



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

Form 51-102F1

**FOR THE YEARS ENDED DECEMBER 31,  
2014 AND 2013**

**Q4  
2014**

# 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, 2014 and 2013.

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, 2014 and 2013 (included as part of Neovasc Inc.'s annual filing).

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™, Neovasc Reducer™ and 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;
- 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 as issued by the International Accounting Standards Board ("IFRS") and is expressed in Canadian dollars.

Date: March 30, 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 as a result of mitral heart valve disease (it was estimated that in 2013 mitral regurgitation will affect approximately 5.7 million people in the United States and the European Union). 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.

Initial implantations of the valve have been undertaken in humans under special compassionate use exemptions (to date, four human implants of the Tiara have been completed under such exemptions). The Company is currently undertaking additional activities to set up formal multicenter clinical trials for the Tiara device. Additional development activities are ongoing to further refine the device and develop additional sizes.

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 compassionate use type cases with varying results.

Neovasc believes that there are several unique attributes of the Tiara device that may provide advantages over other approaches and that it will likely be one of the first 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. 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 December 31, 2014, the Company has spent approximately \$16 million developing the product and anticipates that it may require an additional \$10-15 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 has received conditional Investigational Device Exemption ("IDE") approval from the United States Food and Drug Administration ("FDA") 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 mitral regurgitation ("MR"). Severe MR is a critical condition that affects millions of patients and, if left untreated, can lead to heart failure or death. This FDA conditional approval allows clinical investigators to begin enrolling patients at participating United States medical centers once local hospital and related approvals are in place. This is an important step towards Tiara becoming one of the first transcatheter mitral valve replacement devices available for treating United States patients. 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). With this FDA approval, TIARA-I is expected to enroll patients at three highly respected United States medical centers: Columbia University Medical Center / New York-Presbyterian Hospital (New York), Lenox Hill Hospital (New York) and Cedars-Sinai Medical Center (Los Angeles). The Company is now focusing on training participating clinical teams and obtaining institutional approvals with the goal of enrolling the first United States patients in 2015.

TIARA-I also has received ethics committee approval at Antwerp Cardiovascular Center / ZNA Middelheim in Belgium and competent authority notification in that country. First European enrollment in the trial occurred in November 2014. Applications are underway for additional centers in Europe and Canada.

### **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 .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.

## *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. 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 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 will continue to supply LeMaitre with surgical patches until LeMaitre is able to receive appropriate regulatory approvals and start manufacture of the surgical patches themselves, anticipated for some time in 2015. 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, 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.

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. 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 projects that leverage the Company's existing technologies, infrastructure and expertise.

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

The Company has incurred operating losses of \$19,061,098 for the year ended December 31, 2014 (2013:\$6,750,250) and has a deficit of \$97,155,101 at December 31, 2014 compared to a deficit of \$78,094,003 as at December 31, 2013. As at December 31, 2014 the Company had \$6,025,013 in cash and cash equivalents and \$11,999,999 in short-term investments in guaranteed investment certificates, which mature within one year. In addition, 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) 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 (including some directors, officers and employees). 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 audited consolidated financial statements for the years ended December 31, 2014 and 2013.

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

Results for the years ended December 31, 2014 and 2013 follow:

#### **Losses**

The losses for the year ended December 31, 2014 were \$19,061,098, or \$0.36 basic and diluted loss per share, as compared with a loss of \$6,750,250, or \$0.14 basic and diluted loss per share for the same period in 2013. The \$12,310,848 increase in the loss incurred for the year ended December 31, 2014 compared to the same period in 2013 can be substantially explained by a \$7,551,821 increase in share-based payments, a \$3,144,541 increase in general and administrative expenses and a \$2,450,633 increase in product development and clinical trial expenses. These increases in expenses were partially offset by a \$988,970 increase in the gross profit for the same period. Under the Black Scholes model used to value the options, the significantly higher price of the Company's shares in 2014 produced a higher overall valuation of the options issued, and therefore resulted in a higher non-cash charge to the income statement in 2014.

#### **Revenues**

Revenues increased 35% year-over-year to \$15,863,451 for the year ended December 31, 2014, compared to revenues of \$11,747,636 for the same period in 2013.

Product sales for the year ended December 31, 2014 were \$2,262,880, compared to \$2,694,977 for the same period in 2013, representing a decrease of 16%. 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 receives appropriate regulatory approvals and start manufacture of the surgical patches itself. It is anticipated that Neovasc will cease manufacturing all surgical patches for LeMaitre in 2015.

Contract manufacturing revenues for year ended December 31, 2014 were \$3,355,115, compared to \$1,776,893 for the same period in 2013, representing an increase of 89%. Year over year the Company has seen the overall number of customers in contract manufacturing decline by approximately 50% but the largest customers all showed significant year over year revenue growth. 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.

Revenues from consulting services for the year ended December 31, 2014 were \$10,245,456, compared to \$7,275,766 for the same period in 2013, representing an increase of 41%. Year over year the Company has seen its three largest consulting services accounts grow and they now account for 95% of the consulting services revenues. 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 year ended December 31, 2014 was \$10,112,941, compared to \$7,083,877 for the same period in 2013. The overall gross margin for the year ended December 31, 2014 was 36%, compared to 40% gross margin for the same period in 2013. Year over year product sales margins declined due to a reduction in raw material yields and due to a shift in the product mix toward lower margin patches. In addition manufacturing services margins declined due to increased production overhead as the Company has improved the robustness of its chemistry lab and quality assurance to meet customer requirements as they transition to commercial production.

## Expenses

Total expenses for the year ended December 31, 2014 were \$24,916,950, compared to \$11,772,728 for the same period in 2013, representing an increase of \$13,144,222, or 112%. The increase in total expenses for the year ended December 31, 2014 compared to the same period in 2013 reflects a \$7,454,040 increase in share-based payment, a \$3,144,541 increase in general and administrative expenses and a \$2,450,633 increase in product development and clinical trial expenses to advance the Tiara and Reducer development programs.

Selling expenses for the year ended December 31, 2014 were \$176,431, compared to \$78,475 for the same period in 2013, as the company initiated activities in preparation for Reducer commercialization. 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 year ended December 31, 2014 were \$11,853,675, compared to \$4,846,935 for the same period in 2013, representing an increase of \$7,006,740, or 145%. The increase in general and administrative expenses for the year ended December 31, 2014 compared to the same period in 2013 can be substantially explained by a \$3,862,199 increase in share-based payments and by a \$3,114,541 increase in other expenses. The \$3,114,541 increase includes approximately \$1,440,000 related to accounting, listing and legal expenses incurred while completing the Company's dual listing on the Nasdaq and graduation to the TSX main board and other corporate restructuring, approximately \$800,000 related to litigation expenses, approximately \$370,000 related to an increase in general and administrative staff and an increase in the size of the scientific advisory board as well as an increase in compensation to the board, senior management and the scientific advisory board, approximately \$200,000 related to a write down of an amount owed by one customer, approximately \$150,000 related to the rent of new administration office and insurance, and approximately \$140,000 relates to an increase in travel activities.

Product development and clinical trial expenses for the year ended December 31, 2014 were \$12,886,844, compared to \$6,847,318 for the same period in 2013, representing an increase of \$6,039,526, or 88%. The increase in product development and clinical trial expenses for the year ended December 31, 2014 was due to \$3,588,893 increase in share-based payment, a \$1,138,818 increase in cash-based employee expenses as the Company hired additional staff to build up a clinical trial team and a \$1,270,725 increase in other expenses, respectively, 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 year ended December 31, 2014 compared to the same period in 2013. 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 year ended December 31, 2014 was \$105,342, compared to other income of \$358,719 for the same period in 2013. The Company benefited from significant foreign exchange gains on its foreign currency-denominated cash and cash equivalents and accounts receivable in 2013.

Result for the quarters ended December 31, 2014 and 2013 follow:

## Losses

The net loss for the quarter ended December 31, 2014 was \$7,620,570, or \$0.14 basic and diluted loss per share, compared with a loss of \$2,211,875, or \$0.05 basic and diluted loss per share for the same period in 2013.

## Revenues

Revenues for the quarter ended December 31, 2014 were \$3,353,441 compared to \$3,311,550 for the same period in 2013, representing an increase of 1%. There was a year-over-year increase in contract manufacturing of \$984,705 offset by a decrease of \$385,796 in product sales and \$557,018 in consulting services.

## Cost of Goods Sold

The cost of goods sold for the quarter ended December 31, 2014 were \$2,662,748, compared to \$2,056,349 for the same period in 2013. The gross margin for the quarter ended December 31, 2014 was 21%, compared to 38% for the same period in 2013. During the quarter the Company incurred the initiation costs of improvements to its chemistry lab and quality assurance to meet customer requirements as they transition to commercial production, without a corresponding improvement in revenues.

## Expenses

Total expenses for the quarter ended December 31, 2014 were \$8,361,395, compared to \$3,567,679 for the same period in 2013, an increase of 134%. The increase is substantially due to an increase of \$2,013,626 in general and administrative expenses and an increase of \$2,685,689 in clinical trial and product development expenses for the Company's two new product development programs.

Selling expenses were \$112,818 for the quarter ended December 31, 2014, compared to \$18,417 for the same period in 2013. General and administrative expenses were \$3,196,693 for the quarter ended December 31, 2014, compared to \$1,183,067 in the same period in 2013, representing an increase of 170%. The increase in general and administrative expenses was principally due to approximately \$1,200,000 increase in share-based payments, approximately \$360,000 increase in litigation expenses, approximately \$100,000 increase in legal and accounting expenses, approximately \$64,000 increase relates to an increase in compensation to the board, senior management and the scientific advisory board, approximately \$93,000 related to the rent of new administration office and insurance and approximately \$80,000 relates to an increase in travel activities. Research and development costs, including product development and clinical trial expenses were \$5,051,884 for the quarter ended December 31, 2014, compared to \$2,366,195 for the same period in 2013, representing an increase of 114%. The increase in year-over-year research and development costs is principally due to increased investment in the Tiara mitral valve program.

## Annual Information

The following is a summary of selected financial information for the three fiscal years to December 31, 2014:

	2014	2013	2012
Revenues	\$ 15,863,451	\$ 11,747,636	\$ 7,819,154
Loss	(19,061,098)	(6,750,250)	(351,368)
Basic and diluted loss per share	(0.36)	(0.14)	(0.01)
Total assets	23,629,260	7,443,382	8,798,596
Total long-term liabilities	157,628	200,084	241,083
Cash dividend declared per share	\$nil	\$nil	\$nil

Revenues have grown significantly year over year as the Company has assisted its customers to develop transcatheter valves. We have seen a concentration of our customer base with only those who have been successful in developing their program continuing to fund development or initiate a contract manufacturing agreement with Neovasc. We anticipate revenues from the tissue business will level out or even decline in future years but also anticipate that we will be able to replace and grow total revenue from the future commercialization of our Tiara and Reducer development products.

We have seen our loss for each year grow. The principle reasons for this growth are an expansion of our research and development activities on the Tiara, an increase in our general administrative costs related to increased litigation costs and increased public listing costs as we listed on the Nasdaq and graduated to the TSX and an increase in the value of share based incentive payments. While we anticipate our litigation costs to increase in the coming periods as we move through the litigation process we expect that both our public listing costs and the share based payment charges will decline, the first as the cost of the initial listing in 2014 were one time in nature and the later because we have amended our compensation structure to be less reliant on share based payments in 2015.

There have been no material changes or discontinuation of operations over the periods except in the normal course of business, nor have there been changes in accounting policies or significant acquisitions or dispositions that have changed the direction of the Company. We remain focused on the development and commercialization of the Tiara and Reducer products over the next several years.

A successful financing in March 2014 and a further financing in 2015 subsequent to the year-end have grown our total assets and we intend to use this capital to execute our development and commercialization plans.

## QUARTERLY INFORMATION

The following is a summary of selected unaudited financial information for the eight fiscal quarters to December 31, 2014:

	December 31, 2014	September 30, 2014	June 30, 2014	March 31, 2014
<b>REVENUE</b>				
Product sales	\$ 297,493	\$ 471,468	\$ 798,921	\$ 694,998
Contract manufacturing	1,081,622	1,366,552	721,225	185,716
Consulting services	1,974,326	2,431,340	2,884,369	2,955,421
	<u>3,353,441</u>	<u>4,269,360</u>	<u>4,404,515</u>	<u>3,836,135</u>
<b>COST OF GOODS SOLD</b>	<u>2,662,748</u>	<u>2,468,747</u>	<u>3,066,924</u>	<u>1,914,522</u>
<b>GROSS PROFIT</b>	<u>690,693</u>	<u>1,800,613</u>	<u>1,337,591</u>	<u>1,921,613</u>
<b>EXPENSES</b>				
Selling expenses	112,818	19,285	24,413	19,915
General and administrative expenses	3,196,693	2,916,141	4,644,387	1,096,454
Product development and clinical trials expenses	5,051,884	3,488,051	3,113,707	1,233,202
	<u>8,361,395</u>	<u>6,423,477</u>	<u>7,782,507</u>	<u>2,349,571</u>
<b>OPERATING LOSS</b>	<u>(7,670,702)</u>	<u>(4,622,864)</u>	<u>(6,444,916)</u>	<u>(427,958)</u>
OTHER INCOME/(EXPENSE)	50,132	34,319	(26,995)	47,886
<b>LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD</b>	<u>\$ (7,620,570)</u>	<u>\$ (4,588,545)</u>	<u>\$ (6,471,911)</u>	<u>\$ (380,072)</u>
<b>BASIC AND DILUTED LOSS PER SHARE</b>	<u>\$ (0.14)</u>	<u>\$ (0.09)</u>	<u>\$ (0.12)</u>	<u>\$ (0.01)</u>
	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>

In 2015 we expect product sales to end as our remaining purchase orders are completed. 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.

Selling expenses have remained relatively consistent from 2013 as efforts have been focused on servicing our existing customers. 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 fourth quarter of 2014 due to a stock-based compensation expense of \$1,471,000 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 financing, 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	\$5,160,036	\$8,339,964
Reducer Development Costs	\$7,500,000	\$581,888	\$6,918,112
Additional Proceeds	\$3,645,349	\$878,413	\$2,766,936
<b>TOTAL</b>	<b>\$24,645,349</b>	<b>\$6,620,337</b>	<b>\$18,025,012</b>

The actual proceeds net of share issue costs 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. 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 combined value of the cash and cash equivalents and investments as at December 31, 2014 is \$18,025,012. The approximate expenditures from proceeds of the bought deal equity financing during the year ended December 31, 2014 were \$6,620,000, of which approximately \$5,160,000 was spent on Tiara Development Costs, \$582,000 was spent on Reducer Development Costs and \$878,000 was spent on working capital items and investment in property, plant and equipment funded from the additional proceeds.

## 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, 2014, the Company had cash and cash equivalents of \$6,025,013 compared to cash and cash equivalents of \$3,403,472 at December 31, 2013, as well as \$11,999,999 invested in short term investments falling due within one year.

Cash used in operating activities for the year ended December 31, 2014, was \$8,925,347, compared to \$4,683,103 for the same period in 2013. For the year ended December 31, 2014, operating expenses were \$9,131,383, compared to \$4,517,510 for the same period in 2013, as more expenses were incurred in general and administrative and research and development and clinical trials activities as discussed elsewhere in this MD&A and working capital items generated cash of \$97,191, compared to working capital items which absorbed cash of \$167,893 for the same period in 2013, as inventory was kept at minimal level at year end, prepaid expenses and other assets increased with the payment of deposits for our leased office space and the payment of our directors and officers insurance in advance rather than on a monthly basis, and accounts payable increased aligned with the increase of production, administration and research and development activities.

For the year ended December 31, 2014, the Company invested \$11,999,999 in longer term investments, as its cash and cash equivalents are sufficient to meet its obligations in the short-term. For the year ended December 31, 2014, the Company invested \$1,248,974 in property, plant and equipment, compared to \$1,041,188 for the same period in 2013. During 2014 and 2013, the Company invested capital to expand its clean room and manufacturing facilities and research and development capabilities.

For the year ended December 31, 2014, net cash provided by financing activities was \$24,795,861, compared to \$2,921,781 for the same period in 2013. On March 26, 2014, the Company closed a bought deal equity prospectus offering 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 share issue costs were \$506,651.

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, 2014 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 December 31, 2014 were denominated in Canadian dollars. The Company is exposed to foreign currency fluctuations on \$448,623 of its cash and cash equivalents held in United States dollars and European euros.

## **EVENTS DURING THE YEAR**

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

## **SUBSEQUENT EVENTS**

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) 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 (including some directors, officers and employees).

## **OUTSTANDING SHARE DATA**

As at March 30, 2015, the Company had 66,414,715 common voting shares issued and outstanding. Further, the following securities are convertible into common shares of the Company: 7,464,018 stock options with a weighted average price of \$3.18. The fully diluted share capital of the Company at March 30, 2015 is 73,878,733.

## **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.

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 December 31, 2014:

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	\$ 202,219	\$ 44,591	\$ 92,861	\$ 64,767	\$ -
Operating leases	728,186	178,992	417,924	122,380	8,890
<b>Total</b>	<b>\$ 930,405</b>	<b>\$ 223,583</b>	<b>\$ 510,785</b>	<b>\$ 187,147</b>	<b>\$ 8,890</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 years ended December 31, 2014 and 2013, 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.

## **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 year ended December 31, 2014, there have been no changes in accounting policies and the new mandatory accounting policies adopted during the year did not have a significant impact to the current or prior year financial statements.

### **FINANCIAL INSTRUMENTS**

The Company's financial instruments include its cash and cash equivalents, investments, accounts receivable, long-term debt, 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.

**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).