Neovasc Inc.
Management's Discussion and Analysis

FOR THE YEARS ENDED
DECEMBER 31 2018, 2017 AND 2016

(Expressed in U.S. Dollars)

Q4
2018

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 years ended December 31, 2018, 2017 and 2016 and should read in conjunction with the audited consolidated financial statements and notes thereto for the years ended December 31 2018, 2017 and 2016 (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.

On September 18, 2018, the Company effected a share consolidation (reverse stock split) of its issued and outstanding common shares in the capital of the Company (the "Common Shares") on the basis of one post-consolidation Common Share for every one hundred pre-consolidation Common Shares. All references in this MD&A to Common Shares and options have been retroactively adjusted to reflect the share consolidation. The number of warrants and aggregate principle amount of the senior secured convertible notes (the "Notes") outstanding as of the date of the consolidation were not affected by the consolidation, but the Common Shares issuable upon exercise of the warrants or conversion of the Notes have been and will be adjusted proportionally to the share consolidation ratio, as applicable.

Additional information about the Company, including the Company's audited consolidated financial statements and Annual Report on Form 20-F, is available on SEDAR at www.sedar.com and as filed with the U.S. Securities and Exchange Commission (the "SEC") on the website of the SEC at 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", "plan", "may", "will", "estimate", "continue", "intend", "believe", "target", "potential", "seek", "explore" 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 intended use of the net proceeds from the February 2019 underwritten public offering of Common Shares (the "February 2019 Financing");
- our intended use of the net proceeds from the March 2019 underwritten public offering of Common Shares (the "March 2019 Financing", and together with the February 2019 Financing, the "2019 Financings");
- our estimates regarding our fully diluted share capital and future dilution to shareholders;
- our intention to remediate our material weakness in internal control over financial reporting ("ICFR") as of December 31, 2018;
- 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;

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- the anticipated timing of additional implantations in the TIARA-II trial and our intention to initiate additional investigational sites in 2019 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, including our ability to improve current prototypes;
- 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 and claims;
- our ability to replace historical 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;
- 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 plans to increase Reducer implants in Europe in 2019;
- our expectation that in 2019 more German clinics will negotiate and finalize reimbursement negotiations with German insurance companies relating to the Reducer;
- 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;
- the composition and compensation of our management team and board of directors;
- the impact of foreign currency exchange rates; and
- the composition and compensation of our board of directors and senior management team in the future.

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 Notes issued pursuant to the November 2017 private placement (the “2017 Private Placement”), 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 Notes issued pursuant to the 2017 Private Placement, 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;

- risks relating to the conversion of Notes issued pursuant to the 2017 Private Placement, which may encourage short sales by third parties;
- risks relating to the possibility that our Common Shares may be delisted from the Nasdaq Capital Market ("Nasdaq") or the Toronto Stock Exchange ("TSX"), which could affect their market price and liquidity;
- risks relating to the Company's conclusion that it did not have effective ICFR as of December 31, 2018;
- 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 effect 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 Notes issued pursuant to the 2017 Private Placement;
- 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;
- capital will be available on terms that are favorable to us; and
- our ability to retain and attract key personnel, including members of our board of directors and senior management team.

By their very nature, forward-looking statements or information involve known and unknown risks, uncertainties and other factors that may cause our actual results, events or developments, or industry results, to be materially different from any future results, events or developments expressed or implied by such forward-looking statements or information. In evaluating these statements, prospective purchasers should specifically consider various factors, including the risks outlined herein, under "*Risk Factors*" in our Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as filed with the SEC at 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.

The Company advises you that these cautionary remarks expressly qualify in their entirety all forward looking statements attributable to the Company or persons acting on its behalf.

Date: March 21, 2019

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.

In November 2017, Neovasc completed the 2017 underwritten public offering (the "2017 Public Transaction" and collectively with the 2017 Private Placement, the "2017 Financings") 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 its litigation with Edwards Lifesciences CardiAQ LLC ("CardiAQ") formerly known as CardiAQ Valve Technologies 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. The only securities issued pursuant to the 2017 Financings that remain outstanding are $10,825,000 aggregate principal amount of the Notes. For a description of the terms of the 2017 Financings and the securities issued pursuant to the 2017 Financings, see "Operating Results" and "Share Capital" of the Company's Annual Report on Form 20-F and the prospectus supplement, dated November 10, 2017 (the "Prospectus Supplement") and the forms of securities, each as filed or furnished under the Company's profiles on SEDAR at www.sedar.com and on the SEC's website at www.sec.gov.

The Company and its subsidiaries now operate as follows: Neovasc Inc. is the Canadian public company and 100% owner of each of the subsidiary entities. NMI and Neovasc (US) Inc. ("NUS") are the operating companies for the group. They hold the majority of the tangible assets and NMI holds the Peripatch tissue license. NMI and NUS employ the majority of the employees of the Company. NTI holds all the intangible assets related to the Tiara and NML holds all the intangible assets related to the Reducer program. NMI charges both NTI and NML for the development services performed by its employees to develop the Tiara and the Reducer respectively. NML receives a royalty based on the Reducer revenues generated by NMI. NUS charges NMI for development services performed by its employees to develop the Tiara and the Reducer respectively and these are then passed on through NMI to NTI and NML respectively. Neovasc GmbH conducts sales and marketing activities on behalf of NMI as part of the license agreement between NML and NMI for NMI to manufacture, distribute and sell the Reducer on behalf of NML. Neovasc Management Inc provides executive management services to Neovasc Inc.

Neovasc's Strategy

The Company's core strategy is to focus on re-establishing trust and confidence with its stakeholders, to re-structure the Company's financing and to continue the development and commercialization of its products, the Tiara and the Reducer, providing minimally invasive medical devices for a cardiovascular market that the Company believes is both growing and under-served by current treatment solutions.

Key elements of this strategy include:

- Tiara — expanding the Company's clinical experience of the Tiara, continuing enrollment in and expansion of the TIARA-II multi-center CE Mark clinical study, and applying for CE Mark approval in approximately 2020. Finalizing the TIARA-I study. Initiating the formal development process of a conceptually developed transfemoral trans-septal Tiara system for preclinical bench and animal studies to successful completion, followed by initiation of a first human feasibility clinical study.
- Reducer — continuing therapy development of the Reducer, and supplementing the successful COSIRA prospective, multicenter, randomized, double-blind, sham-controlled clinical study with additional clinical experience through the Company's targeted commercial launch of the Reducer in Europe and enrollment in the REDUCER-I, real world post-market observational clinical study. Improving revenue growth in Europe by leveraging the recently renewed NUB 1 status in Germany and by further accelerated therapy development. Seeking strategic alternatives and alliances to build on the growing enthusiasm in the market for, and adoption of, the Reducer, in order to broaden and deepen therapy penetration in Europe, the Middle East and Africa. Continuing to execute on our US strategy and work with the FDA to fine tune the requirements for entrance into the US market, based on the Breakthrough Device designation.
- Financial and organizational restructuring to establish a lean and accountable organization with stable capitalization. We are currently exploring additional financing options to bring additional capital into the Company and will provide public updates when appropriate.

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 currently in the clinical trial phase providing a minimally invasive transcatheter device for 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 regurgitation, the majority of them with functional Mitral Regurgitation. The 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. Many of these patients are treated in Europe 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 35 mm and 40 mm Tiara valve. First clinical use of the 40mm Tiara occurred in the fourth quarter of 2015. These two sizes allow for the treatment of approximately 75% of the annulus sizes in this high-risk patient population, in our TIARA-I and TIARA-II Clinical Studies. Currently, approximately 18% of this high-risk patient population meet all inclusion criteria for the Tiara studies and can be treated.

As of March 19, 2019, 71 patients have been treated with Tiara in either the TIARA-I Early Feasibility Clinical Study, compassionate use cases or in our TIARA-II CE Mark Clinical Study. Neovasc believes that early results have been encouraging. The 30-day survival rate for the 70 patients treated with the Tiara (i.e. those treated more than 30 days ago) is 89% with one patient now over five years post implant. The Tiara has successfully treated both functional and degenerative Mitral Regurgitation patients, as well as patients with pre-existing prosthetic aortic valves and mitral surgical annuloplasty rings.

The medical community is showing more interest in exploring this new treatment option for patients who are unable or unsuited to receive a surgical valve replacement or repair, demonstrated by the increased interest of more European clinics to participate in the TIARA-II Clinical Study. There are currently 16 active sites across Germany, Israel, Spain, and the UK with additional sites being activated in Germany and The Netherlands. The Company continues to conduct pre/post implant analysis to review the overall screening criteria. Additional field clinical engineering support has been established in Europe to provide patient screening and case support.

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.

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, its D shape, enabling a better anatomical fit and less risk of left ventricular outflow tract obstruction, and its unique combined skirt and anchoring mechanism. The Tiara has successfully treated 16 patients with previous aortic valves (AVR), including mechanical, bioprosthetic and TAVI, without any LVOT obstruction, no peri-procedural deaths or paravalvular leak. Data on the first twelve patients with previous AVR, treated with Tiara was published in 2018 in Circulation: Cardiovascular Interventions.

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. 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 Company reported that the Tiara was featured in a “live case” broadcast on October 19, 2018 at the 32nd Annual European Association of Cardio-Thoracic Surgery meeting. The live case was performed by Dr. Lenard Conradi, and Dr. Ulrich Schaefer of the University Medical Center Hamburg-Eppendorf, (Hamburg, Germany), where they successfully implanted a 40mm Tiara transcatheter mitral valve in a patient suffering from severe mitral regurgitation.

The Tiara valve is made up of two major components: the leaflets which are made from the Peripatch bovine tissue licensed from Boston Scientific, a fabric skirt, 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 further development of the Tiara. The Tiara delivery system is manufactured, packaged and labelled in-house by the Company using customized standard catheter construction components that are readily available through vendors.

The TIARA-II study is estimated to cost approximately $15 million. 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 mitral valve replacement devices. Neovasc is managing and conducting the TIARA-II study itself in conjunction with certain service providers who undertake 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.

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 is targeting applying for CE Mark approval in Europe in approximately late 2020, assuming sufficient patients will have been enrolled with sufficient follow-up time by then. There is no assurance that European regulatory filing and an 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.

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. Since then Neovasc has received regulatory and ethics committee approvals to conduct the study in Germany, Israel, Spain and the United Kingdom.

Reducer

The Reducer is a treatment for patients with refractory angina, a painful and debilitating condition that occurs when the coronary arteries deliver an inadequate supply of blood to the heart muscle, despite treatment with standard revascularization or cardiac drug therapies.

Worldwide, coronary artery disease ("CAD") is the leading cause of death. It is the largest contributor to the global burden of disease as reflected in disability-adjusted life years, a measure which combines premature mortality and the prevalence and severity of ill-health. On this measure, the impact of CAD increased by 29% in the period 1990 to 2010. This reflects the worldwide shift to those chronic diseases associated with an ageing global population. The most frequent (and often the first) manifestation of stable CAD is chronic stable angina. As a result, angina is a significant burden of healthcare systems worldwide. There is a clear association between more frequent angina and greater utilization of healthcare resources.

Refractory angina, resulting in continued symptoms despite maximal medical therapy without revascularization options, is estimated to affect 600,000 to 1.8 million Americans, with 50,000 to 100,000 new cases per year. A recent publication in the European Heart Journal by Crea et al., stated persistence of angina caused by incomplete coronary revascularization may occur in up to 30% in the current era, although definitions of incomplete revascularization are heterogeneous.

The pain associated with refractory angina can make it difficult for patients to engage in routine activities, such as walking or climbing stairs. Clinical studies demonstrate that the Reducer can provide significant relief of chest pain in refractory angina patients. A significant proportion of the angina patients in the United States and in Europe 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. There continues to be interest from the medical community to explore the use of Reducer for other indications. Further clinical trials will need to be conducted to explore this possibility.

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, 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. Neovasc believes that further studies may demonstrate that additional patient populations may benefit from treatment with Reducer and thus could further increase its market potential.

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 implant procedure requires minimal training for experienced interventionalists. Once guide wire access to the coronary sinus is achieved, implantation typically takes less than 20 minutes.

Using a catheter-based procedure, the Reducer is implanted in the coronary sinus (the main vein draining blood from the heart muscle). Following implantation, the Reducer becomes covered with endothelial tissue after about 4-6 weeks. This tissue coverage creates a permanent (but reversible, if necessary) 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 focal narrowing provides a backwards pressure elevation in the coronary sinus which is intended to improve blood perfusion to ischemic territories of the heart muscle by forcing redistribution of blood from the less ischemic areas to the more ischemic areas of the heart muscle. This can result 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 fifteen patients suffering from chronic refractory angina who were followed out to six months, and then again at three years post implantation. The six-month results from this clinical trial were published in the Journal of the American College of Cardiology and three-year follow-up data was presented at the annual scientific meeting of the American College of Cardiology in March 2010. In this clinical trial, implantation of the Reducer resulted in significant clinical improvements in stress test and perfusion measurements, as well as in overall quality of life in the majority of the patients 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 Company completed the COSIRA, a prospective, multicenter, randomized, double-blind, sham-controlled study to assess the safety and effectiveness of the Reducer device in 2013. The COSIRA trial's primary endpoint was a two-class improvement in Angina pain, six months after implantation in patients' ratings on the Canadian Cardiovascular Society ("CCS") angina grading scale, a four-class functional classification that is widely used to characterize the severity of angina symptoms and disability. Only patients with severe angina, CCS Class 3 or 4, were enrolled in the COSIRA trial. The COSIRA trial analysis showed that the study met the primary endpoint, with patients receiving the Reducer achieving a statistically significant improvement in CCS scores (two classes or better) compared to patients receiving a sham control (18 of 52 [34.6%] of the Reducer patients improved $\geqslant$ 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.

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, 190 patients have been enrolled across 20 centers that are active in Italy, Germany, Belgium, Netherlands, United Kingdom and Switzerland.

In 2018 an article by Parikh, Parth et al., was published in the Journal of the American College of Cardiology (JACC) titled, "First-in-Human Use of Coronary Sinus Reducer in Patients with Refractory Angina". This article describes the long term clinical and anatomical follow-up of patients with severe angina pectoris treated with Reducer more than 12 years ago.

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. More recent studies and publications of Reducer patients have conformed closely with the results of the COSIRA trial. We refer the reader to the following publications:

- "Coronary Sinus Reducer Implantation for the Treatment of Chronic Refractory Angina" by Dr. Giannini et al., published in Volume 11, Issue 8 of the Journal of the American College of Cardiology in April 2018 and related Editorial
- "Coronary sinus Reducer implantation improves symptoms, ischemia, and physical capacity in patients with refractory angina unsuitable for myocardial revascularization: a single center experience" by Dr. Konigstein, et al., published in EuroIntervention Volume 14.
- "Safety and efficacy of reducer: A multi-center clinical registry-REDUCE study, by Dr. Giannini et al., published in the International Journal of Cardiology 269 (2018) 40-44,
- Review of the topic: Konigstein M, Giannini F, Banai S: The Reducer Device in Patients with Angina Pectoris: Mechanisms, Indications and Perspectives. European Heart Journal 2018 Mar 14;39(11):925-933.

Following the positive data from the COSIRA trial, the Company initiated a pilot launch of the Reducer in select European markets in early 2015. The Company has signed distribution agreements in multiple jurisdictions across Europe. Direct sales are underway in select centers in Germany. Based on the initial results from the targeted launch, Neovasc has developed an expanded sales plan and strategy for 2019 and beyond. Any 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 2018 was encouraging with a 55% increase in revenue compared to 2017.

The Reducer therapy requires broader therapy development in the market and in particular with referring physicians. The Company has launched pilot programs in Germany, with additional support from a professional therapy development organization, to learn more about therapy development challenges and opportunities.

We are seeing a growing level of enthusiasm in Europe for the Reducer therapy and we believe that the therapy has significant potential. In order to further accelerate the penetration of the therapy, we are open to considering strategic alternatives for the Reducer, including potential alliances in Europe, the United States and the rest of the world.

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. Spyrantis and Professor Banai in the Sana-Klinikum Lichtenberg. During May 2018, at the Euro PCR Conference in Paris, the Reducer was showcased during a dedicated Reducer symposium.

On March 5, 2019, the Company reported the Reducer was featured in a “live case” broadcast to more than 3000 participants at the Cardiovascular Research Technologies (CRT) meeting in Washington D.C. The successful live case was performed by Dr Giannini at Maria Cecilia Hospital in Cotignola, Italy.

On June 20, 2018, the Company announced the first U.S. patient had been implanted with the Reducer under compassionate use. On October 3, 2018, the Company reported the positive follow-up for this patient noting that the patient was able to walk several miles without any symptoms. The patient has reduced his use of nitroglycerin from 2-3 times a week to 1 or 2 times per month. A second patient received a Reducer implant under Compassionate Use on January 31, 2019 in the U.S. The most recent update from the attending physician indicated that this second patient was doing well.

Regulatory Status

The Reducer is approved for sale in Europe, having received CE Mark designation in November 2011. In preparation for product launch, Neovasc completed development of 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 approximately $20 million. U.S. marketing approval is expected about 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.

On October 10, 2018, the Company announced that the FDA has granted “Breakthrough Device Designation” for the Reducer. The FDA grants this designation in order to expedite the development and review of a device that demonstrates compelling potential to provide a more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases.

On December 20, 2018, Neovasc filed a comprehensive Q-Sub submission to the FDA with all available Reducer Clinical evidence, requesting a Sprint FDA discussion meeting. The Neovasc team, together with two top U.S. Cardiologists, met with the FDA proposing moving forward with a PMA submission using the available Neovasc clinical evidence including the prospective, multicenter, randomized, double-blind, sham controlled study assessing the safety and efficacy of the Reducer in 104 patients in the European Union and Canada (COSIRA), a multi-center, multi-country, three-arm observational post market study (REDUCER-I), and supportive safety and efficacy data from peer-reviewed journals.

On February 20, the Company announced that the FDA had informed Neovasc that, despite “Breakthrough Device Designation”, the FDA review team recommends collection of further pre-market blinded data prior to PMA submission. Through the Sprint discussion process, Neovasc will continue discussions with the FDA and their senior management to attempt to bring this promising refractory angina device therapy to U.S. patients as soon as possible.

New Products/Components/Cycles

Tiara

An additional strategic and focused activity for the Company in the Mitral Valve space is the 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 usable implantation technique. These development activities are taking place both in the Company’s Vancouver, BC 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 enhance 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. We plan to initiate the formal development of this system, based on the completed conceptual work at the end of the first quarter of 2019.

Reducer

The Reducer is a late-stage product with European CE Mark approval. The Company initiated a pilot launch of the Reducer in select European markets in 2015. The Company has also been exploring initiation of the Reducer sales in other non-US markets and has signed distribution agreements in several countries. Any sales of the product in the United States would follow obtaining U.S. regulatory approval, if such approval is granted, as described further above.

A well-known and well-established medical device contract manufacturer is manufacturing the Reducer for the Company. The majority of the components that make up the Reducer are readily available; however, two critical components of the device are not. The balloon portion of the delivery system is technically challenging to manufacture and the Reducer device, whilst a basic technology, must be manufactured in Israel due to restrictions on the transfer of intellectual property and manufacturing out of Israel stemming from certain research grants received by NML prior to the acquisition in July 2008.

Peripatch Technology used in our Tiara Mitral Valve

The basic Peripatch technology licensed from Boston Scientific was established over 25 years ago, when the material was used to fashion the leaflets and other components in surgical heart valves.

Neovasc sources its bovine tissue from abattoirs in New Zealand for the manufacture of Tiara devices. There is a degree of capacity constraint related to the supply of raw tissue but the risk of disruption is minimal, due to the relatively small amounts of tissue required for the current Tiara programs.

While a definitive pattern of demand has not yet been established and the effect is expected to be minimal, the cyclical nature of the meat industry could conceivably have an impact on the quality and availability of raw tissue and could potentially impact the yields and margins for the product over the course of any given year. Further information about Peripatch can be found above under the heading “Neovasc’s Products”.

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 losses and comprehensive losses of $108,042,868 and $109,052,460 for the year ended December 31, 2018, respectively (2017: $22,908,721 and $24,859,117) and has a deficit of $332,735,195 at December 31, 2018 compared to a deficit of $224,692,327 as at December 31, 2017. As at December 31, 2018 the Company had $9,242,809 in cash and cash equivalents (2017: $17,507,157).

The Company will 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, 2018, the Company had approximately $9.2 million in cash and cash equivalents, sufficient cash to sustain operations until approximately May 2019. After receipt of the net proceeds of approximately $4.05 million from the February 2019 Financing on February 28, 2019 and the net proceeds of approximately $4.25 million from the March 2019 Financing on March 15, 2019, the Company expects that its cash is sufficient to sustain operations until approximately September 2019. The Company will need to obtain additional debt or equity financing later in 2019 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 Report on Form 20-F, which is available on SEDAR at sedar.com and as filed with the SEC at www.sec.gov.

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.

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.

There are other ongoing litigation matters more fully described in "Contractual Obligations and Contingencies" below.

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 2017 Warrants and conversion of Notes issued pursuant to the 2017 Financings have resulted in significant dilution to our shareholders. Future conversions of the Notes 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 and with the SEC at 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 conversions, see the Company's Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as filed with the SEC at www.sec.gov.

FOREIGN OPERATIONS

The Company changed functional currency on October 1, 2017 from Canadian to U.S. dollars.

The majority of the Company's revenues are derived from product sales in 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, 2018, 2017 and 2016.

DISCUSSION OF OPERATIONS AND FINANCIAL CONDITION

<u>Results for the years ended December 31, 2018 and 2017 follow:</u>

Losses

The losses and comprehensive losses for the year ended December 31, 2018 were $108,042,868 and $109,052,460, respectively, or $7.63 basic and diluted loss per share, as compared with losses and comprehensive losses of $22,908,721 and $24,859,117, respectively, or $28.10 basic and diluted loss per share, for the same period in 2017.

The $84,193,343 increase in the comprehensive loss incurred for the year ended December 31, 2018 compared to the same period in 2017 can be substantially explained by a $85,190,307 increase in other losses (the accounting treatment of the 2017 Financings resulting in an increase in charges of $83,092,711 in the year) and a $321,175 increase in operating losses ($754,153 increase in general and administrative expenses and a $1,428,235 reduction in product development and clinical trials expenses as the Company continues to control costs).

Revenues

Revenues decreased 68% to $1,749,133 for the year ended December 31, 2018, compared to revenues of $5,389,014 for the same period in 2017. In December 2017, the Company closed its contract manufacturing and consulting services business and is now focused on the commercialization of its own product, the Reducer.

Sales of the Reducer for the year ended December 31, 2018 were $1,749,133 compared to $1,128,126 for the same period in 2017, representing an increase of 55%. 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.

Cost of Goods Sold

The cost of goods sold for the year ended December 31, 2018 was $366,258 compared to $3,477,821 for the same period in 2017. The overall gross margin for the year ended December 31, 2018 was 79%, compared to 35% gross margin for the same period in 2017. The gross margin now reflects the gross margin on the Reducer product only, whereas the comparable period included contract manufacturing and consulting services.

Expenses

Total expenses for the year ended December 31, 2018 were $33,852,958 compared to $34,060,101 for 2017, representing a decrease of $207,143 or 1%. The decrease in total expenses for the year ended December 31, 2018 compared to 2017 can be substantially explained by a $1,428,235 decrease in product development and clinical trial expenses as we continue to preserve cash resources offset by a $754,153 increase in general and administrative expenses and a $466,939 increase in selling expenses.

Selling expenses for the year ended December 31, 2018 were $1,353,165, compared to $886,226 for 2017, representing an increase of $466,939, or 53%. The increase in selling expenses for the year ended December 31, 2018 compared to 2017 reflects an increase in costs incurred for commercialization activities related to the Reducer. The Company continues to minimize its selling expenses as the cash resources of the Company are still limited.

General and administrative expenses for the year ended December 31, 2018 were $16,438,936, compared to $15,684,783 for 2017, representing an increase of $754,153 or 5%. The increase in general and administrative expenses for the year ended December 31, 2018 compared to 2017 can be substantially explained by a $1,067,205 increase in stock based compensation and a $2,379,790 charge for collaboration and settlement expenses and a $2,749,968 charge for settlement expenses (see “Consolidated Statements and Other Financial Information — Legal Proceedings” of the Company's Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as file with the SEC at www.sec.gov.) and a $1,441,125 increase in other expenses including a substantial increase in legal expenses as we renewed the base shelf prospectus, filed XBRL for the first time and filed our annual report on the more demanding Form 20-F, as compared to the Form 40-F filed in 2017, offset by a decrease in expenses related to the 2017 Financings of $5,447,182 and a decrease in litigation expenses of $1,870,225.

Product development and clinical trial expenses for the year ended December 31, 2018 were $16,060,857 compared to $17,489,092 for 2017, representing a decrease of $1,428,235 or 8%. The decrease in product development and clinical trial expenses for the year ended December 31, 2018 was the result of a $918,016 decrease in employee expenses and a $330,906 decrease in share-based payments due to a restructuring of the Company in early 2017 and a $120,999 decrease in other expenses, as the Company continues to control costs.

The Company’s expenses are subject to inflation and cost increases. 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 loss for the year ended December 31, 2018 was $75,465,692 compared to other income of $9,724,615 for 2017, an adverse change of $85,190,307. The increase in the other loss can be substantially explained by the accounting treatment of the 2017 Financings resulting in a $83,092,712 adverse change (charges of $75,712,610 in the year compared to other income of $7,380,102 in the prior year) and a $2,901,782 adverse change in foreign exchange losses and gains compared to the prior year.

Tax Expense

The tax recovery for the year ended December 31, 2018 was $107,093 compared to $484,428 in 2017. 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 incurred.

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

Losses

The losses and comprehensive losses for the year ended December 31, 2017 were $22,908,721 and $24,859,117, respectively, or $28.10 basic and diluted loss per share, as compared with losses and comprehensive losses of $86,494,893 and $82,397,922, respectively, or $128.21 basic and diluted loss per share, for the same period in 2016.

The $63,586,172 decrease in the loss for the period 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 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%.

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 primary U.S. 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 three months ended December 31, 2018 and 2017 follow:

Losses

The income and comprehensive income for the three months ended December 31, 2018 were $11,620,015 and $10,842,733 respectively, or $0.51 basic earnings per share, as compared with losses and comprehensive losses of $5,026,466 and $5,026,466, respectively, or $6.16 basic and diluted loss per share, for the same period in 2017.

The $16,646,481 increase in the income incurred for the three months ended December 31, 2018 compared to the same period in 2017 can be substantially explained by a $14,652,143 increase in other income, substantially due to the accounting treatment of the 2017 Financings, and a $2,902,915 decrease in general and administrative expenses related to the decrease in $5,447,182 expenses from the 2017 Financings.

Revenues

Revenues decreased 57% to $523,424 for the three months ended December 31, 2018, compared to revenues of $1,227,625 for the same period in 2017. In December 2017, the Company closed its contract manufacturing and consulting services business and is now focused on the commercialization of its own product, the Reducer.

Sales of the Reducer for the three months ended December 31, 2018 were $523,424 compared to $285,598 for the same period in 2017, representing an increase of 83%. 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.

Cost of Goods Sold

The cost of goods sold for the three months ended December 31, 2018 was $93,519 compared to $1,136,804 for the same period in 2017. The overall gross margin for the three months ended December 31, 2018 was 82%, compared to 7% gross margin for the same period in 2017. The gross margin now reflects the gross margin on the Reducer product only, whereas the comparable period included contract manufacturing and consulting services.

Expenses

Total expenses for the three months ended December 31, 2018 were $10,742,892, compared to $12,301,582 for the same period in 2017, representing a decrease of $1,558,690 or 13%. The increase in total expenses for the three months ended December 31, 2018 compared to the same period in 2017 can be substantially explained by a $2,902,915 decrease in general and administrative expenses due to the decrease of $5,447,182 related to expenses from the 2017 Financings offset by a $393,857 increase in selling expenses due to an increase in costs incurred for commercialization activities related to the Reducer and a $950,368 increase in product development and clinical trial expenses from increased share-based payments as options were granted.

Selling expenses for the three months ended December 31, 2018 were $614,742, compared to $220,885 for the same period in 2017, representing an increase of $393,857, or 178%. The increase in selling expenses for the three months ended December 31, 2018 compared to the same period in 2017 reflects an increase in costs incurred for commercialization activities related to the Reducer. The Company continues to manage its selling expenses as the cash resources of the Company are still limited.

General and administrative expenses for the three months ended December 31, 2018 were $5,415,634, compared to $8,318,549 for the same period in 2017, representing a decrease of $ 2,902,915 or 35%. The decrease in general and administrative expenses for the three months ended December 31, 2018 compared to the same period in 2017 can be substantially explained by a decrease of $5,447,182 related to expenses from the 2017 Financings offset by a $2,749,968 charge for settlement expenses (see "Consolidated Statements and Other Financial Information — Legal Proceedings" of the Company's Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as file with the SEC at www.sec.gov).

Product development and clinical trial expenses for the three months ended December 31, 2018 were $4,712,516 compared to $3,762,148 for the same period in 2017, representing an increase of $950,368 or 25%. The increase in product development and clinical trial expenses for the three months ended December 31, 2018 was primarily the result of a $556,030 increase in share-based payments as options were granted.

The Company's expenses are subject to inflation and cost increases. 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 three months ended December 31, 2018 was $21,862,040 compared to other income of $7,209,897 for the same period in 2017, an increase of $14,652,143. The increase in the other income can be substantially explained by the accounting treatment of the 2017 Financings resulting in charges of $14,506,846 in the quarter.

Tax Expense

The tax expense for the three months ended December 31, 2018 was $70,961 compared to $25,602 for the same period in 2017. 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 incurred.

<u>Results for the three months ended December 31, 2017 and 2016 follow:</u>

Losses

The comprehensive losses for the three months ended December 31, 2017 were $5,026,466, or $6.16 basic and diluted loss per share, as compared with losses and comprehensive income of $37,213,791 and $37,095,024, or $54.00 basic loss and $47.00 fully diluted earnings per share for the same period in 2016.

The $42,240,257 decrease in the loss for the period 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 continued to focus its business away from its traditional revenue streams towards development and commercialization of its own products, the Reducer and the Tiara.

Reducer sales for the three months ended 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 $7,209,897, compared to $43,957,927 for the same period in 2016, a decrease in other income of $36,748,030. 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).

Annual Information

The following is a summary of selected financial information for the three fiscal years to December 31, 2018:

	2018	2017	2016
Revenues	$ 1,749,133	$ 5,389,014	$ 9,512,796
Loss	(108,042,868)	(22,908,721)	(86,494,893)
Basic and diluted loss per share	(7.63)	28.10	128.21
Total assets	11,993,294	22,206,443	98,809,503
Total long-term liabilities and damages provision	13,384,415	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.

The accounting treatment of the 2017 Financings as derivative financial instruments resulted in non-cash charges of $75,712,610 for the year ended December 31, 2018, substantially explaining the significant increase in loss compared to 2017.

QUARTERLY INFORMATION

The following is a summary of selected unaudited financial information for the twelve fiscal quarters to December 31, 2018:

	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
REVENUE				
Reducer	$ 523,424	$ 480,540	$ 405,247	$ 339,922
	523,424	480,540	405,247	339,922
COST OF GOODS SOLD	93,519	96,743	88,603	87,393
GROSS PROFIT	429,905	383,797	316,644	252,529
EXPENSES				
Selling expenses	614,742	202,947	248,538	286,938
General and administrative expenses	5,415,634	6,340,747	2,213,464	2,469,091
Product development and clinical trials expenses	4,712,516	3,490,696	3,858,255	3,999,391
	10,742,892	10,034,390	6,320,257	6,755,420
OPERATING LOSS	(10,312,986)	(9,650,593)	(6,003,613)	(6,502,891)

Other Income/(expense)	21,862,040	(4,932,151)	(43,071,578)	(49,324,003)
Tax expense	70,961	(54,000)	(70,400)	(53,654)
GAIN/ (LOSS) FOR THE PERIOD	$ 11,620,015	$ (14,636,744)	$ (49,145,591)	$ (55,880,548)
BASIC AND DILUTED LOSS PER SHARE	$ 0.51	$ (0.78)	$ (3.66)	$ (38.59)

	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
REVENUE				
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
COST OF GOODS SOLD	1,136,804	659,686	872,703	808,628
GROSS PROFIT	90,821	715,207	432,433	672,732
EXPENSES				
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
OPERATING LOSS	(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)
LOSS FOR THE PERIOD	$ (5,026,466)	$ (4,695,960)	$ (5,341,308)	$ (7,844,987)
BASIC AND DILUTED LOSS PER SHARE	$ (6.17)	$ (5.95)	$ (6.78)	$ (9.97)

	December 31, 2016	September 30, 2016	June 30, 2016	March 31, 2016
REVENUE				
Reducer	$ 282,515	$ 262,546	$ 246,122	$ 213,765
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
COST OF GOODS SOLD	2,052,969	2,201,440	1,391,708	1,445,644
GROSS PROFIT	708,153	832,560	319,224	561,098
EXPENSES				
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
OPERATING LOSS	(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)
PROFIT/(LOSS) FOR THE PERIOD	$ 37,213,791	$ (29,135,086)	$ (83,692,460)	$ (10,881,138)
BASIC AND DILUTED LOSS PER SHARE	$ 54.16	$ (43.57)	$ (125.18)	$ (16.28)

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 continues its focused commercialization of the Reducer in select countries in Europe. General and administrative expense reached peaks in the third quarter of 2018 due to the accrual of future collaboration and license fees and an increase in share-based payments as options were granted, in the fourth quarter of 2017 due to expense related to obtaining the Notes 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 since the litigation loss in the second quarter of 2016 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	$18,000,000	$NIL
NET PROCEEDS	$60,000,000	$60,000,000	$NIL

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. In the twelve months ended December 31, 2018, the Company recorded proceeds of $13,799,599 from the exercise of Series C common share purchase warrants of the Company (each, a "Series C Warrant"), which has funded the Company after proceeds from the 2017 Financings were exhausted. Approximately $9.2 million of the proceeds from the exercise of Series C Warrants remained as cash on hand as at December 31, 2018.

DISCUSSION OF LIQUIDITY AND CAPITAL RESOURCES

Results for the years ended December 31, 2018 and 2017 follow:

Neovasc finances its operations and capital expenditures with cash generated from operations and through equity and debt financings. As at December 31, 2018 the Company had cash and cash equivalents of $9,242,809 compared to cash and cash equivalents of $17,507,157 as at December 31, 2017. The Company will require significant additional financing in order to continue to operate its business. Given the current nature of the Company's capital structure, there can be no assurance that such financing will be available on favorable terms, or at all.

The Company is in a positive working capital position of $2,464,167, with current assets of $10,739,930 and current liabilities of $8,275,763. The Company will require additional working capital in order to continue to operate its business and there can be no assurance that such additional working capital will be available on favorable terms, or at all.

Cash used in operating activities for the twelve months ended December 31, 2018 was $22,794,748, compared to $138,613,945 for the same period in 2017. For the twelve months ended December 31, 2018, operating activities were $23,924,650, compared to $26,403,092 for the same period in 2017, a decrease of $2,478,442. Net cash provided from the net change in non-cash working capital items for the twelve months ended December 31, 2018 was $1,124,891, compared to a net cash outflow of $112,067,771 in the same period in 2017. The decrease in net cash outflow can be attributed to the payment of the damages and interest awards in relation in the Company's primary U.S. litigation with CardiAQ in 2017.

Net cash received from investing activities for the twelve months ended December 31, 2018 was $713,752 compared to net cash applied to investing activities of $69,496,853 for the same period in 2017, primarily due the release of cash held in escrow to settle damages and interest awards in the Company's primary U.S. litigation with CardiAQ in 2017.

The majority of the revenue and expenses of the Company are incurred in the parent and in two of its subsidiaries, NMI, which is located in Canada, and Neovasc (US) Inc. which is located in the United States. There were no significant restrictions on the transfer of funds between these entities during the periods ended December 31, 2018 and 2017 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 $1,508,963 of its cash and cash equivalents and restricted cash held in Canadian dollars and Euros.

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 was 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 were cash liabilities as the liability for the Notes and the derivative liability from the 2017 Financings are accounting entries to account for the value of the instruments issued in the 2017 Financings.

Cash used in operating activities for the year ended December 31, 2017 was $138,613,945, compared to $39,794,159 for the same period in 2016. The Company settled the $112,519,117 damages and interest awards in connection with its primary U.S. litigation with CardiAQ in full in 2017. For the year ended December 31, 2017, operating expenses were $26,403,092, 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 applied to 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 in 2017 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.

2017 Financings

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 17, 2017, the Company completed 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 Warrant, (iii) one Series B common share purchase warrant of the Company (each, a "Series B Warrant") and (iv) 0.40 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 entitled 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 entitled 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 entitled 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 entitled 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 were 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 entitled 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 “2017 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.

Concurrent with the 2017 Public Transaction, the Company completed the 2017 Private Placement for the sale of $32,750,000 aggregate principal amount of the Notes of the Company and Series E common share purchase warrants of the Company (the “Series E Warrants”) to purchase one Common Share at a price of $1.61 per Series E Warrant. As a result of the February 2019 Financing, the exercise prices of the Notes were adjusted to $0.45. The Notes were issued with an original issue price of $850 per $1,000 principal amount of note. The Notes initially carried 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. The maturity date of the Notes was extended to May 17, 2020, pursuant to certain waiver agreements between the Company and the holders of the Notes, along with certain other amendments. The form of waiver agreement is available on the Company’s profiles on SEDAR at www.sedar.com and with the SEC at www.sec.gov. 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 had 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.

As of March 19, 2019, all of the warrants issued pursuant to the 2017 Financings have been either exercised or exchanged, such that no such warrants remain outstanding.

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 and with the SEC at 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 “Risk Factors” and “Share Capital” of the Company's Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as file with the SEC at www.sec.gov.

Conversions of Notes and Exercises of 2017 Warrants

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. As of March 19, 2019, all of the 25,676,368 Series B Warrants initially granted and 10,273,972 Series B Warrants issued upon exercise of Series C Warrants have been exercised and all of the 22,431,506 Series F Warrants initially granted have been exercised in each case using the cashless alternate net number mechanism for 18,343,551 Common Shares. As of March 19, 2019, all of the 10,273,972 Series C Warrants initially granted have been exercised, for proceeds to the Company of $14,999,999. Such exercises of Series C Warrants resulted in the issuance of 102,740 Common Shares and the issuance of an additional 10,273,972 Series A Warrants. As of March 19, 2019, all of the warrants issued pursuant to the 2017 Financings have been either exercised or exchanged, such that no 2017 Warrants remain outstanding.

As of March 19, 2019, of the $32,750,000 aggregate principle amount of Notes initially issued, $21,925,000 aggregate principle amount has been converted using the alternate conversion price mechanism, resulting in the issuance of 19,773,718 Common Shares, and $10,825,000 aggregate principle amount remains outstanding. As a result of the February 2019 Financing, the conversion price of the Notes reset, as of that time, to $0.45.

For a description of the risks associated with 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 and with the SEC at www.sec.gov. For a description of the risks associated with these securities, the amount of such securities exercised or converted to date, the dilution to date and the potential dilution in the future due to such exercises or conversions, see the Company's Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as file with the SEC at www.sec.gov.

SUBSEQUENT EVENTS

On January 3, 2019, the Company received the Market Value Notification Letter from the Nasdaq Listing Qualifications Department notifying the Company that it was not in compliance with the $35 million minimum market value requirement set forth in the Nasdaq Marketplace Rules. The Market Value Notification Letter does not impact the Company's listing on the Nasdaq at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided 180 calendar days, or until July 2, 2019, to regain compliance. The Company intends to monitor the market value of its listed securities between now and July 2, 2019 and intends to attempt to cure the deficiency within the prescribed grace period.

On January 14, 2019, the Company received the Bid Price Notification Letter from the Nasdaq Listing Qualifications Department notifying the Company that it was not in compliance with the $1.00 minimum bid price requirement set forth in the Nasdaq Marketplace Rules. The Bid Price Notification Letter does not impact the Company's listing on the Nasdaq at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided 180 calendar days, or until July 15, 2019, to regain compliance. The Company intends to monitor the closing bid price of its common shares between now and July 15, 2019 and intends to attempt to cure the deficiency within the prescribed grace period.

In the event the Company does not regain compliance with the Nasdaq minimum market value or minimum bid price rules within the prescribed compliance periods, the Company may be eligible for additional time to regain compliance or may face delisting. Nasdaq also has broad discretionary public interest authority that it can exercise to apply additional or more stringent criteria for the continued listing of the Common Shares, or suspend or delist securities even if the securities meet all enumerated criteria for continued listing on the Nasdaq. The Nasdaq could use this discretionary authority at any time to delist the Common Shares. There can be no assurance that Nasdaq will not exercise such discretionary authority. In addition, there is no assurance that the Company will be able to regain compliance with the minimum bid price and minimum market value requirements prior to expiration of the prescribed compliance periods, or if it does, that the Company will be able to maintain such compliance as a result of the risks and uncertainties described above.

On January 22, 2019, the Company announced that pursuant to a settlement reached with Edwards Lifesciences PVT, Inc. and Edwards Lifesciences (Canada) Inc. (collectively, the "Edwards Plaintiffs"), the patent infringement action that the Edwards Plaintiffs had previously commenced in the Federal Court of Canada against the Company, Boston Scientific and Livanova, will be dismissed on a no-costs basis.

On January 23, 2019, the Company announced that the *Journal of the American College of Cardiology: Cardiovascular Interventions* had published a peer-reviewed article on the use of dipyridamole stress perfusion cardiac magnetic resonance to assess the performance of the Reducer, titled "Coronary Sinus Reducer Implantation to Reduce the Ischemic Burden in Refractory Angina."

On January 29, 2019, the Company announced that it had completed the Phase 1 requirements of the TIARA-II study in both Germany and the United Kingdom and has received approval to proceed with Phase 2 of the TIARA-II study.

On January 30, 2019, the Company announced that the German Institute for the Hospital Remuneration System had awarded the Reducer NUB status 1 designation again for 2019.

On February 11, 2019, the Company announced that the Pierangeli Clinic of Pescara, Italy had initiated a program to provide its patients access to the Reducer.

On February 13, 2019, the Company received proceeds of $1,200,400 from the exercise of Series C Warrants, which represents an increase in cash and cash equivalents of approximately 13% compared to the reported cash and cash equivalents of $9,242,809 as at December 31, 2018. The Company issued 8,222 2017 Warrant Shares, 822,192 Series A Warrants and 822,192 Series B Warrants upon exercise of the Series C Warrants. As of March 19, 2019, all of the Series B Warrants (including those issued upon exercise of the Series C Warrants) had been exercised using the cashless alternative net number mechanism for 2,233,347 Common Shares. On March 11, 2019, all of the remaining Series A Warrants (including those issued upon exercise of the Series C Warrants) were surrendered and cancelled pursuant to the Exchange.

On February 20, 2019, the Company announced that it had entered into a settlement agreement with Endovalve Inc. and Micro Interventional Devices, Inc. (collectively, "Endovalve"). This agreement resolved certain potential claims against the Company. The settlement agreement contemplates certain fees being paid by Neovasc to Endovalve, including settlement fees in installments totaling $3 million over the two and a half years following the agreement's execution. In addition, Neovasc agreed to pay Endovalve a royalty of 1.3% on the annual net sales of the Tiara following the first commercial sale of the Tiara. Also contained in the settlement agreement are buy-out clauses that allow Neovasc, or an acquirer of Neovasc or the Tiara assets, to buy out these royalty obligations. As part of the settlement agreement, the claims against Neovasc Inc. and Neovasc Tiara Inc. (the “Neovasc Defendants”) were dismissed with prejudice.

On December 20, 2018, the Company filed a comprehensive Q-Sub submission to the FDA with all available Reducer clinical evidence, requesting a Sprint FDA discussion meeting. The Neovasc team, together with two top U.S. Cardiologists, met with the FDA proposing moving forward with a PMA submission using the available Neovasc clinical evidence. On February 20, 2019, the Company announced that the FDA had informed Neovasc that, despite “Breakthrough Device Designation”, the FDA review team recommends collection of further pre-market blinded data prior to PMA submission. Through the Sprint discussion process, Neovasc will continue discussions with the FDA and their senior management, to attempt to bring this promising refractory angina device therapy to U.S. patients as soon as possible.

On February 21, 2019, the Company announced that a patient implanted with the Tiara had celebrated her fifth anniversary since undergoing the procedure. The Company believes that this patient is the longest surviving transcatheter mitral valve replacement therapy recipient in the world.

On February 27, 2019, the Company announced that it would present a corporate overview at the 8th Annual SVB Leerink Global Healthcare Conference held on February 27-March 1, 2019 in New York, NY.

On February 28, 2019, the Company completed an underwritten public offering of 11,111,111 Common Shares, at a price of $0.45 per Common Share, for gross proceeds of approximately $5 million before deducting the underwriting commission and offering expenses payable by the Company. The Company intends to use the approximately $4.02 million net proceeds of the February 2019 Financing for the development and commercialization of the Reducer, development of the Tiara and general corporate and working capital purposes. As part of the underwriter's compensation in the February 2019 Financing, the Company issued the underwriter warrants (the “February Broker Warrants”) to purchase in aggregate up to a 722,222 Common Shares, exercisable at a price per Common Share equal to $0.5625 for a period of three years following issuance.

On March 4, 2019, the Company announced that the Tiara was featured in an update presentation at the Cardiovascular Research Technologies (CRT) meeting held March 2-5, 2019 in Washington, D.C.

On March 5, 2019, the Company announced that the Reducer was featured in a “Live Case” broadcast at the Cardiovascular Research Technologies (CRT) meeting held March 2-5, 2019 in Washington, D.C.

On March 12, 2019, the Company announced that it had entered into Exchange Agreements with the holders of all of its outstanding Series A common share purchase warrants (the "Series A Warrants") and Series E Warrants issued pursuant to the 2017 Financings, pursuant to which the Company issued an aggregate of approximately 496,239 Common Shares for the surrender and cancellation of all of the Series A Warrants and Series E Warrants outstanding, on the basis of 0.0085 of a Common Share for each Series A Warrant or Series E Warrant (the “Exchange”). Following completion of the Exchange, there are no longer any warrants remaining outstanding from the 2017 Financings.

On March 14, 2019, the Company announced that it had successfully completed its 2019 mandatory Surveillance Audit with its Notified Body, resulting in the maintenance of the Regulatory Certification (EC marking) and maintenance of the ISO 13485: 2016 certification of its quality management system.

On March 15, 2019, the Company completed an underwritten public offering of 11,111,111 Common Shares, at a price of $0.45 per Common Share, for gross proceeds of approximately $5 million before deducting the underwriting commission and offering expenses payable by the Company. The Company intends to use the approximately $4.25 million net proceeds of the March 2019 Financing for the development and commercialization of the Reducer, development of the Tiara and general corporate and working capital purposes. As part of the underwriter's compensation in the March 2019 Financing, the Company issued the underwriter warrants (the “March Broker Warrants”, and together with the February Broker Warrants, the "Broker Warrants") to purchase in aggregate up to a 722,222 Common Shares, exercisable at a price per Common Share equal to $0.5625 for a period of three years following issuance.

On March 21, 2019, the Company announced that the Appeals Court in Munich rendered its decision with respect to the Company's litigation with CardiAQ in Germany. The Appeals Court amended the decision of the German Court and dismissed the complaint of CardiAQ in full.

OUTSTANDING SHARE DATA

As at March 19, 2019, the Company had 61,985,116 common voting shares issued and outstanding. Further, the following securities are convertible into Common Shares: 3,682,469 stock options with a weighted average price of $7.70, 1,444,444 Broker Warrants and the $10,825,000 Notes that could convert into 24,055,555 Common Shares (not taking into account the alternate conversion price mechanism in the Notes). Our fully diluted share capital as of the same date is 91,167,584. Our fully diluted share capital, adjusted on the assumption that all the outstanding Notes are exercised using the alternate conversion price at the closing price on March 19, 2019 is 94,869,863.

CONTRACTUAL OBLIGATIONS AND CONTINGENCIES

Contingencies

Litigation

The Company is engaged as a defendant and appellant in certain lawsuits, as further described below. Litigation resulting from third-party 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 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. The oral hearing of the appeal before the Appeals Court of Munich was held on November 8, 2018. During that hearing CardiAQ dropped its affirmative appeal of the underlying decision, while maintaining its opposition to Neovasc's appeal. The decision of the Appeals Court of Munich was rendered on March 21, 2019, wherein it amended the decision of the German Court and dismissed the complaint of CardiAQ in full.

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 the Court denied this motion on September 28, 2018. On August 3, 2018, Neovasc wrote the presiding District Judge regarding potential resolution of the case including as to a statutory procedure available with the Patent Office concerning certain dependent claims of U.S. Patent 9,770,329 in particular, and the Court held a hearing to discuss this issue on September 13, 2018. No other litigation schedule or deadlines have been set; the Court has stayed the case until April 15, 2019 to allow the parties to discuss a potential resolution. Litigation is inherently uncertain. Therefore, until these matters have been resolved to their conclusion by the appropriate courts the Company cannot give any assurance as to the outcome.

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 United States Court of Appeals for the Federal Circuit. 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"), the Neovasc Defendants were added as defendants to an existing action commenced by the Edwards Plaintiffs 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 Edwards Plaintiffs that the manufacturing, assembly, use, sale and export of the Lotus Aortic Valve devices by the BSC/Livanova Defendants infringes on the Edwards Plaintiffs' patents. In February 2017, the Neovasc Defendants were added to the Edwards Plaintiffs' claim making related allegations. In summary, the Edwards 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 Edwards Plaintiffs seek various declarations, injunctions and unspecified damages and costs. The Neovasc Defendants filed their Statement of Defence in November 2017. The other defendants filed their Statement of Defence and Counterclaim against the Edwards Plaintiffs on April 30, 2018. On January 22, 2019, the Company announced that pursuant to a settlement reached with the Edwards Plaintiffs, the patent infringement action that the Edwards Plaintiffs had previously commenced in the Federal Court of Canada against the Company, Boston Scientific and Livanova will be dismissed on a no-costs basis.

On August 3, 2018, the Company announced that it had entered into a collaboration and licensing agreement with Penn Medicine and the Gorman Cardiovascular Research Group at the University of Pennsylvania, which resolved certain potential claims against the Company that had been previously disclosed.

On September 7, 2018, Endovalve filed a complaint in the United States District Court for the District of New Jersey against the Neovasc Defendants, alleging claims for trade secret misappropriation, breach of contract, and unfair competition. Endovalve alleged that it was a former customer of Neovasc Inc., and that the Neovasc Defendants improperly used trade secrets in the development of Tiara. The complaint sought injunctive relief, money damages, and attorneys' fees.

When the Company assesses that it is more likely that a present obligation exists at the end of the reporting period and that the possibility of an outflow of economic resources embodying economic benefits is probable, a provision is recognized and contingent liability disclosure is required. The Company has accrued $2,749,968 as at December 31, 2018 representing the discounted value of the future payments anticipated under the settlement agreement signed with Endovalve on February 20, 2019. The Company has not accrued for any future royalty payments in the settlement agreement with Endovalve as the amounts are undeterminable at this time.

Contractual obligations

The following table summarizes our contractual obligations as at December 31, 2018:

Contractual Obligations	Total	Less than 1 year	2-3 years	4-5 years
Operating leases	$1,397,351	$479,301	$816,189	$101,861

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, 2018, 2017 or 2016, 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, 2018, 2017 and 2016.

RISK FACTORS

A comprehensive list of the risks and uncertainties affecting us can be found in our most recent Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as filed with the SEC at 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 has established and applied a provision matrix to the trade accounts receivables balances in order to calculate an allowance for doubtful accounts on adoption of IFRS 9. 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, risk free interest rate, volatility and forfeiture rates and making assumptions about them.

Determination of functional currency

The Company determines its functional currency as the United States dollar 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.

Deferred tax assets

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

Contingent Liabilities

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

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 Company's warrants and 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, 2018 are disclosed in Note 15 to the Company's audited consolidated financial statements as at and for the years ended December 2018, 2017 and 2016.

CHANGES IN ACCOUNTING POLICIES INCLUDING INITIAL ADOPTION

During the year ended December 31, 2018, 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, 2018.

ADOPTION OF NEW STANDARD

Accounting standard issued and effective January 1, 2018

IFRS 9 – Financial Instruments

The Company adopted IFRS 9 on January 1, 2018 in accordance with the transitional provisions of the standard. IFRS 9 addresses the classification, measurement and recognition of financial assets and liabilities and supersedes the guidance relating to the classification and measurement of financial instruments in IAS 39, Financial Instruments: Recognition and Measurement (IAS 39).

IFRS 9 requires financial assets to be classified into three measurement categories on initial recognition: those measured at fair value through profit and loss, those measured at fair value through other comprehensive income and those measured at amortized cost. Measurement and classification of financial assets is dependent on the entity's business model for managing the financial assets and the contractual cash flow characteristics of the financial asset. For financial liabilities, the standard retains most of the IAS 39 requirements.

The main change is that, in cases where the fair value option is taken for financial liabilities, the part of a fair value change relating to an entity's own credit risk is recorded in other comprehensive income rather than the income statement, unless this creates an accounting mismatch.

The Company has assessed the classification and measurement of financial assets and financial liabilities under IFRS 9 and has summarized the original measurement categories under IAS 39 and the new measurement categories under IFRS 9 in the following table:

	Measurement Category	
	Original (IAS 39)	**New (IFRS 9)**
Financial assets:		
Cash and cash equivalents, cash held in escrow	Loans and receivables	Amortized cost
Trade receivables	Loans and receivables	Amortized cost
Financial liabilities:		
Accounts payable and accrued liabilities	Amortized cost	Amortized cost
Derivative liability from financing	Fair value through profit or loss	Fair value through profit or loss
Convertible Note	Fair value through profit or loss	Fair value through profit or loss or OCI (for own credit risk)

As a result of the change in measurement categories for the Notes, an adjustment of $1,009,592 for the twelve months ended December 31, 2018 has been made to opening retained earnings and accumulated other comprehensive income to reclassify the change in fair value associated with the Company's own credit risk. There has been no other change in the carrying value of our financial instruments or to previously reported figures as a result of changes to the measurement categories in the table noted above.

IFRS 9 introduces a new three-stage expected credit loss model for calculating impairment for financial assets. IFRS 9 no longer requires a triggering event to have occurred before credit losses are recognized. An entity is required to recognize expected credit losses when financial instruments are initially recognized and to update the amount of expected credit losses recognized at each reporting date to reflect changes in the credit risk of the financial instruments. There is a simplified approach where expected credit losses can be estimated and recognized upon initial recognition of the receivables. In addition, IFRS 9 requires additional disclosure requirements about expected credit losses and credit risk.

The Company has reviewed expected credit losses on trade receivables on transition to IFRS 9. The Company also implemented a process for managing and estimating provisions relating to trade receivables going forward under IFRS 9. For trade accounts receivables, the Company has applied the simplified approach for determining expected credit losses which requires us to determine the lifetime expected losses for all trade receivables.

The expected lifetime credit loss provision for trade receivables is based on historical counterparty default rates and adjusted for relevant forward-looking information, when required. As the majority of customers are considered to have low default risk and the Company does not extend credit to customers with high default risk, historical default rates are low and the lifetime expected credit loss allowance for trade receivables is nominal as at January 1, 2018 and December 31, 2018. Accordingly, the Company did not record an adjustment relating to the implementation of the expected credit loss model for trade receivables.

IFRS 15 – Revenue from contracts with customers

The Company adopted IFRS 15 on January 1, 2018 in accordance with the transitional provisions of the standard.
The IASB issued IFRS 15 Revenue from Contracts with Customers, a new standard for the recognition of revenue, which replaces IAS 18 Revenue, IAS 11 Construction Contracts, and related interpretations. IFRS 15 is effective for annual

periods beginning on or after January 1, 2018. The new standard is based on the principle that revenue is recognized when control of a good or service transfers to a customer.

The standard is required to be adopted either retrospectively or using a modified retrospective approach. In accordance with the transition provisions in IFRS 15, the Company has adopted the new standard using the modified retrospective method; the cumulative effect of initially applying the standard is recognized as an adjustment to the opening balance of retained earnings as of January 1, 2018. Comparative prior year periods are not restated. The adoption of IFRS 15 did not result in any changes in the timing of revenue recognition for the Company's goods and services and therefore no adjustment to opening retained earnings was necessary.

Accounting standard issued and effective January 1, 2019

IFRS 16 - Leases

IFRS 16 Leases will replace IAS 17 Leases. IFRS 16 eliminates the classification of leases as either operating leases or finance leases for a lessee. Instead, all leases are treated in a similar way to finance leases applying IAS 17. Leases are 'capitalized' by recognizing the present value of the lease payments and showing them either as lease assets (right-of-use assets) or together with property, plant and equipment. If lease payments are made overtime, a company will also recognize a financial liability representing its obligation to make future lease payments. The IASB has set the effective date to annual periods beginning on or after January 1, 2019. The Company has not early adopted this standard and is currently evaluating any potential impact.

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.

IFRIC 23 – Uncertainty over Income Tax Treatments

In June 2017, the IASB issued IFRIC 23, Uncertainty over Income Tax Treatments. This interpretation specifies that if an entity concludes it is probable that the taxation authority will accept an uncertain tax treatment, it shall determine the tax result consistently with the tax treatment used or planned to be used in its income tax filing. If it is not probable, the entity shall reflect the effect of uncertainty for each uncertain tax treatment by using either of the following methods, depending on which one the entity expects to better predict the resolution of the uncertainty:

- Most likely amount: single most likely amount in a range of possible outcomes;
- Expected value: sum of the probability-weighted amounts in a range of possible outcomes.

An entity shall apply IFRIC 23 for annual reporting periods beginning on or after January 1, 2019 with earlier application permitted. The Company will not early adopt IFRIC 23 and does not expect a significant impact.

FINANCIAL INSTRUMENTS

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

FINANCIAL RISK MANAGEMENT

(a) Foreign exchange risk

A portion of the Company's revenues are derived from product sales in Europe, denominated in Euros. Management has considered the stability of the foreign currency and the impact a change in the exchange rate may have on future earnings during the forecasting process. The Euro represents approximately 23% of the revenue for the year ended December 31, 2018 (year ended December 2017 and 2016: 65% and 38%, respectively). A 10% change in the foreign exchange rates for the Euro for foreign currency denominated accounts receivable will impact net income as at December 31, 2018 by approximately $6,000 (as at December 31, 2017 and 2016: $50,000 and $49,000, respectively), and a similar change in foreign currency denominated accounts payable, which are denominated in Canadian dollars and Euros, will impact net income by approximately $13,000 and $30,000, respectively, as at December 31, 2018 (as at December 31, 2017 and 2016, $32,000 and $10,000, respectively). The Company does not hedge its foreign exchange risk.

(b) Interest rate risk

The Company is not exposed to material cash flow interest rate risk on fixed rate cash balances, and short-term accounts receivable.

(c) Liquidity risk

As at December 31, 2018, the Company had $9,242,809 in cash and cash equivalents as compared to cash and cash equivalents of $17,507,157 and $22,954,571 at December 31, 2017 and 2016, respectively. 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. After receipt of the net proceeds of approximately $4.05 million from the February 2019 Financing on February 28, 2019 and the net proceeds of approximately $4.25 million from the March 2019 Financing on March 15, 2019, the Company expects that its cash is sufficient to sustain operations until approximately September 2019 at the current burn rate. 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.

(e) 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, 2018 is $637,421 (as at December 31, 2017 and 2016: $1,201,292 and $2,532,114, respectively). As at December 31, 2018, the Company had $311,642 (as at December 31, 2017 and 2016: $588,282 and $1,555,469, respectively) of trade accounts receivable that were overdue, according to the customers' credit terms. During the year ended December 31, 2018 the Company wrote down $489,449 of accounts receivable owed by customers (year ended December 2017 and 2016: $26,931 and $5,556, respectively).

The Company may also have credit risk related to its cash and cash equivalents and restricted cash, with a maximum exposure of $9,682,545 as at December 31, 2018 (as at December 31, 2017 and 2016: $17,985,417 and $93,404,331, respectively). 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 PROCEDURES AND INTERNAL CONTROL OF FINANCIAL REPORTING

The Company's management, under the supervision of the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), has designed disclosure controls and procedures ("DC&P") and internal control over financial reporting, based on the *Internal Control – Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). DC&P are defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") as those controls and procedures designed to ensure that information required to be disclosed in the annual filings and interim filings and other reports filed or submitted by the Company under the Exchange Act is duly recorded, processed, summarized and reported, within the time periods specified in rules and forms of the SEC.

DC&P are designed to provide reasonable assurance that material information relating to the Company is made known to the CEO and CFO during the reporting period and the information required to be disclosed by the Company is recorded, processed, summarized and reported in a timely and appropriate manner. ICFR is designed to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with international financial reporting standards. Due to the inherent limitations associated with any such controls and procedures, management recognizes that, no matter how well designed and operated, they may not prevent or detect misstatements on a timely basis.

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 as at December 31, 2018.

The Company's management, under the supervision of the CEO and CFO, has evaluated both the design and operating effectiveness of its DC&P and ICFR and concluded that a material weakness in ICFR occurred during the quarter ending September 30, 2018 as detailed below.

A material weakness is a significant deficiency, or combination of significant deficiencies, that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will occur and not be detected by management before the financial statements are published. Controls can potentially be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based on part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In light of the aforementioned material weakness, management conducted a thorough review of all non-routine agreements for the year ended December 31, 2018. As a result of this review, management believes that there are no material inaccuracies or omissions of material fact and, to the best its knowledge, believes that the consolidated financial statements for the year ended December 31, 2018 fairly present in all material respects and financial condition and results of operations for the Company in conformity with international financial reporting standards.

Material Weakness in ICFR

On August 3, 2018 the Company entered into the Penn Agreement with Penn. This was a non-routine agreement and there was a material weakness in the ICFR such that the future payments to be made under the Penn Agreement were not correctly accounted for. As this was a non-routine transaction there was no specific control in place to review the Penn Agreement for potential future liabilities. The future payments committed to in the Penn Agreement were approved by the board and senior management, but the liability was not recorded in the quarter ended September 30, 2019 as there was no control in place to ensure this happened. In the condensed interim consolidated financial statements for the nine months ended September 30, 2018, the Company correctly recorded the first payment paid to Penn in the period, but did not accrue for the fair value of the future payments contractually agreed to in the Penn Agreement.

Prior to the filing of the annual report on Form 20-F, the consolidated financial statements and the management discussion and analysis for the year ended December 31, 2018, the Penn Agreement was further reviewed, the material weakness in the controls was identified and the Company filed amended and restated condensed interim consolidated financial statements and management discussion and analysis for the three and nine months ended September 30, 2018 on February 22, 2019. The impact of the amendment and restatement was to accrue for the fair value of the future payments contractually agreed to in the Penn Agreement increasing the loss for the period ended September 30, 2018 and the accrued liabilities as at September 30, 2018 by $1,379,790.

In its assessment of the effectiveness of ICFR as of December 31, 2018, the Company determined that there were control deficiencies that constituted a material weakness in ICFR relating to the accrual for the fair value of future payments under non-routine agreements. Due to this material weakness, management concluded that ICFR was not effective as of December 31, 2018.

Remediation for Material Weakness in ICFR

The Company has developed and implemented a remediation plan to address the material weakness described above. Specifically, the Company plans to increase the strength of design and operating effectiveness for internal control over non-routine agreements. The Company will also undertake the following actions to improve ICFR:

- Flag all non-routine agreements for senior management review to ensure that any potential future liabilities are identified and accrued during the period the agreement is signed.
- Deploy an internal control compliance program, in accordance with COSO, designed to identify potential deficiencies in DC&P and ICFR throughout the year ending December 31, 2019, to ensure that deficiencies are identified and remediated in a timely manner.
- Further mature DC&P and ICFR practices in addition to enhancing risk assessment, control design assessment and operating effectiveness testing practices throughout the year ending December 31, 2019.

ADDITIONAL INFORMATION

Additional information about the Company, including the Company's Financial Statements and Annual Report on Form 20-F, are available on SEDAR at www.sedar.com and on the website of the SEC at www.sec.gov.