the BOSS. Together these technologies had an initial valuation on July 1, 2008 of \$8.8 million. Neovasc is uncertain when it will be able to recommence development of these technologies and does not anticipate any revenues from these technologies in the next three years. Neovasc has fully written down these technologies.

Both the Reducer, from Neovasc Medical, initially valued at \$10.7 million and the Ostial Balloon device, from B-Balloon, which has evolved into the Ostial D3, initially valued at \$2.1 million are still under development. Their amortized valuation before any impairment testing at December 31, 2008 was \$10.0 million and \$1.8 million respectively. Their combined valuation of \$11.8 million before impairment is 17 times greater than the capital market valuation of the intangible assets of the Company and there is strong evidence to suggest that the assets have been impaired.

When comparing the forecasts for the two technologies prepared in January 2009 to those prepared in June 2008 there are some marked differences: The start of revenue from each product has been deferred by as much as a year, as the development process has slowed because of cost restrictions, and the revenue projections have been revised down as Neovasc believes that adoption may be slower, demand may be lower and selling price may be impacted by the economic crisis.

As a result of the market indicators and the Company's impairment testing, the Company recorded an impairment charge of \$19,503,930 to write down the net book value of acquired technologies to \$nil.

#### **Termination of Distribution Agreement**

On December 22, 2008, the distribution agreement between Neovasc and a third party distributor was terminated. On termination the Company was required to repurchase inventory held by the distributor less a 25% restocking fee. As a result, Neovasc repurchased \$198,838 of Peripatch inventory and \$200,383 of Aegis inventory. To recognize the liability for the repurchase of the inventory the Company offset \$305,831 of accounts receivable and interest due from the distributor (the right of offset being specifically allowed under the terms of the agreement) and set up an additional liability of \$301,788 for the balance remaining.

Under EIC-156 *Accounting by a vendor for consideration given to a customer*, Neovasc is required to recognize

the inventory repurchase as a reduction in revenue and the income statement impact of the termination was to reverse revenue of \$516,601, decrease cost of goods sold by \$308,203 and recognize interest income of \$45,024 (for the interest due on accounts receivable.)

On March 26, 2009, once the inventory had been received and passed quality control inspection Neovasc notified the distributor of the value of the inventory returned. As at the date of this filing the Company has not received any notice of litigation or arbitration from the distributor regarding this termination.

#### **Inventory Write Down**

During the fourth quarter of the 2008 Neovasc severed its direct sales force employees who sold the Company's Metricath products and terminated its distributor of Aegis products. As a result, the Company has limited sales channels through which to sell the Metricath and Aegis product lines. While Management continues to look for new distributors to carry these products there is no certainty, when, or if, they will be able to find a suitable partner.

The Company values inventory at the lower of cost and net realizable value. With no certain sales in 2009 from these products the Company could not reasonably estimate the net realizable value for these product lines and attributed a \$nil value to all Metricath and Aegis inventory. As a result the Company incurred an inventory write down of \$626,925, including the Aegis product returned by Medsurg.

#### **Repayable contribution write back**

As noted above, the Metricath products do not currently have an established sales channel and Neovasc cannot predict whether or not it will be able to establish a suitable channel in the future and generate revenue from these products in 2009. As a result, the Company released the \$320,445 liability for the repayable contribution agreement. The repayable contribution agreement is an Industrial Research Assistance Program forgivable loan which is repayable at a royalty rate of 2.1% of gross revenues from Metricath products and which is wholly forgiven on July 1, 2015 if not already paid out through royalties.

#### **Product Portfolio**

##### **Peripatch Products**

Neovasc manufactures the *PeriPatch™* line of surgical tissue products. The Peripatch line consists of several flexible, biomaterial tissue products made from animal sources. They are chemically treated with proprietary technology to prevent their degradation and to maintain their biocompatibility. Peripatch products are used for vascular repair and reconstruction, as well as in other soft tissue repair. The products are biocompatible, allowing optimal incorporation with the body's host

tissue, and no special sutures are required to make a secure seal.

The product line includes: the *PeriPatch™ Sheet*, *MatrixBP* and *PeriPatch™ EQ Sheet*, rectangular patches made from bovine (cow) or equine (horse) tissue, that are applied as internal bandages to repair weak or damaged organs or vessels; and the *PeriPatch™ Aegis*, and *PeriPatch™ Aegis EQ*, new (products for staple line reinforcement used during endoscopic (minimally invasive) surgical procedures.) There are approximately two million surgical procedures performed annually around the world where tissue products may be applied.

#### *Regulatory Status*

The Peripatch Sheet and MatrixBP are cleared for sale in the U.S., Canada and Mexico. The Peripatch EQ Sheet is approved for sale in the European Union and in Canada. The Aegis is cleared for sale in the United States.

#### *Distribution*

As discussed above, on December 22, 2008 the existing distribution agreement for the Peripatch and Aegis products was terminated and Neovasc subsequently signed a new third party distribution contract to distribute certain Peripatch products in the United States and Europe and continues to supply a number of other Peripatch distributors in the rest of the world.

Going forward Neovasc intends to find strategic partners and distributors to market the Peripatch products to specific market segments. For example, the Company has signed a distribution agreement with a company which specifically focused on vascular surgical call points.

The Company provides training and promotional materials to its current distributors and is working to find new distributors in selected target markets. 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 U.S.

Currently, the Company has distribution agreements for its Peripatch products covering the United States and Canada as well as selected countries in Europe and elsewhere.

#### **Metricath System**

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

Metricath catheters are used during angioplasty, a procedure used to open arteries where blood flow is restricted by plaque (the accumulation of fats and

cholesterol). To perform angioplasty, doctors thread a balloon-tipped catheter through the vasculature and inflate the balloon at the site of the blockage, opening the narrowed vessel. Once the vessel is open, doctors often implant a stent (a small metal mesh tube) to prevent it from re-closing and to maintain proper blood flow.

Metricath provides the user with precise measurements of an 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. As an added benefit, Metricath catheters can also take measurements inside an implanted stent to ensure that it is fully open. In the case of the Metricath Gemini, a second, high-pressure balloon on the catheter may be used to expand under-deployed stents.

Accurate measurement is believed to be an important factor in patients' post-procedure outcomes, as it helps doctors confirm that stents are deployed properly within arteries. In 2006, the medical community identified a link between the use of drug-coated stents and an increased risk of blood clotting, or "thrombosis," as compared to situations where bare-metal (uncoated) stents are used. While it has not been determined definitively why this is the case, there are clinical indications that factors include the under-sizing of stents and/or under-expansion of stents against the artery wall in conjunction with the stents' drug coating or polymer. As a result, there has been increased clinical focus on proper stent selection and expansion to help minimize the risk of stent thrombosis. Anecdotal evidence from the field suggests that physician awareness of the need to accurately size and place stents is continuing to increase, for reasons of potential liability as well as clinical utility. Metricath has the potential to offer improved care by reducing the risk of thrombosis associated with drug-coated stents. By using Metricath to confirm artery and stent size, doctors can be more confident that stents fit correctly within the arteries in which they are placed.

The Metricath System was developed in response to the limitations of existing measurement technologies that are either insufficiently accurate or prohibitively expensive and time-consuming to gain widespread market acceptance. Obtaining accurate measurements is problematic using conventional imaging techniques such as angiography. Intravascular ultrasound (IVUS) catheters can provide precise vascular measurements; however, IVUS is comparatively expensive and time-consuming to use. IVUS takes approximately three times longer to set up and use than Metricath and has a disposable cost of between two and three times that of Metricath. In addition, where IVUS requires the purchase or lease of a complex image acquisition and analysis

system, Metricath imposes minimal capital costs on users.

Current estimates are that approximately 2.5 million stent implantation procedures are performed globally each year. The Metricath System is intended to be a simple and cost-effective vascular measurement tool that can be adopted easily into standard treatment practices.

#### *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. In the fourth quarter of 2007 the Company filed a Pre-Market Approval ("PMA") application for U.S Food and Drug Administration ("FDA") approval of the Metricath Gemini for coronary procedures in the U.S. This application followed completion of the Gemini Angioplasty and Arterial Measurement Evaluation ("GAAME") clinical trial which was undertaken to provide the clinical data required to support this application (see "Product Development and Clinical Trials"). In April 2008, the Company received an initial FDA response to this application completed its response to the FDA and submitted additional supporting data in the first quarter of 2009.

#### *Distribution*

During 2008, the Metricath line was sold via direct sales in the U.S. and Canada and via distributors in other countries. As part of a larger cost reduction exercise the direct sales force staff were terminated and as discussed above there is currently 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. This includes provision of treated tissue for incorporation into products such as percutaneous heart valves and covered stents. Revenue earned from various contract agreements varies throughout the year depending on customer needs.

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

In the fourth quarter of 2007, the Company submitted a PMA application to the FDA to approve the Metricath Gemini for coronary applications in the U.S. The Company supported its application with data from the GAAME trial which was completed in the third quarter of 2007. In April 2008, Neovasc announced that it had received an interim response to its PMA application from the FDA. The response requested additional information related to clinical and non-clinical aspects of the

application. Neovasc has submitted the requested information and is awaiting response from the FDA. The FDA has also completed an inspection of Neovasc' manufacturing and sterilization facility as part of the PMA application process. The FDA inspection took place at the beginning of June, 2008 and the Company successfully passed the inspection with no deviations or warnings.

#### **Product Development**

Product development at the Company is presently focused on the commercialization of key technologies obtained through the Acquisitions, as well as extension of the tissue product lines to specialty applications.

The primary focus of Neovasc's product development activities is on the Reducer product. Reducer is an hourglass shaped stent which is implanted in the coronary sinus to treat refractory angina – chronic heart pain resulting from inadequate blood flow to the heart muscle which typically does not respond well to conventional treatments. The Reducer acts to restrict outflow of de-oxygenated blood from the heart muscle which may provide relief of symptoms of refractory angina in certain patients. Reducer prototypes have demonstrated positive results in multiple animal trials and in human trials published in peer-reviewed journals and Neovasc intends to file for a CE mark approval of the device in 2009. Receipt of approval for this CE mark application would enable the Company to begin marketing the product in the European Union.

#### **Sales & Marketing**

The Company's sales and marketing activities for 2009 are being focused on serving tissue product customers and distributors, and contract manufacturing clients as well as maintaining the existing client base for Metricath products.

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

The Company has incurred operating losses of \$34,259,565 for the year ended December 31, 2008 (2007: \$7,830,954) and has a deficit of \$59,889,963 as at December 31, 2008 (2007: \$25,630,398). 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 tighten 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 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 a significant level of development, regulatory, production and commercialization activity. Other than the standard operating risks associated with such a venture, the Company's management is not aware of any trend, commitment, event or uncertainty in the life science industry that is presently known or is reasonably expected to have a material effect on the Company's business, financial condition or results of operations. 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 the 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.

A portion of Metricath catheter sales efforts are targeting use in renal artery stenting procedures. In addition, certain ostial catheter products under development also target use in renal artery stenting procedures. In 2007, the Centers of Medicare and Medicaid Services (CMS), the largest U.S. health care payer, generated a national

coverage analysis and initiated reconsideration of its coverage policy for percutaneous transluminal angioplasty of the renal arteries. On February 14, 2008, CMS issued its final decision memo to make no changes, continuing to leave coverage and reimbursement decisions to the discretion of regional Medicare contractors. Individual contractor decisions may adversely affect this market by reducing the number of renal stent implantations undertaken in the U.S.

## **FOREIGN OPERATIONS**

The majority of the Company's revenues are derived from product sales in the United States, primarily denominated in United States currency. 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. During the year ended December 31, 2008, the increase in the value of US dollar to Canadian dollar has had a positive effect on the Company's results of operation. However, 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, 2008 and 2007.

## **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 years ended December 31, 2008, compared to those for the same period ended December 31, 2007 and compares the financial

condition at December 31, 2008 to that at December 31, 2007.

The Statements of operations include the results of Neovasc for the year ended December 31, 2008 and those of Neovasc Medical and B-Balloon from July 1 to December 31, 2008. Comparatively, the results of operations for the year ended December 31, 2007 only reflected the results of operation of Neovasc.

### **Results of Operations**

Results for the year ended December 31, 2008 and 2007 follow:

#### **Net Losses**

The consolidated net loss for the year ended December 31, 2008 was \$34,259,565 or \$2.94 basic loss per share as compared with a net loss of \$7,830,954 or \$1.59 basic loss per share for the comparative period in 2007.

#### **Revenues**

Revenues increased 2% year over year from \$1,517,873 for the year ended December 31, 2007 to \$1,546,239 for the year ended December 31, 2008.

Sales of catheter products for the year ended December 31, 2008 were \$262,118 a marginal increase over sales of \$258,017 in the comparable period in 2007, despite a heavy investment in a direct sales force and a substantial marketing effort. As described above the direct sales force has been terminated and the Company is looking for a new distributor to carry its Metricath product.

Sales of tissue and surgical products and services for the year ended December 31, 2008 were \$1,284,121, as compared to sales of \$1,259,856 for the year ended December 31, 2007, a marginal increase of approximately 2%. These revenues were derived from the sales of Peripatch products and contract manufacturing revenues. In the fourth quarter the Company reduced revenues by \$516,601 associated with the repurchase of inventory from a terminated distribution agreement. Revenue in the prior quarters was correctly recognized at that time and the reduction in revenue arises solely from the termination of the 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 year ended December 31, 2008 were \$708,300 as compared to \$799,593 in 2007, and the overall gross margin for 2008 was 54% as compared to 47% in 2007. The gross margin for 2008 has been positively impacted by termination of the distribution agreement discussed above. Due to the existence of the 25% restocking fee only 75% of the inventory returned resulted in a payment obligation of the

Company and a corresponding revenue reduction, while 100% of the reacquired inventory was recognized and resulted in a reversal of cost of goods sold. The 25% of revenue remaining effectively has a zero cost of goods and positively impacts the gross margin for 2008.

#### **Expenses**

Total expenses for the year ended December 31, 2008 and 2007 were \$33,175,047 and \$8,426,224 respectively. The increase in expenses for 2007 to 2008 can be explained by an increase in operating expenses associated with additional costs incurred by the newly acquired activities in Israel of \$1,940,462, an impairment of intangible assets of \$23,061,012, inventory write down of \$626,925, and an offsetting recovery on the repayable contribution agreement of \$320,445.

Sales and marketing expenses were \$3,245,886 for the year ended December 31, 2008 as compared to \$2,839,897 for the same periods in 2007, and increase of 14%. Despite the increased sales and marketing efforts revenues were not increasingly significantly and the direct sales force continued to be a drain on cash resources. Without additional products to sell and without significant growth in the Metricath sales the Company terminated the direct sales force in the fourth quarter of 2008 and will continue to minimize sales and marketing costs until new products from the acquisitions and other sources are ready for market.

General and administrative expenses for the year ended December 31, 2008 were \$3,459,800 as compared to \$2,282,283 in 2007, an increase of 52%. In 2008, the increase in general and administrative costs of \$1,177,517 over the comparative period can largely be explained by \$514,797 incurred in Israel, a large and unusual stock compensation charge relating to the immediate vesting of all of the Medical Ventures options existing at the time of the Acquisitions of \$174,853 and one-time expenses related to the integration and consolidation of the new subsidiaries.

Product development and clinical trial expenses of \$3,101,869 for the year ended December 31, 2008 as compared to \$2,744,913 for the year ended December 31, 2007, an increase of 13%. The \$1,345,987 product development and clinical trial expense incurred in Israel to develop the newly acquired technologies contributed to the increase in this period.

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

Amortization and other expenses for the year ended December 31, 2008 were \$1,922,457 as compared to other expense of \$123,010 for the same periods in 2007. An amortization charge on the acquired technologies of \$2,129,570 has been incurred in 2008.

During the fourth quarter of 2008, we have taken significant steps to control the expenditures of the

Company. Since the initial combination of the acquired companies on July 1, 2008 over 45% of the staff have been made redundant and all work on development projects without projected revenues within the next 18 months has been suspended.

Results for the quarter ended December 31, 2008 and 2007 follow:

#### Net Losses

The consolidated net loss for the quarter ended December 31, 2008 was \$26,598,294 or \$1.50 basic loss per share as compared with a net loss of \$2,300,229 or \$0.47 basic loss per share for the comparative period in 2007.

#### Revenues

Revenues for the quarter ended December 31, 2008 were \$91,809 compared to \$626,974 for the comparative period in 2007.

In the fourth quarter of 2009 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, 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 in comparison to \$372,956 expense in the fourth quarter of 2008.

#### Expenses

Total expenses for the quarter ended December 31, 2008 and 2007 were \$25,990,251 and \$2,387,794 respectively. The increase in expenses between the fourth quarter of 2007 to 2008 can be explained by an increase in operating expenses associated with

additional costs incurred by the newly acquired activities in Israel as they were wound up during the quarter of \$736,124, an impairment of intangible assets of \$23,061,012, inventory write down of 532,521, and an offsetting recovery on the repayable contribution agreement of \$320,445.

Sales and marketing expenses were \$894,470 for the quarter ended December 31, 2008 as compared to \$785,773 for the same periods in 2007, and increase of 14%. During prior quarters in 2008, the Company had increased the size of its sales force and marketing effort but during the quarter took the decision to terminated its direct sales force.

General and administrative for the quarter ended December 31, 2008 were \$844,819 as compared to \$483,681 in 2007, an increase of 75%. In 2008, the increase in general and administrative costs over the comparative period can largely be explained by costs incurred in Israel.

Product development and clinical trial expenses of \$977,874 for the quarter ended December 31, 2008 as compared to \$683,379 for the quarter ended December 31, 2007, an increase of 43%. The development and clinical trial expense incurred in Israel to develop the newly acquired technologies contributed to the increase in this period.

#### Amortization and Other expenses

Amortization and other expenses for the quarter ended December 31, 2008 were \$703,225 as compared to other expense of \$166,453 for the same period in 2007. An amortization charge on the acquired technologies of \$1,064,785 has been incurred in the fourth quarter of 2008, offset by a \$273,568 foreign exchange gain in the same period.

#### Annual Information

The following is a summary of selected financial information for the three fiscal years to December 31, 2008:

	Years ended December 31		
	2008	2007	2006
Sales	\$ 1,546,239	\$ 1,517,873	\$ 1,082,830
Net loss	(34,259,565)	(7,830,954)	(5,483,962)
Basic and diluted loss per share	(2.94)	(0.08)	(0.08)
Total assets	4,820,523	5,689,800	5,286,557
Total long term liabilities	427,576	725,499	529,480
Cash dividend declared per share	\$nil	\$nil	\$nil

## Quarterly Information

The following is a summary of selected unaudited financial information for the eight fiscal quarters to December 31, 2008:

	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 and surgical products and services	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	<u>703,225</u>	<u>1,107,791</u>	<u>54,174</u>	<u>57,266</u>
<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>(0.31)</u>

	Quarter Ended - Unaudited			
	December 31, 2007	September 30, 2007	June 30, 2007	March 31, 2007
<b>Sales</b>				
Catheter products	\$ 81,004	\$ 55,306	\$ 51,432	\$ 70,275
Tissue/surgical products	545,970	163,534	294,379	255,973
	<u>626,974</u>	<u>218,840</u>	<u>345,811</u>	<u>326,248</u>
Cost of sales	<u>372,956</u>	<u>105,897</u>	<u>201,189</u>	<u>119,551</u>
<b>Expenses</b>				
Selling	785,773	801,805	785,131	467,188
General and administration	483,681	504,988	783,663	509,951
Product development and clinical trials	683,379	618,971	790,643	651,920
Inventory Write Down	434,961	-	124,170	-
	<u>2,387,794</u>	<u>1,925,764</u>	<u>2,483,607</u>	<u>1,629,059</u>
EBITDA	<u>(2,133,776)</u>	<u>(1,812,821)</u>	<u>(2,338,985)</u>	<u>(1,422,362)</u>
Amortization/Other expenses	<u>166,453</u>	<u>(10,645)</u>	<u>(30,488)</u>	<u>(2,310)</u>
<b>Net loss</b>	<u>(2,300,229)</u>	<u>(1,802,176)</u>	<u>(2,308,497)</u>	<u>(1,420,052)</u>
Basic loss per share	<u>(0.47)</u>	<u>(0.32)</u>	<u>(0.46)</u>	<u>(0.41)</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 December 31, 2008, the Company had cash and cash equivalents of \$2,498,439 as compared to cash of \$3,242,404 as of December 31, 2007. At December 31, 2008 the Company had working capital of \$2,123,519 as compared to working capital of \$3,431,266 at December 31, 2007. In addition, at December 31, 2008 the Company had restricted cash related to a security on long-term debt of \$50,000 (December 31, 2007 - \$50,000) included in long-term assets.

Cash used in operations was \$8,477,808 for the year ended December 31, 2008, as compared to \$6,439,828 for the year ended December 31, 2007, an increase of \$2,037,980. The increase in cash usage was related to the increase in expenses borne by the Company at the newly acquired operations in Israel and in the increase sales and marketing expenditures.

Net cash used in investing activities was \$111,998 for year ended December 31, 2008 compared to cash used of \$542,316 in 2007. On July 1, 2008, the Company completed the Acquisitions. The cash spent to acquire the companies was \$845,241. 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. In 2007 the comparative expenditure was \$542,316 as an additional building was acquired during the year.

Concurrent with the Acquisitions, 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 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 of loans from parties related to B-Balloon.

On April 24, 2007, the Company closed a public offering by way of a short form prospectus dated April 13, 2007, the Company issued 1,935,456 units of the Company at a price of \$4.00 per unit (on a consolidated basis) for aggregate gross proceeds of \$7,741,824, net of share issue costs of \$834,271. Each unit consisted of one common share and one-half of one non-transferable common share purchase warrant entitling the holder to purchase one additional common share for every whole warrant at a price of \$5.00 per share, expiring on October 24, 2008. On closing, the Agents received non-transferable share purchase warrants to purchase up to 82,968 common shares at a price of \$4.00 per share exercisable until October 24, 2008. Subsequent to the

financing on May 4, 2007, the Agent exercised 58,077 agent warrants at \$4.00 per share for gross proceeds of \$232,310 and the remaining agent warrants were re-priced to \$5.00 per share.

Since its inception the Company has had negative cash flows from operations as it continues its product development activities. The Company anticipates that it will require additional funding in 2009 to support its ongoing operations and product development. However, the current financial market conditions have increased the risk that such funding will not be possible. There is no assurance that such additional funds will be available for the Company. If adequate funds are not available, the Company may be required to scale back or abandon some activities and may in a worst case impact the Company's ability to continue as a going concern. The Company's financial statements do not include any adjustments that might result from this uncertainty.

## **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. The maximum amount of the claim is \$25,000.

## **SUBSEQUENT EVENTS**

On February 2, 2009, pursuant to the Company's stock option plan, the Company issued 487,500 stock options at an exercise price of \$0.40 including 60,000 granted to named officers of the Company and 427,500 granted to directors of the Company.

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 \$2.0 million. Each unit consists 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 \$0.30 per share for a period of one year after the closing date of the offering.

## **OUTSTANDING SHARE DATA**

Pursuant to the Acquisitions, the Company issued 5,273,800 and 4,610,091 common shares to the securityholders of B-Balloon and Neovasc Medical respectively and assumed 584,200 options from B-Balloon and 512,515 options and 735,394 share purchase warrants from Neovasc Medical. In addition, through a private equity financing, the Company issued 2,081,251 units of common shares. Each unit consists of

one common share of the Company and 0.62 of a warrant.

As at December 31, 2008, the Company had 17,702,026 common voting shares issued and outstanding. Further, the following securities are convertible into exercisable or exchangeable for common shares of the Company: 2,177,182 stock options with a weighted average price of \$0.57, and 2,065,769 share purchase warrants with exercise prices ranging from \$1.38 to \$5.00. The fully diluted share capital of the Company at December 31, 2008 is 12,172,746.

#### **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 audited annual 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 year ended December 31, 2008.

#### **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.