



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

Form 51-102F1

**FOR THE YEARS ENDED DECEMBER 31,  
2013 AND 2012**

**2013**

## 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, 2013 and 2012.

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 years ended December 31, 2013 and 2012 (included as part of Neovasc Inc.'s annual filing).

### FORWARD-LOOKING STATEMENTS

This Annual Information Form, contains forward-looking statements within the meaning of applicable Canadian securities legislation and U.S. securities legislation that may not be based on historical fact, including, without limitation, statements containing the words "believe", "may", "plan", "will", "estimate", "continue", "anticipate", "intend", "expect" and similar expressions. Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as the factors we believe are appropriate. Forward-looking statements in this Annual Information Form include, but are not limited to, statements relating to:

- our intention to expand the indications for which we may market Tiara™ (which does not have regulatory approval and is not commercialized) and Reducer™ (which has CE mark approval for sale in the European Union);
- our plans to develop and commercialize products and the timing of these development programs;
- whether we will receive, and the timing and costs of obtaining, regulatory approvals;
- the cost of post-market regulation if we receive necessary regulatory approvals;
- clinical development of our products, including the results of current and future clinical trials;
- our ability to enroll patients in our clinical trials;
- the benefits and risks of our products as compared to others;
- our ability to establish, maintain and defend intellectual property rights in our products;
- whether our third party collaborators will maintain their intellectual property rights in the technology we license;
- our need for additional financing and our estimates regarding our capital requirements and future revenues and profitability;
- our estimates of the size of the potential markets for our products;
- our selection and licensing of products;
- our potential relationships with distributors and collaborators with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;
- sources of revenues and anticipated revenues, including contributions from distributors and collaborators, product sales, license agreements and other collaborative efforts for the development and commercialization of products;
- our creation of an effective direct sales and marketing infrastructure for approved products we elect to market and sell directly;
- the rate and degree of market acceptance of our products;
- our anticipated listing of our common shares on the Nasdaq Capital Market and graduation to the TSX;
- the timing and amount of reimbursement for our products;
- the success and pricing of other competing therapies that may become available;
- our retention and hiring of qualified employees in the future;
- the manufacturing capacity of third-party manufacturers for our products;
- the competition we face from other companies, research organizations, academic institutions and government agencies, and the risks such competition pose to our products;
- the confidential information we possess about patients, customers and core business functions, and the information technologies we use to protect it;
- our intention to continue directing a significant portion of our resources into sales expansion;
- our ability to get our products approved for use; and
- government legislation in all countries that we already, or hope to, sell our products in, and its effect on our ability to set prices, enforce patents and obtain product approvals or reimbursements.

Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by us, are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies, many of which, with respect to future events, are subject to change. The factors and assumptions used by us to develop such forward-looking statements include, but are not limited to, the assumption that:

- our ability to reach agreements with regulatory agencies;
- recruitment to clinical trials will continue;
- the regulatory requirements, including patient exposure, for approval of marketing authorization applications will be maintained;
- genericisation of markets for Tiara and Reducer will develop;
- the time required to analyze and report the results of our clinical studies will be consistent with past timing;
- market data and reports reviewed by us are accurate;
- our current good relationships with our suppliers and service providers will be maintained;
- availability of capital on terms that are favourable to us;
- the success of current and future clinical trials; and
- feasibility of future clinical trials.

By their very nature, forward-looking statements or information involve known and unknown risks, uncertainties and other factors that may cause our actual results, events or developments, or industry results, to be materially different from any future results, events or developments expressed or implied by such forward-looking statements or information. In evaluating these statements, prospective purchasers should specifically consider various factors, including the risks outlined herein, under the headings "Risk Factors". Should one or more of these risks or uncertainties or a risk that is not currently known to us materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this Annual Information Form and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. Investors are cautioned that forward-looking statements are not guarantees of future performance and investors are cautioned not to put undue reliance on forward-looking statements due to their inherent uncertainty.

All financial information is prepared in accordance with International Financial Reporting Standards ("IFRS") and is expressed in Canadian dollars.

Date: April [17], 2014

## **OVERVIEW**

### **Description of the Business**

Neovasc is a specialty medical device company that develops, manufactures and markets products for the rapidly growing cardiovascular marketplace. Its products include the Tiara technology in development for the transcatheter treatment of mitral valve disease, the Reducer for the treatment of refractory angina and a line of advanced biological tissue products that are used as key components in third-party medical products including transcatheter heart valves.

Neovasc's business operations started in March 2002, with the acquisition of Neovasc Medical Inc. ("NMI") (formerly PM Devices Inc.). NMI manufactured a line of collagen based surgical patch products. The products are made from chemically treated pericardial tissue. In 2012, the Company sold the rights to the surgical patch products to Lemaitre Vascular Inc. ("LeMaitre"), but retained rights to the underlying tissue technology for all other uses.

In May 2003, Neovasc acquired Angiometrx Inc. ("ANG"). ANG developed a technology called the Metricath, a catheter-based device that allowed clinicians to measure artery and stent size and confirm deployment during interventional treatment of coronary and peripheral artery disease. In 2009, Neovasc ceased all activities related to Metricath.

In July 2008, Neovasc acquired two pre-commercial vascular device companies based in Israel: Neovasc Medical Ltd. ("NML") and B-Balloon Ltd. ("BBL"). NML developed and owned intellectual property 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. BBL developed certain products intended to solve problems encountered 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. Currently Neovasc is not developing any of the BBL technologies and is focusing its product development efforts on NML's treatment for refractory angina.

In late 2009, Neovasc started initial activities to develop novel technologies for catheter-based treatment of mitral valve disease. Based on the early positive results of these activities, the Company launched a program to develop the Tiara transcatheter mitral valve.

### **Product Portfolio**

#### **Tiara**

In the second quarter of 2011, the Company formally initiated a new project to develop the Tiara, a product for treating mitral valve disease. The Tiara is in early clinical stage development to provide a minimally invasive transcatheter device for the millions of patients who experience mitral regurgitation as a result of mitral heart valve disease (in 2013 it is estimated that mitral regurgitation affects approximately 5.7 million people in the U.S. and EU5). Mitral regurgitation is often severe and can lead to heart failure and death. Unmet medical need in these patients is high. Currently, a significant percentage of patients with severe mitral regurgitation are not good candidates for conventional surgical repair or replacement due to frailty or comorbidities. There are approximately 2.4 million patients suffering from significant mitral regurgitation in the United States. Currently there is no transcatheter mitral valve replacement device approved for use in any market.

Preclinical program and prototype devices of the Tiara have undergone evaluation in animal and bench models. Neovasc believes it has developed distinctive solutions to the difficulties of developing a safe and effective transcatheter mitral valve device and early results have been promising. Initial implantations of the valve have been undertaken in humans under special compassionate use exemptions (to date, two human implants of the Tiara have been completed under such exemptions).

While many challenges remain prior to achieving commercial production (including positive clinical trials and obtaining regulatory approval from the relevant authorities), the Tiara device is being widely recognized at leading cardiovascular medical conferences as one of the leading devices exploring this new treatment option for patients who are unable or unsuited to receive an open heart surgical valve replacement or repair. There are several other transcatheter mitral valve replacement devices in development by third parties, however, none have reached the stage of clinical trials (although it has been reported that one transcatheter mitral valve was implanted in a European patient who subsequently died a few days later from causes that were reported by the company as being unrelated to the performance of the valve and another

company has reported two temporary implants of valves that were removed after a few hours – it is believed that these implants were intended to be acute only to assess the feasibility of the valve). On March 6, 2014, Edwards Lifesciences reported that in February and March 2014, it had completed the first three implants of its FORTIS transapical mitral valve at a hospital in London, U.K. and that the patients were reported to be recovering but few other details were given.

Neovasc believes that there are several unique attributes of the Tiara device that may provide advantages over other approaches and that it will be one of the leading transcatheter mitral valve replacement therapies to begin a formal series of human implantations. There is no certainty that the Tiara device will successfully proceed through clinical testing and ultimately receive regulatory approval to treat these patients, nor is it possible to determine at this time if any of the other development stage devices will succeed in obtaining regulatory approval.

The Tiara valve is made up of two major components: the leaflets and skirt, which are made from the Company's Peripatch™ ("Peripatch") tissue, and the nitinol frame (to which the leaflets and skirt are attached), which is manufactured by a well-established specialty manufacturer in the medical device industry. However, if this supplier were unable to provide the nitinol frame in the future, it would seriously impact the further development of the Tiara device. The Tiara delivery system is manufactured in-house by the Company using components that are readily available.

#### *Regulatory Status*

The Tiara is an early clinical-stage development product without regulatory approvals in any country. The Company will continue to fund development of the product as cash flow allows and anticipates applying for CE mark approval in Europe in the next two to four years. To the end of December 31, 2013, the Company has spent approximately \$7.8 million developing the product and anticipates that it may require an additional \$10-15 million dollars to apply for CE mark. There is no assurance that European regulatory approval will be granted in the time frame anticipated by management, or granted at any time in the future. There is no expectation that this product will be revenue-generating in the near term, although management believes that the product is addressing an important unmet clinical need and that the demand for the product is high.

#### **Reducer**

The Reducer is a treatment for patients with refractory angina, a painful and debilitating condition that occurs when the coronary arteries deliver an inadequate supply of blood to the heart muscle, despite treatment with standard revascularization or cardiac drug therapies. It affects approximately 620,000 individuals in the U.S., who typically lead severely restricted lives as a result of their disabling symptoms, and its incidence is growing. The Reducer provides relief of angina symptoms by altering blood flow in the heart's venous system, thereby increasing the perfusion of oxygenated blood to ischemic areas of the heart muscle.

The pain associated with refractory angina can make it difficult for patients to engage in routine activities, such as walking or climbing stairs. 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 muscle back to the right atrium of the heart. Pilot clinical studies demonstrate that the Reducer provides significant relief of chest pain in refractory angina patients. There are approximately 620,000 refractory angina patients in the United States 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 a substantial market opportunity for the Reducer product. If physicians adopt the 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 targeting a currently untreatable patient population. A refractory patient by definition is resistant to other therapies. A patient who has refractory angina is not a surgical candidate, cannot benefit from existing interventional cardiology therapies and is not receiving adequate relief from available drug regimens to manage their chest pain. As such there are currently no direct competitors to the Reducer as the patient will have exhausted all other treatment options before a Reducer is considered. Once the Reducer is established as a standard of care for the refractory angina patient, Neovasc believes that the Reducer may also be considered for use in the larger population of recurrent angina patients (patients who are receiving repeat treatments for angina pain) and thus increase its market potential.

The Reducer's primary endpoint is a two-class improvement six months after implantation in patients' ratings on the Canadian Cardiovascular Society ("CCS") angina grading scale, a four-class functional classification that is widely used to characterize the severity of angina symptoms and disability. Only patients with severe angina, CCS Class 3 or 4, were

enrolled in the COSIRA (“**C**oronary **S**inus Reducer for treatment of **R**efractory **A**ngina”) trial. The COSIRA analysis showed that the study met the primary endpoint, with patients receiving the Reducer achieving a statistically significant improvement in CCS scores (two classes or better) compared to patients receiving a sham control (18 of 52 (34.6%) of the Reducer patients improved  $\geq 2$  CCS classes compared to 8 of 52 (15.4%) of the control patients (p-value = 0.024)). The analysis also showed that patients treated with the Reducer showed a statistically significant improvement of one or more CCS classes compared to the sham control patients (37 of 52 (71.2%) of the Reducer patients showed this improvement compared to 22 of 52 (40.1%) of the control patients (p-value = 0.003)).

The Reducer is an hourglass-shaped, balloon-expandable, stainless steel, bare metal “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 9 French sheath compatible and operates over a .035 inch guide wire. The implantation procedure is quick and requires minimal training. Once guide wire access to the coronary sinus is achieved, implantation typically takes less than 20 minutes.

Following implantation, the 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, which restores a more normal ratio of epicardial to 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 and chest pain. The physiological mechanism behind this effect is well documented in medical literature.

The clinical utility of this approach was demonstrated by a number of analogous approaches used in the past that achieved positive 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. The Reducer was developed to deliver this therapy in a safe, simple and effective manner via a minimally invasive catheter that is consistent with contemporary medical practice.

The Reducer has demonstrated excellent results in multiple animal studies and in a clinical trial of fifteen 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 follow-up data was presented at the annual scientific meeting of the American College of Cardiology 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 in overall quality of life in the majority of the patients. These improvements were maintained for the three years of the study. During this period, the Reducer appeared safe and well tolerated in these patients. More recently, the Company completed COSIRA – a multi-center, double blinded sham controlled study intended to assess the safety and efficacy of the Reducer in a rigorous, controlled manner. The results of COSIRA were positive and are discussed in more detail below.

Following this positive data from the COSIRA trial, the Company expects to pilot launch the Reducer in selected European markets in late 2014. The Company will also explore initiation of Reducer sales in other non-US markets. It is anticipated that sales of the product in the United States would follow obtaining U.S. regulatory approval, if and when such approval is granted, as described further below.

#### *Regulatory Status*

The Reducer is approved for sale in Europe, having received CE-mark designation in November 2011. In preparation for product launch, Neovasc has completed development of the commercial-generation Reducer and the product is currently being transferred to commercial scale manufacture. The Company has completed a clinical trial named COSIRA that is expected to provide data to support broad commercialization of the Reducer product. COSIRA is a double-blinded, randomized, sham controlled, multi-center trial of 104 patients at 11 clinical investigation sites. The study completed enrollment in early 2013 and on November 6, 2013, the Company reported topline results for its COSIRA trial assessing the efficacy and safety of the Reducer. As discussed above, the data shows that the Reducer achieved its primary endpoint, significantly improving the symptoms and functioning of patients disabled by previously untreatable refractory angina. The COSIRA trial also confirmed that the Reducer is safe and well tolerated. The safety and efficacy data from the randomized, controlled COSIRA trial is consistent with results seen in previous non-randomized pilot studies of the Reducer. Placement of the Reducer is performed using a minimally-invasive transvenous procedure that is similar to implanting a coronary stent and takes approximately 20 minutes. The Company has also initiated Registries in Europe

and Israel to collect additional clinical data from patients treated with the Reducer. Data from the COSIRA trial and the patient registries is expected to provide critical support for adoption and use of the Reducer product in Europe and was presented at the American College of Cardiology (“ACC”) 63rd Annual Scientific Session & Expo on March 29, 2014.

Neovasc is also developing a U.S. regulatory approval strategy that will address the requirement for a larger randomized clinical trial, which is mandatory in the United States. The Company expects to begin this trial in 2015. U.S. marketing approval is expected about two to four years after the clinical trial begins. There is no assurance that U.S. regulatory approval will be granted in the time frame anticipated by management, or granted at any time in the future. The cost of the U.S. clinical trial is expected to be \$15 million.

## **Peripatch Products**

Neovasc produces Peripatch, an advanced biological tissue product that is 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 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. Peripatch tissue was originally developed to fabricate artificial heart valves and has a 25-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 aortic heart valve leaflets.

The product line includes Peripatch surgical patches, which are rectangular patches made from bovine tissue, applied as internal bandages to repair weak or damaged organs or vessels. On October 31, 2012, Neovasc amended its agreement with LeMaitre allowing LeMaitre to exercise its option to purchase certain specific rights to Neovasc’s biological vascular surgical patch technology on an accelerated basis. Under the terms of the amendment, LeMaitre is permitted to use the Peripatch technology for the sole purpose of manufacturing surgical patches that it markets as its XenoSure™ surgical patch product line. Neovasc will continue to supply LeMaitre with surgical patches at a reduced price until March 31, 2014 or until LeMaitre is able to receive appropriate regulatory approvals and start manufacture of the surgical patches themselves (anticipated around the end of 2014), whichever is sooner. At that time, Neovasc will cease manufacture of surgical patches for this specific application.

The Company also provides a range of custom Peripatch products to industry customers for incorporation into their own products, such as transcatheter heart valves, covered stents and other specialty cardiovascular devices. These include Peripatch tissue fabricated from bovine and porcine sources and offered in a wide variety of shapes and sizes. Neovasc works closely with its industry customers to develop and supply tissue to meet their specific needs, such as for transcatheter heart valve leaflets. This often includes providing tissue in custom shapes or molded to three dimensional configurations. The Company also provides product development and specialized manufacturing services related to Peripatch tissue-based products such as transcatheter heart valves. The Company actively consults with a range of heart valve programs in order to refine their products and provide tissue to meet their needs and also provides transcatheter valve prototyping, pilot manufacture and commercial manufacture services to a range of customers.

Although the generic method of processing tissue in a way similar to the Peripatch is widely used, the Company’s competitive position stems from its own proprietary process that is supported by a 25-year implant history for use as a surgical heart valve. A company that establishes its own process will have to go through a significant and costly series of studies to prove that their process produces tissue that is suitable as a medical device. The Peripatch product has already met these requirements and has already been validated through many years of successful use in multiple applications. Neovasc’s customers make the decision to use the Company’s tissue rather than take on the demanding and lengthy process of developing their own tissue processing operation. As stated elsewhere herein, Neovasc is not aware of any other company in the world that both provides such tissue and partners with customers to provide specialized heart valve development and manufacturing services.

The basic Peripatch technology was established over 25 years ago, when the material was used to fashion the leaflets and other components in surgical heart valves. Neovasc’s processing of the material is a trade secret and proprietary to the Company. However, the use of the product in transcatheter minimally invasive heart valves and other medical devices such as covered stents and artificial hearts are new uses for the technology. Appropriate testing is conducted to ensure the appropriateness and durability of the tissue for a new application before the medical device can be approved for use,

and there is some additional risk when applying the technology to a new product or when amending to, or adding to, the fixation process to meet a new demand, such as for three dimensional shape setting of the tissue.

The supply of Peripatch products and the associated product development, consulting and specialized manufacturing services related to Peripatch tissue-based products represents 100% of the Company's current revenues.

#### *Regulatory Status*

Peripatch tissue manufactured from bovine tissue is approved for sale in the United States, the European Union and Canada. While the Company does not have stand-alone approval for its porcine tissue products, third party products fabricated from Neovasc's porcine tissue are approved for sale in European Union markets. Regulatory agencies, such as the Canadian Food Inspection Agency, regulate the import and export of such tissue. A number of third-party products which incorporate Peripatch tissue are approved for sale (i.e. such products have obtained regulatory approval, such as a CE-mark or Canadian medical device license) or have pending approvals in various markets. There is no assurance that further regulatory approvals for third-party products will be obtained.

#### *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 the Company's 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 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 commercially successful devices that incorporate Neovasc tissue. Revenue earned from various contract agreements varies throughout the year depending on customer needs.

#### **Clinical Trials**

The Company is presently in the process of obtaining the clinical trial data required to support European commercial launch of the Reducer product. The COSIRA trial, which commenced in September 2010 and concluded enrollment in May 2013, is expected to generate data to support commercialization, as well as additional regulatory approval applications to be filed in other jurisdictions. The Company is also enrolling patients receiving the Reducer product in clinical registries in Europe and Israel, with the expectation that data from these registries will support wider adoption and use of the Reducer in refractory angina patients.

#### **Product Development**

Product development at the Company is currently focused on completing commercialization of the Reducer as well as early-stage development work on the Tiara program. The Company is also undertaking product development work under contract for third-parties. These third-party projects are typically focused on supporting the development of products that incorporate Peripatch tissue. These activities generate near-term revenues for Neovasc from consulting activities and also are expected to drive longer-term growth as a result of the revenues that may result from future commercial sales of new products incorporating the Peripatch tissue, as well as the related manufacturing services the Company could provide for these customers once their products reach the market. The Company may also investigate other potential new internal projects that leverage the Company's existing technologies, infrastructure and expertise.

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

The Company has incurred operating losses of \$6,750,250 for the year ended December 31, 2013 (2012: \$351,368) and has a deficit of \$78,094,003 at December 31, 2013 compared to a deficit of \$71,343,753 as at December 31, 2012. As at December 31, 2013 the Company had \$3,403,472 in cash and cash equivalents. The Company believes it has sufficient funds for the next 12 months but, further into the future, the Company 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 economic crisis has significantly tightened the credit markets and may result in required funds not being available to the Company at the time needed 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 what its future operating results will be. 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. 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 technologies and products; the Company's ability to obtain and enforce timely patent protection of its technologies and products; the Company's ability to develop, manufacture and commercialize its products cost-effectively and according to the 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 European euros, while the majority of the Company's costs are denominated in Canadian dollars. The Company expects that foreign currency denominated international sales will continue to account for a the majority of its revenues. Consequently, a decrease in the value of a relevant foreign currency in relation to the Canadian dollar will have an adverse effect on the Company's results of operations, with lower than expected revenue amounts and gross margins being reported in the Company's Canadian dollar financial statements. In addition, any decrease in the value of the United States dollar or European euro occurring in between the time a sale is consummated and the time payment is received by Neovasc will lead to a foreign exchange loss being recognized on the foreign-currency denominated trade account receivable. 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, 2013 and 2012.

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

Results for the years ended December 31, 2013 and 2012 follow:

### **Loss**

The losses for the year ended December 31, 2013 were \$6,750,250, or \$0.14 basic and diluted loss per share, compared with a loss of \$351,368, or \$0.01 basic and diluted loss per share for the same period in 2012. The \$6,398,882 increase in the loss incurred for the year ended December 31, 2013 compared to the same period in 2012 can be substantially explained by an increase in operating losses, mostly through increases in product development and clinical trials expenses in 2013, and a decrease in other income as 2012 saw unusually high income generated through a gain on sale

of a license. On October 31, 2012, Neovasc finalized its agreement with LeMaitre allowing LeMaitre to exercise its option to purchase certain specific rights to Neovasc's biological vascular surgical patch product technology on an accelerated basis, at an agreed price of US\$4,600,000.

### **Revenues**

Revenues increased 50% year-over-year to \$11,747,636 for the year ended December 31, 2013, compared to revenues of \$7,819,154 for the same period in 2012.

Product sales for the year ended December 31, 2013 were \$2,694,977, compared to \$3,264,851 for the same period in 2012, representing a decrease of 17%. Product sales are solely comprised of sales of surgical patches to LeMaitre. On the sale of a license to LeMaitre to produce these surgical patches in-house, Neovasc also agreed to continue to supply LeMaitre with surgical patches at a significant price discount, until LeMaitre receives appropriate regulatory approvals and start manufacture of the surgical patches themselves. Lemaitre anticipates receiving the appropriate regulatory approvals towards the end of 2014. At that time, Neovasc will cease manufacturing all surgical patches for LeMaitre.

Contract manufacturing revenues for the year ended December 31, 2013 were \$1,776,893, compared to \$2,005,058 for the same period in 2012, representing a decrease of 11%. In the fourth quarter of 2013, there was a significant decrease in contract manufacturing revenues, as one customer adopted a new sterilization process and no product could be sterilized or shipped until this adoption is completed. Work in Progress also increased as Neovasc continued to manufacture up to the point of sterilization and it is anticipated that revenues will resume in the first half of 2014.

Revenues from consulting services for the year ended December 31, 2013 were \$7,275,766, compared to \$2,549,245 for the same period in 2012, representing an increase of 185%. The bulk of the growth in 2013 was the result of the Company growing consulting revenues earned with each of its top five consulting services customers and to a lesser extent attracting a number of new smaller customers. The Company's consulting service revenues are contract-driven and they can fluctuate from quarter-to-quarter and year-to-year as current projects are completed and new projects start. The Company hopes and anticipates that it will be able to convert more of its current consulting services customers into contract manufacturing customers as they advance their product development programs towards commercialization and market introduction. However, this change is dependent on their product development success and is therefore difficult to project.

Where possible the Company updates its charge out rates and product prices on an annual basis to maintain its margins and reflect increases in the cost of goods sold. Most customer contracts include a mechanism to calculate the price increase or to limit the maximum increase allowable each year.

### **Cost of Goods Sold**

The cost of goods sold for the year ended December 31, 2013 was \$7,083,877, compared to \$4,640,302 for the same period in 2012. The overall gross margin for the year ended December 31, 2013 was 40%, compared to 41% gross margin for the same period in 2012. Whilst gross margins have remained relatively stable in recent years, fluctuations reflect the different margin rates achieved in the Company's mix of consulting and contract manufacturing projects and product revenue streams. Neovasc anticipates an improvement in margins in 2014 as the sale of low margin surgical strips to Lemaitre is discontinued and the revenue mix shifts to higher margin contract manufacturing and consulting services.

### **Expenses**

Total expenses for the year ended December 31, 2013 were \$11,772,728, compared to \$8,107,079 for the same period in 2012, representing an increase of 45%. The increase in total expenses for the year ended December 31, 2013 compared to the same period in 2012 reflects increases in general and administrative expenses of \$888,985, primarily from one-time non-recurring expenses and legal and other expenses associated with strategic and product development activities, as well as product development and clinical trial expenses of \$2,867,262 to advance the Tiara and Reducer development programs.

Selling expenses for the year ended December 31, 2013 were \$78,475, compared to \$169,073 for the same period in 2012. The Company is continuing to maintain relatively constant and modest selling and marketing costs while it focuses on growing its business-to-business revenue streams.

General and administrative expenses for the year ended December 31, 2013 were \$4,846,935, compared to \$3,957,950 for the same period in 2012, representing an increase of \$888,985, or 22%. In 2013, the Company incurred additional costs establishing a dedicated regulatory affairs team and handling legal and other expenses associated with strategic and product development activities.

Product development and clinical trial expenses for the year ended December 31, 2013 were \$6,847,318, compared to \$3,980,056 for the same period in 2012, representing an increase of \$2,867,262, or 72%. The increase in product development and clinical trial expenses was due to an increase in development expenses as the Company invested in its two major new product initiatives: completing the COSIRA clinical trial for the Reducer and advancing the Tiara mitral valve development program.

The Company's expenses are subject to inflation and cost increases. Salaries and wages have increased on average by 3% in the year ended December 31, 2013 compared to the same period in 2012. The Company has not seen a significant increase in the price of any of the components used in the manufacture of its products and services.

#### **Other income**

The other income for the year ended December 31, 2013 was \$358,719, compared to other income of \$4,576,859 for the same period in 2012. The Company has benefited from significant foreign exchange gains on its foreign currency-denominated cash and cash equivalents in 2013. On October 31, 2012, Neovasc finalized its agreement with LeMaitre Vascular allowing LeMaitre to exercise its option to purchase certain specific rights to Neovasc's biological vascular surgical patch product technology on an accelerated basis, at an agreed price of US \$4,600,000.

Result for the quarters ended December 31, 2013 and 2012 follow:

#### **Profit or Loss**

The net loss for the quarter ended December 31, 2013 was \$2,211,875, or \$0.05 basic and diluted loss per share, compared with a profit of \$3,637,192 or \$0.08 basic earnings per share and \$0.07 diluted earnings per share for the same period in 2012. The profit incurred in the quarter ended December 31, 2012 was due to \$4,598,160 gain from the sale of a license (as discussed in the "Loss" section).

#### **Revenues**

Revenues for the quarter ended December 31, 2013 were \$3,311,550 compared to \$2,465,615 for the same period in 2012, representing an increase of 34%, mostly due to a year-over-year increase in consulting services of \$1,160,290 offset by a decrease of \$766,559 in contract manufacturing.

#### **Cost of Goods Sold**

The cost of goods sold for the quarter ended December 31, 2013 were \$2,056,349, compared to \$1,491,125 for the same period in 2012. The costs rose in line with the increase in sales. The gross margin for the quarter ended December 31, 2013 was 38%, compared to 40% for the same period in 2012.

#### **Expenses**

Total expenses for the quarter ended December 31, 2012 were \$3,567,679, compared to \$1,929,331 for the same period in 2012, an increase of 85%. The increase is substantially due to an increase of \$1,336,900 in clinical trial and product development expenses for the Company's two new product development programs.

Selling expenses were \$18,417 for the quarter ended December 31, 2013, compared to \$36,560 for the same period in 2012. General and administrative expenses were \$1,183,067 for the quarter ended December 31, 2013, compared to \$863,476 in the same period in 2012, representing an increase of 37%. The increase in general and administrative expenses was principally due to an increase in corporate and strategic activities accelerate in line with revenue growth and product development advancements. Research and development costs, including product development and clinical trial expenses were \$2,366,195 for the quarter ended December 31, 2013, compared to \$1,029,295 for the same period in 2012, representing an increase of 130%. The increase in year-over-year research and development costs is principally due to increased investment in Neovasc's two major new product initiatives: the COSIRA clinical trial for the Reducer and the development of the Tiara mitral valve program.

## Annual Information

The following is a summary of selected financial information for the three fiscal years to December 31, 2013:

	2013	2012	2011
Sales	\$ 11,747,636	\$ 7,819,154	\$ 5,255,761
Loss	(6,750,250)	(351,368)	(3,860,176)
Basic and diluted loss per share	(0.14)	(0.01)	(0.09)
Total assets	7,443,382	8,798,596	6,300,116
Total long-term liabilities	200,084	241,083	280,642
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, 2013:

	December 31, 2013	September 30, 2013	June 30, 2013	March 31, 2013
<b>REVENUE</b>				
Product sales	\$ 683,289	\$ 654,809	\$ 766,834	\$ 590,045
Contract manufacturing	96,917	583,466	521,361	575,149
Consulting services	2,531,344	2,395,616	1,504,620	844,186
	<u>3,311,550</u>	<u>3,633,891</u>	<u>2,792,815</u>	<u>2,009,380</u>
<b>COST OF GOODS SOLD</b>	<u>2,056,349</u>	<u>2,160,092</u>	<u>1,632,155</u>	<u>1,235,281</u>
<b>GROSS PROFIT</b>	<u>1,255,201</u>	<u>1,473,799</u>	<u>1,160,660</u>	<u>774,099</u>
<b>EXPENSES</b>				
Selling expenses	18,417	7,366	31,685	21,007
General and administrative expenses	1,183,067	1,009,473	928,663	1,725,732
Product development and clinical trials expenses	2,366,195	1,878,943	1,613,609	988,571
	<u>3,567,679</u>	<u>2,895,782</u>	<u>2,573,957</u>	<u>2,735,310</u>
<b>OPERATING LOSS</b>	<u>(2,312,478)</u>	<u>(1,421,983)</u>	<u>(1,413,297)</u>	<u>(1,961,211)</u>
OTHER INCOME/(EXPENSE)	100,603	(17,843)	174,904	101,055
<b>LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD</b>	<u>\$ (2,211,875)</u>	<u>\$ (1,439,826)</u>	<u>\$ (1,238,393)</u>	<u>\$ (1,860,156)</u>
<b>BASIC AND DILUTED LOSS PER SHARE</b>	<u>\$ (0.05)</u>	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>
	December 31, 2012	September 30, 2012	June 30, 2012	March 31, 2012
<b>REVENUE</b>				
Product sales	\$ 866,866	\$ 946,117	\$ 742,226	\$ 709,642
Contract manufacturing	677,695	527,557	458,359	341,447
Consulting services	921,054	532,266	434,023	661,902
	<u>2,465,615</u>	<u>2,005,940</u>	<u>1,634,608</u>	<u>1,712,991</u>
<b>COST OF GOODS SOLD</b>	<u>1,491,125</u>	<u>1,275,096</u>	<u>994,809</u>	<u>879,272</u>
<b>GROSS PROFIT</b>	<u>974,490</u>	<u>730,844</u>	<u>639,799</u>	<u>833,719</u>
<b>EXPENSES</b>				
Selling expenses	36,560	40,503	48,783	43,227
General and administrative expenses	863,476	937,202	943,467	1,213,805
Product development and clinical trials expenses	1,029,295	950,275	1,166,502	833,984
	<u>1,929,331</u>	<u>1,927,980</u>	<u>2,158,752</u>	<u>2,091,016</u>
<b>OPERATING LOSS</b>	<u>(954,841)</u>	<u>(1,197,136)</u>	<u>(1,518,953)</u>	<u>(1,257,297)</u>
OTHER INCOME/(EXPENSE)	4,592,033	(9,778)	2,598	(7,994)
<b>LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD</b>	<u>\$ 3,637,192</u>	<u>\$ (1,206,914)</u>	<u>\$ (1,516,355)</u>	<u>\$ (1,265,291)</u>
<b>BASIC AND DILUTED LOSS PER SHARE</b>	<u>\$ 0.08</u>	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>

Revenues have been cyclical in nature, but show an increasing trend from quarter to quarter. The slightly unpredictable nature of revenues is expected as third party development projects are difficult to predict and may start or stop suddenly depending on the needs of the customer.

Selling expenses have remained relatively consistent from 2012 as efforts have been focused on servicing our existing customers. General and administrative expense reached a peak in the first quarter of 2013 mainly due to a stock-based compensation expense of \$878,816 which included options granted and vested immediately in the quarter. Product development and clinical trial costs peaked in the fourth quarter of 2013 due to the COSIRA clinical trial and the preclinical Tiara project expenses.

## **DISCUSSION OF LIQUIDITY AND CAPITAL RESOURCES**

Neovasc finances its operations and capital expenditures with cash generated from operations, lines of credit, long-term debt and equity financings. At December 31, 2013, the Company had cash and cash equivalents of \$3,403,472 compared to cash and cash equivalents of \$5,861,120 at December 31, 2012.

In 2013, cash used in operating activities was \$4,683,103 compared to \$2,037,440 for the same period in 2012. The increase was principally due to an increase in operating expenses and a decrease in cash generated by working capital items. In 2013, operating expenses were \$4,517,510, compared to \$2,465,923 for the same period in 2012, as more expenses were incurred in research and development and clinical trials activities. Working capital items used cash of \$167,893, compared to working capital items generating cash of \$410,390 for the same period in 2012, as accounts receivable and inventory absorbed more cash associated with increased production activities and revenue growth and the increase in work in progress related to one customer changing their sterilization process.

In 2012, \$4,253,298 was received from LeMaitre as the first payment of the proceeds from sale of a license and in 2013 \$344,862 was received as full and final payment for the license (as discussed in the "Loss" section). In 2013, the Company invested \$1,041,188 in property, plant and equipment, compared to \$312,586 for the same period in 2012. During 2013, the Company invested capital to expand its clean room and manufacturing facilities and research and development capabilities. Finally, in 2012, a \$1,504,290 investment in GICs maturing on October 15, 2012 was re-classified as cash equivalents.

In 2013, net cash provided by financing activities was \$2,921,781 compared to \$49,048 for the same period in 2012. During 2013, the Company issued 2,335,250 common shares, upon the exercise of warrants issued as part of the Company's August 2011 financing. Proceeds received from the exercise of the 2,335,250 warrants amounted to \$2,919,062.

The majority of the revenue and expenses of the Company are incurred in the parent and in one of its subsidiaries, NMI, both of which are Canadian companies. There are no significant restrictions on the transfer of funds between these entities and during the year ended December 31, 2013 the Company also had no complications in transferring funds to and from its subsidiaries in Israel.

The majority of the Company's cash and cash equivalents at December 31, 2013 were denominated in Canadian dollars. The Company is exposed to foreign currency fluctuations on \$922,105 of its cash and cash equivalents held in United States dollars and European euros.

## **SUBSEQUENT EVENTS**

On March 26, 2014, the Company closed a bought deal equity financing underwritten by Cormark Securities Inc., which placed 4,192,000 common shares of Neovasc at a price of \$6.00 per common share, for gross cash proceeds to the Company of \$25,152,000.

## **OUTSTANDING SHARE DATA**

As at April 17, 2014, the Company had **[48,387,302]** common voting shares issued and outstanding. Further, the following securities are convertible into common shares of the Company: **[8,610,698]** stock options with a weighted average price of \$1.06. The fully diluted share capital of the Company at April 17, 2014 is 56,998,000.

## CONTRACTUAL OBLIGATIONS

The following table summarizes out contractual obligations as of December 31, 2013:

Contractual Obligations	Payments due by Period					
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years	
Long term Debt Obligations	\$ 243,632	\$ 43,548	\$ 90,781	\$ 95,240	\$ 14,063	
Operating leases	32,544	26,244	6,300	-	-	
Total	<b>\$ 276,176</b>	<b>\$ 69,792</b>	<b>\$ 97,081</b>	<b>\$ 95,240</b>	<b>\$ 14,063</b>	

## OFF BALANCE SHEET ARRANGEMENTS

The Company has no off balance sheet arrangements.

## RELATED PARTY TRANSACTIONS

There were no ongoing contractual commitments and transactions with related parties during the year ended December 31, 2013 and 2012, other than those compensation based payments disclosed in Note 20 of the financial statements.

## 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 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 IFRS 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, 2013.

The Company files Form 52-109FV1 – *Certification of annual filings – venture issuer basic certificate* and chose to discuss the design and evaluation of its disclosure controls and procedures (“DC&P”) in the MD&A. As a venture issuer, the Company is not required to certify the design and evaluation of the Company’s DC&P and has not completed such an evaluation. The Company acknowledges that there are inherent limitations on the ability of the CEO and CFO to design and implement DC&P for the Company on a cost effective basis and this may result in additional risks to the quality, reliability, transparency and timeliness of the interim and annual filings and other reports provided.

## ADDITIONAL INFORMATION

Further information, including public disclosure filed with the applicable securities regulatory authorities, is available on the Company’s public profile page at [www.sedar.com](http://www.sedar.com).