



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

**FOR THE YEARS ENDED DECEMBER 31  
2017, 2016 AND 2015**

(Expressed in U.S. Dollars)

**Q4  
2017**

## MANAGEMENT'S DISCUSSION AND ANALYSIS

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") covers the audited consolidated financial statements of Neovasc Inc. (the "Company", "Neovasc", "we", "us", or "our") for the years ended December 31, 2017, 2016 and 2015 and should be read in conjunction with the audited consolidated financial statements and notes thereto for the years ended December 31, 2017, 2016 and 2015 (included as part of Neovasc's annual filing).

The Company has prepared this MD&A with reference to National Instrument 51-102 – Continuous Disclosure Obligations of the Canadian Securities Administrators.

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, is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on Form 6-K filed with the U.S. Securities and Exchange Commission (the "SEC"), which is available on the website of the SEC 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 to continue as a going concern;
- 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 approximately 2020 and look for potentially faster pathways to such approval;
- the anticipated timing of additional implantations in the TIARA-II trial and our intention to initiate additional investigational sites in 2018 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 plans to develop and commercialize the Tiara transfemoral trans-septal system;
- our strategy to refocus our business towards development and commercialization of the Reducer and the Tiara;
- the amount of estimated additional litigation expenses required to defend the Company in ongoing lawsuits;
- our ability to replace declining revenues from the tissue and consulting services businesses 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;
- 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 Europe;
- our ability to advance and complete the COSIRA-II IDE pivotal clinical trial;
- our intention to continue directing a significant portion of our resources into sales expansion;

- the decline of consulting services revenue after the Company ceased such operations in 2017;
- our ability to get our products approved for use;
- the benefits and risks of our products as compared to others;
- our ability to find strategic alternatives for adoption of the Reducer, including potential alliances in order to broaden and deepen therapy penetration and potentially advance the COSIRA-II study;
- our estimates of the size of the potential markets for our products including the anticipated market opportunities for the Reducer and the Tiara;
- 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 ability to meet our financial and organizational restructuring goals to establish a lean and accountable organization with stable capitalization;
- our ability to meet our cash expenditure covenants;
- 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:

- the substantial doubt about our ability to continue as a going concern;
- risks relating to the warrants issued pursuant to the November 2017 underwritten public offering of 6,609,588 Series A units (the "Series A Units") of the Company and 19,066,780 Series B units (the "Series B Units" and together with the Series A Units, the "Units"), at a price of \$1.46 per Unit (the "2017 Public Transaction") and the warrants and senior secured convertible notes (the "Notes") issued pursuant to the November 2017 private placement (the "2017 Private Placement", and together with the 2017 Public Transaction, the "2017 Financings"), resulting in significant dilution to our shareholders;
- risks relating to our need for significant additional future capital and our ability to raise additional funding;
- risks relating to cashless exercise and adjustment provisions in the warrants (the "Warrants") and Notes issued pursuant to the 2017 Financings, which could make it more difficult and expensive for us to raise additional capital in the future and result in further dilution to investors;
- risks relating to the sale of a significant number of common shares of the Company ("Common Shares");
- risks relating to the exercise of Warrants or conversion of Notes issued pursuant to the 2017 Financings, which may encourage short sales by third parties;
- risks relating to the possibility that our Common Shares may be delisted from the Nasdaq or the TSX, which could affect their market price and liquidity;
- risks relating to our Common Share price being volatile;
- risks relating to the influence of significant shareholders of the Company over our business operations and share price;
- risks relating to our significant indebtedness, and its affect on our financial condition;
- risks relating to claims by third parties alleging infringement of their intellectual property rights;
- risks relating to lawsuits that we are subject to, which could divert our resources and result in the payment of significant damages and other remedies;
- 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 use of our products in unapproved circumstances, which could expose us to liabilities;
- 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 our dependence on limited products for substantially all of our current revenues;
- risks relating to our exposure to adverse movements in foreign currency exchange rates;
- risks relating to the possibility that we could lose our foreign private issuer status under U.S. federal securities laws;
- 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;
- risks relating to 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;
- risks relating to our ability to successfully identify and complete corporate transactions on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances;
- risks relating to our ability to successfully enter into fundamental transactions ("Fundamental Transactions") as defined in the Series C Warrants issued pursuant to the 2017 Financings (the "Series C Warrants");
- anti-takeover provisions in our constating documents which could discourage a third party from making a takeover bid beneficial to our shareholders; and
- risks relating to conflicts of interests among the Company's officers and directors as a result of their involvement with other issuers.

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 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 in our Annual Information Form, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on Form 6-K filed with the SEC 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: March 28, 2018

## 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.

In late 2016, Neovasc sold its tissue processing technology and facility for \$67,909,800 to Boston Scientific Corporation ("Boston Scientific"), and concurrently, Boston Scientific invested an additional \$7,090,200 in Neovasc for a 15% equity interest in the Company. Under the terms of the equity investment, Boston Scientific purchased 11,817,000 common shares of Neovasc at a price of \$0.60 per common share, for gross proceeds of \$7,090,200. Under the terms of the asset purchase agreement, Neovasc has been granted a license to the purchased assets 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.

Additionally, throughout the years 2014 to 2017, the Company announced a number of developments pertaining to litigation, all as more fully discussed under the heading "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein.

### Product Portfolio

#### Tiara

In 2009, Neovasc started initial activities to develop novel technologies for catheter-based treatment of mitral valve disease. 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 transapically delivered Tiara is in the early clinical development stage to provide a minimally invasive transcatheter device for the patients who experience severe Mitral Regurgitation as a result of functional (most patients) or degenerative mitral heart valve disease, combined with an enlarged left ventricle. There are millions of patients worldwide who suffer from severe Mitral valve dysfunction (regurgitation), the majority of them with functional Mitral Regurgitation and unmet medical need in these patients is high. Mitral Regurgitation is often severe and can lead to heart failure and death. 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. Some of these patients are treated today via minimally invasive mitral valve repair procedures; however, these procedures are also complex, can take a long period of time to complete

and the clinical outcomes may not be optimal. Currently there is no transcatheter mitral valve replacement device approved for use in any market.

Our clinical experience to date has been with the 35mm and 40mm Tiara. First clinical use of the 40mm Tiara occurred in the fourth quarter of 2015. These two sizes enable us to treat approximately 75% of this high-risk patient population, as it relates to the size of the Mitral valve annulus, in our TIARA I and TIARA II Clinical studies. Currently, about 20% of the patients enrolled in these studies with severe Mitral Regurgitation, meet all inclusion criteria and are treated with the Tiara.

To date, 50 patients have been implanted with the Tiara in TIARA-I early feasibility, compassionate use cases and in our TIARA-II CE Mark Clinical Study. Neovasc believes that early results have been encouraging. The 30-day survival rate for the first 49 patients implanted with the Tiara (i.e. those implanted more than 30 days ago) is 45/49 or 92% with one patient now over four years post implant and another over two years post implant. The Tiara has been successfully implanted in both functional and degenerative Mitral Regurgitation patients, as well as in patients with pre-existing prosthetic aortic valves and mitral surgical annuloplasty rings.

The results from our clinical experience to-date in these studies and compassionate use cases have been instrumental in helping to demonstrate the potential of the Tiara. We have been able to refine the screening criteria, physician training, and implantation procedure. 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 commercialization (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 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 valve replacement or any form of repair. There are several other transcatheter mitral valve replacement devices in development by third parties, some of which have been implanted in early feasibility type studies and CE Mark studies with varying results.

An additional strategic and focused activity for the Company in the Mitral Valve space is the re-initiated development of the transfemoral, trans-septal version of the Tiara Mitral Valve, which the Company believes has the potential to lead to a breakthrough for the optimal treatment of severe Mitral Regurgitation, by providing a safe and broadly use-able implantation technique. These development activities are taking place both in the Company's Vancouver and New Brighton, MN facilities. Outside of the development of a unique and innovative delivery system, the Company will make a few minor, but meaningful changes to the current Tiara valve, in order to enable trans-septal delivery & deployment, as well as to further increase the suitable patient population, while maintaining the core features and functionality of the current valve in order to leverage clinical and technical performance data. The Company expects to have the first prototypes completed in 2 weeks following the date hereof and is currently scheduling animal and cadaver feasibility studies for June, 2018.

The Company is also in the process of establishing more field clinical engineering support in Europe, which will allow it to support additional sites, as well as reduce the time from when a site identifies a patient to when they are enrolled and scheduled to have the procedure.

Neovasc believes that there are several unique attributes of the Tiara that may provide advantages over other approaches to mitral valve replacement, in particular the low atrial profile, it's D shape, enabling a better anatomical fit and less risk of left ventricular outflow tract obstruction, and its unique combined skirt and anchoring mechanism. There is no certainty that the Tiara will successfully proceed through clinical evaluation 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 approximately 2020. There is no assurance that European regulatory approval will be granted in the time frame anticipated by management or granted at any time in the future. There is no expectation that this product will be revenue-generating in the near term, although management believes that the product is addressing an important unmet clinical need and that the demand for the product is high.

On October 9, 2014, Neovasc announced that it received conditional IDE approval from the FDA to initiate the U.S. arm of its TIARA-I feasibility study for the Tiara, followed by full approval on December 31, 2014. The TIARA-I study is a multinational, multicenter early feasibility study being conducted to assess the safety and performance of Neovasc's Tiara mitral valve system and implantation procedure in high-risk surgical patients suffering from severe Mitral Regurgitation. Severe Mitral Regurgitation is a critical condition that affects millions of patients and, if left untreated, can lead to heart failure or death. This FDA conditional approval allows clinical investigators to begin enrolling patients at participating U.S. medical centers once local hospital and related approvals are in place. This is an important step towards Tiara becoming one of the first transcatheter mitral valve replacement devices available for treating 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 exemptions in Canada, Europe and Israel.

On November 28, 2016, the Company announced that it had received both regulatory and ethics committee approval to initiate the TIARA-II study in Italy. The TIARA-II study is a 115 patient, non-randomized, prospective clinical study intended to provide the clinical data required to support obtaining CE Mark approval for the Tiara, which would enable Neovasc to market the device in Europe. In May 2017, the Company received regulatory approval to initiate enrollment in its CE Mark study in Germany and in July 2017, the Company received regulatory approval to initiate enrollment in its CE Mark study in the UK. The Company is currently in the process of qualifying additional clinical sites in Germany and is evaluating obtaining approvals to enroll patients in additional countries, such as in Spain, the Netherlands and Israel. The key business objective of this activity is to enable sales of the product into the European marketplace. The TIARA-II study is estimated to cost approximately \$18-20 million. The exact timing for completion of enrollment in the study is unknown at this time and is dependent on a number of factors, including screening rates, local regulatory approvals and our ability to raise sufficient additional capital to complete the TIARA-II study. Neovasc is targeting to complete enrollment and receive CE Mark approval and begin Tiara sales in Europe in approximately 2020. However, due to the inherent uncertainty around gaining regulatory approval to market an implantable heart valve product and raising additional capital, this timeline is subject to extension. Neovasc is managing and conducting the TIARA-II study itself in conjunction with certain service providers who undertake certain portions of data collection, data management, data analysis, safety and event monitoring and similar functions. The Tiara is currently manufactured for use in these studies by Neovasc at its own facilities following required medical device quality requirements. In the event of a positive outcome from the TIARA-II study and the Company successfully obtaining CE Mark approval, the Tiara would be commercially manufactured in the same manner at Neovasc's facility.

## **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 (percutaneous coronary intervention or coronary artery bypass graft) or cardiac drug therapies. It currently affects approximately 1.5 million patients in the United States and Europe, with a yearly incidence of roughly 40,000 patients. Of this overall patient population, we estimate that about 160,000 current patients have the indications for the current Reducer therapy. The Reducer has been shown to relieve symptoms of angina 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. Clinical studies have demonstrated that the Reducer can provide significant relief of chest pain in refractory angina patients. There are approximately 160,000 refractory angina patients in the United States and in Europe who are potential candidates for the

current Reducer therapy, 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 patient population that has failed to gain relief of their symptoms, despite other medical treatment options. 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 the COSIRA trial to assess the efficacy of the Reducer device. The COSIRA trial's primary endpoint was a two-class improvement in Angina pain, six months after implantation in patients' ratings on the 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 will become incorporated into the endothelial tissue (in about four to six weeks) 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, A first-in-human clinical trial of 15 patients suffering from chronic refractory angina were followed out to 6 months, and then again at 3 years post implant. The six-month results from this clinical trial were published in the Journal of the American College of Cardiology and the 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 at 6 months and these same results were

noted at the three year follow up. During this period, the Reducer appeared safe and well tolerated in these patients. The COSIRA trial – a multi-center, randomized, double-blind, sham-controlled study intended to assess the safety and efficacy of the Reducer in a rigorous, controlled manner was completed in 2013. The results of the 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 may provide additional data to support expanded adoption of the Reducer for the intended patient population.

Following the positive results 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 2018 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.

Based on achieving NUB 1 status in Germany and a general positive reception in the European market, with positive experiences by many physicians from the treatment of their own patients with the Reducer, we are seeing an increase in adoption of the Reducer therapy in Europe. The commercial progress for the Reducer in the first 2018 quarter to-date has been encouraging with a 41% increase in implants compared to the same time-period of 2017. While we only have a very small sales organization in Europe, we are still planning on a doubling of Reducer implants in Europe during 2018 (and an almost tripling of Reducer implants in Germany).

Because of the market development status of the Reducer therapy and the observed increase in adoption in Europe, we also believe it may be prudent to attempt to penetrate the market more broadly and deeply via a strategic collaboration with a third party company, which we will pursue during 2018.

We see a growing level of enthusiasm in Europe for the Reducer therapy and we believe that the therapy has a lot of potential, but that Neovasc can only take this therapy so far. We are therefore open to considering strategic alternatives for Reducer, including potential alliances, in order to broaden and deepen its penetration in EMEA, the United States and the rest of the world. The Company received FDA approval in late 2017 for the COSIRA-II IDE study, as approximately 380 patient Clinical study, to be conducted at up to 35 centers in the United States. The principal investigator and co-principal investigator are already appointed for this study but we currently lack the funding for its execution. A strategic alliance could dramatically improve the time to market for this device in the United States, while broadening the approach, as well as potentially improving the company's cash flow.

### *Regulatory Status*

The Reducer is approved for sale in Europe, having received CE Mark designation in November 2011. Neovasc has completed additional development activities for the commercial-generation Reducer and the product is currently in commercial scale manufacture.

On November 3, 2017, Neovasc received FDA approval for a US IDE clinical trial, COSIRA II (a trial design similar to the COSIRA study). While the principal investigator and co-principal investigator for this study have already been appointed, the Company is currently evaluating the timing for starting this U.S. clinical trial, funding being the largest impediment. The cost of this U.S. clinical trial is expected to be \$15-20 million. 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.

In 2016, Neovasc initiated the REDUCER-I observational study as a multi-center, multi-country, three-arm study collecting long-term data from European patients implanted with the Reducer. The study is expected to enroll up to 400 patients. Currently, 147 patients have been enrolled across 18 centers that are active in Italy, Germany, Belgium, Netherlands, United Kingdom and Switzerland. On January 18, 2018, the Company reported the Reducer was featured in a "live case" broadcast to more than 800 participants at the Kardiologie Symposium 2018 held in Berlin, Germany. The successful live case was performed by Dr. Spyrtantis and Professor Banai in the Sana-Klinikum Lichtenberg.

## **Tissue Products**

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 own tissue-related programs, including advancing the Tiara through its clinical and regulatory pathways.

While there still was revenue during 2017 associated with the tissue products, the Company ceased operations of its consulting services and contract manufacturing revenue line items in 2017 and there are no further revenues associated with these activities expected in 2018.

## **Product Development**

Product development activities have recently started at the Company for the development of a transfemoral trans-septal version of the Tiara system, focused on a suitable and novel transfemoral trans-septal delivery system, as well as on a few important but minor changes to the Tiara valve to make it deliverable in this manner and to further penetrate the patient population. These development activities are taking place both in our Vancouver facility as well as in our New Brighton, MN facility. Furthermore, engineering resources are continuing to support manufacturing for both the Reducer system (commercially available in Europe), as well as for the Tiara system for clinical studies.

## **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 \$22,908,721 and \$24,859,117 for the year ended December 31, 2017, respectively (2016: \$86,494,893 and \$82,397,922) and has a deficit of \$224,692,327 at December 31, 2017 compared to a deficit of \$201,783,606 as at December 31, 2016. As at December 31, 2017 the Company had \$17,507,157 in cash and cash equivalents (2016: \$22,954,571). 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 Company will be able to raise additional capital through debt or equity or other means on terms acceptable to the Company or at all. There is also 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. The terms of the 2017 Financings included, amongst other things, future priced securities, full ratchet anti-dilution clauses and a senior convertible debt instrument secured on substantially all of the assets of the Company. These terms may make it more difficult to obtain additional debt or equity financing in the future. As at December 31, 2017, the Company had approximately \$17.5 million in cash and cash equivalents, sufficient cash for approximately nine months of operations and will need to obtain additional debt or equity financing later in 2018 to fund ongoing operations. The Company can give no assurance that it will be able to raise the additional funds needed, on terms agreeable to the Company, or at all. These circumstances indicate the existence of material uncertainty and cast substantial doubt about the Company's ability to continue as a going concern. For a description of the risks relating to the Company's need for additional financing and the securities issued pursuant to the 2017 Financings see the Company's Annual Information Form, which is available on SEDAR at [sedar.com](http://sedar.com) and on Form 6-K furnished to the SEC at [www.sec.gov](http://www.sec.gov).

## **Litigation Matters**

Between June 2016 and November 2017, Neovasc was engaged in litigation with CardiAQ in the U.S. District Court for the District of Massachusetts and, upon appeal, in the United States Court of Appeals for the Federal Circuit (the "Appeals Court"). On November 13, 2017, the final mandate was issued by the Appeals Court and approximately \$112 million damages and interest awards became due and payable. The Company had approximately \$70 million placed in escrow but needed to raise an additional approximately \$42 million or face bankruptcy proceedings. On November 17, 2017, the Company closed the 2017 Financings for gross proceeds of approximately \$65 million and used approximately \$42 million to settle the remaining damages and interest awards.

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: 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.

## **Risks relating to the 2017 Financings**

The securities issued pursuant to the 2017 Financings contain, among other things, so-called full-ratchet anti-dilution and future pricing provisions, which create a high degree of risk relating to, among other things, significant dilution to shareholders and the Company's ability to raise additional financing. The exercise of warrants issued pursuant to the 2017 Financings have already resulted in significant dilution to our shareholders and may result in further significant dilution in the future. For details concerning the terms of the securities issued pursuant to the 2017 Financings, see the prospectus supplement and the forms of such securities filed on SEDAR at [www.sedar.com](http://www.sedar.com) and with the SEC at [www.sec.gov](http://www.sec.gov). For a description of the risks associated with these securities, the amount of such securities exercised to date, the dilution to date and the potential dilution in the future due to such exercises or conversions, see the Company's Annual Information Form, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on Form 6-K furnished to the SEC at [www.sec.gov](http://www.sec.gov).

## **FOREIGN OPERATIONS**

The Company changed functional currency on October 1<sup>st</sup>, 2017 from Canadian to U.S. dollars.

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. A

decrease in the value of the Euro in relation to the U.S. 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 U.S. dollar financial statements. In addition, any decrease in the value of the 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 audited consolidated financial statements for the years ended December 31, 2017, 2016 and 2015.

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

Results for the years ended December 31, 2017 and 2016 follow:

### **Losses**

The operating losses and comprehensive losses for the year ended December 31, 2017 were \$22,908,721 and \$24,859,117, respectively, or \$0.28 basic and diluted loss per share, as compared with losses of \$86,494,893 and \$82,397,922, or \$1.28 basic and diluted loss per share, for the same period in 2016.

The \$63,586,172 decrease in the operating loss incurred for the year ended December 31, 2017 compared to the same period in 2016 can be substantially explained by a \$111,781,096 damages provision in relation in the Company's litigation with CardiAQ charged in year ended December 31, 2016 and an offsetting of a \$65,095,733 gain on sale of assets related to an agreement with Boston Scientific in the same year. The accounting treatment of the 2017 Financings resulted in a net \$7,380,102 gain and foreign exchange changes accounted for a \$5,690,603 gain between the years. In addition, there was a \$3,498,004 reduction in general and administrative expenses (of which, \$10,759,788 relates to a decrease in litigation expenses offset by expenses related to the 2017 Financings of \$5,447,182) and a decrease of in product development and clinical trial expenses of \$1,875,411.

### **Revenues**

Revenues decreased 43% to \$5,389,014 for the year ended December 31, 2017, compared to revenues of \$9,512,796 for the same period in 2016. 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. In December 2017, the Company closed its contract manufacturing and consulting services.

Sales of the Reducer for the year ended December 31, 2017 were \$1,128,126, compared to \$1,004,948 for the same period in 2016, representing an increase of 12%. The Company is encouraged by the progress this year, but recognizes that future revenues may be unstable before the Reducer becomes widely adopted. 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 year ended December 31, 2017 were \$949,379, compared to \$3,746,521 for the same period in 2016, representing a decrease of 75%. The decrease in revenue for the year ended December 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 \$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 own tissue-related programs, including advancing the Tiara through its clinical and regulatory pathways.

Revenues from consulting services for the year ended December 31, 2017 were \$3,311,509, compared to \$4,761,327 for the same period in 2016, representing a decrease of 30%. The loss is indicative of the trend the Company was seeing in consulting service revenue prior to closing its consulting services.

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

### **Cost of Goods Sold**

The cost of goods sold for the year ended December 31, 2017 was \$3,477,821, compared to \$7,091,761 for the same period in 2016. The overall gross margin for the year ended December 31, 2017 was 35%, compared to 25% 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 year ended December 31, 2017 were \$34,060,101, compared to \$39,243,928 for the same period in 2016, representing a decrease of \$5,183,827 or 13%. The decrease in total expenses for the year ended December 31, 2017 compared to the same period in 2016 reflects a \$3,498,004 reduction in general and administrative expenses (of which, \$10,759,788 relates to a decrease in litigation expenses offset by expenses related to the 2017 Financings of \$5,447,182) and a \$1,875,411 decrease in product development and clinical trial expenses to preserve cash resources.

Selling expenses for the year ended December 31, 2017 were \$886,226, compared to \$696,638 for the same period in 2016, representing an increase of \$189,588, or 27%. The increase in selling expenses for the year ended December 31, 2017 compared to the same period in 2016 reflects an increase in costs incurred for commercialization activities related to the Reducer. The Company continues to minimize its selling expenses in the light of the impact of litigation on the cash resources of the Company.

General and administrative expenses for the year ended December 31, 2017 were \$15,684,783, compared to \$19,182,787 for the same period in 2016, representing a decrease of \$3,498,004 or 18%. The decrease in general and administrative expenses for the year ended December 31, 2017 compared to the same period in 2016 can be substantially explained by a \$10,759,788 decrease in litigation expenses offset by an increase in expenses related to the 2017 Financings of \$5,447,182.

Product development and clinical trial expenses for the year ended December 31, 2017 were \$17,489,092 compared to \$19,364,503 for the same period in 2016, representing a decrease of \$1,875,411 or 10%. The decrease in product development and clinical trial expenses for the year ended December 31, 2017 was the result of a decision and need to preserve cash resources until the decision from the Appeals Court in the litigation with CardiAQ was final.

The Company's expenses are subject to inflation and cost increases. Salaries and wages have increased on average by 4% in the year ended December 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 Loss**

The other income for the year ended December 31, 2017 was \$9,724,615, compared to a loss of \$49,471,477 for the same period in 2016, an increase in other income of \$59,196,092. The increase in the other income can be substantially explained by a \$111,781,096 damages provision in relation in the Company's litigation with CardiAQ charged in year ended December

31, 2016 and an offsetting \$65,095,733 gain on sale of assets related to an agreement with Boston Scientific in the same year. The accounting treatment of the 2017 Financings resulted in a \$7,380,102 net gain and foreign exchange changes accounted for a \$5,690,603 gain between the years.

## **Tax Expense**

The tax expense for the year ended December 31, 2017 was \$484,428, compared to \$200,523 for the same period in 2016. Neovasc (US) Inc. was established in 2015 to provide 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. In addition, the Company resolved its tax due to the State of California and paid \$290,539 to bring the account up to date.

Results for the years ended December 31, 2016 and 2015 follow:

## **Losses**

The operating losses and comprehensive losses for the year ended December 31, 2016 were \$86,494,893 and \$82,397,922 respectively, or \$1.28 basic and diluted loss per share, as compared with losses of \$26,730,490 and \$35,116,695, or \$0.41 basic and diluted loss per share for the same period in 2015. The \$59,764,403 increase in the operating loss incurred for the year ended December 31, 2016 compared to the same period in 2015 can be substantially explained by a \$111,781,096 damages provision related to the litigation with CardiAQ, a \$65,095,733 gain on sale of assets related to the agreement with Boston Scientific described below, a \$5,269,711 increase in general and administrative expenses (of which \$6,111,912 relates to an increase in litigation expenses), a \$2,183,108 increase in product development and clinical trial expenses, and a \$4,981,309 increase in other income. Litigation expenses for the year ended December 31, 2016 represented a loss of \$0.20 basic and diluted loss per share compared to a loss of \$0.11 basic and diluted loss per share for the same period in 2015. The Company incurred significant costs in defending itself in lawsuits filed by CardiAQ.

## **Revenues**

Revenues decreased 4% year-over-year to \$9,512,796 for the year ended December 31, 2016, compared to revenues of \$9,929,940 for the same period in 2015. 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 focused its business away from its traditional revenue streams towards development and commercialization of its own products, the Reducer and the Tiara. The Company ceased its production of surgical patches (product sales) in the second quarter of 2015.

Reducer sales for the year ended December 31, 2016 were \$1,004,948, compared to \$526,412 for the same period in 2015, representing an increase of 91%. The second year of the commercialization of the Reducer has been considered successful based on the amount of internal resources applied to the Reducer.

Product sales for the year ended December 31, 2016 were \$nil, compared to \$353,736 for the same period in 2015. Neovasc ceased manufacturing surgical patches in the second quarter of 2015.

Contract manufacturing revenues for the year ended December 31, 2016 were \$3,746,521, compared to \$3,236,978 for the same period in 2015, representing an increase of 16%. The increase in revenue for the year ended December 31, 2016 compared to the same period in 2015 is primarily due to growing revenues from Boston Scientific. 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. Going forward, contract manufacturing revenues will decline with the loss of Boston Scientific as a customer and revenues will be derived from a smaller customer base.

Revenues from consulting services for the year ended December 31, 2016 were \$4,761,327, compared to \$5,812,814 for the same period in 2015, representing a decrease of 18%. The loss is indicative of the trend the Company saw in consulting service revenue.

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

### **Cost of Goods Sold**

The cost of goods sold for the year ended December 31, 2016 was \$7,091,761, compared to \$6,938,134 for the same periods in 2015. The overall gross margin for the year ended December 31, 2016 was 25%, compared to 30% gross margin for the same period in 2015. The Company saw its gross margins decline due to a change in the product mix. The lower margin the Company received on its sales to Boston Scientific was only partially offset by the higher margins on the Reducer revenue.

### **Expenses**

Total expenses for the year ended December 31, 2016 were \$39,243,928, compared to \$31,750,140 for the same period in 2015, representing an increase of \$7,493,788 or 24%. The increase in total expenses for the year ended December 31, 2016 compared to the same period in 2015 reflects a \$40,969 increase in selling expenses as the Company commercializes the Reducer, a \$5,269,711 increase in general and administrative expenses (of which \$6,111,912 relates to an increase in litigation expenses) and a \$2,183,108 increase in product development and clinical trial expenses to advance the Tiara and the Reducer development programs.

Selling expenses for the year ended December 31, 2016 were \$696,638, compared to \$655,669 for the same period in 2015, representing an increase of \$40,969, or 6%. The increase in selling expenses for the year ended December 31, 2016 compared to the same period in 2015 reflects costs incurred commercialization activities for the Reducer in 2016. The Company minimized its increase in selling expenses in the light of higher litigation costs and the impact of litigation on the Company in 2016.

General and administrative expenses for the year ended December 31, 2016 were \$19,182,787 compared to \$13,913,076 for the same period in 2015, representing an increase of \$5,269,711, or 38%. The increase in general and administrative expenses for the year ended December 31, 2016 compared to the same period in 2015 can be substantially explained by a \$6,111,912 increase in litigation expenses, offset by a \$813,075 decrease in share-based payments. In 2016 the Company adjusted its compensation plan to directors, officers and senior management, decreasing the number of options granted by 75%, replacing these options with a smaller cash based bonus plan and increasing officers and senior management's base salaries by 10%.

Product development and clinical trial expenses for the year ended December 31, 2016 were \$19,364,503, compared to \$17,181,395 for the same period in 2015, representing an increase of \$2,183,108, or 13%. The increase in product development and clinical trial expenses for the year ended December 31, 2016 was due to a \$1,183,962 increase in cash-based employee expenses as the Company hired additional staff to advance product development and a \$2,076,259 increase in other expenses as the Company invested in its two major new product initiatives, offset by a \$1,243,976 decrease in share-based payments.

The Company's expenses are subject to inflation and cost increases. Salaries and wages increased on average by 3% in the year ended December 31, 2016 compared to the same period in 2015. The Company did not see a material increase in the price of any of the components used in the manufacture of its products and services in 2016.

### **Other Income and Loss**

The other loss for the year ended December 31, 2016 was \$49,471,477, compared to other income of \$2,195,195 for the same period in 2015, a change of \$51,666,672. This amount is made up of \$111,781,096 damages provision related to the litigation with CardiAQ (see "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein), a

\$2,690,129 increase in the unrealized loss on the damages provision and a \$1,894,473 increase in the loss on foreign exchange, offset by a \$65,095,733 gain on sale of assets related to the agreement with Boston Scientific.

### **Tax Expense**

The tax expense for the year ended December 31, 2016 was \$200,523, compared to \$167,351 for the same period in 2015. 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.

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

### **Losses**

The operating losses and comprehensive losses for the three months ended December 31, 2017 were \$5,026,466, or \$0.06 basic and diluted loss per share, as compared with income of \$37,213,791 and \$37,095,024, or \$0.54 basic earnings and \$0.47 fully diluted earnings per share for the same period in 2016.

The \$42,240,257 decrease in the operating loss incurred for the three months ended December 31, 2017 compared to the same period in 2016 can be substantially explained by a \$70 million damages provision related to the jury award against the Company and a \$21 million enhanced damages provision against the Company in its litigation with CardiAQ, charged in the year ended December 31, 2017, a \$5,857,116 increase in general and administrative expenses (of which \$1,065,390 was a decrease in litigation expense offset by \$5,447,182 increase in financing fees from derivative liabilities), and a \$65 million decrease in gain on sale of asset attributed to the Boston Scientific sale. The Company has incurred significant costs in defending itself in lawsuits filed by CardiAQ.

### **Revenues**

Revenues decreased 56% to \$1,227,625 for the three months ended December 31, 2017, compared to revenues of \$2,761,122 for the same period in 2016. 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. The Company anticipates that by the end of 2018 all revenue will be derived from the Reducer product.

Reducer sales for the three months ended December 31, 2017 were \$285,598 compared to \$282,515 for the same period in 2016, representing an increase of 1%. 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 December 31, 2017 were \$465,205, compared to \$1,355,385 for the same period in 2016, representing a decrease of 66%. The decrease in revenue for the three months ended December 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 \$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. In 2017, the Company has redirected their focus away from contract manufacturing. Going forward, with the reorganization of the Company concentrating on the Tiara and the Reducer, all contract manufacturing revenue streams will be exhausted. The Company ceased all contract manufacturing revenues at the end of December 2017.

Revenues from consulting services for the three months ended December 31, 2017 were \$476,822 compared to \$1,123,222 for the same period in 2016, representing a decrease of 58%. The decrease is indicative of the trend the Company is seeing in consulting service revenue. The Company ceased all consulting services revenues at the end of December 2017.

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 December 31, 2017 was \$1,136,804, compared to \$2,052,969 for the same periods in 2016. The overall gross margin for the three months ended December 31, 2017 was 7%, compared to 26% gross margin for the same period in 2016. The Company has seen its gross margins decrease due to a change in focus towards Tiara and Reducer, closing its contract manufacturing and consulting businesses.

## Expenses

Total expenses for the three months ended December 31, 2017 were \$12,301,582, compared to \$7,437,156 for the same period in 2016, representing an increase of \$4,864,426 or 65%. The decrease in total expenses for the three months ended December 31, 2017 compared to the same period in 2016 reflects a \$5,857,116 increase in general and administrative expenses (of which \$5,447,182 was an increase in financing fees for the derivative liability) and a \$1,071,842 decrease in product development and clinical trial expenses to preserve cash resources.

Selling expenses for the three months ended December 31, 2017 were \$220,885, compared to \$141,733 for the same period in 2016, representing an increase of \$79,152, or 56%. The increase in selling expenses for the three months ended December 31, 2017 compared to the same period in 2016 reflects costs incurred for commercialization activities for the Reducer in 2017. The Company continues to minimize its selling expenses in the light of the impact of litigation on the Company.

General and administrative expenses for the three months ended December 31, 2017 were \$8,318,549 compared to \$2,461,433 for the same period in 2016, representing an increase of \$5,857,116 or 238%. The increase in general and administrative expenses for the three months ended December 31, 2017 compared to the same period in 2016 can be substantially explained by a \$5,447,182 increase in financing fee from derivative liabilities.

Product development and clinical trial expenses for the three months ended December 31, 2017 were \$3,762,148 compared to \$4,833,990 for the same period in 2016, representing a decrease of \$1,071,842 or 22%. The overall gradual decrease in product development and clinical trial expenses for the three months ended December 31, 2017 occurred as the Company focused on clinical activities and slowed product development activities to preserve cash resources.

The Company's expenses are subject to inflation and cost increases. Salaries and wages have increased on average by 4% in the year ended December 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 income for the three months ended December 31, 2017 was \$7,174,159, compared to \$43,957,927 for the same period in 2016, a decrease in other income of \$36,783,768. The decrease in the other income can be substantially explained by a \$65 million decrease in gain on sale of asset from Boston Scientific and a \$21 million decrease in the charge for the damages provision. Included within other income for the three months ended December 31, 2017 is a charge of \$738,021 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), (2016: \$nil).

## Tax Expense

The tax expense for the three months ended December 31, 2017 was \$25,602 compared to \$15,133 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.

Results for the three months ended December 31, 2016 and 2015 follow:

## Losses

The net profit for the quarter ended December 31, 2016 was \$37,213,791, or \$0.54 basic earnings and \$0.47 fully diluted earnings per share, compared with a loss of \$7,383,608, or \$0.11 basic and diluted loss per share for the same period in 2015.

## Revenues

Revenues for the quarter ended December 31, 2016 were \$2,761,122 compared to \$2,224,046 for the same period in 2015. Reducer revenues increased by 47% to \$282,515 for the quarter compared to \$192,013, for the same period in 2015. Contract manufacturing and consulting services revenues were slightly increased in comparison to the same period in 2015.

## Cost of Goods Sold

The cost of goods sold for the quarter ended December 31, 2016 was \$2,052,969, compared to \$1,942,140 for the same period in 2015. The gross margin for the quarter ended December 31, 2016 was 26%, compared to 13% for the same period in 2015. In 2015, the Company issued a credit note to a single customer, which reduced margins from 23% to 13% for the fourth quarter of 2015.

## Expenses

Total expenses for the quarter ended December 31, 2016 were \$7,437,156, compared to \$8,352,093 for the same period in 2015, representing a decrease of 11%. The decrease results from a \$1,037,249 decrease in general and administrative expenses offset by a \$273,035 increase in clinical trial and product development expenses for the Company's two new product development programs.

Selling expenses were \$141,733 for the quarter ended December 31, 2016, compared to \$292,456 for the same period in 2015, representing a decrease of 52%, due to lower sales consulting, less travel and lower stock compensation costs in 2016. General and administrative expenses were \$2,461,433 for the quarter ended December 31, 2016, compared to \$3,498,682 for the same period in 2015, representing a decrease of 30%, due to a decrease in litigation expenses of \$537,872 and a \$296,782 decrease in share-based payments. Product development and clinical trials expenses were \$4,833,990 for the quarter ended December 31, 2016, compared to \$4,560,955 for the same period in 2015 representing an increase of 6% due to an increased investment in the Tiara development program.

## Other Income and Loss

The other income for the quarter ended December 31, 2016 was \$43,957,927, compared to \$853,930 for the same period in 2015, representing an increase of \$43,103,997. This amount is made up of a \$65,095,733 gain on sale of assets related to the agreement with Boston Scientific and a \$1,740,923 gain on foreign exchange offset by a \$20,781,096 damages provision related to the interest award in the primary U.S. litigation with CardiAQ (see "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein) and a \$2,113,872 increase in the unrealized loss on the damages provision.

## Tax Expense

The tax expense for the quarter ended December 31, 2016 was \$15,133, compared to \$167,351 for the same period in 2015. 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. In 2015, the full tax charge for the year was recorded in the fourth quarter of the year.

## Annual Information

The following is a summary of selected financial information for the three fiscal years to December 31, 2017:

	2017	2016	2015
Revenues	\$ 5,389,014	\$ 9,512,796	\$ 9,929,940
Loss	(22,908,721)	(86,494,893)	(26,730,490)
Basic and diluted loss per share	(0.28)	(1.28)	(0.41)
Total assets	22,206,443	98,809,503	61,228,394
Total long-term liabilities and damages provision	32,577,647	111,781,096	-
Cash dividend declared per share	\$nil	\$nil	\$nil

Revenues have declined year-over-year as the development of transcatheter aortic valves by our customers has reached its peak. The Company closed all of its revenue generating business segments except its Reducer business at the end of 2017.

The Company has incurred significant costs in defending itself in lawsuits filed by CardiAQ. In 2016 the Company provided \$111,781,096 for damages and interest awards related to the primary U.S. litigation with CardiAQ (see "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein), which is only partially offset by a \$65,095,733 gain on sale of assets related to the agreement with Boston Scientific.

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 Tiara through its clinical and regulatory pathways.

The Company remains focused on the development and commercialization of the Tiara and the Reducer over the next several years. The 2017 Financings completed in November 2017 allowed us to settle the claims against us related to the primary U.S. litigation with CardiAQ and continue our business. The Company intends to use the remaining capital to execute our development and commercialization plans.

## QUARTERLY INFORMATION

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

	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
<b>REVENUE</b>				
Reducer	\$ 285,598	\$ 334,208	\$ 247,555	\$ 260,765
Contract manufacturing	465,205	197,494	152,717	133,963
Consulting services	476,822	843,191	904,864	1,086,632
	1,227,625	1,374,893	1,305,136	1,481,360
<b>COST OF GOODS SOLD</b>	1,136,804	659,686	872,703	808,628
<b>GROSS PROFIT</b>	90,821	715,207	432,433	672,732
<b>EXPENSES</b>				
Selling expenses	220,885	253,791	224,382	187,168
General and administrative expenses	8,318,549	1,864,302	2,253,219	3,248,713
Product development and clinical trials expenses	3,762,148	4,422,641	4,250,780	5,053,523
	12,301,582	6,540,734	6,728,381	8,489,404
<b>OPERATING LOSS</b>	(12,210,761)	(5,825,527)	(6,295,948)	(7,816,672)
Other Income/(expense)	7,209,897	1,473,493	1,012,926	28,299
Tax expense	(25,602)	(343,926)	(58,286)	(56,614)
<b>LOSS FOR THE PERIOD</b>	\$ (5,026,466)	\$ (4,695,960)	\$ (5,341,308)	\$ (7,844,987)
<b>BASIC AND DILUTED LOSS PER SHARE</b>	\$ (0.06)	\$ (0.06)	\$ (0.07)	\$ (0.10)
	December 31, 2016	September 30, 2016	June 30, 2016	March 31, 2016
<b>REVENUE</b>				
Reducer	\$ 282,515	\$ 262,546	\$ 246,122	\$ 213,765
Product sales	-	-	-	-
Contract manufacturing	1,355,385	1,543,516	240,837	606,783
Consulting services	1,123,222	1,227,938	1,223,973	1,186,194
	2,761,122	3,034,000	1,710,932	2,006,742
<b>COST OF GOODS SOLD</b>	2,052,969	2,201,440	1,391,708	1,445,644
<b>GROSS PROFIT</b>	708,153	832,560	319,224	561,098
<b>EXPENSES</b>				
Selling expenses	141,733	208,884	181,174	164,847
General and administrative expenses	2,461,433	3,466,825	7,427,124	5,827,405
Product development and clinical trials expenses	4,833,990	4,742,691	5,705,035	4,082,787
	7,437,156	8,418,400	13,313,333	10,075,039
<b>OPERATING LOSS</b>	(6,729,003)	(7,585,840)	(12,994,109)	(9,513,941)
Other income/(expense)	43,957,927	(21,461,950)	(70,648,431)	(1,319,023)
Tax expense	(15,133)	(87,296)	(49,920)	(48,174)
<b>PROFIT/(LOSS) FOR THE PERIOD</b>	\$ 37,213,791	\$ (29,135,086)	\$ (83,692,460)	\$ (10,881,138)
<b>BASIC AND DILUTED LOSS PER SHARE</b>	\$ 0.54	\$ (0.44)	\$ (1.25)	\$ (0.16)
	December 31, 2015	September 30, 2015	June 30, 2015	March 31, 2015
<b>REVENUE</b>				
Reducer	\$ 192,013	\$ 159,394	\$ 134,607	\$ 40,398
Product sales	-	10,228	120,097	223,411
Contract manufacturing	963,864	737,336	972,216	563,562
Consulting services	1,068,169	1,566,729	1,700,464	1,477,452
	2,224,046	2,473,687	2,927,384	2,304,823
<b>COST OF GOODS SOLD</b>	1,942,140	1,573,068	1,815,354	1,607,572
<b>GROSS PROFIT</b>	281,906	900,619	1,112,030	697,251
<b>EXPENSES</b>				
Selling expenses	292,456	113,913	125,478	123,822
General and administrative expenses	3,498,682	4,552,966	3,535,042	2,326,386
Product development and clinical trials expenses	4,560,955	4,908,752	4,280,295	3,431,393
	8,352,093	9,575,631	7,940,815	5,881,601
<b>OPERATING LOSS</b>	(8,070,187)	(8,675,012)	(6,828,785)	(5,184,350)
Other income/(expense)	853,930	1,041,842	76,447	222,976
Tax expense	(167,351)	-	-	-
<b>LOSS FOR THE PERIOD</b>	\$ (7,383,608)	\$ (7,633,170)	\$ (6,752,338)	\$ (4,961,374)
<b>BASIC AND DILUTED LOSS PER SHARE</b>	\$ (0.11)	\$ (0.11)	\$ (0.10)	\$ (0.08)

The Company closed its contract manufacturing and consulting services revenue generating business segments at the end of 2017 and the only revenue going forward will be derived from sales of the Reducer.

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 fourth quarter of 2017 due to expense related to obtaining the convertible note and in the second quarter of 2016 mainly due to litigation expenses during the jury trial in the primary U.S. litigation with CardiAQ. While we aim to increase product development and clinical trial activities quarter over quarter, with quarterly fluctuations depending on the activities conducted in that quarter to develop the Tiara and the Reducer, the Company has been resource constrained and has seen a decline in those expenses over the four quarters of 2017 as we have been forced to defer or cancel certain otherwise desirable projects we would like to have undertaken.

## USE OF PROCEEDS

	PROPOSED USE OF NET PROCEEDS	ACTUAL USE OF NET PROCEEDS	
	2017 Financings	Use of Proceeds	Remaining to be Spent
Settlement of litigation damages	\$42,000,000	\$42,000,000	\$NIL
Development and other expenses	\$18,000,000	\$492,893	\$17,507,157
<b>NET PROCEEDS</b>	<b>\$60,000,000</b>	<b>\$42,492,893</b>	<b>\$17,507,157</b>

In November 2017, Neovasc completed two financing transactions, the 2017 Public Transaction and the 2017 Private Placement, for aggregate gross proceeds of approximately \$65 million. The Company used the net proceeds of the 2017 Financings to fully fund the approximately \$42 million balance of the damages and interest awards in the case of CardiAQ v. Neovasc Inc. (after subtracting the approximately \$70 million that the Company had paid into escrow), with remaining funds being used (i) to partially fund the ongoing Tiara clinical program; (ii) to support the completion of the TIARA-II study; (iii) continue commercialization of the Reducer; and (iv) for general corporate purposes.

## DISCUSSION OF LIQUIDITY AND CAPITAL RESOURCES

### Results for the years ended December 31, 2017 and 2016 follow:

Neovasc finances its operations and capital expenditures with cash generated from operations and equity and debt financings. As at December 31, 2017 the Company had cash and cash equivalents of \$17,507,157 compared to cash and cash equivalents of \$22,954,571 as at December 31, 2016. The Company will require significant additional financing in order 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 is in a negative working capital position of \$6,060,895, with current assets of \$20,043,002 and current liabilities of \$26,103,897. However, of the current liabilities, only 1,844,955 are cash liabilities, the liability for the convertible Notes and the derivative liability from the 2017 Financings are accounting entries to account for the value of the instruments issued in the financings completed in November 2017.

Cash used in operating activities for the year ended December 31, 2017, was \$138,613,946, compared to \$39,794,159 for the same period in 2016. The Company settled the \$112,519,117 litigation damages in full in 2017. For the year ended December 31, 2017, operating expenses were \$26,403,093, compared to \$37,220,923 for the same period in 2016, a decrease of \$10,841,962 that can be substantially explained by a 5,690,603 gain related to foreign exchange between the two periods and a \$5,856,239 reduction in departmental cash expenses.

Net cash provided by investing activities for the year ended December 31, 2017 was \$69,496,853 compared to net cash applied by investing activities of \$3,364,190 in 2016 as the \$70,000,000 held in escrow was released to settle the damages and interest awards in the Company's primary U.S. litigation with CardiAQ.

Net cash provided by financing activities for the year ended December 31, 2017, was \$65,578,699 compared to \$7,129,852 for the same period in 2016 as the Company completed the 2017 Financings.

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 years ended December 31, 2017 and 2016 and 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 \$17,985,417 of its cash and cash equivalents and restricted cash held in U.S. dollars and Euros.

## Financing

In November 2017, Neovasc completed two financing transactions, the 2017 Public Transaction and the 2017 Private Placement, for aggregate gross proceeds of approximately \$65 million. The Company used the net proceeds of the 2017 Financings to fully fund the approximately \$42 million balance of the damages and interest awards in the case of *CardiaQ v. Neovasc Inc.* (after subtracting the approximately \$70 million that the Company had paid into escrow), with remaining funds being used (i) to partially fund the ongoing Tiara clinical program; (ii) to support the completion of the TIARA-II study; and (iii) for general corporate purposes.

On November 9, 2017, the Company priced the underwritten 2017 Public Transaction of 6,609,588 Series A units (the "Series A Units") of Neovasc and 19,066,780 Series B units (the "Series B Units" and together with the Series A Units, the "Units") of Neovasc, at a price of \$1.46 per Unit for gross proceeds of approximately \$37.487 million, before deducting the underwriting discounts and commissions and other estimated offering expenses payable by Neovasc. The price of \$1.46 per Unit represents the market price (as defined in the TSX Company Manual) of Neovasc's common shares as of the date of announcement of the 2017 Financings.

Each Series A Unit was comprised of (i) one common share of the Company (each, a "Unit Share"), (ii) one Series A common share purchase warrant of the Company (each, a "Series A Warrant"), (iii) one Series B common share purchase warrant of the Company (each, a "Series B Warrant") and (iv) 0.40 Series C warrant (each, a "Series C Warrant") to purchase a unit (each, a "Series C Unit") comprised of one Common Share, one Series A Warrant and one Series B Warrant. Each Series B Unit was comprised of (i) either one Unit Share or one pre-funded Series D common share purchase warrant of the Company (each, a "Series D Warrant"), (ii) one Series A Warrant, (iii) one Series B Warrant, (iv) 0.40 Series C Warrant, and (v) 1.1765 Series F common share purchase warrant of the Company (each, a "Series F Warrant"). The Series A Units and Series B Units separated into their component parts upon distribution.

Each Series A Warrant entitles the holder to purchase one Common Share (each, a "Series A Warrant Share") at an exercise price of \$1.61 per Series A Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2022. Each Series B Warrant entitles the holder to purchase one Common Share (each, a "Series B Warrant Share") at an exercise price of \$1.61 per Series B Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2019. Each Series C Warrant entitles the holder to purchase a Series C Unit comprised of a Common Share (each a "Series C Unit Share"), a Series A Warrant and a Series B Warrant, at an exercise price of 1.46 per Series C Unit at any time prior to 11:59 p.m. (New York time) on November 17, 2019. Each Series D Warrant entitles the holder to purchase one Common Share (each, a "Series D Warrant Share") at an exercise price of \$1.46 per Series D Warrant Share, all of which are pre-funded except for a nominal exercise price of \$0.01 per Series D Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2022. Each Series F Warrant entitles the holder to purchase one Common Share (each, a "Series F Warrant Share" and together with the Series A Warrant Shares, Series B Warrant Shares, Series C Unit Shares, and Series D Warrant Shares, the "Warrant Shares") at an exercise price of 1.61 per Series F Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2019. The Warrants are subject to adjustment, at any time prior to their expiry. The exercise price of the Series A Warrants, Series B Warrants and Series F Warrants are subject to full-ratchet anti-dilution adjustment in certain circumstances. If a registration statement covering the issuance or resale of the Warrant Shares is not available for the issuance or resale of such Warrant Shares each Series A Warrant, Series B Warrant, Series D Warrant and Series F Warrant may be exercised on a "net" or "cashless" basis. Each Series B Warrant and Series F Warrant may be exercised on an Alternate Net Number basis, as described in the prospectus supplement and the forms of such securities filed on SEDAR at [www.sedar.com](http://www.sedar.com) and furnished to the SEC at [www.sec.gov](http://www.sec.gov).

Concurrent with the 2017 Public Transaction, the Company completed the 2017 Private Placement for the sale of \$32,750,000 aggregate principal amount of senior secured convertible Notes of the Company and Series E warrants (the "Series E Warrants") to purchase one Common Share at a price of \$1.61 per Series E Warrant. The Notes were issued with an original issue price of \$850 per \$1,000 principal amount of note. The Notes have an 18-month term and carry an interest rate of 0.0% per annum (increasing to 15% upon an event of default) from November 17, 2018. Interest on the Notes will commence accruing on November 17, 2018, will be computed on the basis of a 360-day year and twelve 30-day months and will be payable in cash on January 1, 2018 and on the first day of each calendar quarter thereafter up to, and including, the maturity date. The Series E Warrants have the same terms and conditions as the Series A Warrants.

The Notes are secured by a first priority security interest on all of Neovasc's assets. The Notes and Series E Warrants are subject to adjustment, at any time prior to their expiry. The Notes contain, among other things, provisions relating to future-priced conversion or exercise formula and full-ratchet anti-dilution and the Series E Warrants contain full-ratchet anti-dilution provisions. If a registration statement covering the issuance or resale of the Warrant Shares is not available for the issuance or resale of such Warrant Shares, each Series E Warrant may be exercised on a "net" or "cashless" basis.

For a description of the terms of the securities issued pursuant to the 2017 Financings, see the prospectus supplement and the forms of such securities filed on SEDAR at [www.sedar.com](http://www.sedar.com) and with the SEC at [www.sec.gov](http://www.sec.gov). For a description of the risks associated with these securities, the amount of such securities exercised to date, the dilution to date and potential dilution in the future due to such exercises or conversions, see the Company's Annual Information Form, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on Form 6-K filed furnished to SEC at [www.sec.gov](http://www.sec.gov).

#### Results for the years ended December 31, 2016 and 2015 follow:

Neovasc finances its operations and capital expenditures with cash generated from operations and equity financings. As at December 31, 2016 the Company had cash and cash equivalents of \$22,954,571 compared to cash and cash equivalents of \$55,026,171 as at December 31, 2015. The Company's working capital deficit is \$17,497,931 as at December 31, 2016 compared to a working capital surplus of \$54,274,867 as at December 31, 2015.

Cash used in operating activities for the year ended December 31, 2016, was \$39,794,159, compared to \$21,282,958 for the same period in 2015. For the year ended December 31, 2016, operating expenses were \$37,215,852, compared to \$22,693,678 for the same period in 2015. The cash expenditures on litigation (litigation expenses less change in accounts payable related to litigation) were approximately \$13.1 million and cash expenditures on research and development and clinical trials (expenses less share based payments and depreciation and less change in accounts payable related to research and development) were approximately \$17.9 million. Working capital items absorbed cash of \$2,427,075, compared to working capital items generating cash of \$821,165 for the same period in 2015. This was principally due to an increase in accounts receivable which absorbed cash due at year end due to a final payment received immediately after the year end from Boston Scientific and a decrease in accounts payable and accrued liabilities as operational activities declined.

For the year ended December 31, 2016, net cash absorbed by investing activities was \$3,364,190 compared to the net cash generated from investing activities of \$7,179,364 in 2015. The Company received net proceeds, after incurring selling expenses of \$168,060, of \$67,741,740 from the sale of assets to Boston Scientific and placed \$70,000,000 in a joint escrow account to be used if any of the awards in the litigation with CardiAQ remain payable after the appeal of the case is heard. In addition, for the year ended December 31, 2016, the Company invested \$656,170 in property, plant and equipment, compared to \$2,143,128 for the same period in 2015. The Company continued to invest capital to expand its clean room, chemical laboratory and manufacturing facilities and research and development capabilities, which it then subsequently sold to Boston Scientific. In 2015, there was a decrease in investments of \$9,322,492 as investments were liquidated from investments into cash and cash equivalents.

For the year ended December 31, 2016, net cash provided by financing activities was \$7,192,852, compared to \$70,804,938 for the same period in 2015. On December 13, 2016 and as part of the Boston Scientific agreement, the Company issued 11,817,000 shares at \$0.60 per share from treasury for net proceeds of \$7,054,660 after share issue costs of \$35,540. On February 3, 2015, the Company closed an underwritten public offering of 12,075,000 common shares of the Company (of which 10,415,000 common shares were issued from treasury and 1,660,000 common shares were sold by certain directors,

officers and employees of the Company) at a price per share of \$7.19 for aggregate gross proceeds of approximately \$74,883,850 for the Company and \$11,935,400 for the selling security holders. The share issue costs incurred by the Company were \$5,004,640.

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 years ended December 31, 2016 and 2015 the Company had no complications in transferring funds to and from its subsidiaries in Israel and the United States.

The Company was exposed to foreign currency fluctuations on \$518,038 of its cash and cash equivalents held in Canadian dollars and Euros as at December 31, 2017.

## **SUBSEQUENT EVENTS**

### **Nasdaq Notifications**

On January 2, 2018, the Company received written notification (the "Bid Price Notification Letter") from the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was not in compliance with the \$1.00 minimum bid price requirement set forth in the Nasdaq rules for continued listing on the Nasdaq Capital Market. The Bid Price Notification Letter does not impact the Company's listing on the Nasdaq Capital Market at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided 180 calendar days, or until July 2, 2018, to regain compliance. The Company intends to monitor the closing bid price of its common shares between now and July 2, 2018 and intends to cure the deficiency within the prescribed grace period. During this time, the Company expects that its common shares will continue to be listed and trade on the Nasdaq Capital Market.

On March 22, 2018, the Company received written notification (the "Market Value Notification Letter") from the Nasdaq notifying the Company that it was not in compliance with the \$35 million minimum market value requirement set forth in the Nasdaq rules for continued listing on the Nasdaq Capital Market. The Market Value Notification Letter does not impact the Company's listing on the Nasdaq Capital Market at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided 180 calendar days, or until September 18, 2018, to regain compliance. The Company intends to monitor the market value of its listed securities between now and September 18, 2018 and intends to cure the deficiency within the prescribed grace period. During this time, the Company expects that its common shares will continue to be listed and trade on the Nasdaq Capital Market.

### **Appointment of New CEO**

On January 22, 2018 the Company appointed Fred Colen as the new President and CEO of Neovasc.

### **German NUB Status 1 for Reducer**

On February 1, 2018 the "Institut für das Entgeltssystem im Krankenhaus", the German Institute for the Hospital Remuneration System awarded Neovasc Reducer, a CE-Marked medical device for the treatment of refractory angina, NUB status 1 designation for 2018.

### **Remedial TSX Delisting Conclusion**

On March 8, 2018, the Company received confirmation that the TSX had determined that the Company satisfied TSX's applicable requirements for continued listing and that the Company would not be delisted from the TSX exchange at this time.

### **Warrant Exercises**

The Series A Warrants, Series B Warrants, Series C Warrants, Series E Warrants and Series F Warrants were each subject to a hold period that restricted each warrant from being exercised until January 17, 2018.

On January 30, 2018, the remaining 1,698,841 Series D Warrants were exercised for gross proceeds of \$16,699 and 1,698,841 shares were issued from treasury.

None of the 25,676,368 Series A Warrants, 10,273,972 Series C Warrants or 22,431,506 Series E Warrants issued pursuant to the 2017 Financings have been exercised and all such warrants remain outstanding.

As of March 28, 2018, of the 25,676,368 Series B Warrants initially granted, 11,170,788 have been exercised using the cashless alternative net number mechanism for 149,350,096 common shares of the Company and of the 22,431,506 Series F Warrants initially granted, 21,041,660 have been exercised using the cashless Alternate Net Number mechanism for 223,427,286 common shares of the Company. As of March 28, 2018, there were 14,505,580 B Warrants and 1,389,846 F Warrants outstanding. For a description of the risks associated with the securities issued pursuant to the 2017 Financings, the amount of such securities exercised to date, the dilution to date, and the potential dilution in the future due to such exercises or conversions, see the Company's Annual Information Form, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on Form 6-K furnished to the SEC at [www.sec.gov](http://www.sec.gov).

## **OUTSTANDING SHARE DATA**

As at March 28, 2018, the Company had 477,441,751 common voting shares issued and outstanding. Further, the following securities are convertible into common shares of the Company: 9,419,117 stock options with a weighted average price of C\$3.13, 74,277,272 warrants and a convertible note that could convert into 22,431,507 common shares (not taking into account the alternate conversion price mechanism). Our fully diluted share capital as of the same date is 583,569,647. Our fully diluted share capital, adjusted on the assumption that all the remaining Series B Warrants and Series F Warrants are exercised using the cashless alternative net number mechanism and the outstanding Notes are exercised using the alternate conversion price at the closing price on March 27, 2018 is 1,519,760,607.

For details concerning the terms of the securities issued pursuant to the 2017 Financings, see the prospectus supplement and the forms of such securities filed on SEDAR at [www.sedar.com](http://www.sedar.com) and with the SEC at [www.sec.gov](http://www.sec.gov). For a description of the risks associated with these securities, the amount of such securities exercised to date, the dilution to , and the potential dilution in the future due to such exercises or conversions, see the Company's Annual Information Form, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on Form 6-K furnished to the SEC at [www.sec.gov](http://www.sec.gov).

## **CONTRACTUAL OBLIGATIONS AND CONTINGENCIES**

### ***Contingencies***

#### **Litigation with CardiAQ**

The Company is engaged as a defendant and appellant in lawsuits involving CardiAQ, as further described below. Litigation resulting from CardiAQ's claims has been and 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 the remaining 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 loss of intellectual property rights that could have a material adverse effect on the Company and its financial condition.

#### **Claims by CardiAQ in Germany**

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. After a hearing held on December 14, 2016, the German Court rendered its decision on June 16, 2017, granting co-ownership of the European patent application to CardiAQ but denying their claim for full entitlement. There are no monetary awards associated with these matters and no damages award has been recognized. On July 14, 2017, Neovasc filed a notice of appeal against the German Court's decision with the Appeals Court of Munich. On July 20, 2017, CardiAQ filed a notice of appeal with the same court. Both parties have in the meantime substantiated their respective appeals. No hearing date has yet been set by the court. As a next step, both parties have been given a deadline to file written responses by March 30, 2018. The case is likely to be

heard in the third or fourth quarter of 2018, and there is likely to be further exchanges of written submissions between the parties in the time leading up to that hearing.

### **Claims by CardiAQ in the United States**

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. On October 4, 2017, CardiAQ amended its pleading to add a third claim for correction of patent inventorship as to Neovasc's U.S. Patent No. 9,770,329. The lawsuit does not seek money damages and would not prevent the Company from practicing these patents. The Company moved to dismiss the complaint on November 16, 2017, and that motion remains pending.

Between June 2016 and November 2017, Neovasc was engaged in litigation with CardiAQ in the U.S. District Court for the District of Massachusetts (the "Court") and, upon appeal, in the Appeals Court. This litigation concerned intellectual property rights ownership, unfair trade practices and breach of contract relating to Neovasc's transcatheter mitral valve technology, including the Tiara. 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. The Court later awarded CardiAQ \$21 million in enhanced damages on the trade secret claim for relief and \$20,675,154 in pre-judgment interest and \$2,354 per day in post-judgment interest from November 21, 2016. Neovasc and CardiAQ each appealed on various grounds, and on September 1, 2017, the Appeals Court affirmed the trial court judgment against Neovasc, and denied CardiAQ's cross-appeal. On November 13, 2017, the final mandate was issued by the Appeals Court and approximately \$70 million was released from escrow to CardiAQ to partially settle approximately \$112 million damages and interest awards. Upon closing of the 2017 Financings on November 17, 2017, the Company used approximately \$42 million from the \$65 million net proceeds of the 2017 Financings to settle the remaining damages and interest awards.

### **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 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. The Neovasc Defendants filed their Statement of Defence in November 2017. The other defendants have not yet filed their Statements of Defence. The Neovasc Defendants intend to vigorously defend themselves.

The Company is aware of a potential claim involving another party's intellectual property rights, which the Company is investigating and believes to be without merit. The Company is in preliminary discussions with that party and believes that settlement of the matter, if warranted, can be achieved on reasonable commercial terms.

### **Contractual obligations**

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

Contractual Obligations	Total	Less than 1 year	2-3 years	4-5 years
Operating leases	\$1,334,061	\$343,564	\$613,844	\$376,653

### **OFF BALANCE SHEET ARRANGEMENTS**

The Company has no off-balance sheet arrangements.

## RELATED PARTY TRANSACTIONS

There were no ongoing contractual commitments and transactions with related parties during the years ended December 31, 2017, 2016 or 2015, other than those as described elsewhere herein and those compensation-based payments disclosed in Note 23 of the consolidated financial statements for the years ended December 31, 2017, 2016 and 2015.

## RISK FACTORS

A comprehensive list of the risks and uncertainties affecting us can be found in our most recent Annual Information Form, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on Form 6-K furnished to the SEC at [www.sec.gov](http://www.sec.gov). Investors are urged to consult and carefully consider these risk factors as an investment in the securities of the Company should be considered a highly speculative investment.

## CRITICAL ACCOUNTING ESTIMATES AND MANAGEMENT JUDGMENT

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

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

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

#### *Determination of presentation currency*

The Company has elected to adopt the United States 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.

#### *Accounting for financing and determination of fair value of derivative liabilities*

The determination of the accounting treatment for the financing transaction completed in November 2017 is an area of significant management judgment. In particular, this involved the determination of whether the warrants issued and the conversion feature associated with the convertible note should be classified as equity or as derivative liabilities. The difference between the transaction amount and the fair value of the instruments issued in connection with the financing gives rise to a loss which has been deferred as the fair values were not determined using only observable market inputs. The manner in which the deferred loss will be recognized within income involves management judgment.

The warrants and convertible notes will be measured at fair value through profit and loss at each period end. The calculations of the fair value of these instruments involves the use of a number of estimates and a complex valuation model. The carrying amounts of these liabilities may change significantly as a result of changes to these estimates. Details of the estimates used as at December 31, 2017 are disclosed in Note 15.

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

During the year ended December 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 year ended December 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 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.

The Company performed a preliminary analysis to assess the impact of this standard and continues to develop a comprehensive plan to guide the implementation. The Company's earns revenue from three sources: the Reducer, contract manufacturing and consulting services. The Company's product sales ceased in 2015 and its consulting services and contract manufacturing ceased at the end of 2017. The adoption of IFRS 15 will not have a material impact on its revenue recognition policies or cash flows as a result of the adoption of this standard.

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.

While the company continues to assess all potential impacts and transition provisions of this standard, the company believes that the most significant impact will be related to the accounting for operating leases associated with office space. At this time, a quantitative estimate of the effect of the new standard has not been determined, but the company anticipates a material impact to its statements of financial position due to the recognition of the present value of unavoidable future lease payments as lease assets and lease liabilities. The measurement of the total lease expense over the term of the lease is unaffected by the new standard; however, the required presentation on the consolidated statements of earnings (loss) will result in lease expenses being presented as depreciation of lease assets and finance costs rather than being fully recognized as general and administrative costs.

## **FINANCIAL INSTRUMENTS**

The Company's financial instruments include its cash and cash equivalents, restricted cash, 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 ("U.S.") and Europe ("EU"), primarily denominated in U.S. and EU 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. U.S. and EU currency represents approximately 35% and 65% of the revenue for the year ended December 31, 2017 (2016: 62% and 38% respectively and 2015: 48% and 52%). A 10% change in the foreign exchange rates for the EU currency for foreign currency denominated accounts receivable will impact net income as at December 31, 2017 by approximately \$50,000 (as at December 31, 2016: U.S. and EU currencies: \$202,000 and \$49,000 respectively and as at December 31, 2015: \$84,000 and \$60,000 respectively), and a similar change for foreign currency denominated accounts payable will impact net income by approximately \$32,000 as at December 31, 2017 (as at December 31, U.S. and EU currencies: 2016: \$123,000 and \$10,000 respectively and as at December 31, 2015: \$164,000 and \$24,000, respectively). The Company does not hedge its foreign exchange risk.

(b) Interest rate risk - The Company is not exposed to cash flow interest rate risk on fixed rate cash balances, and short-term accounts receivable and accounts payable without interest.

(c) Liquidity risk – As at December 31, 2017, the Company had \$17,507,157 in cash and cash equivalents as compared to cash and cash equivalents of \$22,954,571 at December 31, 2016 and \$55,026,171 at December 31, 2015. On November 13, 2017, the final mandate was issued by the court in the Company's primary U.S. litigation with CardiAQ, approximately \$70 million was released from escrow to CardiAQ to partially settle the approximately \$112 million damages and approximately \$42 million became due and payable. On November 17, 2017 the Company closed the 2017 Financings for gross proceeds of approximately \$65 million and approximately \$42 million from the net proceeds of the 2017 Financings was used to settle the remaining damages and interest awards (see Notes 1(b), 7, 14 and 24). Further to this and in the longer term, 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 a monthly basis and compares actual performance to the budget for the period. The Company believes it has sufficient funds to fund operations through approximately the third financial quarter of 2018. 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.

(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 maximum exposure, if all of the Company's customers were to default at the same time is the full carrying value of the trade accounts receivable as at December 31, 2017 is \$1,201,292 (2016: \$2,532,114 and 2015: \$1,393,533). As at December 31, 2017, the Company had \$588,282 (as at December 31, 2016: \$1,555,469 and 2015: \$91,813) of trade accounts receivable that were overdue, according to the customers' credit terms. During the year ended December 31, 2017 the Company wrote down \$26,931 of accounts receivable owed by customers (year ended December 31, 2016: \$5,556 and 2015: \$25,893). The Company may also have credit risk related to its cash and cash equivalents, with a maximum exposure of \$17,985,417 as at December 31, 2017 (as at December 31, 2016: \$93,404,331 and 2015: \$55,026,171). The Company minimizes its risk to cash and cash equivalents by maintaining the majority of its cash and cash equivalents 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.

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. 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 year ended December 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 SEC at [www.sec.gov](http://www.sec.gov).