



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

**FOR THE THREE MONTHS ENDED  
MARCH 31, 2017 AND 2016**

(Expressed in U.S. Dollars)

**Q1  
2017**

## MANAGEMENT'S DISCUSSION AND ANALYSIS

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") covers the unaudited condensed interim consolidated financial statements of Neovasc Inc. (the "Company", "Neovasc", "we", "us", or "our") for the three months ended March 31, 2017 and 2016.

This MD&A should be read in conjunction with the unaudited condensed interim consolidated financial statements and notes thereto for the three months ended March 31, 2017 and 2016 (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, 2016 and 2015.

The Company has prepared this MD&A with reference to National Instrument 51-102 – Continuous Disclosure Obligations of the Canadian Securities Administrators. 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"), and Neovasc Reducer™ ("Reducer") are our trademarks; other trademarks, product names and company names appearing herein are the property of their respective owners.

All financial information is prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board and is expressed in U.S. dollars. The Company presents its consolidated financial statements in U.S. dollars.

Additional information about the Company, including the Company's audited consolidated financial statements and Annual Information Form, are available on SEDAR at [www.sedar.com](http://www.sedar.com) and in the Company's Annual Report on Form 40-F, which is available on the website of the U.S. Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS

This MD&A contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and applicable Canadian securities laws. The words "expect", "anticipate", "may", "will", "estimate", "continue", "intend", "believe" and other similar words or expressions are intended to identify such forward-looking statements. 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 ability, in an appeal of the verdict, to reduce the amount of the \$70 million damages award made following a jury trial in Boston, Massachusetts, on certain trade secret claims made by CardiAQ Valve Technologies Inc. ("CardiAQ") and the \$21 million enhanced damages award following post trial hearings and the approximate \$21 million in interest award following post-trial hearings (see "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein);
- the conduct or possible outcomes of any actual or threatened legal proceedings, including the Company's ongoing litigation with CardiAQ and the other matters described in "Contractual Obligations and Contingencies" herein (see also "Trends, Risks and Uncertainties" herein);
- our ability to continue as a going concern;
- the amount of estimated additional litigation expenses required to defend the Company in lawsuits filed by CardiAQ;
- the Company's expectations with respect to the length of the appellate process in the litigation with CardiAQ;
- our need for significant additional financing and our estimates regarding our capital requirements and future revenues, expenses and profitability;
- our intention to expand the indications for which we may market the Tiara (which does not have regulatory approval and is not commercialized) and the Reducer (which has CE Mark approval for sale in the European Union);
- clinical development of our products, including the results of current and future clinical trials and studies;
- our intention to apply for CE Mark approval for the Tiara in the next one to two years;
- our intention to initiate additional investigational sites for the Tiara-II trial in 2017 as required approvals are obtained;
- our plans to develop and commercialize products, including the Tiara, and the timing and cost of these development programs;

- our strategy to refocus our business towards development and commercialization of the Reducer and the Tiara;
- our ability to replace declining revenues from the tissue business with revenues from the Reducer and the Tiara in a timely manner;
- whether we will receive, and the timing and costs of obtaining, regulatory approvals for the Reducer and the Tiara;
- the cost of post-market regulation if we receive necessary regulatory approvals;
- our ability to enroll patients in our clinical trials, studies and compassionate use cases in Canada, the United States and in Europe;
- our intention to continue directing a significant portion of our resources into sales expansion;
- the expected decline of consulting services revenue in the long-term as our consulting customers become contract manufacturing customers or cease being customers;
- our ability to get our products approved for use;
- the benefits and risks of our products as compared to others;
- our estimates of the size of the potential markets for our products, including the anticipated market opportunity for the Reducer;
- 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; and
- the impact of foreign currency exchange rates.

Forward-looking statements are based on estimates and assumptions made by the Company in light of its experience and its perception of historical trends, current conditions and expected future developments, as well as other factors that the Company believes are appropriate in the circumstances. Many factors could cause the Company's actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements, including, without limitation:

- risks relating to our litigation with CardiAQ, including the Company's ability to successfully appeal the validity of the awards as well as the ruling on inventorship, which create material uncertainty and which cast substantial doubt on our ability to continue as a going concern;
- the substantial doubt about our ability to continue as a going concern.
- risks relating to our need for significant additional future capital and our ability to raise additional funding;
- risks relating to claims by third parties alleging infringement of their intellectual property rights;
- our ability to establish, maintain and defend intellectual property rights in our products;
- risks relating to results from clinical trials of our products, which may be unfavorable or perceived as unfavorable;
- our history of losses and significant accumulated deficit;
- risks associated with product liability claims, insurance and recalls;
- risks relating to competition in the medical device industry, including the risk that one or more competitors may develop more effective or more affordable products;
- risks relating to our ability to achieve or maintain expected levels of market acceptance for our products, as well as our ability to successfully build our in-house sales capabilities or secure third-party marketing or distribution partners;
- our ability to convince public payors and hospitals to include our products on their approved products lists;
- risks relating to new legislation, new regulatory requirements and the efforts of governmental and third party payors to contain or reduce the costs of healthcare;
- risks relating to increased regulation, enforcement and inspections of participants in the medical device industry, including frequent government investigations into marketing and other business practices;
- risks associated with the extensive regulation of our products and trials by governmental authorities, as well as the cost and time delays associated therewith;
- risks associated with post-market regulation of our products;
- health and safety risks associated with our products and our industry;

- risks associated with our manufacturing operations, including the regulation of our manufacturing processes by governmental authorities and the availability of two critical components of the Reducer;
- risk of animal disease associated with the use of our products;
- risks relating to the manufacturing capacity of third-party manufacturers for our products, including risks of supply interruptions impacting the Company's ability to manufacture its own products;
- risks relating to breaches of anti-bribery laws by our employees or agents;
- risks associated with future changes in financial accounting standards and new accounting pronouncements;
- our dependence upon key personnel to achieve our business objectives;
- our ability to maintain strong relationships with physicians;
- risks relating to the sufficiency of our management systems and resources in periods of significant growth;
- risks associated with consolidation in the health care industry, including the downward pressure on product pricing and the growing need to be selected by larger customers in order to make sales to their members or participants;
- our ability to successfully identify and complete corporate transactions on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances;
- anti-takeover provisions in our constating documents which could discourage a third party from making a takeover bid beneficial to our shareholders;
- risks relating to conflicts of interests among the Company's officers and directors as a result of their involvement with other issuers; and
- risks relating to the influence of significant shareholders of the Company over our business operations and share price.

Forward-Looking 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 material factors and assumptions used by us to develop such forward-looking statements include, but are not limited to:

- our ability, in an appeal of the verdict, to reduce or successfully defend against the amount of the \$70 million damages award, \$21 million enhanced damages award and approximate \$21 million interest award and reverse the ruling on inventorship in connection with our litigation with CardIAQ;
- our ability to continue as a going concern;
- our regulatory and clinical strategies will continue to be successful;
- our current positive interactions with regulatory agencies will continue;
- recruitment to clinical trials and studies will continue;
- the time required to enroll, analyze and report the results of our clinical studies will be consistent with projected timelines;
- current and future clinical trials and studies will generate the supporting clinical data necessary to achieve approval of marketing authorization applications;
- the regulatory requirements for approval of marketing authorization applications will be maintained;
- our current good relationships with our suppliers and service providers will be maintained;
- our estimates of market size and reports reviewed by us are accurate;
- our efforts to develop markets and generate revenue from the Reducer will be successful;
- genericisation of markets for the Tiara and the Reducer will develop; and
- capital will be available on terms that are favorable 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 the "Risk Factors" section of our Annual Information Form, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and in our Annual Report on Form 40-F, which is available on the website of the U.S. Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov). These factors should be considered carefully, and readers should not place undue reliance on the Company's forward-looking statements. 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.

Date: May 10, 2017

## 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 and the Reducer for the treatment of refractory angina.

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 the 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 positive results of these activities, the Company launched a program to develop the Tiara transcatheter mitral valve.

Additionally, throughout the years 2014 to 2016, the Company announced a number of developments pertaining to litigation, all as more fully discussed herein under the heading "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein.

### 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 (in 2014 it was estimated that mitral regurgitation affects approximately 4.1 million people in the United States). 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 1.7 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.

Clinical experience to date has been with the 35mm Tiara and the 40mm Tiara. First clinical use of the 40mm Tiara occurred in the fourth quarter of 2015 and first use of the 45mm Tiara is targeted for 2018. The additional sizes will allow Neovasc to expand treatment to a broader population of patients.

As of March 31, 2017, 26 patients have been implanted with the Tiara in early feasibility and compassionate use cases and Neovasc believes that early results have been encouraging. The 30-day survival rate for these first 26 patients implanted with the Tiara is 23/26 or 88% with one patient now over three years post implant. The Tiara has been successfully implanted in both functional and degenerative mitral regurgitation patients, as well as patients with pre-existing prosthetic aortic valves and mitral surgical rings. In addition, since March 31, 2017 an additional two patients have been treated.

The results from these early feasibility and compassionate use cases have been instrumental in helping to demonstrate the potential of the Tiara as well as refining the implantation procedure, patient selection criteria and the device itself. Careful patient selection continues to be critical as the Company and clinical community continue to learn more about treating this population of very sick patients.

While many challenges remain prior to achieving commercial production (including, but not limited to, positive clinical trial and study results and obtaining regulatory approval from the relevant authorities), the Company believes the Tiara is being widely recognized as one of the leading devices exploring this new treatment option for patients who are unable or unsuited to receive an open heart surgical mitral valve replacement or repair. There are several other transcatheter mitral valve replacement devices in development by third parties which have been implanted in early feasibility type studies and CE mark studies with varying results.

Neovasc believes that there are several unique attributes of the Tiara that may provide advantages over other approaches to mitral valve replacement. There is no certainty that the Tiara 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. 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 approximately two years. As at March 31, 2017, the Company has spent approximately \$42.8 million developing the Tiara and anticipates that it may require an additional \$16-21 million as it moves forward to achieve CE Mark approval. 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, the Company announced that it received conditional investigational device exemption approval from the U.S. Food and Drug Administration ("FDA") to initiate the U.S. arm of the TIARA-I study for the Tiara. The TIARA-I study is a multinational, multicenter early feasibility study being conducted to assess the safety and performance of the Tiara mitral valve system and implantation procedure in high-risk surgical patients suffering from severe mitral regurgitation. This FDA conditional approval allows clinical investigators to begin enrolling patients at participating U.S. medical centers once local hospital and related approvals are in place. This is an important step towards the Tiara becoming one of the first transcatheter mitral valve replacement devices available for treating U.S. patients. The TIARA-I study will enroll up to 30 patients globally and is being overseen by a multidisciplinary committee of internationally recognized physicians. The Tiara has also been implanted under compassionate use approvals in Canada and elsewhere and implantations under similar approvals are anticipated to continue in the future.

On November 28, 2016, the Company announced that it had received both regulatory and ethics committee approval to initiate the Tiara Transcatheter Mitral Valve Replacement Study (TIARA-II) in Italy. The TIARA-II study is a 115 patient, non-randomized, prospective clinical study evaluating the Tiara's safety and performance. It is expected that data from this study will be used to file for CE Mark approval. The first implantation in the TIARA-II trial was conducted by the medical team at San Raffaele Hospital in Milan, Italy in April of 2017. In May 2017, the Company received regulatory approval to initiate enrollment in its CE Mark study in Germany. The Company will continue to seek regulatory approval in additional jurisdictions in the coming quarters. The Company will be initiating additional investigational sites in 2017 in Italy and Germany and in other countries as required approvals are obtained.

## 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 600,000 to 1.8 million Americans, with 50,000 to 100,000 new cases per year in the United States who are not eligible for conventional treatments and 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 600,000 to 1.8 million Americans, with 50,000 to 100,000 new cases per year 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. 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 Company is also exploring additional potential indications for the Reducer.

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 the 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 Coronary Sinus Reducer for Treatment of Refractory Angina clinical trial ("COSIRA") to assess the efficacy of the Reducer device. The COSIRA trial'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 trial 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 trial results were published in the New England Journal of Medicine in February 2015.

The Reducer is an hourglass-shaped, balloon-expandable, stainless steel, bare metal 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 15 patients suffering from chronic refractory angina who were followed for three years after implantation. The six-month results from this clinical trial were published in the Journal of the American College of Cardiology and three-year 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 the COSIRA trial – 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 trial were positive and are discussed in more detail below. More recently, additional studies conducted by third parties and showing positive results from the Reducer implantations have been published and presented in medical forums. It is anticipated that as the commercial use of the Reducer continues to expand, additional third party studies, investigations and presentations will be undertaken. If the results from such third-party activities continue to show positive results from the product they will provide additional data to support expanded adoption of the Reducer for the intended patient population.

Following this positive data from the COSIRA trial, the Company initiated a pilot launch of the Reducer in select European markets in early 2015. The Company has signed distribution agreements in a number of European countries as well as Saudi Arabia and has initial sales into these countries. Based on the initial results from the targeted launch, Neovasc is presently developing an expanded sales plan and strategy for 2017 and beyond. It is anticipated that sales of the product in the United States would follow obtaining U.S. 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 the COSIRA trial that is expected to provide data to support broad commercialization of the Reducer. The COSIRA trial 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 trial 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. Neovasc has begun discussions with the FDA on the development of a randomized investigational device exemption trial in the United States. The Company is currently evaluating the timing for starting this trial. U.S. marketing approval is expected about two to four years after the clinical trial begins. There is no assurance that U.S. regulatory approval will be granted in the time frame anticipated by management, or granted at any time in the future. The cost of the U.S. clinical trial is expected to be \$20-25 million.

#### **Tissue 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 a proprietary process, it licenses from Boston Scientific Corporation (“Boston Scientific”), 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 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 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 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 a proprietary process that is supported by a 25-year implant history for use as a surgical heart valve. A company that establishes its own process will have to go through a significant and costly series of studies to prove that their process produces tissue that is suitable as a medical device. The Peripatch product has already met these requirements and has already been validated through many years of successful use in multiple applications. Neovasc's customers make the decision to use the Company's tissue rather than take on the demanding and lengthy process of developing their own tissue processing operation.

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. The processing of the material is a trade secret and was proprietary to the Company prior to the transaction with Boston Scientific. Neovasc sold the Peripatch technology and trade secrets to Boston Scientific in 2016 and Boston Scientific has licensed the technology back to the Company in a perpetual, fully paid, royalty free license. 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 82% of the Company's current revenues.

In December, 2016, the Company entered into an agreement for Boston Scientific to acquire the Company's advanced biologic tissue capabilities and certain manufacturing assets and make a 15% equity investment in Neovasc, for a total of \$75 million in cash. Under the terms of the approximate \$68 million asset purchase agreement the Company has been granted a license to the purchased trade secrets and know-how and access to the sold facilities to allow it to continue its tissue and valve assembly activities for its remaining customers, and continue its own tissue-related programs, including advancing the Tiara through its clinical and regulatory pathways.

#### *Regulatory Status*

While the Company does not maintain stand-alone marketing approval for its tissue products, 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 Peripatch tissue into their vascular device products such as heart valves. The goal of these activities is to drive near-term revenues as well as support development of a long-term revenue stream through the ongoing provision of tissue and manufacturing services to customers with commercially successful devices that incorporate Neovasc tissue. Revenue earned from various contract agreements varies throughout the year depending on customer needs.

## Product Development

Product development at the Company is currently focused on completing commercialization of the Reducer as well as clinical stage and pre-commercialization development work on the Tiara. 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

### Losses and Additional Funding Requirements

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.

The Company has incurred operating and comprehensive losses of \$7,844,987 and \$7,927,304 for the three months ended March 31, 2017 respectively (2016: \$10,881,138 and \$7,591,702) and has a deficit of \$209,628,593 at March 31, 2017 compared to a deficit of \$201,783,606 as at December 31, 2016. As at March 31, 2017 the Company had \$16,206,632 in cash and cash equivalents (2016: \$46,903,192). The Company believes it may need to raise additional capital to fund its short and medium term objectives for the Tiara and the Reducer 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.

### Litigation with CardiAQ

On May 19, 2016, following a trial in Boston, Massachusetts, a jury awarded \$70 million on certain trade secret claims made by CardiAQ. On October 31, 2016, following post-trial motions in the trial court stemming from the trial jury's verdict, the judge awarded an additional \$21 million in enhanced damages to the jury's award. On January 18, 2017, the judge granted CardiAQ's motion for pre- and post-judgment interest. The Court awarded \$20,675,154 in pre-judgment interest and assessed a running rate of \$2,354 per day in post-judgment interest from November 16, 2016 until the judgment is satisfied, unless the Company prevails on appeal. The Company recognized a damages provision in the amount of \$70 million as at June 30, 2016, \$91 million as at September 30, 2016 and approximately \$112 million as at December 31, 2016. Since the year end, interest in the damages provision has been accruing on a daily basis.

On December 23, 2016, the trial court granted a stay of judgment pending the completion of the appeal. Under the terms of the stay, the Company has deposited \$70 million into a joint escrow account and entered into a general security agreement related to the remaining damages awarded by the court. Unless the Company is successful in an appeal of the verdict, or otherwise is successful in reducing the amount of the \$112 million awards to an amount less than the \$70 million currently held in the joint escrow account, the Company will require a significant additional financing in order to pay the damages and to continue to operate its business. There can be no assurance that the Company will be successful in its post-trial motions and/or any appeal of the verdict or that such financing will be available on favorable terms, or at all.

The Company intends to continue to vigorously defend itself in the litigation with CardiAQ. The outcome of these matters, including whether the Company will be required to pay some or all of the jury award of \$70 million, enhanced damages award of \$21 million and interest award of approximately \$21 million, is not currently determinable. Costs, and fees may be due on any award granted by the court. The determination of any attorneys' fees and the costs of litigation would be the subject of further rulings from the court. The amounts of any attorneys' fees and costs are currently undeterminable.

Litigation is inherently uncertain. Therefore, until these matters have been resolved to their ultimate conclusion by the appropriate courts, the Company cannot give any assurances as to the outcome. If the Company is unsuccessful in its defense of the claims, including any appeal of the verdict in the litigation with CardiAQ, or is unable to settle the claims in a manner satisfactory to the Company, it may be faced with significant monetary damages that could exceed its resources and/or the loss of intellectual property rights that could have a material adverse effect on the Company and its financial position. These circumstances indicate the existence of material uncertainty and cast substantial doubt about the Company's ability to continue as a going concern (see "Contractual Obligations and Contingencies" herein for a discussion of the CardiAQ litigation and other litigation).

The audited consolidated financial statements do not reflect adjustments that would be necessary if the going concern assumption were not appropriate. Material adjustments may be necessary to the audited consolidated financial statements should these circumstances impair the Company's ability to continue as a going concern.

## Operating Risks

In addition to these litigation matters, the Company may need to raise additional capital prior to the successful commercialization of its products. There is no certainty that the Company's programs will be successfully commercialized or that any required funds will be available to the Company at the time needed or on terms acceptable to the Company.

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: risks related to the Company's litigation with CardiAQ, including the Company's ability to successfully appeal the validity of the awards as well as the ruling on inventorship, which creates material uncertainty and casts substantial doubt on the Company's ability to continue as a going concern; the conduct or possible outcomes of any actual or threatened legal proceedings (including the securities class action styled *Grobler v. Neovasc, Inc. et al.* (see "Contractual Obligations and Contingencies" herein), which are inherently uncertain and which could divert our resources and result in the payment of significant damages and other remedies; the potential impact on the Company's business of an adverse decision in the appeal on the question of inventorship; the potential changes in circumstances relating to the Company's financing requirements, whether as a result of the CardiAQ litigation or otherwise and the continued availability of capital to finance the Company's activities; the clinical success of the Tiara; 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 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 Company's ability to conduct and complete successful clinical trials; the Company's ability to garner regulatory approvals for its products in a timely fashion; the Company's ability to attract and retain key personnel, effectively manage growth and smoothly integrate newly acquired businesses or technologies; limitations on third-party reimbursement; instances of product or third-party liability; dependence on a single supplier for some products; animal disease or other factors affecting the quality and availability of raw materials; conflicts of interest among the Company's directors, officers, promoters and members of management; fluctuations in the values of relative foreign currencies; volatility of the Company's share price; fluctuations in quarterly financial results; unanticipated expenses; changes in business strategy; impact of any negative publicity; general political and economic conditions; and acts of god and other unforeseeable events, natural or human-caused.

## FOREIGN OPERATIONS

The majority of the Company's revenues are derived from product sales in the United States and Europe, primarily denominated in U.S. dollars and 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 prior to translation into the U.S. dollar presentation currency. In addition, any decrease in the value of the U.S. dollar or 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. The Company does not conduct any hedging activities to mitigate these foreign exchange risks. 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 months ended March 31, 2017 and 2016.

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

Results for the three months ended March 31, 2017 and 2016 follow:

### **Losses**

The operating losses and comprehensive losses for the three months ended March 31, 2017 were \$7,844,987 and \$7,927,304 respectively, or \$0.10 basic and diluted loss per share, as compared with losses of \$10,881,138 and \$7,677,054, or \$0.16 basic and diluted loss per share for the same period in 2016. The \$1,697,269 decrease in the operating loss incurred for the three months ended March 31, 2017 compared to the same period in 2016 can be substantially explained by a \$2,578,692 decrease in general and administrative expenses (of which \$3,164,430 was a decrease in litigation expense and \$462,676 was an increase in stock-based compensation charges) offset by a \$970,736 increase in product development and clinical trial expenses. The Company has incurred significant costs in defending itself in lawsuits filed by CardiAQ. Total litigation costs since the initial claims were filed in June 2014 are approximately \$21.9 million and the Company may require an additional \$1 million to cover additional litigation expenses up to and including the appeal hearing, scheduled for August 2017.

### **Revenues**

Revenues decreased 26% to \$1,481,360 for the three months ended March 31, 2017, compared to revenues of \$2,006,742 for the same period in 2016. The Company started its sales of the Reducer in the first quarter of 2015 as it initiated its focused commercialization of the product in Europe. The Company continues to focus its business away from its traditional revenue streams towards development and commercialization of its own products, the Reducer and the Tiara.

Reducer sales for the three months ended March 31, 2017 were \$260,765, compared to \$213,765 for the same period in 2016, representing an increase of 22%. The continued success of the commercialization of the Reducer will be dependent on the amount of internal resources allocated to the product, obtaining appropriate reimbursement codes in various territories and correctly managing the referrals process.

Contract manufacturing revenues for the three months ended March 31, 2017 were \$133,963, compared to \$606,783 for the same period in 2016, representing a decrease of 78%. The decrease in revenue for the three months ended March 31, 2017 compared to the same period in 2016 is primarily due to the loss of Boston Scientific as a customer. In December, 2016, the Company entered into an agreement for Boston Scientific to acquire the Company's advanced biologic tissue capabilities and certain manufacturing assets and make a 15% equity investment in Neovasc, for a total of \$75 million in cash. Under the terms of the approximate \$68 million asset purchase agreement the Company has been granted a license to the purchased trade secrets and know-how and access to the sold facilities to allow it to continue its tissue and valve assembly activities for its remaining customers, and continue its own tissue-related programs, including advancing the Tiara through its clinical and regulatory pathways. The Company believes that going forward contract manufacturing revenues will be derived from a smaller customer base as the transcatheter aortic valve market matures.

Revenues from consulting services for the three months ended March 31, 2017 were \$1,086,632, compared to \$1,186,194 for the same period in 2016, representing a decrease of 8%. The loss is indicative of the trend the Company is seeing in consulting service revenue. The Company anticipates that its consulting services revenue will decline in the long-term as its consulting customers continue to transition to becoming contract manufacturing customers or cease to be customers at all.

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 months ended March 31, 2017 was \$808,628, compared to \$1,445,644 for the same periods in 2016. The overall gross margin for the three months ended March 31, 2017 was 45%, compared to 28% gross margin for the same period in 2016. The Company has seen its gross margins increase due to a change in the product mix as Reducer revenues reflect an increasing proportion of the overall revenues.

## **Expenses**

Total expenses for the three months ended March 31, 2017 were \$8,489,404, compared to \$10,075,039 for the same period in 2016, representing a decrease of \$1,585,635 or 16%. The decrease in total expenses for the three months ended March 31, 2017 compared to the same period in 2016 reflects a \$2,578,692 decrease in general and administrative expenses and a \$970,736 increase in product development and clinical trial expenses to advance the Tiara and the Reducer development programs.

Selling expenses for the three months ended March 31, 2017 were \$187,168, compared to \$164,847 for the same period in 2016, representing an increase of \$22,321, or 14%. The increase in selling expenses for the three months ended March 31, 2017 compared to the same period in 2016 reflects costs incurred for commercialization activities for the Reducer in 2016. The Company continues to minimize its selling expenses in the light of ongoing litigation costs and the impact of litigation on the Company.

General and administrative expenses for the three months ended March 31, 2017 were \$3,248,713 compared to \$5,827,405 for the same period in 2016, representing a decrease of \$2,578,692, or 44%. The decrease in general and administrative expenses for the three months ended March 31, 2017 compared to the same period in 2016 can be substantially explained by a \$3,164,430 decrease in litigation expenses, offset by a \$462,676 increase in share-based payments. Due to certain black-out periods during 2016 the Company was unable to grant annual option grants to directors and officers of the Company. The 2016 annual awards were granted in 2017. The charge for 2017 reflects stock-based compensation for both the annual grants for 2016 and 2017.

Product development and clinical trial expenses for the three months ended March 31, 2017 were \$5,053,523, compared to \$4,082,787 for the same period in 2016, representing an increase of \$969,736, or 24%. The increase in product development and clinical trial expenses for the three months ended March 31, 2017 represented an increased investment in the Tiara development program.

The Company's expenses are subject to inflation and cost increases. Salaries and wages have increased on average by 3% in the three months ended March 31, 2017 compared to the same period in 2016. 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 and Loss**

The other loss for the three months ended March 31, 2017 was \$28,299, compared to \$1,319,023 for the same period in 2016, a decrease of \$1,290,724. Included within other loss is a charge of \$211,884 for post-judgment interest on the damages provision related to the litigation with CardiAQ (see "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein). The decrease in the other loss can be explained by a \$52,636 decrease in the loss on foreign exchange and by a \$1,505,875 increase in the unrealized gain on the damages provision.

## **Tax Expense**

The tax expense for the three months ended March 31, 2017 was \$56,614, compared to \$48,174 for the same period in 2016. Neovasc (US) Inc. provides clinical trial services to Neovasc Medical Inc. The cross border intercompany charges from Neovasc (US) Inc. to Neovasc Medical Inc. created a taxable profit in Neovasc (US) Inc. and U.S. federal and state taxes were charged.

## QUARTERLY INFORMATION

The following is a summary of selected unaudited financial information for the eight fiscal quarters to March 31, 2017:

|  | March 31,<br>2017      | December 31,<br>2016  | September 30,<br>2016  | June 30,<br>2016       |
|--|------------------------|-----------------------|------------------------|------------------------|
| <b>REVENUE</b>                                   |                        |                       |                        |                        |
| Reducer  | \$ 260,765             | \$ 282,515            | \$ 262,546             | \$ 246,122             |
| Product sales                                    | -                      | -                     | -                      | -                      |
| Contract manufacturing                           | 133,963                | 1,355,385             | 1,543,516              | 240,837                |
| Consulting services                              | 1,086,632              | 1,123,222             | 1,227,938              | 1,223,973              |
|  | <u>1,481,360</u>       | <u>2,761,122</u>      | <u>3,034,000</u>       | <u>1,710,932</u>       |
| <b>COST OF GOODS SOLD</b>                        | <u>808,628</u>         | <u>2,052,969</u>      | <u>2,201,440</u>       | <u>1,391,708</u>       |
| <b>GROSS PROFIT</b>                              | <u>672,732</u>         | <u>708,153</u>        | <u>832,560</u>         | <u>319,224</u>         |
| <b>EXPENSES</b>                                  |                        |                       |                        |                        |
| Selling expenses                                 | 187,168                | 141,733               | 208,884                | 181,174                |
| General and administrative expenses              | 3,248,713              | 2,461,433             | 3,466,825              | 7,427,124              |
| Product development and clinical trials expenses | 5,053,523              | 4,833,990             | 4,742,691              | 5,705,035              |
|  | <u>8,489,404</u>       | <u>7,437,156</u>      | <u>8,418,400</u>       | <u>13,313,333</u>      |
| <b>OPERATING LOSS</b>                            | <u>(7,816,672)</u>     | <u>(6,729,003)</u>    | <u>(7,585,840)</u>     | <u>(12,994,109)</u>    |
| Other Income/(expense)                           | 28,299                 | 43,957,927            | (21,461,950)           | (70,648,431)           |
| Tax expense                                      | (56,614)               | (15,133)              | (87,296)               | (49,920)               |
| <b>PROFIT/(LOSS) FOR THE PERIOD</b>              | <u>\$ (7,844,987)</u>  | <u>\$ 37,213,791</u>  | <u>\$ (29,135,086)</u> | <u>\$ (83,692,460)</u> |
| <b>BASIC AND DILUTED LOSS PER SHARE</b>          | <u>\$ (0.10)</u>       | <u>\$ 0.54</u>        | <u>\$ (0.44)</u>       | <u>\$ (1.25)</u>       |
|  | March 31,<br>2016      | December 31,<br>2015  | September 30,<br>2015  | June 30,<br>2015       |
| <b>REVENUE</b>                                   |                        |                       |                        |                        |
| Reducer  | \$ 213,765             | \$ 192,013            | \$ 159,394             | \$ 134,607             |
| Product sales                                    | -                      | -                     | 10,228                 | 120,097                |
| Contract manufacturing                           | 606,783                | 963,864               | 737,336                | 972,216                |
| Consulting services                              | 1,186,194              | 1,068,169             | 1,566,729              | 1,700,464              |
|  | <u>2,006,742</u>       | <u>2,224,046</u>      | <u>2,473,687</u>       | <u>2,927,384</u>       |
| <b>COST OF GOODS SOLD</b>                        | <u>1,445,644</u>       | <u>1,942,140</u>      | <u>1,573,068</u>       | <u>1,815,354</u>       |
| <b>GROSS PROFIT</b>                              | <u>561,098</u>         | <u>281,906</u>        | <u>900,619</u>         | <u>1,112,030</u>       |
| <b>EXPENSES</b>                                  |                        |                       |                        |                        |
| Selling expenses                                 | 164,847                | 292,456               | 113,913                | 125,478                |
| General and administrative expenses              | 5,827,405              | 3,498,682             | 4,552,966              | 3,535,042              |
| Product development and clinical trials expenses | 4,082,787              | 4,560,955             | 4,908,752              | 4,280,295              |
|  | <u>10,075,039</u>      | <u>8,352,093</u>      | <u>9,575,631</u>       | <u>7,940,815</u>       |
| <b>OPERATING LOSS</b>                            | <u>(9,513,941)</u>     | <u>(8,070,187)</u>    | <u>(8,675,012)</u>     | <u>(6,828,785)</u>     |
| Other income/(expense)                           | (1,319,023)            | 853,930               | 1,041,842              | 76,447                 |
| Tax expense                                      | (48,174)               | (167,351)             | -                      | -                      |
| <b>LOSS FOR THE PERIOD</b>                       | <u>\$ (10,881,138)</u> | <u>\$ (7,383,608)</u> | <u>\$ (7,633,170)</u>  | <u>\$ (6,752,338)</u>  |
| <b>BASIC AND DILUTED LOSS PER SHARE</b>          | <u>\$ (0.16)</u>       | <u>\$ (0.11)</u>      | <u>\$ (0.11)</u>       | <u>\$ (0.10)</u>       |

The Company anticipates its overall revenues to be focused on a smaller customer base in 2017 and the loss of Boston Scientific as a customer will significantly decrease revenues in 2017. In the long-term the Company also expects its consulting services to decline. The Company is not actively looking for new customers as available development staff and resources are being diverted to the Tiara development program. The Company anticipates that it will be able to replace and grow total revenue from the commercialization of the Reducer and the Tiara in the mid- to long-term.

Selling expenses are expected to generally increase 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 2016 mainly due to litigation expenses during the jury trial with CardiAQ. Product development and clinical trial activities have seen

quarter over quarter increases and decreases depending on the activities conducted in that quarter to develop the Tiara and the Reducer and we expect these expenses to increase in the coming quarters and beyond as we initiate new clinical studies for both products.

## USE OF PROCEEDS

On February 3, 2015, the Company closed an underwritten public offering, which placed 10,415,000 common shares of Neovasc from treasury at a price of \$7.19 per common share for aggregate gross proceeds of approximately \$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. 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   | \$35,000,000                                  | \$23,866,155               | \$11,133,845          |
| Reducer Development Costs | \$10,000,000                                  | \$1,628,654                | \$8,371,346           |
| Additional Proceeds       | \$24,879,210                                  | \$32,828,369               | (\$7,949,159)         |
| <b>TOTAL</b>              | <b>\$69,879,210</b>                           | <b>\$58,293,178</b>        | <b>\$11,586,032</b>   |

The actual proceeds net of share issuance costs from the February 3, 2015 financing to the Company were \$69,879,210. From February 3, 2015 to March 31, 2017 the Company spent \$58,293,178 of the proceeds. \$23,866,155 was spent on Tiara development costs, \$1,628,654 on Reducer development costs and \$32,828,369 was spent on litigation expenses, working capital items and investment in property, plant and equipment funded from the additional proceeds. We have incurred approximately \$21.9 million expenses since the February 2015 financing in connection with the litigation with CardiAQ. Such expenses have exceeded the Company's estimates at the time of the financing and account for the significant depletion of the additional proceeds generated in the financing. The additional proceeds from the February 2015 financing have been fully depleted and we have started using proceeds originally intended for development costs of the Tiara and the Reducer programs. The Company may be forced to limit the scope of its development programs or may require significant additional financing in order to pay for the proposed development programs and to continue to operate its business. There can be no assurance that such financing will be available on favorable terms, or at all. A reduction in the scope of the development programs may cause a reduction in anticipated future revenues of the Company or in other ways harm the Company's competitive position in the future. This may have a material adverse effect on the Company's business.

On December 12, 2016, the Company entered into an agreement for Boston Scientific to acquire the Company's Peripatch tissue capabilities and certain manufacturing assets and make a 15% equity investment in Neovasc, for a total of \$75 million in cash. The Company closed a private placement with Boston Scientific, whereby Boston Scientific purchased a 15% equity investment in the Company or 11,817,000 common shares at price of \$0.60 per share for gross proceeds of \$7,090,200. 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 private placement, 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 |                       |
|-----------------------------------|-------------------------------------|----------------------------|-----------------------|
|                                   | December 12, 2016 Private Placement | Use of Proceeds            | Remaining to be Spent |
| Cash held in escrow               | \$2,258,260                         | \$2,258,260                | \$NIL                 |
| Replacement clean room facilities | \$2,500,000                         | \$175,800                  | \$2,324,200           |
| General expenses                  | \$2,296,400                         | \$NIL                      | \$2,296,400           |
| <b>TOTAL</b>                      | <b>\$7,054,660</b>                  | <b>\$2,434,060</b>         | <b>\$4,620,600</b>    |

The actual proceeds net of share issuance costs from the December 12, 2016 financing to the Company were \$7,054,660. The share issue costs incurred by the Company were \$35,540. Concurrent to, and contingent upon, the non-brokered private placement Boston Scientific purchased certain assets from the Company for \$67,741,740 (net of selling expense of \$168,060). The combined proceeds, after selling expenses and share issue costs, were \$74,796,400 of which \$70,000,000 was placed in a joint escrow account. The balance of \$4,796,400 is to be used, in part or in whole, to replace the clean room facilities that were sold to Boston Scientific and for working capital and general purposes. Management estimates \$2.5 million will be required to replace the clean room facilities. As of March 31, 2017, \$175,880 of these proceeds had been used to secure additional lease premises. Construction of the new clean room facilities has not yet commenced.

The Company may also have to pay all or part of the approximate \$112 million total damages awards in connection with the litigation with CardiAQ. The Company has \$70 million in a joint escrow account from which to pay these awards but anything in excess of \$70 million may have to be paid from the proceeds of the February 2015 financing and/or the December 2016 financing and there may be limited proceeds remaining to further the development programs. These circumstances indicate the existence of a material uncertainty and cast a substantial doubt about the Company's ability to continue as a going concern (see "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein).

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

Neovasc finances its operations and capital expenditures with cash generated from operations and equity financings. As at March 31, 2017 the Company had cash and cash equivalents of \$16,206,632 compared to cash and cash equivalents of \$22,954,571 as at December 31, 2016. The Company's working capital deficit is \$24,221,853 as at March 31, 2017 compared to a working capital deficit of \$17,497,931 as at December 31, 2016. Unless the Company is successful in an appeal of the verdict in the litigation with CardiAQ, or otherwise is successful in reducing the amount of the approximate \$112 million damages award to an amount less than the \$70 million held in escrow, the Company will require significant additional financing in order to pay the damages and to continue to operate its business. There can be no assurance that such financing will be available on favorable terms, or at all.

The Company may be faced with significant monetary damages that could exceed its resources and/or the loss of intellectual property rights that could have a material adverse effect on the Company and its financial condition. These circumstances indicate the existence of material uncertainty and cast substantial doubt about the Company's ability to continue as a going concern (see "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein).

Cash used in operating activities for the three months ended March 31, 2017, was \$6,308,755, compared to \$10,903,712 for the same period in 2016. For the three months ended March 31, 2017, operating expenses were \$6,153,498, compared to \$10,256,486 for the same period in 2016. This can substantially be explained by a decrease in litigation expenses of \$3,164,430 offset by an increase in product development and clinical trial expenses of \$970,736.

Net cash absorbed by investing activities for the three months ended March 31, 2017, was \$351,260 compared to \$305,585 in 2016. In 2017, the Company invested in lease hold improvements for its new facility to replace the facilities sold to Boston Scientific in 2016.

Net cash provided by financing activities for the three months ended March 31, 2017, was \$17,542, compared to \$48,495 for the same period in 2016.

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 were no significant restrictions on the transfer of funds between these entities and during the three months ended March 31, 2017 and 2016 the Company had no complications in transferring funds to and from its subsidiaries in Israel and the United States.

The Company is exposed to foreign currency fluctuations on \$5,577,318 of its cash and cash equivalents held in U.S. dollars and Euros.

## **SUBSEQUENT EVENTS**

There have been no material subsequent events from the end of the period to the date of this report.

## **OUTSTANDING SHARE DATA**

As at May 10, 2017, the Company had 78,897,345 common voting shares issued and outstanding. Further, the following securities are convertible into common shares of the Company: 9,234,029 stock options with a weighted average price of C\$3.57. The fully diluted share capital of the Company at May 10, 2017 is 88,131,374.

## **CONTRACTUAL OBLIGATIONS AND CONTINGENCIES**

### ***Contingencies***

#### **Litigation with CardiAQ**

The Company is engaged as an appellant and a defendant in lawsuits involving CardiAQ, as further described below. Litigation resulting from CardiAQ's claims is expected to be costly and time-consuming and could divert the attention of management and key personnel from our business operations. Although we intend to vigorously defend ourselves against these claims, we cannot assure that we will succeed in appealing and defending any of these claims and that judgments will not be upheld against us. If we are unsuccessful in our appeal and defense of these claims or unable to settle the claims in a manner satisfactory to us, we may be faced with significant monetary damages and/or loss of intellectual property rights, that could have a material adverse effect on the Company and its financial condition. These circumstances indicate the existence of a material uncertainty and cast material doubt on the Company's ability to continue as a going concern.

On June 6, 2014, Neovasc was named in a lawsuit filed by CardiAQ in the U.S. District Court for the District of Massachusetts ("the Court") concerning intellectual property rights ownership, unfair trade practices and breach of contract relating to Neovasc's transcatheter mitral valve technology, including the Tiara.

On June 23, 2014, CardiAQ also filed a complaint against Neovasc in Munich, Germany ("the German Court") requesting that Neovasc assign its right to one of its European patent applications to CardiAQ. The German Court is expected to render its decision in May 2017 after a hearing which was held on December 14, 2016. There are no monetary awards associated with these matters and no damages award has been recognized.

On April 25, 2016, the Court granted Neovasc's motion for summary judgment on CardiAQ's claim for fraud.

On May 19, 2016, following a trial in Boston, Massachusetts, a jury found in favor of CardiAQ and awarded \$70 million on the trade secret claim for relief, and no damages on the contractual claims for relief.

On May 27, 2016, the Court granted Neovasc's motion for judgment as a matter of law on the Massachusetts Gen. Law. Ch. 93A claim.

Following post-trial motions, on October 31, 2016, the Court awarded CardiAQ \$21 million in enhanced damages on the trade secret claim for relief, and denied Neovasc's motions for a new trial.

On October 31, 2016, the Court also denied CardiAQ's motion for an injunction that would have shut down the development of the Tiara, thus allowing the Company to continue development and commercialization of the Tiara. The Court issued an injunction requiring Neovasc to certify, by November 7, 2016, destruction of information that CardiAQ sent to Neovasc during the parties' 2009-2010 business relationship, destruction of any related work product that incorporates such information, and return of any related CardiAQ prototypes. The Company filed a timely certification of compliance with this injunction.

In the cause of action relating to patent inventorship, CardiAQ claimed that two individuals should be added as inventors to a Neovasc patent. In the October 31, 2016 order, the Court also ruled on the patent inventorship claim. In that order, the Court ruled in favor of CardiAQ on the issue of inventorship of Neovasc's patent. There are no monetary awards associated with these matters and no damages award has been recognized. The Company is appealing this decision of the Court. Unless the Company is successful at appeal, two individuals associated with CardiAQ will be added as inventors to Neovasc's patent.

On December 23, 2016, the Court issued a stipulated order under which enforcement of the judgment was stayed pending appeal, pursuant to which Neovasc placed \$70 million in a joint escrow account and also executed a General Security Agreement with CardiAQ on January 5, 2017. Neovasc will also require court approval for transactions outside the course

of normal business until such time that an appeal is decided in Neovasc's favor or the Company posts the remaining amount of money judgment into the joint escrow account.

On January 18, 2017, the Court issued a final judgment, and granted CardiAQ's motion for pre- and post-judgment interest. The Court awarded \$20,675,154 in pre-judgment interest and \$2,354 per day in post-judgment interest from November 21, 2016.

Neovasc filed a renewed notice of appeal with the United States Court of Appeals for the Federal Circuit (the "Appeals Court") on January 18, 2017. CardiAQ subsequently filed a notice of cross-appeal. Neovasc moved the Appeals Court to expedite its appeal on January 24, 2017. The Company will appeal the validity of the award, the ruling on inventorship, and related issues stemming from the trial court verdict and October 31 order. The appellate process may take up to a year to complete.

On February 28, 2017, Neovasc filed its opening appellate brief in the Appeals Court. On April 21, CardiAQ filed its principal appellate brief responding to Neovasc's opening brief and arguing its cross-appeal on the Court's denial of its request for injunctive relief. Neovasc expects oral argument on its appeal in August 2017 and a ruling is expected to follow a few months afterward. With respect to CardiAQ's cross-appeal, the standard of review is abuse of discretion. If the Federal Circuit were to rule that the trial court abused its discretion in denying injunctive relief, it would in that case likely remand to the trial court for further proceedings. One potential outcome among others could be an injunction prohibiting Neovasc from further operating its Tiara business for some period of time.

On March 24, 2017, CardiAQ filed a related lawsuit in the Court, asserting two claims for correction of patent inventorship as to Neovasc's U.S. Patents Nos. 9,241,790 and 9,248,014. The lawsuit does not seek money damages and would not prevent the Company from practicing these patents. The Company has not yet filed its response to the complaint.

When the Company assesses that it is more likely that a present obligation exists at the end of the reporting period and that the possibility of an outflow of economic resources embodying economic benefits is probable, a provision is recognized and contingent liability disclosure is required. As at March 31, 2017, the Company has fully provided for the damages awards described above.

### **Securities Class Action Lawsuit**

On June 6, 2016, an alleged purchaser of Neovasc common shares filed a lawsuit, on behalf of a putative class of purchasers of Neovasc securities, against Neovasc (as well as against Chief Executive Officer, Alexei Marko, and Chief Financial Officer, Christopher Clark) in the Court concerning alleged violations of the United States securities laws. The case is styled as Sergio Grobler, individually and on behalf of all others similarly situated v. Neovasc Inc., Alexei Marko, and Christopher Clark, Case No. 1:16-cv-11038-RGS. The complaint filed in the lawsuit, which principally based the plaintiff's claims on the Company's prior disclosures regarding the lawsuit filed by CardiAQ in the Court, did not specify the amount of damages sought. On November 22, 2016, the Court granted the Company's and the officers' motion to dismiss, dismissing the lawsuit in its entirety and denying the plaintiff leave to amend the complaint. The plaintiff filed a motion to vacate the order dismissing the lawsuit, and, on January 12, 2017, the Court denied that motion. The case is now closed. Following the ruling on the motion to vacate, and as of the present time, the plaintiff has not appealed the dismissal of the lawsuit. Whether the plaintiff will take any action to engage in future proceedings concerning this matter is not currently determinable, nor would it be possible to accurately predict the outcome or quantum of any such future proceedings to the Company at this time.

When the Company assesses that it is more likely that no present obligation exists at the end of the reporting period and that the possibility of an outflow of economic resources embodying economic benefits is remote, no provision is recognized and no contingent liability disclosure is required.

### **Other Matters**

By way of Amended Statement of Claim in Federal Court of Canada Action T-1831-16 (the "Action") Neovasc Inc. and Neovasc Medical Inc. (the "Neovasc Defendants") were added as defendants to an existing action commenced by Edwards Lifesciences PVT, Inc. and Edwards Lifesciences (Canada) Inc. against Livanova Canada Corp., Livanova PLC, Boston Scientific Corporation and Boston Scientific Ltd. (collectively, the "BSC/Livanova Defendants"). The Action was first filed in October 2016 and first concerned an allegation by the plaintiffs that the manufacturing, assembly, use, sale and export of

the Lotus Aortic Valve devices by the BSC/Livanova Defendants infringes on the plaintiffs' patents. In February, 2017, the Neovasc Defendants were added to the plaintiffs' claim making related allegations. In summary, the plaintiffs make three types of allegations as against the Neovasc Defendants: (a) indirect infringement claims; (b) direct infringement claims; and (c) claims of inducement. The plaintiffs seek various declarations, injunctions and unspecified damages and costs. Defences have yet to be filed. The Neovasc Defendants intend to vigorously defend themselves.

When the Company assesses that it is more likely that no present obligation exists at the end of the reporting period and that the possibility of an outflow of economic resources embodying economic benefits is remote, no provision is recognized and no contingent liability disclosure is required.

### **Contractual obligations**

The following table summarizes our contractual obligations as at March 31, 2017:

| Contractual Obligations | Total              | Less than 1 year | 2-3 years        | 4-5 years        |
|-------------------------|--------------------|------------------|------------------|------------------|
| Operating leases        | <b>\$1,450,723</b> | <b>\$257,546</b> | <b>\$658,616</b> | <b>\$534,561</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 three months ended March 31, 2017 and 2016, other than those as described elsewhere herein and those compensation-based payments disclosed in Note 20 of the unaudited condensed interim consolidated financial statements for the three months ended March 31, 2017 and 2016.

### **PROPOSED TRANSACTIONS**

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

### **CRITICAL ACCOUNTING ESTIMATES AND MANAGEMENT JUDGMENT**

The preparation of the 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 and 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, unless circumstances suggest collectability is assured. 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. Management uses a number of factors to determine the primary economic environment in which the Company operates; it is normally the one in which it primarily generates and expends cash. As the Company is still a development-stage entity, it considers the currency in which it expends cash on its research and development activities to be a key element in this assessment.

#### **Determination of presentation currency**

The Company has elected to adopt the U.S. dollar as its presentation currency, to improve comparability of its financial information with other publicly traded businesses in the life sciences industry.

#### **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 estimates of future taxable income.

#### **Contingent Liabilities**

Contingent liabilities are assessed continually to determine whether an outflow of resources embodying economic benefits has become probable. If it becomes probable that an outflow of future economic benefits will be required for an item previously dealt with as a contingent liability, a provision is recognized in the consolidated financial statements of the period in which the change in probability occurs.

The Company has considered the significance of the accounting estimates on its financial position, changes in financial position and financial performance. The most significant accounting estimate is the assessment of the contingent liabilities. The unaudited condensed interim consolidated financial statements would be significantly amended if management had determined that the outflow of resources embodying economic benefits was possible and not probable. Had this determination been made the damages provision of \$211,884 would not have been recorded as at March 31, 2017 and the loss for the three months ended March 31, 2017 of \$7,844,987 would be a loss of \$7,633,103 as no interest charges would have been recorded. There would have been no change in the cash position of the Company as at March 31, 2017.

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

During the three months ended March 31, 2017, there have been no changes in accounting policies, except as disclosed herein. The Company has not adopted any new accounting policies during the three months ended March 31, 2017.

#### **CHANGES IN ACCOUNTING PRONOUNCEMENTS**

The Company has reviewed new and revised accounting pronouncements that have been issued but are not yet effective. The Company has not early adopted any of these standards, but will adopt by their respective mandatory application date. The Company is currently assessing their impact on its consolidated financial statements.

The new standard for financial instruments (IFRS 9) introduces extensive changes to IAS 39's guidance on the classification and measurement of financial assets and introduces a new 'expected credit loss' model for the impairment of financial assets. IFRS 9 also provides new guidance on the application of hedge accounting.

IFRS 9 divides all financial assets into two classifications – those measured at amortized cost and those measured at fair value. Classification is made at the time the financial asset is initially recognized when the entity becomes a party to the contractual provisions of the instrument. The transition guidance is complex and mainly requires retrospective application.

Most of the requirements in IAS 39 for the classification and measurement of financial liabilities have been carried forward unchanged to IFRS 9. Where an entity chooses to measure its own debt at fair value, IFRS 9 now requires the amount of the change in fair value due to changes in the issuing of the entity's own credit risk to be presented in other comprehensive income. An exception to the new approach is made where the effects of changes in the liability's credit risk would create or enlarge an accounting mismatch in profit or loss, in which case all gains or losses on that liability are to be presented in profit or loss. The requirements in IAS 39 related to de-recognition of financial assets and financial liabilities have been incorporated unchanged into IFRS 9. The new standard is required to be applied for annual reporting periods beginning on or after January 1, 2018. Early application of this standard is permitted.

IFRS 15 presents new requirements for the recognition of revenue, replacing IAS 18 'Revenue', IAS 11 'Construction Contracts', and several revenue-related Interpretations. The new standard establishes a control-based revenue recognition model and provides additional guidance in many areas not covered in detail under existing IFRSs, including how to account for arrangements with multiple performance obligations, variable pricing, customer refund rights, supplier repurchase options, and other common complexities.

IFRS 15 applies to contracts with customers to provide goods or services, including construction contracts and licensing of intellectual property. It will not apply to certain contracts within the scope of other IFRSs such as lease contracts, insurance contracts, financing arrangements, financial instruments, guarantees other than product warranties, and non-monetary exchanges between entities in the same line of business to facilitate sales to third-party customers. The new standard is required to be applied for annual reporting periods beginning on or after January 1, 2018. Early application of this standard is permitted.

IFRS 16 Leases sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract. All leases result in the lessee obtaining the right to use an asset at the start of the lease and, if lease payments are made over time, also obtaining financing. Accordingly, from the perspective of the lessee, IFRS 16 eliminates the classification of leases as either operating leases or finance leases as is required by IAS 17 Leases and, instead, introduces a single lessee accounting model. From the perspective of the lessor, IFRS 16 substantially carries forward the accounting requirements in IAS 17. Accordingly, a lessor continues to classify its leases as operating leases or finance leases, and accounts for those two types of leases differently. The new standard is required to be applied for annual reporting periods beginning on or after January 1, 2019. Early application of this standard is permitted.

## **FINANCIAL INSTRUMENTS**

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

### **(a) Foreign exchange risk**

The majority of the Company's revenues are derived from product sales in the United States and Europe, primarily denominated in United States and European Union currencies. Management has considered the stability of the foreign currency and the impact a change in the exchange rate may have on future earnings during the forecasting process. The Company does not hedge its foreign exchange risk.

### **(b) Interest rate risk**

The Company receives interest on its investment in High Interest Savings Accounts at variable interest rates.

### **(c) Liquidity risk**

The Company is dependent on the profitable commercialization of its products or obtaining additional debt or equity financing to fund ongoing operations until profitability is achieved. The Company monitors its cash flow on the monthly basis and compares actual performance to the budget for the fiscal year. The Company believes it has sufficient funds to fund operations for the next 2 to 3 quarters. The Company may obtain additional debt or equity financing during that period. Further into the future the Company is dependent on the profitable commercialization of its products or obtaining additional debt or equity financing to fund ongoing operations until profitability is achieved.

The Company has been successful in staying the total approximate \$112 million damages award in the litigation with CardiAQ and has placed \$70 million in a joint escrow account. Unless the Company is successful in post-trial motions and/or an appeal of the verdict, or otherwise is unsuccessful in reducing the amount of these awards, the Company will require significant additional financing in order to pay the damages and to continue to operate its business. There can be no assurance that such financing will be available on favorable terms, or at all.

### **(d) Credit risk**

Credit risk arises from the possibility that the entities to which the Company sells products may experience financial difficulty and be unable to fulfill their contractual obligations. This risk is mitigated by proactive credit management policies that include regular monitoring of the debtor's payment history and performance. The Company does not require collateral from its customers as security for trade accounts receivable but may require certain customers to pay in advance of any work being performed or product being shipped.

The Company may also have credit risk related to its cash and cash equivalents. The Company minimizes its risk to cash and cash equivalents by dealing with Canadian Chartered Banks.

## **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 March 31, 2017, 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 March 31, 2017 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 consolidated 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. Due to inherent limitations, ICFR 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 U.S. Jumpstart Our Business Startups Act of 2012, the Company will not be required to comply with the auditor attestation requirements of the U.S. 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 DC&P and ICFR during the three months ended March 31, 2017, that have materially affected, or are reasonably likely to affect our DC&P and ICFR.

**ADDITIONAL INFORMATION**

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