



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

**FOR THE THREE AND NINE MONTHS ENDED  
SEPTEMBER 30 2018 AND 2017**

**Q3  
2018**

## MANAGEMENT'S DISCUSSION AND ANALYSIS

This Amended and Restated Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") covers the unaudited amended and restated condensed interim consolidated financial statements of Neovasc Inc. (the "Company", "Neovasc", "we", "us", or "our") for the three and nine months ended September 30, 2018 and 2017.

This amended and restated MD&A should be read in conjunction with the unaudited amended and restated condensed interim consolidated financial statements and notes thereto for the three and nine months ended September 30, 2018 and 2017 (included as part of Neovasc Inc.'s quarterly filing) as well as the audited consolidated financial statements and notes thereto and the MD&A for the years ended December 31, 2017, 2016 and 2015 and Annual Report on Form 20-F.

The Company has amended and restated the condensed interim financial statements for the three and nine months ended September 30, 2018 as the Company did not accrue for the future payments to be made under the terms of collaboration and settlement agreement with the University of Pennsylvania as press released on August 3, 2018. The impact of the adjustment is to accrue for \$1,379,790 of additional future collaboration and settlement payments in the current period increasing the loss for the period and the accrued liabilities as at September 30, 2018. Only information directly relating to this adjustment have been updated in this amended and restated MD&A as compared to the management's discussion and analysis previously filed.

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 (as defined below) on the basis of one post-consolidation Common Share for every one hundred preconsolidation Common Shares. All references in this amended and restated 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 Notes (as defined below) were not affected by the consolidation, but the Common Shares issuable upon exercise of the warrants or conversion of the Notes will be adjusted proportionally to the share consolidation ratio.

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](http://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](http://www.sec.gov).

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

This amended and restated 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", "strategy", "future", "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 amended and restated 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 estimates regarding our fully diluted share capital and future dilution to shareholders;
- 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 late 2020, assuming sufficient patients will have been enrolled with sufficient follow-up time by then;
- the anticipated timing of additional implantations in the TIARA-II trial and our intention to initiate additional investigational sites in 2018 as required approvals are obtained;
- our plans to develop and commercialize products, including the Tiara, and the timing and cost of these development programs;
- our plans to develop and commercialize the Tiara transfemoral trans-septal system, 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 and studies, in Canada, the United States and Europe;
- our ability to treat patients under compassionate use cases;
- 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 ability to attain faster access to the U.S. market for the Reducer through alternative regulatory strategies;
- our plans to increase Reducer implants in Europe in 2018;
- 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 goals to establish a lean and accountable organization with stable capitalization;
- our ability to meet our cash expenditure covenants;
- our creation of an effective direct sales and marketing infrastructure for approved products we elect to market and sell directly;
- the rate and degree of market acceptance of our products;
- the timing and amount of reimbursement for our products; and
- the impact of foreign currency exchange rates.

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

- the substantial doubt about our ability to continue as a going concern;
- risks relating to the warrants issued pursuant to the November 2017 underwritten public offering of 6,609,588 Series A units (the "Series A Units") of the Company and 19,066,780 Series B units (the "Series B Units" and together with the Series A Units, the "Units"), at a price of \$1.46 per Unit (the "2017 Public Transaction") and the warrants and senior secured convertible notes (the "Notes") issued pursuant to the November 2017 private placement (the "2017 Private Placement", and together with the 2017 Public Transaction, the "2017 Financings"), resulting in significant dilution to our shareholders;
- risks relating to our need for significant additional future capital and our ability to raise additional funding;
- risks relating to our negative operating cash flow and our ability to raise additional funds;

- risks relating to cashless exercise and adjustment provisions in the warrants (the “Warrants”) and Notes issued pursuant to the 2017 Financings, which could make it more difficult and expensive for us to raise additional capital in the future and result in further dilution to investors;
- risks relating to the sale of a significant number of common shares of the Company (“Common Shares”);
- risks relating to the exercise of Warrants or conversion of Notes issued pursuant to the 2017 Financings, which may encourage short sales by third parties;
- risks relating to the possibility that our Common Shares may be delisted from the Nasdaq Capital Market (“Nasdaq”) or the Toronto Stock Exchange (“TSX”), which could affect their market price and liquidity;
- risks relating to our Common Share price being volatile;
- risks relating to the influence of significant shareholders of the Company over our business operations and share price;
- risks relating to our significant indebtedness, and its 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;
- risks relating to 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;
- risks relating to 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;
- risks relating to 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;
- risks relating to our ability to maintain strong relationships with physicians;
- risks relating to the sufficiency of our management systems and resources in periods of significant growth;
- risks associated with consolidation in the health care industry, including the downward pressure on product pricing and the growing need to be selected by larger customers in order to make sales to their members or participants;
- risks relating to our ability to successfully identify and complete corporate transactions on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances;
- risks relating to our ability to successfully enter into fundamental transactions (“Fundamental Transactions”) as defined in the series C warrants issued pursuant to the 2017 Financings (the “Series C Warrants”);

- risks relating to 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 and reimbursement;
- 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 in the "Risk Factors" section in our Annual Report on Form 20-F, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and as filed with the SEC at [www.sec.gov](http://www.sec.gov). These factors should be considered carefully, and readers should not place undue reliance on the Company's forward-looking statements. Should one or more of these risks or uncertainties or a risk that is not currently known to us materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this amended and restated MD&A and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. Investors are cautioned that forward-looking statements are not guarantees of future performance and investors are cautioned not to put undue reliance on forward-looking statements due to their inherent uncertainty.

Date: Information contained in this amended and restated MD&A is based on the information available to the Company as of November 14, 2018

## **OVERVIEW**

### **Description of the Business**

Neovasc is a specialty medical device company that develops, manufactures and markets products for the rapidly growing cardiovascular marketplace. Its products include the Tiara technology in development for the transcatheter treatment of mitral valve disease and the Reducer for the treatment of refractory angina.

Neovasc's business operations started in March 2002, with the acquisition of Neovasc Medical Inc. ("NMI") (formerly PM Devices Inc.). NMI manufactured a line of collagen based surgical patch products. The products are made from chemically treated pericardial tissue. In 2012, the Company sold the rights to the surgical patch products to LeMaitre Vascular, Inc. ("LeMaitre"), but retained rights to the underlying tissue technology for all other uses.

In May 2003, Neovasc acquired Angiometrx Inc. ("ANG"). ANG developed a technology called the Metricath, a catheter-based device that allowed clinicians to measure artery and stent size and confirm deployment during interventional treatment of coronary and peripheral artery disease. In 2009, Neovasc ceased all activities related to Metricath and on January 1, 2015 ANG was amalgamated into NMI.

In July 2008, Neovasc acquired two pre-commercial vascular device companies based in Israel: Neovasc Medical Ltd. ("NML") and B-Balloon Ltd. ("BBL"). NML developed and owned intellectual property related to the Reducer, a novel catheter-based treatment for refractory angina, a debilitating condition resulting from inadequate blood flow to the heart muscle. In 2009, Neovasc ceased all activities related to BBL's technologies and is in the process of voluntarily liquidating BBL.

In late 2009, Neovasc started initial activities to develop novel technologies for the catheter-based treatment of mitral valve disease. Based on the positive results of these activities, the Company launched a program to develop the Tiara transcatheter mitral valve.

In late 2016, Neovasc sold its tissue processing technology and facility for \$67,909,800 to Boston Scientific Corporation ("Boston Scientific"), and concurrently, Boston Scientific invested an additional \$7,090,200 in Neovasc for a 15% equity interest in the Company investing \$7,090,200 for 118,170 Common Shares of Neovasc at a price of \$60 per Common Share.

Additionally, throughout the years 2014 to 2018, the Company announced a number of developments pertaining to litigation, all as more fully discussed under the heading "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein.

### **Product Portfolio**

#### **Tiara**

In 2009, Neovasc started initial activities to develop novel technologies for catheter-based treatment of mitral valve disease. In the second quarter of 2011, the Company formally initiated a new project to develop the Tiara, a product for treating mitral valve disease. The transapically delivered Tiara is 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.

To date, 63 patients have been implanted with Tiara in the TIARA-I Early Feasibility Clinical Study, compassionate use cases and in our TIARA-II CE Mark Clinical Study. Neovasc believes that early results have been encouraging. The 30-day survival rate for the 63 patients implanted with the Tiara (i.e. those implanted more than 30 days ago) is 53/59 or 90% with one patient now over four years post implant and five patients over two years post implant. The Tiara has been successfully implanted in both functional and degenerative Mitral Regurgitation patients, as well as in patients with pre-existing prosthetic aortic valves and mitral surgical annuloplasty rings.

On average the apical in/out procedure time for Tiara implants as of November 5, 2018 is approximately 20 minutes. The shortest procedure time was 8 minutes and the longest procedure time was 55 minutes.

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. The following table sets forth the results from our Tiara clinical trials as at the date hereof:

	<u>Tiara Since 2014</u>	<u>TIARA-I</u>	<u>TIARA-II</u>	<u>Compassionate Use</u>
<b>Treated</b>	63	21	20	22
<b>30 Day Survival rate</b>	90%	85%	94%	91%
(Patients who have reached the 30-day timepoint)	(53/59)	(17/20)	(16/17)	(20/22)

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. 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. The Company is currently activating several new investigational sites in multiple geographies. 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, which will support the additional sites, both from a patient screening support perspective as well as from a case support perspective.

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 are continuing small acute animal and bench studies to optimize system design and we plan to complete the design concept during Q1 of 2019.

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. 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 Tiara valve is made up of two major components: the leaflets which are made from the Peripatch 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 in-house by the Company using components that are readily available.

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 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.

### *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 October 9, 2014, Neovasc announced that it received conditional IDE approval from the FDA to initiate the U.S. arm of its TIARA-I feasibility study for the Tiara, followed by full approval on December 31, 2014. The TIARA-I study is a multinational, multicenter early feasibility study being conducted to assess the safety and performance of Neovasc’s Tiara mitral valve system and implantation procedure in high-risk surgical patients suffering from severe Mitral Regurgitation. Severe Mitral Regurgitation is a critical condition that affects millions of patients and, if left untreated, can lead to heart failure or death. This is an important step towards Tiara becoming one of the first transcatheter mitral valve replacement devices available for treating U.S. patients. The TIARA-I study will enroll up to 30 patients in the U.S., Canada and Belgium. and is being overseen by a multidisciplinary committee of internationally recognized physicians. The Tiara has also been implanted under compassionate use exemptions in Canada, Europe and Israel.

On November 28, 2016, the Company announced that it had received both regulatory and ethics committee approval to initiate the TIARA-II study in Italy. The TIARA-II study is a 115 patient, non-randomized, prospective clinical study intended to provide the clinical data required to support obtaining CE Mark approval for the Tiara, which would enable Neovasc to market the device in Europe. In May 2017, the Company received regulatory approval to initiate enrollment in its CE Mark study in Germany and in July 2017, the Company received regulatory approval to initiate enrollment in its CE Mark study in the UK. The Company currently has 13 activated centers: seven in Germany, four in Italy and two in the UK. We are currently planning on activating additional clinical sites in November and December in Israel, Germany, the Netherlands and Spain, as well as qualifying additional clinical sites to a maximum of 20 sites overall. The time period to initiate a new site in already approved countries has historically taken at least 3 months. The TIARA-II study is estimated to cost approximately \$15 million. The exact timing for completion of enrollment in the study is unknown at this time and is dependent on a number of factors, including screening rates, local regulatory approvals and our ability to raise sufficient additional capital to complete the TIARA-II study. Since enrollment is at a slower than expected rate, Neovasc is actively monitoring actual clinical enrollment performance and is evaluating opportunities for possible improvement in clinical enrollment performance. 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.



## 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.

Using a catheter-based procedure, the Reducer is implanted in the coronary sinus (the main vein draining blood from the heart muscle). The Reducer has been shown to relieve symptoms of angina by creating a focal narrowing and a backwards pressure elevation in the coronary sinus. The Reducer 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. We also refer the reader to publications: “Safety and efficacy of reducer: A multi-center clinical registry-REDUCE study, published in the *International Journal of Cardiology* 269 (2018) 40-44, and to a 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.

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 provides 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 Company has completed the randomized, sham controlled COSIRA trial to assess the safety and effectiveness of the Reducer device. The COSIRA trial's primary endpoint was a two-class improvement in Angina pain, six months after implantation in patients' ratings on the Canadian Cardiovascular Society (“CCS”) angina grading scale, a four-class functional classification that is widely used to characterize the severity of angina symptoms and disability. Only patients with severe angina, CCS Class 3 or 4, were enrolled in the COSIRA trial. The COSIRA trial analysis showed that the study met the primary endpoint, with patients receiving the Reducer achieving a statistically significant improvement in CCS scores (two classes or better) compared to patients receiving a sham control (18 of 52 (34.6%) of the Reducer patients improved  $\geq 2$  CCS classes compared to 8 of 52 (15.4%) of the control patients (p-value = 0.024)). The analysis also showed that patients treated with the Reducer showed a statistically significant improvement of one or more CCS classes compared to the sham control patients (37 of 52 (71.2%) of the Reducer patients showed this improvement compared to 22 of 52 (42.3%) of the control patients (p-value = 0.003)). The COSIRA trial results were published in the *New England Journal of Medicine* in February 2015.

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, 179 patients have been enrolled across 19 centers that are active in Italy, Germany, Belgium, Netherlands, United Kingdom and Switzerland.

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.

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 COSIRA trial — a multi-center, randomized, double-blind, sham-controlled study intended to assess the safety and efficacy of the Reducer in a rigorous, controlled manner was completed in 2013. The results of the COSIRA trial were positive and are discussed in more detail below. More recently, additional studies conducted by third parties and showing positive results from the Reducer implantations have been published and presented in medical forums. It is anticipated that as the commercial use of the Reducer continues to expand, additional third-party studies, investigations and presentations will be undertaken. If the results from such third-party activities continue to show positive results from the product they may provide additional data to support expanded adoption of the Reducer for the intended patient population. More recent studies and publications of Reducer patients have conformed closely with the results of the COSIRA trial. We refer the reader to the recent publication “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. Further, we refer the reader to a recent TCTMD publication, as well as a recent publication in EuroIntervention by Dr. Konigstein, et al., and a recent publication in the International Journal of Cardiology by Dr Giannini et al, on a multi-center clinical registry (REDUCE Study).

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 2018 and beyond. It is anticipated that sales of the product in the United States would follow obtaining U.S. regulatory approval, if such approval is granted, as described further below.

Based on achieving NUB 1 status in Germany and a general positive reception in the European market, with positive experiences by many physicians from the treatment of their own patients with the Reducer, we are seeing an increase in adoption of the Reducer therapy in Europe. The commercial progress for the Reducer in the third quarter of 2018 was encouraging with a 44% increase in revenue compared to the same time-period of 2017. The Reducer revenue for the first three quarters of 2018 increased 45% over the same time-period of 2017. More than 20 clinics in Germany have begun

and completed the reimbursement negotiations with the German health insurance companies and have now established a satisfactory overall reimbursement amount for the Reducer procedure (including the Reducer product at list price), while others are either in the negotiation process or will negotiate later this year, per pre-set negotiation cycles.

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 see a growing level of enthusiasm in Europe for the Reducer therapy and we believe that the therapy has a lot of 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. Spyrtanis 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 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.

### *Regulatory Status*

The Reducer is approved for sale in Europe, having received CE Mark designation in November 2011. In preparation for product launch, Neovasc has completed development of the commercial-generation Reducer and the product is currently 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. The Company is working closely with FDA through this process.

### **Tissue Products**

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

### **Product Development**

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

## **TRENDS, RISKS AND UNCERTAINTIES**

### **Losses and Additional Funding Requirements**

Neovasc has a limited operating history, which makes it difficult to predict how its business will develop or what its future operating results will be. The Company has a history of operating losses since its inception and will need to generate significantly greater revenues than it has to date to achieve and maintain profitability. There is no certainty of future profitability, and results of operations in future periods cannot be predicted based on results of operations in past periods. The securities of the Company should be considered a highly speculative investment.

The Company has incurred operating and comprehensive losses of \$9,650,593 and \$14,290,417 and \$22,157,097 and \$119,895,193 for the three and nine months ended September 30, 2018, respectively (2017: \$5,825,527 and \$5,807,836, and \$19,938,147 and \$19,832,651 for the comparative periods, respectively) and has a deficit of \$344,355,210 at September 30, 2018 compared to a deficit of \$224,692,327 as at December 31, 2017. As at September 30, 2018 the Company had \$14,487,483 in cash and cash equivalents (as at December 31, 2017: \$17,507,157).

The Company believes it 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.

The unaudited amended and restated condensed interim 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.

As at September 30, 2018, and incorporating the cash received subsequent to the period end, the Company had approximately \$14.49 million in cash and cash equivalents, sufficient cash for approximately eight months of operations at the current rate of expenditures. The Company will need to raise additional capital in the short or medium term. Given the current nature of the Company's capital structure 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](http://sedar.com) and as filed with the SEC at [www.sec.gov](http://www.sec.gov).

### **Litigation Matters**

Between June 2016 and November 2017, Neovasc was engaged in litigation with CardiAQ Valve Technologies Inc. ("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 warrants and conversion of the Notes issued pursuant to the 2017 Financings have already resulted in significant dilution to our shareholders and may result in further significant dilution in the future. For details concerning the terms of the securities issued pursuant to the 2017 Financings, see the prospectus supplement and the forms of such securities filed on SEDAR at [www.sedar.com](http://www.sedar.com) and filed with or furnished to the SEC at [www.sec.gov](http://www.sec.gov). For a description of the risks associated with these securities, the amount of such securities exercised to date, the dilution to date and the potential dilution in the future due to such exercises or conversions, see the Company's Annual Report on Form 20-F, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and as filed with the SEC at [www.sec.gov](http://www.sec.gov).

### **FOREIGN OPERATIONS**

The Company determined that its functional currency changed from the Canadian dollar to the US dollar effective October 1, 2017.

The majority of the Company's revenues are derived from product sales in the United States and Europe, primarily denominated in U.S. dollars and Euros, while the majority of the Company's costs are denominated in Canadian dollars. A decrease in the value of the Euro in relation to the U.S. dollar will have an adverse effect on the Company's results of operations, with lower than expected revenue amounts and gross margins being reported in the Company's U.S. dollar financial statements. In addition, any decrease in the value of the Euro occurring in between the time a sale is consummated and the time payment is received by Neovasc will lead to a foreign exchange loss being recognized on the foreign currency denominated trade account receivable. The fluctuation of foreign exchange may impose an adverse effect on the Company's results of operations and cash flows in the future. The Company does not conduct any hedging activities to mitigate these foreign exchange risks. Additionally, Neovasc may be materially and adversely affected by increases in duty rates, exchange or price controls, repatriation restrictions, or other restrictions on foreign currencies. The Company's international operations are subject to certain other risks common to international operations, including, without limitation: government regulations; import restrictions and, in certain jurisdictions, reduced protection for the Company's intellectual property rights.

Foreign currency translation gains and losses arising from normal business operations are credited to or charged to operations in the period incurred. To date, Neovasc has not entered into any foreign exchange forward contracts.

## SELECTED FINANCIAL INFORMATION

The following discussion should be read in conjunction with the unaudited amended and restated condensed interim consolidated financial statements for the three and nine months ended September 30, 2018 and 2017.

### DISCUSSION OF OPERATIONS AND FINANCIAL CONDITION

Results for the three months ended September 30, 2018 and 2017 follow:

#### Losses

The operating losses and comprehensive losses for the three months ended September 30, 2018 were \$9,650,593 and \$14,290,417 respectively, or \$0.78 basic and diluted loss per share, as compared with losses of \$5,825,527 and \$5,807,836, respectively, or \$5.95 basic and diluted loss per share, for the same period in 2017.

The \$8,482,581 increase in the comprehensive loss incurred for the three months ended September 30, 2018 compared to the same period in 2017 can be substantially explained by a \$6,405,644 increase in other losses (the accounting treatment of the 2017 Financings resulting in charges of \$5,026,218 in the quarter and a \$1,550,719 net reduction in foreign exchange gains received in the same quarter last year) and a \$4,476,445 increase in general and administrative expenses (including a \$1,406,822 increase in stock based compensation, as incentive grants were made during the quarter and a \$2,379,790 charge for collaboration and settlement expenses (see "Contingencies" below)) offset by a \$1,458,203 reduction in other comprehensive losses and a \$931,945 reduction in product development and clinical trials expenses as the Company continues to control costs.

#### Revenues

Revenues decreased 65% to \$480,540 for the three months ended September 30, 2018, compared to revenues of \$1,374,893 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 September 30, 2018 were \$480,540 compared to \$334,208 for the same period in 2017, representing an increase of 44%. 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 September 30, 2018 was \$96,743 compared to \$659,686 for the same period in 2017. The overall gross margin for the three months ended September 30, 2018 was 80%, compared to 52% 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 September 30, 2018 were \$10,034,390, compared to \$6,540,734 for the same period in 2017, representing an increase of \$3,493,656 or 53%. The increase in total expenses for the three months ended September 30, 2018 compared to the same period in 2017 can be substantially explained by a \$4,476,445 increase in general and administrative expenses due to a \$1,406,822 increase in stock based compensation, as incentive grants were made during the third quarter of 2018 and a \$2,379,790 charge for collaboration and settlement expenses (see "Contingencies" below) offset by a \$931,945 decrease in product development and clinical trial expenses as we continue to preserve cash resources.

Selling expenses for the three months ended September 30, 2018 were \$202,947, compared to \$253,791 for the same period in 2017, representing a decrease of \$50,844, or 20%. The decrease in selling expenses for the three months ended September 30, 2018 compared to the same period in 2017 reflects a decrease in costs incurred for commercialization

activities related to the Reducer as we have reduced our attendance at conferences during the quarter. The Company continues to minimize its selling expenses as the cash resources of the Company are still limited.

General and administrative expenses for the three months ended September 30, 2018 were \$6,340,747, compared to \$1,864,302 for the same period in 2017, representing an increase of \$4,476,445 or 240%. The increase in general and administrative expenses for the three months ended September 30, 2018 compared to the same period in 2017 can be substantially explained by a \$1,406,822 increase in share-based payments (as the option awards in 2018 were higher in quantity and value than in 2017), a \$2,379,790 increase in collaboration and settlement expenses, and a \$892,535 increase in other expense offset by a \$471,993 decrease in litigation expenses (as there are fewer ongoing litigation matters).

Product development and clinical trial expenses for the three months ended September 30, 2018 were \$3,490,696 compared to \$4,422,641 for the same period in 2017, representing a decrease of \$931,945 or 21%. The decrease in product development and clinical trial expenses for the three months ended September 30, 2018 was the result of a \$294,331 decrease in employee expenses due to restructuring of the Company and a \$481,747 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 three months ended September 30, 2018 was \$4,932,151 compared to other income of \$1,473,493 for the same period in 2017, an adverse change of \$6,405,644. The increase in the other loss can be substantially explained by the accounting treatment of the 2017 Financings resulting in charges of \$5,026,218 in the quarter and a \$1,550,719 net reduction in foreign exchange gains received in the same quarter last year.

### **Tax Expense**

The tax expense for the three months ended September 30, 2018 was \$54,000 compared to \$343,926 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.

Results for the nine months ended September 30, 2018 and 2017 follow:

### **Losses**

The operating losses and comprehensive losses for the nine months ended September 30, 2018 were \$22,157,097 and \$119,895,193 respectively, or \$10.59 basic and diluted loss per share, as compared with losses of \$19,938,147 and \$19,832,651, respectively, or \$22.68 basic and diluted loss per share, for the same period in 2017.

The \$100,062,542 increase in the comprehensive loss incurred for the nine months ended September 30, 2018 compared to the same period in 2017 can be substantially explained by the accounting treatment of the 2017 Financings resulting in charges of \$97,599,557 and a \$3,657,068 increase in general and administrative expenses (including a \$754,640 increase in stock based compensation, as incentive grants were made during the third quarter of 2018 and a \$2,379,790 charge for collaboration and settlement expenses (see "Contingencies" below)).

### **Revenues**

Revenues decreased 71% to \$1,225,709 for the nine months ended September 30, 2018, compared to revenues of \$4,161,389 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 nine months ended September 30, 2018 were \$1,225,709 compared to \$842,528 for the same period in 2017, representing an increase of 45%. 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 nine months ended September 30, 2018 was \$272,739 compared to \$2,341,017 for the same period in 2017. The overall gross margin for the nine months ended September 30, 2018 was 78%, compared to 44% gross margin for the same period in 2017. The gross margin now reflects the gross margin on the Reducer product only.

### **Expenses**

Total expenses for the nine months ended September 30, 2018 were \$23,110,067, compared to \$21,758,519 for the same period in 2017, representing an increase of \$1,351,548. The increase in total expenses for the nine months ended September 30, 2018 compared to the same period in 2017 reflects a \$3,657,068 increase in general and administrative expenses due to a \$754,640 increase in stock based compensation, as incentive grants were made during the third quarter of 2018, a \$793,704 charge for restructuring costs and a \$2,379,790 charge for collaboration and settlement expenses (see "Contingencies" below) offset by a \$2,378,602 decrease in product development and clinical trial expenses as we continue to preserve cash resources.

Selling expenses for the nine months ended September 30, 2018 were \$738,423, compared to \$665,341 for the same period in 2017, representing an increase of \$73,082 or 11%. The increase in selling expenses for the nine months ended September 30, 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 minimize its selling expenses as the cash resources of the Company are still limited.

General and administrative expenses for the nine months ended September 30, 2018 were \$11,023,302, compared to \$7,366,234 for the same period in 2017, representing an increase of \$3,657,068 or 50%. The increase in general and administrative expenses for the nine months ended September 30, 2018 compared to the same period in 2017 can be substantially explained by a \$754,640 increase in share-based payments (as the option awards in 2018 were higher in value than in 2017), a \$793,704 charge for employee termination expenses due to restructuring of the Company, a \$2,379,790 charge for collaboration and settlement expense, and a \$1,778,028 increase in other expenses (including a substantial increase in legal expenses as we renewed the base shelf prospectus, filed in XBRL for the first time and filed our annual report on the more demanding Form 20-F, as compare to the Form 40-F filed in 2017) offset by a \$1,770,240 decrease in litigation expenses (as there are fewer ongoing litigation matters), and a \$347,585 decrease in employee expenses due to restructuring of the Company.

Product development and clinical trial expenses for the nine months ended September 30, 2018 were \$11,348,342 compared to \$13,726,944 for the same period in 2017, representing a decrease of \$2,378,602 or 17%. The decrease in product development and clinical trial expenses for the nine months ended September 30, 2018 was the result of a \$886,936 decrease in share-based payments, a \$715,538 decrease in employee expenses due to restructuring of the Company and a \$649,658 decrease in other expenses, as the cash resources of the Company are still limited.

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 nine months ended September 30, 2018 was \$97,327,732 compared to income of \$2,514,718 for the same period in 2017, an adverse change of \$99,842,450. The increase in the other loss can be substantially explained by the accounting treatment of the 2017 Financings, which resulted in a \$97,599,557 increase in net loss between the comparative periods and a decrease in foreign exchange gains of \$2,916,129 compared to last year.

### **Tax Expense**

The tax expense for the nine months ended September 30, 2018 was \$178,054, compared to \$458,826 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.

## QUARTERLY INFORMATION

The following is a summary of selected unaudited financial information for the eight fiscal quarters to September 30, 2018:

	September 30, 2018 (as restated)	June 30, 2018	March 31, 2018	December 31, 2017
<b>REVENUE</b>				
Reducer	\$ 480,540	\$ 405,247	\$ 339,922	\$ 285,598
Contract manufacturing and consulting services	-	-	-	942,027
	480,540	405,247	339,922	1,227,625
<b>COST OF GOODS SOLD</b>	96,743	88,603	87,393	1,136,804
<b>GROSS PROFIT</b>	383,797	316,644	252,529	90,821
<b>EXPENSES</b>				
Selling expenses	202,947	248,538	286,938	220,885
General and administrative expenses	6,340,747	2,213,464	2,469,091	8,318,549
Product development and clinical trials expenses	3,490,696	3,858,254	3,999,391	3,762,148
	10,034,390	6,320,256	6,755,420	12,301,582
<b>OPERATING LOSS</b>	(9,650,593)	(6,003,612)	(6,502,891)	(12,210,761)
Other (expense)/income	(4,932,151)	(43,071,579)	(49,324,003)	7,209,897
Tax expense	(54,000)	(70,400)	(53,654)	(25,602)
<b>LOSS FOR THE PERIOD</b>	\$ (14,636,744)	\$ (49,145,591)	\$ (55,880,548)	\$ (5,026,466)
<b>BASIC AND DILUTED LOSS PER SHARE</b>	\$ (0.78)	\$ (3.66)	\$ (38.59)	\$ (6.17)
	September 30, 2017	June 30, 2017	March 31, 2017	December 31, 2016
<b>REVENUE</b>				
Reducer	\$ 334,208	\$ 247,555	\$ 260,765	\$ 282,515
Contract manufacturing and consulting services	1,040,685	1,057,581	1,220,595	2,478,607
	1,374,893	1,305,136	1,481,360	2,761,122
<b>COST OF GOODS SOLD</b>	659,686	872,703	808,628	2,052,969
<b>GROSS PROFIT</b>	715,207	432,433	672,732	708,153
<b>EXPENSES</b>				
Selling expenses	253,791	224,382	187,168	141,733
General and administrative expenses	1,864,302	2,253,219	3,248,713	2,461,433
Product development and clinical trials expenses	4,422,641	4,250,780	5,053,523	4,833,990
	6,540,734	6,728,381	8,489,404	7,437,156
<b>OPERATING LOSS</b>	(5,825,527)	(6,295,948)	(7,816,672)	(6,729,003)
Other income/(expense)	1,473,493	1,012,926	28,299	43,957,927
Tax expense	(343,926)	(58,286)	(56,614)	(15,133)
<b>PROFIT/(LOSS) FOR THE PERIOD</b>	\$ (4,695,960)	\$ (5,341,308)	\$ (7,844,987)	\$ 37,213,791
<b>BASIC AND DILUTED LOSS PER SHARE</b>	\$ (5.95)	\$ (6.78)	\$ (9.97)	\$ 54.16

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

Selling expenses are expected to generally increase as the Company initiates a focused commercialization of the Reducer in select countries in Europe. General and administrative expense reached a peak in the fourth quarter of 2017 due to expense related to completing the 2017 Financings. While we aim to increase product development and clinical trial activities quarter over quarter, we anticipate quarterly fluctuations depending on the activities conducted in that quarter to develop the Tiara and the Reducer, the Company has been resource constrained and has generally seen a decline in those expenses over the last quarters 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	\$16,599,104	\$1,400,896
<b>NET PROCEEDS</b>	<b>\$60,000,000</b>	<b>\$58,599,104</b>	<b>\$1,400,896</b>

In November 2017, Neovasc completed two financing transactions, the 2017 Public Transaction and the 2017 Private Placement, for aggregate gross proceeds of approximately \$65 million. The Company used the net proceeds of the 2017 Financings to fully fund the approximately \$42 million balance of the damages and interest awards in the case of *CardiAQ v. Neovasc Inc.* (after subtracting the approximately \$70 million that the Company had paid into escrow), with remaining funds being used (i) to partially fund the ongoing Tiara clinical program; (ii) to support the completion of the TIARA-II study; (iii) continue commercialization of the Reducer; and (iv) for general corporate purposes. In the nine months ended September 30, 2018, the Company recorded proceeds of \$13,086,587 from the exercise of Series C Warrants, which, combined with the remaining \$1,400,896 proceeds from the 2017 Financings, equals the cash on hand as at September 30, 2018.

## DISCUSSION OF LIQUIDITY AND CAPITAL RESOURCES

Results for the nine months ended September 30, 2018 and 2017 follow:

Neovasc finances its operations and capital expenditures with cash generated from operations and through equity and debt financings. As at September 30, 2018 the Company had cash and cash equivalents of \$14,487,483 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 \$10,879,816, with current assets of \$15,972,965 and current liabilities of \$5,093,149. However, of the current liabilities, only \$4,119,223 are cash liabilities, the liability for the convertible Notes and the derivative liability from the 2017 Financings are accounting entries to account for the value of the instruments issued in the 2017 Financings. 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 nine months ended September 30, 2018 was \$16,822,109, compared to \$14,242,747 for the same period in 2017. For the nine months ended September 30, 2018, operating expenses were \$17,729,515, compared to \$14,627,842 for the same period in 2017, an increase of \$3,101,673 that can be explained by a \$2,379,790 charge for collaboration and settlement expenses in 2018 (see 'Contingencies' below) and a \$867,402 reduction in gross profit as the Company ended its contract manufacturing and consulting services at the end of 2017. Net cash provided from the net change in non-cash working capital items for the nine months ended September 30, 2018 was \$938,010, compared to a net cash outflow of \$462,544 in the same period in 2017. The increase in net cash inflow can be attributed to a change in the balance sheet structure as the Company closed its consulting services and contract manufacturing businesses.

Net cash received from investing activities for the nine months ended September 30, 2018 was \$715,848 compared to net cash applied to investing activities of \$767,372 for the same period in 2017, primarily due to the receipt of proceeds from the sale of assets of \$865,610, and a \$282,214 decrease in purchase of property, plant and equipment, as there is still a requirement to preserve cash resources in 2018.

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 September 30, 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 \$821,665 of its cash and cash equivalents and restricted cash held in Canadian dollars and Euros.

## Financing

In November 2017, Neovasc completed two financing transactions, the 2017 Public Transaction and the 2017 Private Placement, for aggregate gross proceeds of approximately \$65 million. The Company used the net proceeds of the 2017 Financings to fully fund the approximately \$42 million balance of the damages and interest awards in the case of *CardiAQ v. Neovasc Inc.* (after subtracting the approximately \$70 million that the Company had paid into escrow), with remaining funds being used (i) to partially fund the ongoing Tiara clinical program; (ii) to support the completion of the TIARA-II study; and (iii) for general corporate purposes. Consistent with the rest of this MD&A, the descriptions that follow have been retroactively adjusted to reflect the share consolidation effected by the Company on September 18, 2018.

On November 9, 2017, the Company priced the underwritten 2017 Public Transaction of 6,609,588 Series A Units and 19,066,780 Series B Units, 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) 0.01 common share of the Company (each, a "Unit Share"), (ii) one Series A common share purchase warrant of the Company (each, a "Series A Warrant"), (iii) one Series B common share purchase warrant of the Company (each, a "Series B Warrant") and (iv) 0.40 Series C Warrant to purchase 0.01 units (each, a "Series C Unit") with each whole 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 0.01 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 0.01 Common Share (each, a "Series A Warrant Share") at an exercise price of \$161 per Series A Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2022. Each Series B Warrant entitles the holder to purchase 0.01 Common Share (each, a "Series B Warrant Share") at an exercise price of \$161 per Series B Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2019. As a result of the share consolidation completed on September 18, 2018, the exercise prices of the Series A Warrants and Series B Warrants was adjusted to \$2.4334 per Series A Warrant Share and Series B Warrant Share, respectively. Each Series C Warrant entitles the holder to purchase a Series C Unit comprised of 0.01 Common Shares (each a "Series C Unit Share"), Series A Warrants and Series B Warrants, 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. As a result of the share consolidation completed on September 18, 2018, the exercise price of the Series C Warrants was adjusted to \$1.46 per Series C Unit. Each Series D Warrant entitled the holder to purchase 0.01 Common Share (each, a "Series D Warrant Share") at an exercise price of \$146 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 0.01 Common Share (each, a "Series F Warrant Share" and together with the Series A Warrant Shares, Series B Warrant Shares, Series C Unit Shares, and Series D Warrant Shares, the "Warrant Shares") at an exercise price of \$161 per Series F Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2019. No Series D Warrants or Series F Warrants remain outstanding as at May 10, 2018. The Warrants are subject to adjustment, at any time prior to their expiry. The exercise price of the Series A Warrants and Series B Warrants are subject to full ratchet anti-dilution adjustment in certain circumstances. If a registration statement covering the issuance or resale of the Warrant Shares is not available for the issuance or resale of such Warrant Shares, each Series A Warrant and Series B Warrant may be exercised on a "net" or "cashless" basis. Each Series B Warrant may be exercised on an alternate net number basis, as described in the prospectus supplement and the forms of such securities filed on SEDAR at [www.sedar.com](http://www.sedar.com) and furnished to the SEC at [www.sec.gov](http://www.sec.gov).

Concurrent with the 2017 Public Transaction, the Company completed the 2017 Private Placement for the sale of \$32,750,000 aggregate principal amount of the Notes of the Company and series E warrants (the "Series E Warrants") to purchase 0.01 Common Share at a price of \$161 per Common Share (each, a "Series E Warrant Share"). The Series E Warrants have the same terms and conditions as the Series A Warrants. As a result of the share consolidation completed on September 18, 2018, the exercise price of the Series E Warrants was adjusted to \$2.4334 per Series E Warrant Share. As at November 12, 2018, \$8,685,000 aggregate principle amount of Notes remain outstanding. The Notes were issued with an original issue price of \$850 per \$1,000 principal amount of note. The Notes have an 18-month term and carry an interest rate of 0.0% per annum (increasing to 15% upon an event of default) from November 17, 2018. Interest on the Notes will commence accruing on November 17, 2018, will be computed on the basis of a 360-day year and twelve 30-

day months and will be payable in cash on January 1, 2018 and on the first day of each calendar quarter thereafter up to, and including, the maturity date.

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

For a description of the terms of the securities issued pursuant to the 2017 Financings, see the prospectus supplement and the forms of such securities filed on SEDAR at [www.sedar.com](http://www.sedar.com) and with the SEC at [www.sec.gov](http://www.sec.gov). For a description of the risks associated with these securities, the amount of such securities exercised to date, the dilution to date and potential dilution in the future due to such exercises or conversions, see the Company's Annual Report on Form 20-F, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and as file with the SEC at [www.sec.gov](http://www.sec.gov).

## **SUBSEQUENT EVENTS**

On October 9, 2018, following the implementation of the Company's share consolidation, the Company regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq and was in compliance with all other applicable continued listing requirements. The Nasdaq Listing Panel determined to continue the listing of the Company's Common Shares on the Nasdaq.

On October 10, 2018, the U.S. Food and Drug Administration (the "FDA") granted Breakthrough Device designation to the Reducer. The FDA grants Breakthrough Device 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. To qualify as a Breakthrough Device, there must either be no FDA approved treatments presently available, or the technology must offer significant advantages over existing approved alternatives.

## **WARRANT EXERCISES**

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

As of November 12, 2018, all of the 25,676,368 Series B Warrants initially granted have been exercised using the cashless alternative net number mechanism for 8,481,220 Common Shares and all of the 22,431,506 Series F Warrants initially granted have been exercised using the cashless alternate net number mechanism for 2,957,397 Common Shares.

As of November 12, 2018, of the 10,273,972 Series C Warrants initially granted, 9,451,780 have been exercised for 94,518 Common Shares, 9,451,780 Series A Warrants and 9,451,780 Series B Warrants. None of the 9,451,780 underlying Series A Warrants have been exercised and all of the 9,451,780 underlying Series B Warrants have been exercised using the cashless alternate net number mechanism for 5,031,586 Common Shares.

As of November 12, 2018, cumulatively there were 35,128,148 Series A Warrants, 822,192 Series C Warrants and 22,431,506 Series E Warrants outstanding. The exercise rights on these warrants have been adjusted by the share consolidation and on a post-consolidation basis can only be exercised for 1/100<sup>th</sup> of the original rights of each warrant to purchase Common Shares. For a description of the risks associated with the securities issued pursuant to the 2017 Financings, the amount of such securities exercised to date, the dilution to date, and the potential dilution in the future due to such exercises or conversions, see the Company's Annual Report on Form 20-F, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and as filed with the SEC at [www.sec.gov](http://www.sec.gov).

## **OUTSTANDING SHARE DATA**

As at November 12, 2018, the Company had 24,978,892 common voting shares issued and outstanding. Further, the following securities are convertible into Common Shares: 2,801,137 stock options with a weighted average price of \$2.10, 58,381,846 warrants and \$17,510,000 principal amount of Notes, which could convert into 7,663,953 Common Shares (not taking into account the alternate conversion price mechanism). Our fully diluted share capital as of the same date is 34,546,872. Our fully diluted share capital, adjusted on the assumption that all the issuable Series B Warrants are exercised

using the cashless alternative net number mechanism and the outstanding Notes are exercised using the alternate conversion price at the closing price on November 12, 2018 is 37,717,535.

## **CONTRACTUAL OBLIGATIONS AND CONTINGENCIES**

### ***Contingencies***

#### **Litigation with CardiAQ**

The Company is engaged as a defendant and appellant in lawsuits involving Valve Technologies Inc. (“CardiAQ”), as further described below. Litigation resulting from CardiAQ’s claims has been, and is expected to be, costly and time-consuming and could divert the attention of management and key personnel from our business operations. Although we intend to vigorously defend ourselves against the remaining claims, we cannot assure that we will succeed in appealing and defending any of these claims and that judgments will not be upheld against us. If we are unsuccessful in our appeal and defense of these claims or unable to settle the claims in a manner satisfactory to us, we may be faced with significant loss of intellectual property rights that could have a material adverse effect on the Company and its financial condition.

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

On June 23, 2014, CardiAQ 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.

#### **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 December 27, 2018 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 (the “Appeals Court”). This litigation concerned intellectual property rights ownership, unfair trade practices and breach of contract relating to Neovasc’s transcatheter mitral valve technology, including the Tiara. Following a trial in Boston, Massachusetts, a jury found in favor of CardiAQ and awarded \$70 million on the trade secret claim for relief, and no damages on the contractual claims for relief.

The Court later awarded CardiAQ \$21 million in enhanced damages on the trade secret claim for relief and \$20,675,154 in pre-judgment interest and \$2,354 per day in post judgment interest from November 21, 2016. Neovasc and CardiAQ each appealed on various grounds, and on September 1, 2017, the Appeals Court affirmed the trial court judgment against Neovasc, and denied CardiAQ’s cross appeal. On November 13, 2017, the final mandate was issued by the Appeals Court and approximately \$70 million was released from escrow to CardiAQ to partially settle approximately \$112 million damages and interest awards. Upon closing of the 2017 Financings on November 17, 2017, the Company used approximately \$42 million from the \$65 million net proceeds of the 2017 Financings to settle the remaining damages and interest awards.

## Other Matters

By way of Amended Statement of Claim in Federal Court of Canada Action T-1831-16 (the “Action”) Neovasc Inc. and Neovasc Medical Inc. (the “Neovasc Defendants”) were added as defendants to an existing action commenced by Edwards Lifesciences PVT, Inc. and Edwards Lifesciences (Canada) Inc. (collectively the “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 Plaintiffs that the manufacturing, assembly, use, sale and export of the Lotus Aortic Valve devices by the BSC/Livanova Defendants infringes on the Plaintiffs’ patents. In February 2017, the Neovasc Defendants were added to the Plaintiffs’ claim making related allegations. In summary, the Plaintiffs make three types of allegations as against the Neovasc Defendants: (a) indirect infringement claims; (b) direct infringement claims; and (c) claims of inducement. The plaintiffs seek various declarations, injunctions and unspecified damages and costs. The Neovasc Defendants filed their Statement of Defence in November 2017. The other defendants filed their Statement of Defence and Counterclaim against the Plaintiffs on April 30, 2018. The Neovasc Defendants intend to vigorously defend themselves against the Plaintiff’s claims.

On September 7, 2018, Endovalve Inc. and Micro Interventional Devices, Inc. (collectively “Endovalve”) filed a Complaint in the United States District Court for the District of New Jersey against Neovasc Inc. and Neovasc Tiara Inc. (the “Neovasc Defendants”), alleging claims for trade secret misappropriation, breach of contract, and unfair competition. Endovalve alleges 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 seeks injunctive relief, money damages, and attorneys’ fees. Endovalve has not served the Complaint and therefore no response is due in court at this time. If the Complaint is served, the Neovasc Defendants intend to vigorously defend themselves against Endovalve’s claims.

Following the investigation into a potential claim involving another party’s intellectual property rights, the Company conducted settlement discussions and reached a mutually-agreed upon license and collaboration agreement in August 2018. See the Material Change Report, License and Collaboration Agreement and Side Letter filed on SEDAR at [www.sedar.com](http://www.sedar.com) and furnished to the SEC on Form 6-K at [www.sec.gov](http://www.sec.gov) on August 3, 2018.

## Contractual obligations

The following table summarizes our contractual obligations as at September 30, 2018:

Contractual Obligations	Total	Less than 1 year	2-3 years	4-5 years
Operating leases	\$1,542,370	\$489,014	\$881,272	\$172,084

## OFF BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

## RELATED PARTY TRANSACTIONS

There were no ongoing contractual commitments and transactions with related parties during the three and nine months ended September 30, 2018 or 2017, other than those as described elsewhere herein and those compensation-based payments disclosed in Note 20 of the unaudited amended and restated condensed interim consolidated financial statements for the nine months ended September 30, 2018 and 2017.

## 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](http://www.sedar.com) and as filed with the SEC at [www.sec.gov](http://www.sec.gov). Investors are urged to consult and carefully consider these risk factors as an investment in the securities of the Company should be considered a highly speculative investment.

## CRITICAL ACCOUNTING ESTIMATES AND MANAGEMENT JUDGMENT

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

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

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

#### *Inventories*

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

#### *Allowance for doubtful accounts receivable*

The Company provides for bad debts by setting aside accounts receivable past due more than 121 days unless circumstances suggest collectability is assured. Actual collectability of customer balances can vary from the Company's estimation.

#### *Impairment of long-lived assets*

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

#### *Useful lives of depreciable assets*

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

#### *Share-based payment*

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

#### *Determination of functional currency*

The Company determines its functional currency based on the primary economic environment in which it operates. IAS 21 The Effects of Changes in Foreign Exchange Rates outlines a number of factors to apply in determining the functional currency, which is subject to significant judgment by management. Management uses a number of factors to determine the primary economic environment in which the Company operates; it is normally the one in which it primarily generates and expends cash.

#### *Deferred tax assets*

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

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

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

The Warrants and the Notes will be measured at fair value through profit and loss at each period end. The calculations of the fair value of these instruments involves the use of a number of estimates and a complex valuation model. The carrying amounts of these liabilities may change significantly as a result of changes to these estimates. Details of the estimates used as at December 31, 2017 are disclosed in Note 13 to the amended and restated condensed interim consolidated financial statements.

**CHANGES IN ACCOUNTING POLICIES INCLUDING INITIAL ADOPTION**

During the nine months ended September 30, 2018, there have been no changes in accounting policies, except as disclosed herein. The Company has adopted IFRS 9 Financial Instruments and IFRS 15 Revenue from Contracts with Customers during the nine months ended September 30, 2018.

**CHANGES IN ACCOUNTING PRONOUNCEMENTS**

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 have 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)
<b>Financial assets:</b>		
Cash and cash equivalents, cash held in escrow	Amortized cost	Amortized cost
Trade receivables	Amortized cost	Amortized cost
<b>Financial liabilities:</b>		
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 \$232,310 for the nine months ended September 30, 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 September 30, 2018. Accordingly, the Company did not record an adjustment relating to the implementation of the expected credit loss model for trade receivables.

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.

Effective January 1, 2018, upon adoption of IFRS 15 Revenue from Contracts with Customers, the Company recognizes revenue for services rendered when the performance obligations have been completed, for example, when control of the services transfer to the customer, when the services performed have been accepted by the customer, and when collectability is reasonably assured. The consideration for services rendered is measured at the fair value of the consideration received and allocated based on the Company's standalone selling prices. The standalone selling prices are determined based on the agreed upon list prices at which the Company sells its services in separate transactions. Payment terms with customers vary by country and contract. Standard payment terms are 30 days from invoice date.

Revenue for the sale of the Reducer is recognized when control or ownership of the product is transferred to the customer and collectability is reasonably assured.

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.

## FINANCIAL INSTRUMENTS

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

## FINANCIAL RISK MANAGEMENT

### (a) Fair value estimation

The fair value hierarchy establishes three levels to classify fair value measurements based upon the observability of significant inputs used in the valuation techniques. The three levels of the fair value hierarchy are described below:

Level 1 | Quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 | Inputs other than quoted prices included in level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices)

Level 3 | Inputs for the assets or liability that are not based on observable market data (that is, unobservable inputs)

The following table sets forth the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as at September 30, 2018 and December 31, 2017. As required by IFRS 13, assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

As at September 30, 2018:

	Level 1	Level 2	Level 3	Total
<b>Financial liabilities at fair value through profit and loss</b>				
Convertible Note	\$ -	\$ -	\$ 28,512,950	\$ 28,512,950
Derivative financial liabilities	\$ -	\$ -	\$ 817,222	\$ 817,222

The carrying amounts of financial assets and financial liabilities in each category are as follows:

	Note	September 30, 2018	December 31, 2017
<b>Loans and receivables</b>			
Cash and cash equivalents	6	\$ 14,487,483	\$ 17,507,157
Accounts receivable	7	802,368	1,334,923
Restricted cash	10	464,306	478,260
		<b>\$ 15,754,157</b>	<b>\$ 19,320,340</b>
<b>Other financial liabilities</b>			
Accounts payable and accrued liabilities (as restated)	12	\$ 4,119,223	\$ 1,844,955
<b>Financial liabilities at fair value through profit and loss</b>			
Convertible Note (current)	13	\$ 645,943	\$ 19,997,345
Derivative liability from financing (current)	13	327,983	4,261,597
Convertible Note (non-current)	13	27,867,007	16,831,685
Derivative liability from financing (non-current)	13	489,239	15,745,962
		<b>\$ 33,449,395</b>	<b>\$ 58,681,544</b>

The carrying amounts of cash and cash equivalents, accounts receivable, restricted cash and accounts payable and accrued liabilities are considered a reasonable approximation of fair value due to their short-term nature.

## **(b) 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 22% of the revenue for the nine months ended September 30, 2018 (nine months ended September 2017: U.S. dollar and Euro: 37% and 63%, respectively). A 10% change in the foreign exchange rates for the Euro for foreign currency denominated accounts receivable will impact net income as at September 30, 2018 by approximately \$10,967 (as at September 30, 2017: U.S. dollar and Euro: \$65,000 and \$65,000), and a similar change in foreign currency denominated accounts payable, which are denominated in Canadian dollars and Euros will impact net income by approximately \$22,482 and \$41,711 as at September 30, 2018 (as at September 30, 2017, U.S. dollar and Euro: \$7,000 and \$109,000). The Company does not hedge its foreign exchange risk.

## **(c) 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.

## **(d) Liquidity risk**

As at September 30, 2018, the Company had \$14,487,483 in cash and cash equivalents as compared to cash and cash equivalents of \$17,507,157 at December 31, 2017. The Company is dependent on the profitable commercialization of its products or obtaining additional debt or equity financing to fund ongoing operations until profitability is achieved.

The Company monitors its cash flow on a monthly basis and compares actual performance to the budget for the period. The Company believes it has sufficient funds to fund operations for approximately at least the next eight months 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 September 30, 2018 is \$801,530 (as at December 31, 2017: \$1,201,292). As at September 30, 2018, the Company had \$303,200 (as at December 31, 2017: \$588,282) of trade accounts receivable that were overdue, according to the customers' credit terms. During the three and nine months ended September 30, 2018 the Company wrote down \$489,449 and \$nil respectively, of accounts receivable owed by customers (three and nine months ended September 2017: \$nil and \$40,000, respectively).

The Company may also have credit risk related to its cash and cash equivalents and restricted cash, with a maximum exposure of \$14,951,789 as at September 30, 2018 (as at December 31, 2017: \$17,985,417). The Company minimizes its risk to cash and cash equivalents by maintaining the majority of its cash and cash equivalents with Canadian Chartered Banks.

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

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

To design its ICFR, the Company used the 2013 Internal Control – Integrated Framework (COSO Framework) published by the Committee of Sponsoring Organizations of the Treadway Commission. Due to inherent limitations, ICFR may not prevent or detect misstatements. Because the Company is an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012, the Company will not be required to comply with the auditor attestation requirements of the U.S. Sarbanes-Oxley Act of 2002 for as long as the Company remains an "emerging growth company", which may be for as long as five years following its initial registration in the United States.

There have been no material changes in our DC&P and ICFR during the three months ended September 30, 2018, that have materially affected, or are reasonably likely to affect our DC&P and ICFR.

### **ADDITIONAL INFORMATION**

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