



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

Form 51-102F1

**FOR THE THREE AND SIX MONTHS ENDED  
JUNE 30, 2015 AND 2014**

**Q2  
2015**

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

This discussion and analysis covers the unaudited interim consolidated financial statements of Neovasc Inc. (the "Company" or "Neovasc") for the three and six months ended June 30, 2015 and 2014.

The Management's Discussion and Analysis ("MD&A") of financial condition and results of operations should be read in conjunction with the unaudited condensed interim consolidated financial statements and notes thereto for the three and six months ended June 30, 2015 and 2014 (included as part of Neovasc Inc.'s quarterly filing) as well as the audited consolidated financial statements and notes thereto and the MD&A for the years ended December 31, 2014.

The Company has prepared this MD&A with reference to National Instrument 51-102 "Continuous Disclosure Obligations" of the Canadian Securities Administrators. Under the United States/Canada Multijurisdictional Disclosure System, the Company is permitted to prepare this MD&A in accordance with the disclosure requirements of Canada, which requirements are different than those of the United States.

The names Tiara™ ("Tiara"), Neovasc Reducer™ ("Reducer") and Peripatch™ ("Peripatch") are our trademarks; other trademarks, product names and company names appearing herein are the property of their respective owners.

Additional information about the Company, including the Financial Statements and Annual Information Form, are available on SEDAR at [www.sedar.com](http://www.sedar.com) and on the website of the United States Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This MD&A contains forward-looking statements within the meaning of applicable Canadian securities legislation and United States 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 MD&A 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;
- our ability to get our products approved for use;
- the benefits and risks of our products as compared to others;
- our ability to establish, maintain and defend intellectual property rights in our products;
- 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 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 other third parties, 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;
- 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;
- the conduct or possible outcomes of any actual or threatened legal proceedings;
- our intention to continue directing a significant portion of our resources into sales expansion;
- 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; and
- risks related to lawsuits that could direct our resources and result in the payment of significant damages and other remedies.

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:

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

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 in our Annual Information Form, under the heading “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 MD&A 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”) as issued by the International Accounting Standards Board (“IASB”) and is expressed in Canadian dollars.

Date: August 6, 2015

## 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 and on January 1, 2015 ANG was amalgamated into NMI.

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 Reducer, a novel catheter-based treatment for refractory angina, a debilitating condition resulting from inadequate blood flow to the heart muscle. In 2009, Neovasc ceased all activities related to BBL's technologies and is in the process of voluntarily liquidating BBL.

In late 2009, Neovasc started initial activities to develop novel technologies for the 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 preclinical / early clinical stage development to provide a minimally invasive transcatheter device for the millions of patients who experience mitral regurgitation ("MR") as a result of mitral heart valve disease (it was estimated that in 2013 MR will affect approximately 5.7 million people in the United States and the European Union). MR 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 MR 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 MR in the United States. Currently there is no transcatheter mitral valve replacement device approved for use in any market.

Clinical work to date has been completed using the initial, 35mm size of Tiara and associated delivery system. The Company is actively pursuing expansion of the Tiara size matrix to include two additional sizes (40mm and 45mm) to enable implantation in a broader population of patients. First clinical use of the 40mm size is anticipated in the fourth quarter of 2015 and the 45mm size in early 2016.

The 35mm size Tiara has been implanted in 8 patients to date with encouraging results. One case required conversion to a surgical valve replacement due to valve malposition. In the remaining 7 cases, Tiara was successfully implanted as intended, resulting in a stable and well anchored prosthetic valve with complete resolution of the patient's MR. No significant transvalvular gradients, no left ventricular outflow tract (LVOT) obstruction, and no paravalvular leaks or negative interactions with surrounding structures, including the aortic valve, have been observed. Implantation of Tiara has been successfully undertaken in patients suffering from both degenerative MR and functional MR and in multiple patients with pre-existing prosthetic aortic valves. Implanted patients are continuing to thrive with significantly improved quality of life, with one patient nearing their 18 month post implant follow-up.

To date no mechanical failures of Tiara, including frame fractures or thrombus formation have been observed in clinical use, nor has any other issue been identified requiring significant modification of the current design beyond expansion of the available size matrix.

A more detailed update of clinical results to date will be provided at Transcatheter Cardiovascular Therapeutics (TCT), the world's largest educational meeting specializing in interventional cardiovascular medicine in October 2015.

While many challenges remain prior to achieving commercial production (including, but not limited to, positive clinical trials and obtaining regulatory approval from the relevant authorities), we believe the Tiara device is being widely recognized at 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; some of which have been implanted in patients, with varying results.

Neovasc believes that there are several unique attributes of the Tiara device that may provide advantages over other approaches to mitral valve replacement. 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 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. 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-stage development product without regulatory approvals in any country. The Company intends to 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 June 30, 2015, the Company has spent approximately \$22 million developing the product and anticipates that it may require an additional \$10 million 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.

On October 9, 2014 Neovasc announced that it had received conditional Investigational Device Exemption approval from the United States Food and Drug Administration to initiate the United States arm of its TIARA-I Early Feasibility Trial for the Company's Tiara transcatheter mitral valve. The TIARA-I Early Feasibility Trial is a multinational, multicenter trial being conducted to assess the safety and performance of Neovasc's Tiara mitral valve system and implantation procedure in high-risk surgical patients suffering from severe MR. Severe MR is a critical condition that affects millions of patients and, if left untreated, can lead to heart failure or death. The TIARA-I Early Feasibility Trial will enroll up to 30 patients globally and is being overseen by a multidisciplinary committee of internationally recognized physicians co-chaired by Dr. Martin Leon (Director, Center for Interventional Vascular Therapy Columbia University Medical Center / New York-Presbyterian Hospital) and Dr. Anson Cheung (Professor of Surgery and Director of Cardiac Transplant at St. Paul's Hospital, Vancouver Canada).

The Tiara has been implanted in patients at three centres in Canada, the United States and Europe. In the United States, the TIARA-I is expected to enroll patients at up to four highly respected United States medical centers including Columbia University Medical Center / New York-Presbyterian Hospital (New York) and Cedars-Sinai Medical Center (Los Angeles). Neovasc is now focusing on finalizing activities to add additional centers in the US as well as support the activated centers in screening and enrollment.

In Europe, TIARA-I has received ethics committee approval at Antwerp Cardiovascular Center / ZNA Middelheim in Belgium and competent authority notification in that country.

In Canada, St Paul's Hospital (Vancouver) conducted the first compassionate use implantations of the Tiara. The Company is in the final stages of activating this site to begin screening and enrolling TIARA-I patients, and is in the process of adding two additional sites in Canada for both compassionate use cases and the TIARA-I trial.

By the end of Q3-2015 the Company is targeting to have 8 centres in total recruiting patients to the TIARA-I study.

## **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 United States, who are not eligible for conventional treatments, 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 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 Company has completed a multicenter, randomized, sham controlled study ("COSIRA") to assess the efficacy of the Reducer device. COSIRA's primary endpoint was 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 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 (42.3%) of the control patients (p-value = 0.003)). The COSIRA results were published in the New England Journal of Medicine in February 2015.

The Reducer is an hourglass-shaped, balloon-expandable, stainless steel device, which is implanted in the coronary sinus, creating a restriction in venous outflow from the myocardium (the muscular layer of the heart wall). It is implanted using conventional percutaneous, or needle puncture 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 0.035 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 has initiated a pilot launch of the Reducer in select European markets in 2015. The Company will also explore initiation of Reducer sales in other non-United States markets. It is anticipated that sales of the product in the United States would follow obtaining United States regulatory approval, if such approval is granted, as described further below.

In Q1 2015, the company initiated pilot launch of the Reducer into selected European markets. The Company has signed distribution Agreements in Italy and the UK and filled initial stocking orders for these countries. Activities are also underway to pilot launch Reducer at selected centers in Switzerland and Germany. For the remainder of 2015, Neovasc will primarily focus on the pilot launch in these four countries which make up a significant portion of the European market and then explore opportunities to expand into other territories.

### *Regulatory Status*

The Reducer is approved for sale in Europe, having received CE-mark designation in November 2011. 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. In February 2015, the COSIRA results were published in the *New England Journal of Medicine*. 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.

Neovasc is also developing a United States 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 2016. United States marketing approval is expected about two to four years after the clinical trial begins. There is no assurance that United States regulatory approval will be granted in the time frame anticipated by management, or granted at any time in the future. The cost of the United States clinical trial is expected to be \$15-20 million.

### **Peripatch Products**

Neovasc also 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). 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 plus 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 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 ceased manufacturing all surgical patches in the second quarter of 2015.

The Company also provides a range of custom Peripatch products to industry customers for incorporation into their own products, such as transcatheter heart valves, 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 plus 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 by a third party that was a predecessor company to NMI, 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 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.

#### *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. 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.

## **Product Development**

Product development at the Company is currently focused on commercialization of the Reducer as well as clinical stage and pre-commercial development work on the Tiara program. The Company may also investigate other potential new internal or external projects that leverage the Company's existing technologies, infrastructure and expertise.

## **TRENDS, RISKS AND UNCERTAINTIES**

The Company has incurred operating losses of \$8,303,416 and \$14,461,259 for the three and six months ended June 30, 2015 (three and six months ended June 30, 2014:\$6,471,911 and \$6,851,983) and has a deficit of \$111,616,360 at June 30, 2015 compared to a deficit of \$97,155,101 as at December 31, 2014. As at June 30, 2015 the Company had \$85,654,914 in cash and cash equivalents and \$8,097,717 in short-term investments in guaranteed investment certificates and bonds, which mature within one year. The Company believes it is well funded to pursue its short and medium term objectives for the Tiara and Reducer programs, but may need to raise additional capital prior to the successful commercialization of these products. There is no certainty that the programs will be successfully commercialized or any required funds will be available to the Company at the time needed or on terms acceptable to the Company.

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 operating 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.

Operating risks include but are not limited to: market acceptance of the Company's technologies and products; litigation risk associated with the Company's intellectual property and the Company's defense and protection thereof; the conduct or possible outcomes of any actual or threatened legal proceedings; 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.

These risk factors and others are described in greater detail in the Company's Annual Information Form which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on the website of the United States Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).

## **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 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 FINANCIAL INFORMATION**

The following discussion should be read in conjunction with the unaudited condensed interim consolidated financial statements for the three and six months ended June 30, 2015 and 2014.

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

Results for the three and six months ended June 30, 2015 and 2014 follow:

### **Losses**

The losses for the three and six months ended June 30, 2015 were \$8,303,416 and \$14,461,259, or \$0.12 and \$0.23 basic and diluted loss per share, as compared with a loss of \$6,471,911 and \$6,851,983, or \$0.12 and \$0.13 basic and diluted loss per share for the same periods in 2014. The \$1,831,505 increase in the loss incurred for the three months ended June 30, 2015 compared to the same period in 2014 can be substantially explained by \$2,231,766 increase in general and administrative expenses, \$2,367,102 increase in product development and clinical trial expenses, and offset by a \$2,681,543 decrease in share-based payment. The \$7,609,276 increase in the loss incurred for the six months ended June 30, 2015 compared to the same period in 2014 can be substantially explained by \$1,026,332 decrease in gross profit, \$3,269,281 increase in general and administrative expenses, \$4,861,408 increase in product development and clinical trial expenses, and offset by \$1,363,552 decrease in share-based payment. In the first six months of 2015 and 2014 certain directors, officers and employees of Neovasc were granted options under the Company's established remuneration and incentive plans. However, the number of options granted in the first six months of 2015 was much less than the grant in the same period of 2014, and therefore resulted in a lower non-cash charge to the income statement in 2015.

### **Revenues**

Revenues decreased 18% year-over-year to \$3,599,834 for the three months ended June 30, 2015, compared to revenues of \$4,404,515 for the same period in 2014. Revenues decreased 22% year-over-year to \$6,460,480 for the six months ended June 30, 2015, compared to revenues of \$8,240,650 for the same period in 2014. The Company started its sales of Reducer in the first quarter of 2015 as it initiated its focused commercialization of the product in Europe. The Company also ceased its production of surgical patches in June 2015. The Company anticipates that as revenues from the tissue business decline the revenue from the Reducer will begin to compensate.

Reducer sales for the three months ended June 30, 2015 were \$165,528, compared to \$nil for the same period in 2014. Reducer sales for the six months ended June 30, 2015 were \$215,668, compared to \$nil for the same period in 2014. These sales should be categorized as stocking orders as newly qualified distributors took receipt of their first order of Reducers. The Company anticipates that Reducer sales will gradually grow in 2015, initially with stocking orders from other distributors in other countries and then later in the year, with repeat orders.

Product sales for the three months ended June 30, 2015 were \$147,685, compared to \$798,921 for the same period in 2014, representing a decrease of 82%. Product sales for the six months ended June 30, 2015 were \$424,973, compared

to \$1,493,919 for the same period in 2014, representing a decrease of 72%. Product sales are solely comprised of sales of surgical patches to LeMaitre. Concurrent with 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 discounted price, until LeMaitre received appropriate regulatory approvals and started to manufacture the surgical patches itself. Neovasc ceased manufacturing all surgical patches in June 2015.

Contract manufacturing revenues for the three months ended June 30, 2015 were \$1,195,544, compared to \$721,225 for the same period in 2014, representing an increase of 66%. Contract manufacturing revenues for the six months ended June 30, 2015 were \$1,895,013, compared to \$906,941 for the same period in 2014, representing an increase of 109%. The increase in the three and six months ended June 30, 2015 compared to the same periods in 2014 reflect growth in contract manufacturing revenues earned with one of the Company's customers. The Company has seen a concentration of revenue into fewer larger accounts and expects that this reflects growing demand for those customers' products. Neovasc anticipates that contract manufacturing will continue to grow in the long term as its customers' products receive regulatory approvals and are commercialized, but recognizes that these revenues will be derived from a smaller customer base as the transcatheter aortic market matures.

Revenues from consulting services for the three months ended June 30, 2015 were \$2,091,077, compared to \$2,884,369 for the same period in 2014, representing a decrease of 28%. Revenues from consulting services for the six months ended June 30, 2015 were \$3,924,826, compared to \$5,839,790 for the same period in 2014, representing a decrease of 33%. The decrease in consulting service revenues reflects one customer's development program working towards the end of its development stage. The Company anticipates that our consulting services revenue will decline in the long term as its consulting customers continue to transition to becoming contract manufacturing customers.

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. Some 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 three and six months ended June 30, 2015 was \$2,232,359 and \$4,227,608, respectively, compared to \$3,066,924 and \$4,981,446 for the same periods in 2014. The overall gross margin for the three and six months ended June 30, 2015 was 38% and 35%, respectively, compared to 30% and 40% gross margin for the same periods in 2014. Gross margin improved in Q2 2015 due to increase in raw material yields and the discontinuation of sales of lower margin products.

### **Expenses**

Total expenses for the three and six months ended June 30, 2015 were \$9,764,899 and \$17,064,889, respectively, compared to \$7,782,507 and \$10,132,078 for the same periods in 2014, representing an increase of \$1,982,392 or 25%, and \$6,932,811 or 68%, respectively. The increase in total expenses for the three months ended June 30, 2015 compared to the same period in 2014 reflects a \$2,231,766 increase in general and administrative expenses and a \$2,367,102 increase in product development and clinical trial expenses to advance the Tiara and Reducer development programs, and offset by a \$2,738,571 decrease in share-based payment. The increase in total expenses for the six months ended June 30, 2015 compared to the same period in 2014 reflects a \$3,269,281 increase in general and administrative expenses and a \$4,861,408 increase in product development and clinical trial expenses to advance the Tiara and Reducer development programs, and offset by \$1,442,204 decrease in share-based payment.

Selling expenses for the three and six months ended June 30, 2015 were \$154,302 and \$307,985, respectively, compared to \$24,413 and \$44,328 for the same periods in 2014, representing an increase of \$129,889, or 532%, and \$263,657 or 595%. The increase in selling expenses for the three and six months ended June 30, 2015 compared to the same periods in 2014 reflects costs incurred for Reducer commercialization activities in the first six months of 2015. The Company anticipates a significant increase in selling expenses in 2015 as it initiates a focused commercialization of the Reducer in select countries in Europe.

General and administrative expenses for the three and six months ended June 30, 2015 were \$4,347,076 and \$7,234,486, respectively, compared to \$4,644,387 and \$5,740,841 for the same periods in 2014, representing a decrease of \$297,311, or 6% and an increase of \$1,493,645, or 26%, respectively. The decrease in general and administrative

expenses for the three months ended June 30, 2015 compared to the same period in 2014 can be substantially explained by a \$2,529,077 decrease in share-based payments, and offset by a \$2,231,766 increase in other expenses. The \$2,231,766 increase includes, but is not limited to, approximately \$2,000,000 related to litigation expenses, approximately \$235,000 related to the rent of new administration office, insurance, and information system expenses and approximately \$370,000 related to an increase in general and administrative staff and an increase in compensation to the board, and senior management. The increase in general and administrative expenses for the six months ended June 30, 2015 compared to the same period in 2014 can be substantially explained by a \$3,269,281 increase in other expenses, and offset by \$1,775,636 decrease in share-based payment. The \$3,269,281 increase includes, but is not limited to, approximately \$2,500,000 related to litigation expenses, approximately \$400,000 related to the rent of new administration office, insurance, and information system expenses and approximately \$460,000 related to an increase in general and administrative staff and an increase in compensation to the board and senior management.

Product development and clinical trial expenses for the three and six months ended June 30, 2015 were \$5,263,521 and \$9,522,418, respectively, compared to \$3,113,707 and \$4,346,909 for the same periods in 2014, representing an increase of \$2,149,814, or 69% and \$5,175,509, or 119%. The increase in product development and clinical trial expenses for the three months ended June 30, 2015 was due to a \$781,454 increase in cash-based employee expenses as the Company hired additional staff to advance product development and a \$1,585,648 increase in other expenses as the Company invested in its two major new product initiatives, offset by a \$217,288 decrease in share-based payment. The increase in product development and clinical trial expenses for the six months ended June 30, 2015 was due to \$314,101 increase in share-based payment, a \$1,471,654 increase in cash-based employee expenses as the Company hired additional staff to advance product development and a \$3,389,754 increase in other expenses as the Company invested in its two major new product initiatives.

The Company's expenses are subject to inflation and cost increases. Salaries and wages have increased on average by 6% in the six months ended June 30, 2015 compared to the same period in 2014. The Company has not seen a material 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 three months ended June 30, 2015 was \$94,008, compared to other expense of \$26,995 for the same period in 2014. The other income for the six months ended June 30, 2015 was \$370,758, compared to other income of \$20,891 for the same period in 2014. The Company's investments in high interest savings accounts and guaranteed investment certificates generated \$432,665 interest in the six months ended June 30 2015.

## QUARTERLY INFORMATION

The following is a summary of selected unaudited financial information for the eight fiscal quarters to June 30, 2015:

	June 30, 2015	March 31, 2015	December 31, 2014	September 30, 2014
<b>REVENUE</b>				
Reducer	\$ 165,528	\$ 50,140	\$ -	\$ -
Product sales	147,685	277,288	297,493	471,468
Contract manufacturing	1,195,544	699,469	1,081,622	1,366,552
Consulting services	2,091,077	1,833,749	1,974,326	2,431,340
	<u>3,599,834</u>	<u>2,860,646</u>	<u>3,353,441</u>	<u>4,269,360</u>
<b>COST OF GOODS SOLD</b>	<u>2,232,359</u>	<u>1,995,249</u>	<u>2,662,748</u>	<u>2,468,747</u>
<b>GROSS PROFIT</b>	<u>1,367,475</u>	<u>865,397</u>	<u>690,693</u>	<u>1,800,613</u>
<b>EXPENSES</b>				
Selling expenses	154,302	153,683	112,818	19,285
General and administrative expenses	4,347,076	2,887,410	3,196,693	2,916,141
Product development and clinical trials expenses	5,263,521	4,258,897	5,051,884	3,488,051
	<u>9,764,899</u>	<u>7,299,990</u>	<u>8,361,395</u>	<u>6,423,477</u>
<b>OPERATING LOSS</b>	<u>(8,397,424)</u>	<u>(6,434,593)</u>	<u>(7,670,702)</u>	<u>(4,622,864)</u>
OTHER INCOME/(EXPENSE)	94,008	276,750	50,132	34,319
<b>LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD</b>	<u>\$ (8,303,416)</u>	<u>\$ (6,157,843)</u>	<u>\$ (7,620,570)</u>	<u>\$ (4,588,545)</u>
<b>BASIC AND DILUTED LOSS PER SHARE</b>	<u>\$ (0.12)</u>	<u>\$ (0.10)</u>	<u>\$ (0.14)</u>	<u>\$ (0.09)</u>
	June 30, 2014	March 31, 2014	December 31, 2013	September 30, 2013
<b>REVENUE</b>				
Product sales	\$ 798,921	\$ 694,998	\$ 683,289	\$ 654,809
Contract manufacturing	721,225	185,716	96,917	583,466
Consulting services	2,884,369	2,955,421	2,531,344	2,395,616
	<u>4,404,515</u>	<u>3,836,135</u>	<u>3,311,550</u>	<u>3,633,891</u>
<b>COST OF GOODS SOLD</b>	<u>3,066,924</u>	<u>1,914,522</u>	<u>2,056,349</u>	<u>2,160,092</u>
<b>GROSS PROFIT</b>	<u>1,337,591</u>	<u>1,921,613</u>	<u>1,255,201</u>	<u>1,473,799</u>
<b>EXPENSES</b>				
Selling expenses	24,413	19,915	18,417	7,366
General and administrative expenses	4,644,387	1,096,454	1,183,067	1,009,473
Product development and clinical trials expenses	3,113,707	1,233,202	2,366,195	1,878,943
	<u>7,782,507</u>	<u>2,349,571</u>	<u>3,567,679</u>	<u>2,895,782</u>
<b>OPERATING LOSS</b>	<u>(6,444,916)</u>	<u>(427,958)</u>	<u>(2,312,478)</u>	<u>(1,421,983)</u>
OTHER INCOME/(EXPENSE)	(26,995)	47,886	100,603	(17,843)
<b>LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD</b>	<u>\$ (6,471,911)</u>	<u>\$ (380,072)</u>	<u>\$ (2,211,875)</u>	<u>\$ (1,439,826)</u>
<b>BASIC AND DILUTED LOSS PER SHARE</b>	<u>\$ (0.12)</u>	<u>\$ (0.01)</u>	<u>\$ (0.05)</u>	<u>\$ (0.03)</u>

After a general trend of quarter over quarter revenue growth in the past quarters, there was a decrease in the first quarter of 2015. We anticipate our overall revenues to be focused on a smaller customer base in 2015. Neovasc ceased manufacturing all surgical patches in the second quarter of 2015. In the long term we expect our consulting services to decline. We expect our consulting service customers to transition to become contract manufacturing customers and we are not actively looking for new customers as we are diverting available research and development staff and resources to our Tiara program. We anticipate that we will be able to replace and grow total revenue from the commercialization of our Reducer product in the mid to long-term.

Selling expenses increased in the first and second quarter of 2015 as the Company initiates a focused commercialization of the Reducer in select countries in Europe. General and administrative expense reached a peak in the second quarter of 2014 mainly due to a stock-based compensation expense of \$2,802,674 which included options granted and vested

immediately in the quarter. Product development and clinical trial costs peaked in the second quarter of 2015 due to a stock-based compensation expense of \$1,551,994 and the preclinical and clinical Tiara expenses.

## USE OF PROCEEDS

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.

The following table sets out a comparison of how the Company used the proceeds following the closing date against the intended use of proceeds from the bought deal, including an explanation of any variances and the impact of any variance on the ability of the Company to achieve its business objectives and milestones.

	PROPOSED USE OF NET PROCEEDS	ACTUAL USE OF NET PROCEEDS	
	March 26, 2014 Bought Deal	Use of Proceeds	Remaining to be Spent
Tiara Development Costs	\$13,500,000	\$12,061,724	\$1,438,276
Reducer Development Costs	\$7,500,000	\$1,523,229	\$5,976,771
Additional Proceeds	\$3,645,349	\$3,645,349	-
<b>TOTAL</b>	<b>\$24,645,349</b>	<b>\$17,230,302</b>	<b>\$7,415,047</b>

The actual proceeds net of share issue costs from March 26, 2014 financing were \$24,645,349. The additional proceeds will be used for working capital items and to fund the expansion of our clean rooms and office space. The majority of the proceeds have been invested in high interest savings accounts and guaranteed investment certificates that are shown as part of cash and cash equivalents and investments in the financial statements. The approximate expenditures from proceeds of the bought deal equity financing from March 26, 2014 to June 30, 2015 were \$17,230,000, of which approximately \$12,061,000 was spent on Tiara Development Costs, \$1,523,000 was spent on Reducer Development Costs and \$3,646,000 was spent on working capital items and investment in property, plant and equipment funded from the additional proceeds.

On February 3, 2015, the Company closed an underwritten public offering, which placed 10,415,000 newly issued common shares of Neovasc from treasury at a price of US\$7.19 per common share for aggregate gross proceeds of approximately US\$74,883,850 to the Company. The February 2015 offering also included the sale of 1,660,000 Neovasc common shares on the same terms by certain directors, officers and employees of Neovasc. The Company did not receive any proceeds from the sale of the 1,660,000 Neovasc common shares by the directors, officers and employees.

The following table sets out a comparison of how the Company used the proceeds following the closing date against the intended use of proceeds from the public offering, including an explanation of any variances and the impact of any variance on the ability of the Company to achieve its business objectives and milestones.

	PROPOSED USE OF NET PROCEEDS	ACTUAL USE OF NET PROCEEDS	
	February 3, 2015 Underwritten Public Offering	Use of Proceeds	Remaining to be Spent
Tiara Development Costs	\$43,600,000	-	\$43,600,000
Reducer Development Costs	\$12,500,000	-	\$12,500,000
Additional Proceeds	\$30,983,471	\$745,887	\$30,237,584
<b>TOTAL</b>	<b>\$87,083,471</b>	<b>-</b>	<b>\$86,337,584</b>

The actual proceeds net of share issue costs from the February 3, 2015 financing to the Company were \$87,083,471. The majority of the proceeds have been invested in high interest savings accounts and guaranteed investment certificates that are shown as part of cash and cash equivalents and investments in the financial statements. The Company spent approximately \$746,000 on working capital items and investment in property, plant and equipment funded from the additional proceeds.

The combined value of the cash and cash equivalents and investments as at June 30, 2015 is \$93,752,631.

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

Neovasc finances its operations and capital expenditures with cash generated from operations, lines of credit, and equity financings. At June 30, 2015, the Company had cash and cash equivalents of \$85,654,914 compared to cash and cash equivalents of \$6,025,013 at December 31, 2014, as well as \$8,097,717 invested in short term investments falling due within one year.

Cash used in operating activities for the three and six months ended June 30, 2015, was \$6,350,560 and \$10,642,896, respectively, compared to \$1,389,041 and \$2,162,205 for the same periods in 2014. For the three months ended June 30, 2015, operating expenses were \$7,055,360, compared to \$2,389,329 for the same period in 2014, as more expenses were incurred in general and administrative and research and development and clinical trials activities as discussed elsewhere in this MD&A. Working capital items generated cash of \$484,055, compared to working capital items generated cash of \$964,246 for the same period in 2014, as accounts receivable and inventory generated less cash associated with revenue decrease. For the six months ended June 30, 2015, operating expenses were \$11,731,376, compared to \$2,528,635 for the same period in 2014, as more expenses were incurred in general and administrative and research and development and clinical trials activities as discussed elsewhere in this MD&A. Working capital items generated cash of \$818,275, compared to working capital items generated cash of \$330,257 for the same period in 2014, as accounts receivable generated more cash due to the increase in interest receivables for our investments in GICs, inventory absorbed less cash associated with decrease of revenue and prepaid expenses and other assets increased with the payment of deposits for our leased office space and the payment of our clinical trial insurance and director & officer's insurance in advance rather than on a monthly basis.

For the three months ended June 30, 2015, net cash used by investing activities was \$1,097,797 due to \$5,000,000 GICs matured and put back into cash and cash equivalents, and \$6,097,717 invested into a bond. For the six months ended June 30, 2015, net cash provided by investing activities was \$3,902,282 to fund the Company's obligations in the short-term. For the three and six months ended June 30, 2015, the Company invested \$1,072,590 and \$1,562,728 in property, plant and equipment, compared to \$251,141 and \$317,003 for the same periods in 2014. The Company purchased \$470,260 of land and building in June 2015. The Company continues to invest capital to expand its clean room, chemical lab and manufacturing facilities and research and development capabilities.

For the three months ended June 30, 2015, net cash used by financing activities was \$170,237, as the Company paid out its long-term debt, compared to net cash provided by financing activities \$104,927 for the same period in 2014. For the six months ended June 30, 2015, net cash provided by financing activities was \$87,973,192, compared to \$24,763,569 for the same period in 2014. On February 3, 2015, the Company closed an underwritten public offering of 12,075,000 common shares of the Company (of which 10,415,000 common shares were issued from treasury and 1,660,000 common shares were sold by certain directors, officers and employees of the Company) at a price per share of US\$7.19 for aggregate gross proceeds of approximately US\$74,883,850 for the Company and US\$11,935,400 for the selling security holders. The share issue costs incurred by the Company were \$6,236,783.

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 three and six months ended June 30, 2015 the Company had no complications in transferring funds to and from its subsidiaries in Israel and USA.

The majority of the Company's cash and cash equivalents at June 30, 2015 were denominated in Canadian dollars. The Company is exposed to foreign currency fluctuations on \$4,919,049 of its cash and cash equivalents held in United States dollars and European euros. In addition, the Company's investment \$6,097,717, denominated in US dollar, is exposed to foreign currency fluctuations as well.

## **EVENTS DURING THE QUARTER**

Other than described elsewhere herein, there were no material events during the quarter.

## **SUBSEQUENT EVENTS**

On July 23, 2015, the Board approved a new \$1,000,000 line of credit with the Company's bank. The approved amount includes a \$900,000 revolving line of credit and \$100,000 corporate classic VISA. This line of credit is collateralized by a

first charge over the Company's land and buildings and a general security agreement over all personal property of the business now owned and all personal property acquired in the future. The interest rate for the \$900,000 business operating account overdraft will be calculated at Prime Rate plus 1% per annum.

## OUTSTANDING SHARE DATA

As at August 6, 2015, the Company had 66,551,447 common shares issued and outstanding. Further, the following securities are convertible into common shares of the Company: 7,805,013 stock options with a weighted average price of \$3.78. The fully diluted share capital of the Company at August 6, 2015 is 74,459,960.

## CONTRACTUAL OBLIGATIONS AND CONTINGENCIES

### *Contingencies*

The Company is engaged as a defendant in lawsuits filed by CardiAQ Valve Technologies, Inc. ("CardiAQ"), as further described below. Litigation resulting from CardiAQ's claims could be costly and time-consuming and could divert the attention of management and key personnel from our business operations. We cannot assure that we will succeed in defending any of these claims and that judgments will not be entered against us with respect to the litigation resulting from such claims. If we are unsuccessful in our defense of these claims or unable to settle the claims in a manner satisfactory to us, we may be faced with significant monetary damages, loss of intellectual property rights, or injunctive relief against us that could have a material adverse effect on our business and financial condition.

On June 6, 2014, Neovasc was named in a lawsuit filed by CardiAQ in the U.S. District Court for the District of Massachusetts concerning intellectual property rights ownership, unfair trade practices and a breach of contract relating to Neovasc's transcatheter mitral valve technology, including the Tiara device. On June 23, 2014, CardiAQ also filed a complaint against Neovasc in Germany requesting that Neovasc assign its right to one of its European patent application to CardiAQ. On July 7, 2014, the Company was made aware through a press release issued by CardiAQ of a stay in proceedings for Neovasc's European patent application that is the subject of the German lawsuit. This stay of proceedings was granted without an opportunity for Neovasc to respond to CardiAQ's allegations. The Company requested that the stay be lifted, but the request was denied by the European Patent office pending resolution of the German lawsuit. Neovasc filed its response in the German lawsuit in December 2014.

The Company intends to vigorously defend itself in both lawsuits. On July 29, 2014, in the Massachusetts action, the Company filed a motion to dismiss several of CardiAQ's claims. As a result of the Company's motion, CardiAQ filed a first amended complaint on August 12, 2014, and the Company responded by filing another motion to dismiss several of CardiAQ's claims. The Court granted the motion in part. CardiAQ filed its Second Amended Complaint on January 15, 2015. The Court has issued a case schedule with a trial date in 2016. In the German action, and based on the parties' submissions, the court in Munich will render its decision, which may be a final order or a case management order, on November 20, 2015.

The outcome of these matters is not currently determinable nor is it possible to accurately predict the outcome or quantum of these proceedings to the Company at this time. Until this matter has been resolved by the appropriate Courts, the Company cannot give any assurances as to such outcome. Accordingly, no dollar value has been recorded in the accompanying financial statements.

### *Contractual obligations*

The following table summarizes our contractual obligations as of June 30, 2015:

Contractual Obligations	Total	Payments due by Period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	\$ 911,135	\$ 261,025	\$ 461,179	\$ 188,931	-

## 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 three and six months ended June 30, 2015 and 2014, other than as described elsewhere herein and those compensation based payments disclosed in Note 19 of the financial statements.

## **PROPOSED TRANSACTIONS**

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

## **CRITICAL ACCOUNTING ESTIMATES AND MANAGEMENT JUDGEMENT**

The preparation of consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Significant areas requiring the use of estimates relate to the determination of the net realizable value of inventory (obsolescence provisions), allowance for doubtful accounts receivable, impairment of non-financial assets, useful lives of depreciable assets and expected life, volatility and forfeiture rates for share-based payments.

### *Inventories*

The Company estimates the net realizable values of inventories, taking into account the most reliable evidence available at each reporting date. The future realization of these inventories may be affected by future technology or other market-driven changes that may reduce future selling prices.

### *Allowance for doubtful accounts receivable*

The Company provides for bad debts by setting aside accounts receivable past due more than 121 days or sooner if management determines that certain accounts receivable may be uncollectible. Actual collectability of customer balances can vary from the Company's estimation.

### *Impairment of long-lived assets*

In assessing impairment, the Company estimates the recoverable amount of each asset or cash generating unit based on expected future cash flows and uses an interest rate to discount them. Estimation uncertainty relates to assumptions about future operating results and the determination of a suitable discount rate.

### *Useful lives of depreciable assets*

The Company reviews its estimate of the useful lives of depreciable assets at each reporting date, based on the expected utilization of the assets.

### *Share-based payment*

The Company measures the cost of equity-settled transactions by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option, volatility and forfeiture rates and making assumptions about them.

### *Determination of functional currency*

The Company determines its functional currency based on the primary economic environment in which it operates. IAS 21 The Effects of Changes in Foreign Exchange Rates outlines a number of factors to apply in determining the functional currency, which is subject to significant judgment by management.

### *Deferred tax assets*

Deferred tax assets are recognized in respect of tax losses and other temporary differences to the extent probable that there will be taxable income available against which the losses can be utilized. Judgment is required to determine the amount of deferred tax assets that can be recognized based on estimate of future taxable income.

## **CHANGES IN ACCOUNTING POLICIES INCLUDING INITIAL ADOPTION**

During the three and six months ended June 30, 2015, there have been no changes in accounting policies. The Company has not adopted any new accounting policies during the three and six months ended June 30, 2015.

## **FINANCIAL INSTRUMENTS**

The Company's financial instruments include its cash and cash equivalents, investments, accounts receivable, and accounts payable and accrued liabilities.

## **DISCLOSURE CONTROLS AND INTERNAL CONTROLS OVER FINANCIAL REPORTING**

Disclosure controls and procedures ("DC&P") are designed to provide reasonable assurance that all material information is gathered and reported to senior management, including the Company's Chief Executive Officer and Chief Financial Officer (the "Certifying Officers"), on a timely basis so that appropriate decisions can be made regarding public disclosure within the required time periods specified under applicable Canadian securities laws. The Certifying Officers are responsible for establishing and monitoring the Company's DC&P. The internal control over financial reporting ("ICFR") is designed to provide reasonable assurance that such financial information is reliable and complete. The Certifying Officers are also responsible for establishing and maintaining adequate ICFR for the Company.

As at December 31, 2014, management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the Company's DC&P and ICFR as required by Canadian securities laws. Based on that evaluation, the Certifying Officers have concluded that, as of the end of the period covered by this MD&A, the DC&P were effective to provide reasonable assurance that material information relating to the Company was made known to senior management by others and information required to be disclosed by the Company in its annual filings, interim filings (as such terms are defined under National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings) or other reports filed or submitted by it under securities legislation were recorded, processed, summarized and reported within the time periods specified in securities legislation. The Certifying Officers have evaluated the effectiveness of the Company's ICFR as at December 31, 2014 and have concluded that such ICFR is effective. The Certifying Officers have also concluded that, as of the end of the period covered by this MD&A, the ICFR provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. To design its ICFR, the Company used the 2013 Internal Control – Integrated Framework (COSO Framework) published by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that, as of December 31, 2014, the Corporation's internal control over financial reporting was effective based on those criteria. Due to inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation relating to the effectiveness in future periods are subject to the risk that controls may become inadequate as a result of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate. Because the Company is an "emerging growth company" as defined in the United States Jumpstart Our Business Startups Act of 2012, the Company will not be required to comply with the auditor attestation requirements of the United States Sarbanes-Oxley Act of 2002 for as long as the Company remains an "emerging growth company", which may be for as long as five years following its initial registration in the United States.

There have been no material changes in our internal control over financial reporting or disclosure controls and procedures during the three and six months ended June 30, 2015, that have materially affected, or are reasonably likely to affect our internal control over financing reporting.

## **ADDITIONAL INFORMATION**

Additional information about the Company, including the Financial Statements and Annual Information Form, are available on SEDAR at [www.sedar.com](http://www.sedar.com) and on the website of the United States Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).