Neovasc Inc.
Management's Discussion and Analysis

FOR THE YEARS ENDED
DECEMBER 31 2019, 2018 AND 2017

(Expressed in U.S. Dollars)

Q4
2019

MANAGEMENT'S DISCUSSION AND ANALYSIS

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") covers the consolidated financial statements of Neovasc Inc. (the "Company", "Neovasc", "we", "us", or "our") for the years ended December 31, 2019, 2018 and 2017 and should read in conjunction with the consolidated financial statements and notes thereto for the years ended December 31, 2019, 2018 and 2017 (included as part of Neovasc's annual filing).

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

The names Tiara™ ("Tiara"), and Neovasc Reducer™ ("Reducer") are our trademarks; other trademarks, product names and company names appearing herein are the property of their respective owners.

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

On September 18, 2018, the Company effected a share consolidation (reverse stock split) of its issued and outstanding common shares in the capital of the Company (the "Common Shares") on the basis of one post-consolidation Common Share for every one hundred pre-consolidation Common Shares. On June 25, 2019, the Company effected a share consolidation (reverse stock split) of its issued and outstanding Common Shares on the basis of one post-consolidation Common Share for every ten pre-consolidation Common Shares. All references in this MD&A to Common Shares and options have been retroactively adjusted to reflect the share consolidations. The number of warrants and aggregate principle amount of the notes outstanding were not affected by the consolidations, but the Common Shares issuable upon exercise of the warrants or conversion of the notes have been and will be adjusted in accordance with the adjustment provisions in such warrants or notes, as applicable.

Additional information about the Company, including the Company's consolidated financial statements and Annual Report on Form 20-F, is available on SEDAR at www.sedar.com and as filed with the U.S. Securities and Exchange Commission (the "SEC") on the website of the SEC at www.sec.gov.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS

This MD&A contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and applicable Canadian securities laws. The words "expect", "anticipate", "plan", "may", "will", "estimate", "continue", "intend", "believe", "target", "potential", "seek", "explore" and other similar words or expressions are intended to identify such forward-looking statements. Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as the factors we believe are appropriate. Forward-looking statements in this MD&A include, but are not limited to, statements relating to:

- our ability to continue as a going concern;
- our need for significant additional financing and our estimates regarding our capital requirements and future revenues, expenses and profitability;
- our intended use of the net proceeds from the May 2019 private placement offering of secured convertible debentures and Common Shares (the "May 2019 Financing);
- our intended use of the net proceeds from the January 2020 registered direct offering of series A and series B units (the "January 2020 Financing");
- our estimates regarding our fully diluted share capital and future dilution to shareholders;
- our intention to remediate our material weakness in internal control over financial reporting ("ICFR") as of December 31, 2019, 2018 and 2017;
- our intention to expand the indications for which we may market the Tiara (which does not have regulatory approval and is not commercialized) and the Reducer (which has CE Mark approval for sale in the European Union);

- clinical development of our products, including the results of current and future clinical trials and studies;
- our intention to apply for CE Mark approval for the Tiara in approximately 2020 and to look for potentially faster pathways to such approval;
- the anticipated timing of additional implantations in the TIARA-II trial and our intention to initiate additional investigational sites in 2020 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 ability to grow revenues from the Reducer in a timely manner;
- whether we will receive, and the timing and costs of obtaining, regulatory approvals;
- our efforts to obtain approval for entrance into the U.S. market for the Reducer, including our discussions with the U.S. Food and Drug administration (the "FDA") and potential pathways to the U.S. market;
- the cost of post-market regulation and commercialization if we receive necessary regulatory approvals;
- our ability to enroll patients in our clinical trials, studies and compassionate use cases in Canada, the United States, Europe, Israel and other markets;
- our ability to advance and complete the COSIRA-II IDE pivotal clinical trial;
- our belief the totality of clinical evidence from the COSIRA study, REDUCER-I European Post-Market study and studies published in peer-reviewed journals, will provide reasonable assurance of safety and effectiveness to support a full Premarket Approval application ("PMA");
- our belief that the full PMA application pathway brings the best chance of success within reasonable cost and time constraints for Tiara;
- our belief that the TIARA-I Early Feasibility study demonstrates the safety of the Neovasc transcatheter mitral valve replacement ("TMVR") system;
- our belief that the clinical evidence already available will be sufficient to support the availability of Tiara for the treatment of patients in Europe;
- our intention to continue directing a significant portion of our resources into sales expansion;
- our ability to get our products approved for use;
- the benefits and risks of our products as compared to others;
- our ability to find strategic alternatives for adoption of the Reducer, including potential alliances in order to broaden and deepen therapy penetration and potentially advance the COSIRA-II study;
- our plans to increase Reducer implants in Europe in 2020;
- our expectation that in 2020 more German clinics will negotiate and finalize reimbursement negotiations with German insurance companies relating to the Reducer;
- our estimates of the size of the potential markets for our products including the anticipated market opportunities for the Reducer and the Tiara;
- our potential relationships with distributors and collaborators with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;
- sources of revenues and anticipated revenues, including contributions from distributors and other third-parties, product sales, license agreements and other collaborative efforts for the development and commercialization of products;
- our ability to meet our financial and organizational restructuring goals to establish a lean and accountable organization with stable capitalization;
- our ability to meet our cash expenditure covenants;
- our creation of an effective direct sales and marketing infrastructure for approved products we elect to market and sell directly;
- the rate and degree of market acceptance of our products;
- the timing and amount of reimbursement for our products;
- the composition and compensation of our management team and board of directors;
- the impact of foreign currency exchange rates; and
- the composition and compensation of our board of directors and senior management team in the future.

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

- the substantial doubt about our ability to continue as a going concern;
- risks relating to the senior secured convertible notes (the "2017 Notes") issued pursuant to the November 2017 private placement (the "2017 Private Placement"), resulting in significant dilution to our shareholders;
- risks relating to our need for significant additional future capital and our ability to raise additional funding;
- risks relating to adjustment provisions in the 2017 Notes, which could make it more difficult and expensive for us to raise additional capital in the future and result in further dilution to investors;
- risks relating to the sale of a significant number of Common Shares;
- risks relating to the conversion of 2017 Notes, 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 or the Toronto Stock Exchange ("TSX"), which could affect their market price and liquidity;
- risks relating to the Company's conclusion that it did not have an effective ICFR as of December 31, 2019, 2018 and 2017;
- 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 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 claims by third-parties alleging infringement of their intellectual property rights;
- our ability to establish, maintain and defend intellectual property rights in our products;
- risks relating to results from clinical trials of our products, which may be unfavorable or perceived as unfavorable;
- our history of losses and significant accumulated deficit;
- risks associated with product liability claims, insurance and recalls;
- risks relating to use of our products in unapproved circumstances, which could expose us to liabilities;
- risks relating to competition in the medical device industry, including the risk that one or more competitors may develop more effective or more affordable products;
- risks relating to our ability to achieve or maintain expected levels of market acceptance for our products, as well as our ability to successfully build our in-house sales capabilities or secure third-party marketing or distribution partners;
- our ability to convince public payors and hospitals to include our products on their approved products lists;
- risks relating to new legislation, new regulatory requirements and the efforts of governmental and third-party payors to contain or reduce the costs of healthcare;
- risks relating to increased regulation, enforcement and inspections of participants in the medical device industry, including frequent government investigations into marketing and other business practices;
- risks associated with the extensive regulation of our products and trials by governmental authorities, as well as the cost and time delays associated therewith;
- risks associated with post-market regulation of our products;
- health and safety risks associated with our products and our industry;
- risks associated with our manufacturing operations, including the regulation of our manufacturing processes by governmental authorities and the availability of two critical components of the Reducer;
- risk of animal disease associated with the use of our products;
- risks relating to the manufacturing capacity of third-party manufacturers for our products, including risks of supply interruptions impacting the Company's ability to manufacture its own products;
- risks relating to our dependence on limited products for substantially all of our current revenues;
- risks relating to our exposure to adverse movements in foreign currency exchange rates;

- risks relating to the possibility that we could lose our foreign private issuer status under U.S. federal securities laws;
- risks relating to the possibility that we could be treated as a "passive foreign investment company" ("PFIC");
- risks relating to breaches of anti-bribery laws by our employees or agents;
- risks associated with future changes in financial accounting standards and new accounting pronouncements;
- risks relating to our dependence upon key personnel to achieve our business objectives;
- our ability to maintain strong relationships with physicians;
- risks relating to the sufficiency of our management systems and resources in periods of significant growth;
- risks associated with consolidation in the health care industry, including the downward pressure on product pricing and the growing need to be selected by larger customers in order to make sales to their members or participants;
- risks relating to our ability to successfully identify and complete corporate transactions on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances;
- risks relating to our ability to successfully enter into fundamental transactions as defined in the 2017 Notes issued pursuant to the 2017 Private Placement;
- anti-takeover provisions in our constating documents which could discourage a third party from making a takeover bid beneficial to our shareholders; and
- risks related to the recent coronavirus outbreak or other health epidemics, which could significantly impact our operations, sales or ability to raise capital.

Forward-looking statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by us, are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies, many of which, with respect to future events, are subject to change. The material factors and assumptions used by us to develop such forward-looking statements include, but are not limited to:

- our ability to continue as a going concern;
- our regulatory and clinical strategies will continue to be successful;
- our current positive interactions with regulatory agencies will continue;
- recruitment to clinical trials and studies will continue;
- the time required to enroll, analyze and report the results of our clinical studies will be consistent with projected timelines;
- current and future clinical trials and studies will generate the supporting clinical data necessary to achieve approval of marketing authorization applications;
- the regulatory requirements for approval of marketing authorization applications will be maintained;
- our current good relationships with our suppliers and service providers will be maintained;
- our estimates of market size and reports reviewed by us are accurate;
- our efforts to develop markets and generate revenue from the Reducer will be successful;
- genericisation of markets for the Tiara and the Reducer will develop;
- capital will be available on terms that are favorable to us; and
- our ability to retain and attract key personnel, including members of our board of directors and senior management team.

By their very nature, forward-looking statements or information involve known and unknown risks, uncertainties and other factors that may cause our actual results, events or developments, or industry results, to be materially different from any future results, events or developments expressed or implied by such forward-looking statements or information. In evaluating these statements, prospective purchasers should specifically consider various factors, including the risks outlined herein, under "*Risk Factors*" in our Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as filed with the SEC at www.sec.gov. These factors should be considered carefully, and readers should not place undue reliance on the Company's forward-looking statements. Should one or more of these risks or uncertainties or a risk that is not currently known to us materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this MD&A and we do not intend, and do not assume any obligation, to update these forward-looking statements, except

as required by law. Investors are cautioned that forward-looking statements are not guarantees of future performance and investors are cautioned not to put undue reliance on forward-looking statements due to their inherent uncertainty.

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

Date: March 30, 2020

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 Reducer, for the treatment of refractory angina, which is not currently commercially available in the United States (2 U.S. patients have been treated under Compassionate Use) and has been commercially available in Europe since 2015, and Tiara, for the transcatheter treatment of mitral valve disease, which is currently under clinical investigation in the United States, Canada, Israel and Europe.

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. In 2009, Neovasc ceased all activities related to BBL's technologies and is in the process of voluntarily liquidating BBL.

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

In late 2016, Neovasc sold its tissue processing technology and facility for $67,909,800 to Boston Scientific Corporation ("Boston Scientific"), and concurrently, Boston Scientific invested an additional $7,090,200 in Neovasc for a 15% equity interest in the Company. Under the terms of the equity investment, Boston Scientific purchased 11,817 Common Shares of Neovasc at a price of $600 per Common Share, for gross proceeds of $7,090,200. Under the terms of the asset purchase agreement, Neovasc has been granted a license to the purchased assets and access to the sold facilities to allow it to continue its tissue and valve assembly activities for its remaining customers, and continue its own tissue-related programs, including advancing the Tiara through its clinical and regulatory pathways.

Additionally, throughout the years 2014 to 2019, the Company announced a number of developments pertaining to litigation, all as more fully discussed under the heading "Trends, Risks and Uncertainties" and "Contractual Obligations and Contingencies" herein.

In November 2017, Neovasc completed the 2017 underwritten public offering (the "2017 Public Transaction" and collectively with the 2017 Private Placement, the "2017 Financings") and the 2017 Private Placement, for aggregate gross proceeds of approximately $65 million. The Company used the net proceeds of the 2017 Financings to fully fund the approximately $42 million balance of the damages and interest awards in its litigation with Edwards Lifesciences CardiAQ LLC ("CardiAQ") formerly known as CardiAQ Valve Technologies Inc., (after subtracting the approximately $70 million that the Company had paid into escrow), with remaining funds being used (i) to partially fund the ongoing Tiara clinical program; (ii) to support the completion of the TIARA-II study; and (iii) for general corporate purposes. The only securities issued pursuant to the 2017 Financings that remain outstanding are $3,913,000 aggregate principal amount of the 2017 Notes. For a description of the terms of the 2017 Financings and the securities issued pursuant to the 2017 Financings, see "Operating Results" and "Share Capital" of the Company's Annual Report on Form 20-F and the prospectus supplement, dated November 10, 2017 and the form of 2017 Notes, each as filed or furnished under the Company's profiles on SEDAR at www.sedar.com and on the SEC's website at www.sec.gov.

On February 28, 2019, the Company completed an underwritten public offering of 1,111,111 Common Shares, at a price of $4.50 per Common Share, for gross proceeds of approximately $5 million before deducting the underwriting commission and offering expenses payable by the Company ("February 2019 Financing"). As part of the underwriter's compensation in the February 2019 Financing, the Company issued the underwriter warrants (the "February Broker Warrants") to purchase in aggregate up to a 72,222 Common Shares, exercisable at a price per Common Share equal to $5.625 for a period of three years following issuance.

On March 15, 2019, the Company completed an underwritten public offering of 1,111,111 Common Shares, at a price of $4.50 per Common Share, for gross proceeds of approximately $5 million before deducting the underwriting commission and offering expenses payable by the Company ("March 2019 Financing)" and together with the February 2019 Financing and May 2019 Financing, the "2019 Financings". As part of the underwriter's compensation in the March 2019 Financing, the Company issued the underwriter warrants (the "March Broker Warrants", and together with the February Broker Warrants, the "2019 Broker Warrants") to purchase in aggregate up to a 72,222 Common Shares, exercisable at a price per Common Share equal to $5.625 for a period of three years following issuance.

On May 16, 2019, the Company completed the May 2019 Financing of (i) 15% original issue discount convertible notes ("2019 Notes") with a face value of $11.5 million, for gross proceeds to the Company of $9,775,000, and (ii) 334,951 Common Shares at a price of $5.15 per Common Share, for gross proceeds to the Company of $1,725,000.

On June 4, 2019, Dr. William O'Neill resigned from the board of Directors and Fred Colen was elected in his place, and on September 16, 2019, Jane Hsiao resigned from the board of Directors and Norman Radow was appointed in her place.

On January 6, 2020, the Company completed a registered direct offering of an aggregate of 1,185,000 series A units ("Series A Units") and 1,241,490 series B units ("Series B Units") at a price of US$4.1351 per Series A Unit and US$4.135 per Series B Unit for aggregate gross proceeds to the Company of approximately US$10 million, before deducting placement agent's fees and estimated expenses of the Offering payable by the Company.

On August 22, 2019, the Company received written notification (the "Notification Letter") from the Nasdaq Stock Market LLC (the "Nasdaq") notifying the Company that it is not in compliance with the minimum market value requirement set forth in Nasdaq Rules for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(2) requires companies to maintain a minimum market value of US$35 million and Listing Rule 5810(c)(3)(C) provides that a failure to meet the market value requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the market value of the Company for the 30 consecutive business days from July 10, 2019 to August 20, 2019, the Company no longer meets the minimum market value requirement. The Notification Letter does not impact the Company's listing on the Nasdaq Capital Market at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided 180 calendar days, or until February 17, 2020, to regain compliance with Nasdaq Listing Rule 5550(b)(2). To regain compliance, the Company's market value must exceed US$35 million for a minimum of 10 consecutive business days. The Company did not regain compliance by February 17, 2020. On February 19, 2020, the Company received notice from the Listing Qualifications Staff (the "Staff") of the Nasdaq indicating that the Staff had determined to delist the Company's common shares from Nasdaq unless the Company requests a hearing before the Nasdaq Hearings Panel. On February 26, 2020, the Company requested such a hearing and the date of the hearing has been set by the Nasdaq for April 2, 2020. This request for a hearing will stay any further action by the Staff and the Company's securities will continue to be eligible to trade on Nasdaq at least pending the ultimate conclusion of the hearing process. A delisting from the Nasdaq Capital Market would result in an event of default under the 2017 Notes

The Company and its subsidiaries now operate as follows: Neovasc Inc. is the Canadian public company and 100% owner of each of the subsidiary entities. NMI and Neovasc (US) Inc. ("NUS") are the operating companies for the group. They hold the majority of the tangible assets and NMI holds the Peripatch tissue license. NMI and NUS employ the majority of the employees of the Company. Neovasc Tiara Inc. ("NTI") holds all the intangible assets related to the Tiara and NML holds all the intangible assets related to the Reducer program. NMI charges both NTI and NML for the development services performed by its employees to develop the Tiara and the Reducer respectively. NML receives a royalty based on the Reducer revenues generated by NMI. NUS, the full-fledged distributer of Reducer IP in the US and of Tiara IP globally, charges NMI for development services performed by its employees to develop the Tiara and the Reducer respectively and these are then

passed on through NMI to NTI and NML respectively. Neovasc GmbH conducts sales and marketing activities on behalf of NMI as part of the license agreement between NML and NMI for NMI to manufacture, distribute and sell the Reducer on behalf of NML. Neovasc Management Inc provides executive management services to Neovasc Inc.

Neovasc's Strategy

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

Key elements of this strategy include:

- Tiara — expanding the Company's clinical experience of the Tiara, continuing enrollment in and expansion of the TIARA-II multi-center CE Mark clinical study, and applying for CE Mark approval in approximately 2020. Finalizing the TIARA-I study; enrollment in the TIARA-I study was closed on November 15, 2019 with a total of 27 patients treated. Development of the Tiara transfemoral trans-septal system for preclinical bench and animal studies to successful completion, followed by initiation of a first human feasibility clinical study by the end of 2020.

- Reducer — continuing therapy development of the Reducer, and supplementing the successful COSIRA prospective, multicenter, randomized, double-blind, sham-controlled clinical study with additional clinical experience through the Company's targeted commercial launch of the Reducer in Europe and enrollment in the REDUCER-I, real world post market observational clinical study. Improving revenue growth in Europe by leveraging the renewed NUB 1 status in Germany and by further accelerated therapy development. Seeking strategic alternatives and alliances to build on the growing enthusiasm in the market for, and adoption of, the Reducer, in order to broaden and deepen therapy penetration in Europe and the Middle East. Continuing to execute on our U.S. strategy and work with the FDA to meet the requirements for entrance into the U.S. market. The Company filed a PMA application for this Breakthrough medical device on December 30, 2019 with a request for an Advisory Panel meeting. The Company believes that the totality of clinical evidence from the COSIRA study, REDUCER-I European Post-Market study (with interim results of over 200 of 400 patients enrolled), and multiple independent studies published in peer-reviewed journals, will provide reasonable assurance of safety and effectiveness to support a PMA. While any pathway to U.S. market approval by the FDA carries considerable risk, and there can be no assurance that the PMA will be approved by the FDA in a timely manner or at all, we believe the PMA application pathway brings the best chance of success within reasonable cost and time constraints. While an additional post-market study will most likely be needed and the body of real-world evidence continues to grow, the Company believes that the clinical evidence already available will be sufficient to support the availability of this breakthrough medical device for the treatment of U.S. patients.

- Financial and organizational restructuring to establish a lean and accountable organization with stable capitalization. We are currently exploring additional financing options to bring additional capital into the Company and will provide public updates when appropriate.

Neovasc's Products

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 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 the U.S.

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 20% of this high-risk patient population meet all inclusion criteria for the Tiara studies and can be treated.

As of March 27, 2020, 82 patients have been treated with Tiara in either the TIARA-I Early Feasibility Clinical Study, compassionate use cases or in our TIARA-II CE Mark Clinical Study. Neovasc believes that early results have been encouraging. The 30-day survival rate for the 82 patients treated with the Tiara (i.e. those treated more than 30 days ago) is 89% with one patient now over six years post implant. The Tiara has successfully treated both functional and degenerative Mitral Regurgitation patients, as well as patients with pre-existing prosthetic aortic valves and mitral surgical annuloplasty rings. On November 15, 2019, TIARA-I study enrollment was closed with 27 treated patients enrolled. This decision was not due to any safety concerns. The objective of the TIARA-I Early Feasibility study was to demonstrate the safety of the Neovasc TMVR system, while gathering preliminary information on device performance and clinical outcomes. With the experience to date, we believe that we have accomplished this objective. The patients that are in follow-up will continue to be followed with continued follow up assessments, reporting requirements, etc. as per protocol through their 5-year visits. This decision has no impact on the currently enrolling TIARA-II CE Mark Study. There are currently 18 active sites across Germany, Israel, Spain, the Netherlands and the UK with additional sites in the process of obtaining regulatory approvals.

The results from our clinical experience to-date continues to demonstrate the potential benefit for patients who otherwise have no treatment options. Patient selection continues to be challenging as the Company and clinical community continue to learn more about treating this population of very sick patients.

Neovasc believes that there are several unique attributes of the Tiara that may provide advantages over other approaches to mitral valve replacement, in particular the low atrial profile, its D shape, enabling a better anatomical fit and less risk of left ventricular outflow tract obstruction, and its unique combined skirt and anchoring mechanism. The Tiara has successfully treated 17 patients with previous aortic valves (AVR), including mechanical, bioprosthetic and TAVI, without any LVOT obstruction, no peri-procedural deaths or paravalvular leak. Data on the first twelve patients with previous AVR, treated with Tiara was published in 2018 in Circulation: Cardiovascular Interventions.

There are several other transcatheter mitral valve replacement devices in development by third-parties, some of which have been implanted in early feasibility type studies, pivotal U.S. 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.

The Tiara valve is manufactured, packaged and labelled in-house by the Company and is made up of two major components: the leaflets which are made from the Peripatch bovine tissue licensed from Boston Scientific, a fabric skirt, and the nitinol frame (to which the leaflets and skirt are attached), which is manufactured by a well-established specialty manufacturer in the medical device industry. If this supplier were unable to provide the nitinol frame in the future, it would seriously impact further development of the Tiara. The Tiara delivery system is manufactured, packaged and labelled in-house by the Company using customized standard catheter construction components that are readily available through vendors.

The TIARA-II study is estimated to cost approximately $15 million. While many challenges remain prior to achieving commercialization (including, but not limited to, positive clinical trial results and obtaining regulatory approval from the relevant authorities), the Company believes the Tiara is being recognized as one of the leading mitral valve replacement devices. Neovasc is managing and conducting the TIARA-II study itself in conjunction with certain service providers who undertake portions of data collection, data management, data analysis, safety and event monitoring and similar functions. The Tiara is currently manufactured for use in these studies by Neovasc at its own facilities following required medical

device quality requirements. In the event of a positive outcome from the TIARA-II study and the Company successfully obtaining CE Mark approval, the Tiara would be commercially manufactured in the same manner at Neovasc's facility.

Regulatory Status

The Tiara is an early-stage development product without regulatory approvals in any country. The Company intends to continue to fund development of the product as cash flow allows and is targeting applying for CE Mark approval in Europe in approximately 2020, assuming sufficient patients will have been enrolled with sufficient follow-up time by then. There is no assurance that European regulatory filing and an approval will be granted in the time frame anticipated by management or granted at any time in the future. There is no expectation that this product will be revenue-generating in the near term, although management believes that the product is addressing an important unmet clinical need.

On November 28, 2016, the Company announced that it had received both regulatory and ethics committee approval to initiate the TIARA-II study in Italy. Since then Neovasc has received regulatory and ethics committee approvals to conduct the study in Germany, Israel, Spain, the Netherlands and the United Kingdom.

Reducer

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

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

Refractory angina, resulting in continued symptoms despite maximal medical therapy without revascularization options, is estimated to affect 600,000 to 1.8 million Americans, with 50,000 to 100,000 new cases per year. A recent publication in the Cardiovascular Revascularization Medicine Journal by Benck and Henry suggests that the prevalence of No-Option Refractory Disabling Angina (NORDA) in the U.S. population is between 26,000 and 52,000. Another publication in the European Heart Journal by Crea et al., stated persistence of angina caused by incomplete coronary revascularization may occur in up to 30% in the current era, although definitions of incomplete revascularization are heterogeneous. It further stated that persistent angina is associated with a significant economic burden with healthcare costs almost being two-fold higher among patients with persistent angina post-percutaneous coronary intervention vs. those who become symptom free. Additionally, there is emerging interest in treating patients that have refractory angina despite patent coronary arteries. Angina with non-obstructive coronary artery disease may affect as many as 39% of patients with chest pain according to a study from Patel et. al, published in the New England Journal of Medicine. Furthermore, a publication in Circulation by Lee et. al., suggests upwards of 20% of patients with angina and non-obstructive coronary artery disease have evidence of microvascular dysfunction. Increasing interest in diagnosis and treatment of angina and microvascular dysfunction as evidenced by the 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes provides growing support for Reducer treatment.

The pain and shortness of breath associated with refractory angina can make it difficult for patients to engage in routine activities, such as walking or climbing stairs. Clinical studies demonstrate that the Reducer can provide significant relief of chest pain, shortness of breath and other debilitating symptoms 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 potential 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, shortness of breath and other debilitating symptoms. As such there are currently no direct competitors to the Reducer as the patient will have exhausted all other treatment options before the Reducer is considered. Neovasc believes that further studies may demonstrate that additional patient populations may benefit from treatment with Reducer and thus could further increase its market potential.

The Reducer is an hourglass-shaped, balloon-expandable, stainless steel, bare metal device, which is implanted in the coronary sinus, creating a restriction in venous outflow from the myocardium (the muscular layer of the heart wall). It is implanted using conventional percutaneous, or needle puncture, techniques. The Reducer is provided sterile and pre-loaded on a balloon catheter system. The system is 9 French sheath compatible and operates over a .035 inch guide wire. The implant procedure requires minimal training for experienced interventionalists. Once guide wire access to the coronary sinus is achieved, implantation typically takes less than 20 minutes.

Using a catheter-based procedure, the Reducer is implanted in the coronary sinus (the main vein draining blood from the heart muscle). Following implantation, the Reducer becomes covered with endothelial tissue after about 4-6 weeks. This tissue coverage creates a permanent (but reversible, if necessary) narrowing in the coronary sinus. The coronary sinus is narrowed from a typical diameter of 10-12mm to approximately 3mm at the site of implantation. This focal narrowing provides a backwards pressure elevation in the coronary sinus which is intended to improve blood perfusion to ischemic territories of the heart muscle by forcing redistribution of blood from the less ischemic areas to the more ischemic areas of the heart muscle. This can result in improved perfusion of the endocardium, which helps relieve ischemia and chest pain, shortness of breath and other debilitating symptoms. 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 six months and these same results were noted at the three year follow up. During this period, the Reducer appeared safe and well tolerated in these patients.

The Company completed the COSIRA trial, a prospective, multicenter, randomized, double-blind, sham-controlled study to assess the safety and effectiveness of the Reducer device in 2013. The COSIRA trial's primary endpoint was a two-class improvement in Angina symptoms, 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 III or IV, were enrolled in the COSIRA trial. The COSIRA trial analysis showed that the study met the primary endpoint, with patients receiving the Reducer achieving a statistically significant improvement in CCS scores (two classes or better) compared to patients receiving a sham control (18 of 52 [34.6%] of the Reducer patients improved $\geqslant$ 2 CCS classes compared to 8 of 52 [15.4%] of the control patients [p-value = 0.024]). The analysis also showed that patients treated with the Reducer showed a statistically significant improvement of one or more CCS classes compared to the sham control patients (37 of 52 [71.2%] of the Reducer patients showed this improvement compared to 22 of 52 [42.3%] of the control patients [p-value = 0.003]). The COSIRA trial results were published in the New England Journal of Medicine in February 2015.

In 2016, Neovasc initiated the REDUCER-I observational study as a multi-center, multi-country, three-arm study collecting long-term data from European patients implanted with the Reducer. The study is expected to enroll up to 400 patients.

Currently, 242 patients have been enrolled across 23 centers that are active in Italy, Germany, Austria, Belgium, the Netherlands, the United Kingdom and Switzerland.

In 2018 an article by Parikh, Parth et al., was published in the Journal of the American College of Cardiology (JACC) titled, "First-in-Human Use of Coronary Sinus Reducer in Patients with Refractory Angina". This article describes the long-term structural, anatomic, and clinical durability of the Reducer. Reducers were patent 12 years following implantation, with no signs of strut fractures, dislocation, thrombosis, or migration, and sustained improvement in angina class at six months and three years. These results were also maintained at the 12-year follow-up.

Hundreds of patients have been enrolled in clinical studies conducted by third parties across Europe and Israel relating to the Reducer. These studies continue to show a strong safety profile and positive clinical results that trend closely to the COSIRA randomized study. Many of these studies 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. As a result of the clinical evidence from these studies and publications, the Reducer Therapy has now been recognized in the European Society of Cardiology Guidelines as a treatment option for refractory angina.

There have been numerous publications of clinical results since the COSIRA study was published in the New England Journal of Medicine in 2015. Recently a publication in the European Heart Journal by Gallone, et al., on the "Cost-effectiveness of the coronary sinus Reducer and its impact on the healthcare burden of refractory angina" indicated that the Reducer was consistently cost-effective according to a range of cost-effectiveness thresholds after just one year of implant.

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 2020 and beyond. Any sales of the product in the United States would follow obtaining U.S. regulatory approval, if such approval is granted, as described further below.

Based on achieving NUB 1 status in Germany and a general positive reception in the European market, with positive experiences by many physicians from the treatment of their own patients with the Reducer, we are seeing an increase in adoption of the Reducer therapy in Europe. The commercial progress for the Reducer in 2019 was encouraging with a 20% increase in revenue compared to 2018.

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

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

On January 18, 2018, the Company reported the Reducer was featured in a "live case" broadcast to more than 800 participants at the Kardiologie Symposium 2018 held in Berlin, Germany. The successful live case was performed by Dr. Spyrantis and Professor Banai in the Sana-Klinikum Lichtenberg. During May 2018 and again in 2019, 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. A second patient received a Reducer implant under Compassionate Use on January 31, 2019 in the U.S. The most recent update from the attending physician indicated that this second patient was doing well.

On March 5, 2019, the Company reported the Reducer was featured in a “live case” broadcast to more than 3,000 participants at the Cardiovascular Research Technologies (CRT) meeting in Washington D.C. The successful live case was performed by Dr Giannini at Maria Cecilia Hospital in Cotignola, Italy.

On May 6, 2019, the Company announced that 1,000 patients diagnosed with refractory angina have been treated with the Reducer. The Reducer therapy now benefits from medical evidence spanning 1,000 patients and 14 years of follow up.

On September 3, 2019, the Company announced that the European Society of Cardiology included Neovasc Reducer in the European Practice Guidelines for the Diagnosis and Management of Chronic Coronary Syndromes. The Reducer entered at Class 2 B, the highest recommendation class for therapies addressing refractory angina.

On November 1, 2019, the Company announced it had advised the FDA of its decision to submit a PMA application, and on December 31, 2019, the Company announced the submission of a PMA to the FDA for the Reducer.

Regulatory Status

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

On November 3, 2017, Neovasc received FDA approval for a U.S. IDE clinical trial, COSIRA II (a trial design similar to the COSIRA study). While the principal investigator and co-principal investigator for this study were already appointed, the Company evaluated the timing for starting such a U.S. clinical trial, funding being the largest impediment. The cost of this U.S. clinical trial is expected to be approximately $20 million. U.S. marketing approval is expected about four years after the clinical trial begins. There is no assurance that U.S. regulatory approval will be granted in the time frame anticipated by management, or granted at any time in the future.

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

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

On February 20, 2019, the Company announced that the FDA had informed Neovasc that, despite “Breakthrough Device Designation”, the FDA review team recommends collection of further pre-market blinded data prior to PMA submission.

On June 26, 2019, the Company and two top U.S. Cardiologists, met with FDA to further discuss available clinical evidence for the Reducer, to try to reach agreement on potential options to enter the U.S. Market. FDA provided the Company with guidance towards potential alternate options, including the HDE pathway for class IV refractory angina patients and/or alternate clinical trial designs for a broader refractory angina patient population.

Following the Sprint discussion held with the FDA on October 9, 2019 and weighing all available options a decision was made by the Company to pursue a PMA application for this Breakthrough medical device. The Company believes that the totality of clinical evidence from the COSIRA study, interim results from the REDUCER-I European Post-Market study, and multiple independent studies published in peer-reviewed journals, will provide reasonable assurance of safety and effectiveness to support a PMA. The PMA application was submitted December 30, 2019, with a request for an Advisory Panel meeting. While any pathway to U.S. market approval by the FDA carries considerable risk, and there can be no assurance that the PMA will be approved by the FDA in a timely manner or at all, we believe the full PMA application

pathway brings the best chance of success within reasonable cost and time constraints. While an additional post-market study will most likely be needed and the body of real-world evidence continues to grow, the Company believes that the clinical evidence already available will be sufficient to not further delay the availability of this Breakthrough medical device for the treatment of U.S. patients. In the event that the PMA is approved by the FDA, there can be no assurance that Neovasc will be successful in commencing commercialization of Reducer in the United States on a timely basis or at all, or of the total addressable market size for Reducer.

New Products/Components/Cycles

Tiara

A key 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 several 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 initiated the formal development of this system, based on the completed conceptual work at the end of the first quarter of 2019.

Reducer

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

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

Peripatch Technology used in our Tiara Mitral Valve

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

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

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

TRENDS, RISKS AND UNCERTAINTIES

Losses and Additional Funding Requirements (as restated)

Neovasc has a limited operating history, which makes it difficult to predict how its business will develop or what its future operating results will be. The Company has a history of operating losses since its inception and will need to generate

significantly greater revenues than it has to date to achieve and maintain profitability. There is no certainty of future profitability, and results of operations in future periods cannot be predicted based on results of operations in past periods. The securities of the Company should be considered a highly speculative investment.

The Company has incurred losses and comprehensive losses of $35,131,015 and $33,618,494 for year ended December 31, 2019, respectively (2018: $107,983,475 and $108,993,067) and has a deficit of $366,532,164 at December 31, 2019 compared to a deficit of $331,401,149 as at December 31, 2018. As at December 31, 2019 the Company had $5,292,833 in cash and cash equivalents (December 31, 2018: $9,242,809).

The Company will need to raise additional capital to fund its short and medium-term objectives for the Tiara and the Reducer prior to the successful commercialization of these products. There is no certainty that the Company will be able to raise additional capital through debt or equity or other means on terms acceptable to the Company or at all. There is also no certainty that the programs will be successfully commercialized or any required funds will be available to the Company at the time needed or on terms acceptable to the Company. The terms of the 2017 Financings included, amongst other things, future priced securities, full ratchet anti-dilution clauses and a senior convertible debt instrument secured on substantially all of the assets of the Company. These terms may make it more difficult to obtain additional debt or equity financing in the future.

As at December 31, 2019, the Company had approximately $5.29 million in cash and cash equivalents. On January 6, 2020, the Company completed a registered direct offering for aggregate gross proceeds of $10 million before deducting fees and expenses (see Subsequent Events). If the 2017 Notes are converted prior to the maturity date, the Company expects that its cash on hand as at December 31, 2019 and including the January 2020 Financing is sufficient to sustain operations until approximately August 2020 at the current burn rate. If the 2017 Notes are paid out on the maturity date of May 17, 2020, the Company expects that it will have sufficient cash on hand to sustain operations until June 30, 2020 at the current burn rate. Given the current nature of the Company's capital structure, the Company can give no assurance that it will be able to obtain 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 2017 Notes see the Company's Annual Report on Form 20-F, which is available on SEDAR at sedar.com and as filed with the SEC at www.sec.gov.

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

Litigation Matters

The litigation matters are more fully described in "Contractual Obligations and Contingencies" below.

Operating Risks

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 2017 Notes contain, among other things, so-called full-ratchet anti-dilution and future pricing provisions, which create a high degree of risk relating to, among other things, significant dilution to shareholders and the Company's ability to raise additional financing. The exercise of warrants issued pursuant to the 2017 Financings (the "2017 Warrants") and conversion of 2017 Notes resulted in significant dilution to our shareholders. Future conversions of the 2017 Notes may result in further significant dilution in the future. For details concerning the terms of the 2017 Notes, see the prospectus supplement and the form of 2017 Notes filed on SEDAR at www.sedar.com and with the SEC at www.sec.gov. For a description of the risks associated with the 2017 Notes, the amount of 2017 Notes converted to date, the dilution to date and the potential dilution in the future due to such conversions, see the Company's Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as filed with the SEC at www.sec.gov.

Risks Relating to Potential Global Pandemics

A global pandemic could cause temporary closure of businesses in regions that are significantly impacted by the health crises, or cause governments to take preventative measures such as the closure of points of entry, including ports and borders. These restrictive measures along with market uncertainty could cause an economic slowdown resulting in a decrease in the demand or sales for our products. The recent outbreak of the novel coronavirus (2019-nCoV) has had a negative impact on capital markets and governmental actions to contain the outbreak may impact our ability to transport or market our products or adversely affect our ability to raise capital.

FOREIGN OPERATIONS

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

The majority of the Company's revenues are derived from product sales in Europe, primarily denominated in U.S. dollars and Euros, while the majority of the Company's costs are denominated in Canadian and U.S. 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 consolidated financial statements for the year ended December 31, 2019, 2018 and 2017.

DISCUSSION OF OPERATIONS AND FINANCIAL CONDITION

Results for the years ended December 31, 2019 and 2018 follow (as restated):

Losses

The operating losses and comprehensive losses for the year ended December 31, 2019 were $35,131,015 and $33,618,494 respectively, or $5.40 basic and diluted loss per share, as compared with losses of $107,983,475 and $108,993,067 respectively, or $76.26 basic and diluted loss per share, for the same period in 2018.

The $75,374,573 decrease in the comprehensive loss incurred for the year ended December 31, 2019 compared to the same period in 2018 can be substantially explained by a $70,784,391 decrease in the charges related to the accounting treatment of the 2017 Financing and May 2019 Financing, a $2,522,113 decrease in other comprehensive loss, and a decrease in operating loss of $2,363,610.

Revenues

Revenues increased 20% to $2,092,032 for the year ended December 31, 2019, compared to revenues of $1,749,133 for the same period in 2018. The Company sees continued physician interest and solid scientific credibility for Reducer therapy as evidenced by its validation by the European Society of Cardiology in its recent practice guidelines. We have led in Germany, together with our local partners, various therapy development sessions to stimulate patient flow from general cardiologists to Reducer implanting centers. Germany has been a driver in our gross margin and top line growth. 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 in various territories and correctly managing the referral process.

Cost of Goods Sold

The cost of goods sold for the year ended December 31, 2019 was $458,436 compared to $366,258 for the same period in 2018. The overall gross margin for the year ended December 31, 2019 was 78%, compared to 79% gross margin for the same period in 2018. The Company continues to focus on Germany where the Company sells the Reducer direct for higher margins. The Company voluntarily replaced certain expired inventory of Reducers for newly sterilized product, which reduced the gross margin in the third quarter of 2019 by $59,800.

Expenses

Total expenses for the year ended December 31, 2019 were $31,680,676, compared to $33,793,565 for the same period in 2018, representing a decrease of $2,112,889 or 6%. The decrease in total expenses for the year ended December 31, 2019 compared to the same period in 2018 reflects i) a $4,436,711 decrease in non-cash charges for accretion on collaboration, license and settlement agreements provision, ii) a $735,304 decrease in employee termination expenses, iii) a $458,954 decrease in litigation expenses as litigation matters came to a close, iv) a $1,333,717 increase in overall employee expenses, v) a $662,201 increase in other expenses to reclassify research and development supplies and vi) a $2,012,230 increase in other expenses primarily relating to other product development and clinical trial expenses as the Company continues to incur development and clinical costs related to Tiara and regulatory costs related to Tiara and Reducer.

Selling expenses for the year ended December 31, 2019 were $1,645,985, compared to $1,353,165 for the same period in 2018, representing an increase of $292,820 or 22%. The increase in selling expenses for the year ended December 31, 2019 compared to the same period in 2018 reflects an increase in costs incurred for commercialization activities related to

the Reducer as we add more sales representatives in Germany and increase our commercialization efforts. The investments in Germany are carefully focused on increasing our coverage in the most active Reducer centers and targeting experienced therapy development representatives around the top implanting centers. The new German structure will be established to drive our growth into 2020.

General and administrative expenses for the year ended December 31, 2019 were $10,013,732, compared to $16,438,936 for the same period in 2018, representing a decrease of $6,425,204 or 39%. The decrease in general and administrative expenses for the year ended December 31, 2019 compared to the same period in 2018 can be substantially explained by i) a $4,436,711 decrease in non-cash charges for accretion on collaboration, license and settlement agreements provisions as the liabilities for the collaboration and licensing agreements were accrued during the third quarter in 2018, ii) a $735,304 decrease in employee termination expenses, iii) a $458,954 decrease in litigation expenses as litigation matters have come to a close and iv) a $399,172 decrease in non-cash stock-based compensation charges as fewer incentives were issued in 2019. The Company continues to minimize its general and administrative expenses when possible as the cash resources of the Company are still limited.

Product development and clinical trial expenses for the year ended December 31, 2019 were $20,020,959 compared to $16,001,464 for the same period in 2018, representing an increase of $4,019,495 or 25%. The increase in product development and clinical trial expenses for the year ended December 31, 2019 was the result of i) a $2,674,431 increase in other expenses as the Company continues to incur development and clinical costs related to Tiara and regulatory costs related to Tiara and Reducer, ii) a $931,976 increase in employee expenses iii) a $277,589 increase in non-cash stock-based compensation charges and iv) a $135,499 increase in non-cash depreciation charges.

The Company's expenses are subject to inflation and cost increases. The Company has not seen a material increase in the price of any of the components used in the manufacture of its products and services.

Other Loss

The other loss for the year ended December 31, 2019 was $5,055,142 compared to loss of $75,465,692 for the same period in 2018, a decrease in other loss of $70,410,550. The decrease in the other loss can be substantially explained by a $70,784,391 decrease in charges related to the accounting treatment of the 2017 Financing and May 2019 Financing.

Tax Expense

The tax expense for the year ended December 31, 2019 was $28,793, compared to a $107,093 expense for the same period in 2018. Neovasc (US) Inc. was established in 2015 to provide clinical trial services to Neovasc Medical Inc. The cross border intercompany charges from Neovasc (US) Inc. to Neovasc Medical Inc. created a taxable profit in Neovasc (US) Inc. and U.S. federal and state taxes were charged.

Results for the years ended December 31, 2018 and 2017 follow (as restated):

Losses

The losses and comprehensive losses for the year ended December 31, 2018 were $107,983,475 and $108,993,067, respectively, or $76.26 basic and diluted loss per share, as compared with losses and comprehensive losses of $21,634,068 and $23,584,464, respectively, or $265.37 basic and diluted loss per share, for the same period in 2017.

The $85,408,603 increase in the comprehensive loss incurred for the year ended December 31, 2018 compared to the same period in 2017 can be substantially explained by a $85,190,307 increase in other losses (the accounting treatment of the 2017 Financings resulting in an increase in charges of $83,092,711 in the year) and a $1,536,435 increase in operating losses ($754,153 increase in general and administrative expenses and a $212,975 reduction in product development and clinical trials expenses as the Company continues to control costs).

Revenues

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

Sales of the Reducer for the year ended December 31, 2018 were $1,749,133 compared to $1,128,126 for the same period in 2017, representing an increase of 55%. The Company is encouraged by the progress this year but recognizes that future revenues may be unstable before the Reducer becomes widely adopted. The continued success of the commercialization of the Reducer will be dependent on the amount of internal resources allocated to the product, obtaining appropriate reimbursement codes in various territories and correctly managing the referrals process.

Cost of Goods Sold

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

Expenses

Total expenses for the year ended December 31, 2018 were $33,793,565 compared to $32,785,448 for 2017, representing an increase of $1,008,117 or 3%. The increase in total expenses for the year ended December 31, 2018 compared to 2017 can be substantially explained by a $754,153 increase in general and administrative expenses and a $466,939 increase in selling expenses offset by a $212,975 decrease in product development and clinical trial expenses as we continue to preserve cash resources.

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

General and administrative expenses for the year ended December 31, 2018 were $16,438,936, compared to $15,684,783 for 2017, representing an increase of $754,153 or 5%. The increase in general and administrative expenses for the year ended December 31, 2018 compared to 2017 can be substantially explained by a $1,067,205 increase in stock based compensation and a $2,379,790 charge for collaboration and settlement expenses and a $2,749,968 charge for settlement expenses and a $1,441,125 increase in other expenses including a substantial increase in legal expenses as we renewed the base shelf prospectus, filed XBRL for the first time and filed our annual report on the more demanding Form 20-F, as compared to the Form 40-F filed in 2017, offset by a decrease in expenses related to the 2017 Financings of $5,447,182 and a decrease in litigation expenses of $1,870,225.

Product development and clinical trial expenses for the year ended December 31, 2018 were $16,001,464 compared to $16,214,439 for 2017, representing a decrease of $212,975 as the Company continues to control costs. As restated, for the year ended December 31, 2017 the Company reversed the $1,274,653 Reducer R&D inventory charge decreasing product development and clinical trial expenses.

The Company's expenses are subject to inflation and cost increases. The Company has not seen a material increase in the price of any of the components used in the manufacture of its products and services.

Other Loss

The other loss for the year ended December 31, 2018 was $75,465,692 compared to other income of $9,724,615 for 2017, an adverse change of $85,190,307. The increase in the other loss can be substantially explained by the accounting treatment of the 2017 Financings resulting in a $83,092,712 adverse change (charges of $75,712,610 in the year compared

to other income of $7,380,102 in the prior year) and a $2,901,782 adverse change in foreign exchange losses and gains compared to the prior year.

Tax Expense

The tax expense for the year ended December 31, 2018 was $107,093 compared to $484,428 in 2017. Neovasc (US) Inc. was established in 2015 to provide clinical trial services to Neovasc Medical Inc. The cross border intercompany charges from Neovasc (US) Inc. to Neovasc Medical Inc. created a taxable profit in Neovasc (US) Inc. and U.S. federal and state taxes were incurred.

Results for the three months ended December 31, 2019 and 2018 follow (as restated):

Losses

The operating losses and comprehensive losses for the three months ended December 31, 2019 were $9,573,489 and $11,154,637, respectively, or $1.45 basic and diluted loss per share, as compared with $10,253,593 operating losses and $10,902,126 comprehensive income, or $5.07 basic and diluted earnings per share, for the same period in 2018. The reduction of $1,401,698 in operating losses can be explained by the decrease in general and administrative expenses due to the collaboration and licensing agreement in 2018.

The $22,056,763 decrease in the comprehensive income incurred for the three months ended December 31, 2019 compared to the same period in 2018 can be substantially explained by a $24,709,870 decrease in income related to the accounting treatment of the 2017 Notes and May 2019 Financing, offset by a $1,976,830 decrease in other comprehensive loss.

Revenues

Revenues increased 8% to $565,821 for the three months ended December 31, 2019, compared to revenues of $523,424 for the same period in 2018 as the Company continues its commercialization strategies. Physician interest continues to be high, as displayed at well attended Reducer Symposia during the National Cardiology Meetings of Germany and Italy respectively in Berlin and Milano in October. The validation in September of Reducer Therapy by the ESC in its most recent Practice Guidelines, is a significant milestone, particularly for referring physicians who are considering sending a patient to an implanting center. In Germany we now have four sales representatives. We continue to work on our reimbursement strategies in several European countries to further streamline the processes to get approval for and payment of the ongoing implantations. The Company recognizes that future revenues may be unstable before the Reducer becomes widely adopted. The continued success of the commercialization of the Reducer will be dependent on the amount of internal resources allocated to the product, obtaining appropriate reimbursement codes in various territories and correctly managing the referrals process.

Cost of Goods Sold

The cost of goods sold for the three months ended December 31, 2019 was $109,449 compared to $93,519 for the same period in 2018. The overall gross margin for the three months ended December 31, 2019 was 81%, compared to 82% gross margin for the same period in 2018. The Company voluntarily replaced certain expired inventory of Reducers for newly sterilized product, which increased the cost of goods by $59,800 and reduced the overall gross margin in the third quarter of 2019.

Expenses

Total expenses for the three months ended December 31, 2019 were $10,029,861 compared to $10,683,498 for 2018, representing a decrease of $653,637 or 6%. The decrease in total expenses for the three months ended December 31, 2019 compared to 2018 can be substantially explained by a $2,336,216 decrease in non-cash charges for on collaboration,

license and settlement agreements provisions booked in 2018, offset by a $662,201 increase in other expenses to reclassify R&D supplies and a $1,571,157 increase in other expenses primarily relating to other product development and clinical trial expenses as the Company continues to incur development and clinical costs related to Tiara and regulatory costs related to Tiara and Reducer.

Selling expenses for the three months ended December 31, 2019 were $502,828, compared to $614,742 for 2018, representing a decrease of $111,914 or 18%. 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 December 31, 2019 were $2,671,418, compared to $5,415,634 for the same period in 2018, representing a decrease of $2,744,216. The decrease in general and administrative expenses for the three months ended December 31, 2019 compared to 2018 can be substantially explained by a $2,336,216 decrease in non-cash charges for collaboration, license and settlement agreements provision as liabilities for the collaboration and licensing agreement were accrued during the fourth quarter of 2018, and a $266,517 decrease in litigation expenses as litigation matters came to a close.

Product development and clinical trial expenses for the three months ended December 31, 2019 were $6,855,615 compared to $4,653,122 for 2018, representing an increase of $2,202,493 or 47%. The increase in product development and clinical trial expenses for the three months ended December 31, 2019 can be substantially explained by a a $662,201 increase in other expenses to reclassify research and development supplies and a $1,571,157 increase in other product development and clinical trial expenses as the Company continues to incur development and clinical costs related to Tiara and regulatory costs related to Tiara and Reducer.

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 December 31, 2019 was $2,739,008 compared to other income of $21,862,040 for the same period in 2018, a decrease of $24,601,048. The decrease in the other loss can be substantially explained by a $24,709,870 decrease in income related to the accounting treatment of the 2017 Financing and May 2019 Financing.

Tax Expense

The tax expense for the three months ended December 31, 2019 was $41,688 compared to a $70,961 recovery in 2018. 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 three months ended December 31, 2018 and 2017 follow (as restated):

Losses

The income and comprehensive income for the three months ended December 31, 2018 were $11,679,408 and $10,902,126 respectively, or $5.07 basic earnings per share, as compared with losses and comprehensive losses of $3,751,813 and $5,702,209 respectively or $82.66 basic and diluted loss per share, for the same period in 2017.

The $15,431,221 increase in the income incurred for the three months ended December 31, 2018 compared to the same period in 2017 can be substantially explained by a $14,652,143 increase in other income, substantially due to the accounting treatment of the 2017 Financings, and a $2,902,915 decrease in general and administrative expenses decrease in expenses related to the fees of the 2017 Financings.

Revenues

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

Sales of the Reducer for the three months ended December 31, 2018 were $523,424 compared to $285,598 for the same period in 2017, representing an increase of 83%. The Company is encouraged by the progress this year but recognizes that future revenues may be unstable before the Reducer becomes widely adopted. The continued success of the commercialization of the Reducer will be dependent on the amount of internal resources allocated to the product, obtaining appropriate reimbursement codes in various territories and correctly managing the referrals process.

Cost of Goods Sold

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

Expenses

Total expenses for the three months ended December 31, 2018 were $10,683,498, compared to $11,026,929 for the same period in 2017, representing a decrease of $343,431 or 3%. The increase in total expenses for the three months ended December 31, 2018 compared to the same period in 2017 can be substantially explained by a $2,902,915 decrease in general and administrative expenses due to the decrease of $5,447,182 related to expenses from the 2017 Financings offset by a $393,857 increase in selling expenses due to an increase in costs incurred for commercialization activities related to the Reducer and a $2,165,627 increase in product development and clinical trial expenses includes increased share-based payments as options were granted and the December 31, 2017 adjustment of $1,274,653 for R&D inventory charges.

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

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

Product development and clinical trial expenses for the three months ended December 31, 2018 were $4,653,122 compared to $2,487,495 for the same period in 2017, representing an increase of $2,165,627 or 87%. The increase in product development and clinical trial expenses for the three months ended December 31, 2018 was primarily the result of a $626,271 increase in share-based payments as options were granted, a $480,699 increase in cash-based employee expenses and a $978,719 increase in other product development and clinical trial expenses as the Company continues to incur development and clinical costs related to Tiara and regulatory costs related to Tiara and Reducer. As restated, for the year ended December 31, 2017 the Company reversed the $1,274,653 Reducer R&D inventory charge decreasing product development and clinical trial expenses.

The Company’s expenses are subject to inflation and cost increases. The Company has not seen a material increase in the price of any of the components used in the manufacture of its products and services.

Other Loss

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

Tax Expense

The tax expense for the three months ended December 31, 2018 was $70,961 compared to $25,602 expense 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 twelve fiscal quarters to December 31, 2019:

	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
REVENUE	$ 565,821	$ 500,498	$ 439,920	$ 585,793
COST OF GOODS SOLD	109,449	137,999	66,994	143,994
GROSS PROFIT	456,372	362,499	372,926	441,799
EXPENSES				
Selling expenses	502,828	380,412	394,512	368,233
General and administrative expenses	2,671,418	2,197,922	2,463,461	2,680,931
Product development and clinical trials expenses	6,855,615	4,777,197	4,148,184	4,239,963
	10,029,861	7,355,531	7,006,157	7,289,127
OPERATING LOSS	(9,573,489)	(6,993,032)	(6,633,231)	(6,847,328)
Other (expense)/income	(2,739,008)	775,550	(1,287,267)	(1,804,417)
Tax (expense)/income	(41,688)	15,505	(38,980)	36,370
LOSS FOR THE PERIOD	$ (12,354,185)	$ (6,201,977)	$ (7,959,478)	$ (8,615,375)
BASIC LOSS PER SHARE	$ (1.45)	$ (0.83)	$ (1.17)	$ (2.10)

	December 31, 2018 As restated	September 30, 2018	June 30, 2018	March 31, 2018
REVENUE	$ 523,424	$ 480,540	$ 405,247	$ 339,922
COST OF GOODS SOLD	93,519	96,743	88,603	87,393
GROSS PROFIT	429,905	383,797	316,644	252,529
EXPENSES				
Selling expenses	614,742	202,947	248,538	286,938
General and administrative expenses	5,415,634	6,340,747	2,213,464	2,469,091
Product development and clinical trials expenses	4,653,122	3,490,696	3,858,255	3,999,391
	10,683,498	10,034,390	6,320,257	6,755,420
OPERATING LOSS	(10,253,593)	(9,650,593)	(6,003,613)	(6,502,891)
Other income/(expense)	21,862,040	(4,932,151)	(43,071,578)	(49,324,003)
Tax income/(expense)	70,961	(54,000)	(70,400)	(53,654)
INCOME/(LOSS) FOR THE PERIOD	$ 11,679,408	$ (14,636,744)	$ (49,145,591)	$ (55,880,548)
BASIC (LOSS)/GAIN PER SHARE	$ 5.07	$ (7.80)	$ (36.59)	$ (385.90)

	December 31, 2017 As restated	September 30, 2017	June 30, 2017	March 31, 2017
REVENUE	$ 1,227,625	$ 1,374,893	$ 1,305,136	$ 1,481,360
COST OF GOODS SOLD	1,136,804	659,686	872,703	808,628
GROSS PROFIT	90,821	715,207	432,433	672,732
EXPENSES				
Selling expenses	220,885	253,791	224,382	187,168
General and administrative expenses	8,318,549	1,864,302	2,253,219	3,248,713
Product development and clinical trials expenses	2,487,495	4,422,641	4,250,780	5,053,523
	11,026,929	6,540,734	6,728,381	8,489,404
OPERATING LOSS	(10,936,108)	(5,825,527)	(6,295,948)	(7,816,672)
Other income/(expense)	7,209,897	1,473,493	1,012,926	28,299
Tax expense	(25,602)	(343,926)	(58,286)	(56,614)
LOSS FOR THE PERIOD	$ (3,751,813)	$ (4,695,960)	$ (5,341,308)	$ (7,844,987)
BASIC LOSS PER SHARE	$ 82.66	$ (59.50)	$ (67.80)	$ (99.70)

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

Selling expenses are expected to generally increase as the Company continues its focused commercialization of the Reducer in select countries in Europe. General and administrative expenses reached peaks in the third and fourth quarter of 2018 due to the accrual of future collaboration and license fees. While we aim to increase product development and clinical trial activities quarter over quarter, with quarterly fluctuations depending on the activities conducted in that quarter to develop the Tiara and the Reducer, the Company has been resource-constrained since the litigation loss in the second quarter of 2016 as we have been forced to defer or cancel certain otherwise desirable projects we would like to have undertaken.

USE OF PROCEEDS

	PROPOSED USE OF NET PROCEEDS	**ACTUAL USE OF NET PROCEEDS**	
	2019 FINANCINGS	Use of Proceeds	Remaining to be Spent
Continuing operations	$19,601,526	$14,308,693	$5,292,833
NET PROCEEDS	$19,601,526	$14,308,693	$5,292,833

In May of 2019, the Company completed a private placement of (i) the 2019 Notes with a face value of $11.5 million, for gross proceeds to the Company of $9.78 million and (ii) 334,951 Common Shares of the Company at a price of $5.15 per Common Share, for gross proceeds to the Company of $1.72 million.

The Company has cash on hand of $5.3 million as at December 31, 2019. The Company used all the proceeds from the February 2019 Financing and the March 2019 Financing and has partially used the proceeds from the May 2019 Financing for continuing operations.

DISCUSSION OF LIQUIDITY AND CAPITAL RESOURCES

Results for the years ended December 31, 2019 and 2018 follow (as restated):

Neovasc finances its operations and capital expenditures with cash generated from operations and through equity and debt financings. As at December 31, 2019 the Company had cash and cash equivalents of $5,292,833 compared to cash and cash equivalents of $9,242,809 as at December 31, 2018. 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 negative working capital position of $6,705,728, with current assets of $8,015,830 and current liabilities of $14,721,558. 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.

Net cash applied to operating activities for the year ended December 31, 2019 was $23,972,126, compared to $22,794,748, for the same period in 2018. For the year ended December 31, 2019, cash operating expenses were $25,959,718, compared to $23,865,257 for the same period in 2018, an increase of $2,094,461 as the Company continues to manage its cash flows while still advancing the commercialization and development of its products. Net cash provided from the net change in non-cash working capital items for the year ended December 31, 2019 was $1,831,473, compared to $1,065,498 in the same period in 2018, a $765,975 increase.

Net cash applied to investing activities for the year ended December 31, 2019 was $266,639 compared to net cash received from investing activities of $713,752 for the same period in 2018, primarily due to the $865,610 cash inflow from the sale of a manufacturing building in 2018.

During the year ended December 31, 2019, the Company received net proceeds of $19,601,526 from the 2019 Financings and $1,200,400 from the exercise of 2017 Warrants, compared to $13,086,587 proceeds from the exercise of 2017 Warrants 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 December 31, 2019 and 2018 and the Company had no complications in transferring funds to and from its subsidiaries in Israel and the United States.

The Company is exposed to foreign currency fluctuations on $1,266,206 of its cash and cash equivalents and restricted cash held in Canadian dollars and Euros.

Results for the years ended December 31, 2018 and 2017 follow (as restated):

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

The Company is in a positive working capital position of $6,040,192, with current assets of $12,073,976 and current liabilities of $6,033,784. 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 year ended December 31, 2018 was $22,794,748, compared to $138,613,945 for the same period in 2017. For the year ended December 31, 2018, operating activities were $23,865,257, compared to $25,128,439 for the same period in 2017, a decrease of $1,263,182. Net cash provided from the net change in non-cash working capital items for the year ended December 31, 2018 was $1,065,498, compared to a net cash outflow of $113,342,424 in the same period in 2017. The decrease in net cash outflow can be attributed to the payment of the damages and interest awards in relation in the Company's primary U.S. litigation with CardiAQ in 2017.

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

The majority of the revenue and expenses of the Company are incurred in the parent and in two of its subsidiaries, NMI, which is located in Canada, and Neovasc (US) Inc. which is located in the United States. There were no significant restrictions on the transfer of funds between these entities during the periods ended December 31, 2018 and 2017 and the Company had no complications in transferring funds to and from its subsidiaries in Israel and the United States.

The Company is exposed to foreign currency fluctuations on $1,508,963 of its cash and cash equivalents and restricted cash held in Canadian dollars and Euros.

2017 Financings

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

On November 17, 2017, the Company completed the underwritten 2017 Public Transaction of 6,609,588 Series A units (the "Series A Units") of Neovasc and 19,066,780 Series B units (the "Series B Units" and together with the Series A Units, the "Units") of Neovasc, at a price of $1.46 per Unit for gross proceeds of approximately $37.487 million, before deducting the underwriting discounts and commissions and other estimated offering expenses payable by Neovasc. The price of $1.46 per Unit represented 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) 0.001 Common Share of the Company (each, a "Unit Share"), (ii) one Series A warrant of the Company (each, a "Series A Warrant"), exercisable into 0.001 Common Shares, (iii) one Series B warrant of the Company (each, a "Series B Warrant"), exercisable into 0.001 Common Shares and (iv) 0.40 Series C unit purchase warrant (each a "Series C Warrant") to purchase a unit (each, a "Series C Unit") comprised of 0.001 Common Shares, one Series A Warrant and one Series B Warrant.

Each Series B Unit was comprised of (i) either 0.001 Unit Shares or one pre-funded Series D warrant of the Company (each, a "Series D Warrant") exercisable into 0.001 Common Shares, (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 0.001 Common Share (each, a "Series A Warrant Share") at an exercise price of $1,610 per Series A Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2022. Each Series B Warrant entitled the holder to purchase 0.001 Common Share (each, a "Series B Warrant Share") at an exercise price of $1,610 per Series B Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2019. Each Series C Warrant entitled the holder to purchase a Series C Unit comprised of a Common Share (each a "Series C Unit Share"), a Series A Warrant and a Series B Warrant, at an exercise price of $1,460 per Series C Unit at any time prior to 11:59 p.m. (New York time) on November 17, 2019. Each Series D Warrant entitled the holder to purchase 0.001 Common Share (each, a "Series D Warrant Share") at an exercise price of $1,460 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 0.001 Common Share (each, a "Series F Warrant Share" and together with the Series A Warrant Shares, Series B Warrant Shares, Series C Unit Shares, and Series D Warrant Shares, the "2017 Warrant Shares") at an exercise price of $1,610 per Series F Warrant Share at any time prior to 11:59 p.m. (New York time) on November 17, 2019.

Concurrent with the 2017 Public Transaction, the Company completed the 2017 Private Placement for the sale of $32,750,000 aggregate principal amount of the 2017 Notes of the Company and Series E Common Share purchase warrants of the Company (the "Series E Warrants") to purchase 0.001 Common Share at a price of $1,610 per Common Share. As a result of the February 2019 Financing, the exercise prices of the 2017 Notes were adjusted to $4.50 and as a result of the June 2019 Common Share consolidation, the conversion price of the 2017 Notes reset to $3.95. The 2017 Notes were issued with an original issue price of $850 per $1,000 principal amount of note. The 2017 Notes initially carried an 18-month term and carry an interest rate of 0.0% per annum (increasing to 15% upon an event of default) from November 17, 2018. The maturity date of the 2017 Notes was extended to May 17, 2020, pursuant to certain waiver agreements between the Company and the holders of the 2017 Notes, along with certain other amendments. The form of waiver agreement is available on the Company's profiles on SEDAR at www.sedar.com and with the SEC at www.sec.gov. Interest on the 2017 Notes will commence accruing on November 17, 2018, will be computed on the basis of a 360-day year and twelve 30-day months and will be payable in cash on January 1, 2018 and on the first day of each calendar quarter thereafter up to, and including, the maturity date. The Series E Warrants had the same terms and conditions as the Series A Warrants.

The 2017 Notes are secured by a first priority security interest on all of Neovasc's assets. The 2017 Notes and Series E Warrants are subject to adjustment, at any time prior to their expiry. The 2017 Notes contain, among other things, provisions relating to future-priced conversion or exercise formula and full-ratchet anti-dilution.

As of March 12, 2019, all of the warrants issued pursuant to the 2017 Financings have been either exercised or cancelled, such that no such warrants remain outstanding.

For a description of the terms of the securities issued pursuant to the 2017 Financings, see the prospectus supplement and the forms of such securities filed on SEDAR at www.sedar.com and with the SEC at www.sec.gov. For a description of the risks associated with these securities, the amount of such securities exercised to date, the dilution to date and potential dilution in the future due to conversions, see “Risk Factors” and “Share Capital” of the Company's Annual Report on Form 20-F, which is available on SEDAR at www.sedar.com and as file with the SEC at www.sec.gov.

Conversions of 2017 Notes and Exercises of 2017 Warrants

The Series A Warrants, Series B Warrants, Series C Warrants, Series E Warrants and Series F Warrants were each subject to a hold period that restricted each 2017 Warrant from being exercised until January 17, 2018. As of December 31, 2019, all of the 25,676,368 Series B Warrants initially granted and 10,273,972 Series B Warrants issued upon exercise of Series C Warrants have been exercised and all of the 22,431,506 Series F Warrants initially granted have been exercised. As of December 31, 2019, all of the 10,273,972 Series C Warrants initially granted have been exercised, for proceeds to the Company of $14,999,999. Such exercises of Series C Warrants resulted in the issuance of 10,274 Common Shares and the issuance of an additional 10,273,972 Series A Warrants.

On March 12, 2019, the Company announced that it had entered into exchange agreements with the holders of all of its outstanding Series A Warrants and Series E Warrants, pursuant to which the Company issued an aggregate of approximately 496,236 Common Shares for the surrender and cancellation of all of the Series A Warrants and Series E Warrants outstanding, on the basis of 0.0085 of a Common Share for each Series A Warrant or Series E Warrant (the “Exchange”).

As of March 12, 2019, all of the warrants issued pursuant to the 2017 Financings have been either exercised or cancelled, such that no 2017 Warrants remain outstanding.

As of March 27, 2020, of the $32,750,000 aggregate principle amount of 2017 Notes initially issued, 28,837,000 aggregate principle amount has been converted using the alternate conversion price mechanism, resulting in the issuance of 4,150,735 Common Shares and $3,913,000 aggregate principle amount remains outstanding. As a result of the February 2019 Financing, the conversion price of the 2017 Notes reset, as of that time, to $4.50 and as a result of the June 2019 Common Share consolidation, the conversion price of the 2017 Notes reset to $3.95.

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

SUBSEQUENT EVENTS

On January 6, 2020, the Company announced the registered direct offering (the “Offering”) priced at-the-market under Nasdaq rules of an aggregate of 1,185,000 series A units ("Series A Units") and 1,241,490 series B units ("Series B Units") at a price of US$4.1351 per Series A Unit and US$4.135 per Series B Unit for aggregate gross proceeds to the Company of approximately US$10 million, before deducting placement agent’s fees and estimated expenses of the Offering payable by the Company. Each Series A Unit consists of one Common Share of the Company and one warrant (a "Warrant") to purchase one Common Share. Each Warrant entitles the holder to acquire one Common Share of the Company at a price of US$4.1351 at any time prior to the date which is four years following the date of issuance. Each Series B Unit consists of one pre-funded warrant of the Company (each, a "Pre-Funded Warrant") and one Warrant. Each Pre-Funded Warrant entitles the holder to acquire one Common Share of the Company at a price of US$0.0001 at any time until the exercise in full of each Pre-Funded Warrant. As part of the underwriter's compensation in the January 2020 Financing, the Company issued the underwriter warrants (the "2020 Broker Warrants") to purchase in aggregate up to a 157,721 Common Shares, exercisable at a price per Common Share equal to $5.1689 for a period of three years following issuance.

On February 11, 2020, the Company announced the retainment of independent expert Joshua Mitts, a professor at Columbia University specializing in securities trading and capital markets, to investigate recent past unusual trading activity

in the Company's Common Shares. Professor Mitts will examine trading history related to the unusual volume and downward pressure on the price of the Common Shares of the Company after positive news releases, and the unusual volume and downward pressure on the price of the Common Shares of the Company after the Company announced an update on its compliance with the Nasdaq's minimum value of listed securities rule. The findings of the commissioned report may be provided to appropriate authorities, including the Nasdaq.

On February 19, 2020, the Company received notice from the Staff of the Nasdaq indicating that the Staff had determined to delist the Company's common shares from Nasdaq unless the Company requests a hearing before the Nasdaq Hearings Panel. On February 26, 2020, the Company requested such a hearing and the date of the hearing has been set by the Nasdaq for April 2, 2020. This request for a hearing will stay any further action by the Staff and the Company's securities will continue to be eligible to trade on Nasdaq at least pending the ultimate conclusion of the hearing process. A delisting from the Nasdaq Capital Market would result in an event of default under the 2017 Notes.

Since December 31, 2019, the spread of COVID-19 has severely impacted many local economies around the globe. In many countries, businesses are being forced to cease or limit operations for long or indefinite periods of time. Measures taken to contain the spread of the virus, including travel bans, quarantines, social distancing, and closures of non-essential services have triggered significant disruptions to businesses worldwide, resulting in an economic slowdown. These restrictive measures along with market uncertainty have resulted in difficulties distributing, marketing and selling Reducer in our European markets and has decreased the demand for, and revenue from, Reducer. These restrictive measures may also impact our ability to enroll in our clinical trials or continue further product development of the Tiara. In addition, the recent outbreak of COVID-19 has had a negative impact on capital markets, which may adversely affect our ability to raise capital. The recent decrease in our share price may make raising additional capital more dilutive to our shareholders and may make it harder to remain listed on the Nasdaq. We have not been informed by the FDA in the United States that our application to gain market approval has been delayed.

The Company has determined that these events are non-adjusting subsequent events. Accordingly, the financial position and results of operations as of and for the year ended December 31, 2019 have not been adjusted to reflect their impact. The duration and impact of the COVID-19 pandemic, as well as the effectiveness of government and central bank responses, remains unclear at this time. It is not possible to reliably estimate the duration and severity of these consequences, as well as their impact on the financial position and results of the Company for future periods.

OUTSTANDING SHARE DATA

As of March 27, 2020, subsequent to the effect of the share consolidations, the Company had 11,133,319 Common Shares issued and outstanding. The following securities are convertible into Common Shares: 2,426,490 2020 Warrants with an exercise price of $4.15, 1,509,990 stock options with a weighted average exercise price of $13.18, 482,956 restricted stock units, which are granted subject to shareholder approval at the next shareholders meeting, 144,444 2019 Broker Warrants with an exercise price of $5.625 and 157,721 2020 Broker Warrants with an exercise price of $5.1689, $11,500,000 principal amount of 2019 Notes which could convert into 1,533,333 Common Shares and $3,913,000 principal amount of 2017 Notes which could convert into 990,632 Common Shares (not taking into account the alternate conversion price or anti-dilution mechanisms). Our fully diluted share capital as of the same date is 18,378.885. Our fully diluted share capital, adjusted on the assumption that all of the outstanding 2017 Notes are converted using the alternate conversion price at the closing price on March 27, 2020, is 20,064,724.

CONTRACTUAL OBLIGATIONS AND CONTINGENCIES

Contingencies

Litigation

Litigation resulting from third-party claims has been, and may 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 any future claims that may occur, 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. 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. The decision of the Appeals Court of Munich was rendered on March 21, 2019, wherein it amended the decision of the German Court and dismissed the complaint of CardiAQ in full. There are no monetary awards associated with these matters and no damages award was recognized.

Claims by CardiAQ in the United States

On March 24, 2017, CardiAQ filed a related lawsuit in the U.S. District Court for the District of Massachusetts (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 did not seek money damages and would not have prevented 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 April 17, 2019, the Company resolved the three claims for correction of patent inventorship and, without reaching conclusion on the merits of the claims, the parties agreed to the correction of patent inventorship and added co-inventors to the three patents in question. Each party will bear its own costs. There were no monetary awards associated with these matters and no damages award was recognized.

Other Matters

By way of Amended Statement of Claim in Federal Court of Canada Action T-1831-16 (the "Action"), Neovasc Inc. and Neovasc Tiara 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 "Edwards Plaintiffs") against Livanova Canada Corp., Livanova PLC, Boston Scientific and Boston Scientific Ltd. (collectively, the "BSC/Livanova Defendants"). The Action was first filed in October 2016 and first concerned an allegation by the Edwards Plaintiffs that the manufacturing, assembly, use, sale and export of the Lotus Aortic Valve devices by the BSC/Livanova Defendants infringes on the Edwards Plaintiffs' patents. In February 2017, the Neovasc Defendants were added to the Edwards Plaintiffs' claim making related allegations. On January 22, 2019, the Company announced that pursuant to a settlement reached with the Edwards Plaintiffs, the patent infringement action that the Edwards Plaintiffs had previously commenced in the Federal Court of Canada against the Neovasc Defendants, Boston Scientific and Livanova, has been dismissed on a no-costs basis. No damages award was recognized.

On August 3, 2018, the Company announced that it had entered into a collaboration and licensing agreement with Penn Medicine and the Gorman Cardiovascular Research Group at the University of Pennsylvania (collectively, "UPenn"), which resolved certain potential claims against the Company that had been previously disclosed. The collaboration and licensing agreement with UPenn contemplates certain fees being paid by Neovasc to UPenn, including fees in installments totaling $2.65 million over the four years following the agreement's execution. In addition, Neovasc agreed to pay UPenn a royalty of 1.0-1.5% on the annual net sales of the Tiara following the first commercial sale of the Tiara. Also contained in the collaboration and licensing agreement are buy-out clauses that allow Neovasc, or an acquirer of Neovasc or the Tiara assets, to buy out these royalty obligations. As part of the collaboration and licensing agreement, certain potential claims against the Neovasc Defendants were resolved.

When the Company assesses that it is more likely that a present obligation exists at the end of the reporting period and that the possibility of an outflow of economic resources embodying economic benefits is probable, a provision is recognized and

contingent liability disclosure is required. The Company has accrued $893,902 as at December 31, 2019 representing the discounted value of future payments anticipated under the agreement. The Company has not accrued for any future royalty payments in the settlement agreement with UPenn as the amounts are undeterminable at this time.

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 the Neovasc Defendants, alleging claims for trade secret misappropriation, breach of contract, and unfair competition. Endovalve alleged that it was a former customer of Neovasc Inc., and that the Neovasc Defendants improperly used trade secrets in the development of Tiara. The complaint sought injunctive relief, money damages, and attorneys’ fees. On February 20, 2019, the Company announced that it had entered into a settlement agreement with Endovalve. The settlement agreement with Endovalve contemplates certain fees being paid by Neovasc to Endovalve, including settlement fees in installments totaling $3 million over the two and a half years following the agreement's execution. In addition, Neovasc agreed to pay Endovalve a royalty of 1.3% on the annual net sales of the Tiara following the first commercial sale of the Tiara. Also contained in the settlement agreement are buy-out clauses that allow Neovasc, or an acquirer of Neovasc or the Tiara assets, to buy out these royalty obligations. As part of the settlement agreement, the claims against the Neovasc Defendants were dismissed with prejudice.

When the Company assesses that it is more likely that a present obligation exists at the end of the reporting period and that the possibility of an outflow of economic resources embodying economic benefits is probable, a provision is recognized and contingent liability disclosure is required. The Company has accrued $1,384,705 as at December 31, 2019 representing the discounted value of future payments anticipated under the agreement. The Company has not accrued for any future royalty payments in the settlement agreement with Endovalve as the amounts are undeterminable at this time.

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 years ended December 31, 2019, 2018 and 2017 other than those as described elsewhere herein and those compensation-based payments disclosed in Note 24 Related Party Transactions of the consolidated financial statements for the years ended December 31, 2019, 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 and as filed with the SEC at www.sec.gov. Investors are urged to consult and carefully consider these risk factors as an investment in the securities of the Company should be considered a highly speculative investment.

CRITICAL ACCOUNTING ESTIMATES AND MANAGEMENT JUDGMENT

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

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

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

Inventories

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

Allowance for doubtful accounts receivable

The Company has established and applied a provision matrix to the trade accounts receivables balances in order to calculate an allowance for doubtful accounts on adoption of IFRS 9. Actual collectability of customer balances can vary from the Company's estimation.

Impairment of long-lived assets

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

Useful lives of depreciable assets

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

Share-based payment

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

Determination of functional currency

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

Deferred tax assets

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

Contingent Liabilities

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

Accounting for financing and determination of fair value of derivative liabilities

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

The Company's warrants and convertible notes will be measured at fair value through profit and loss at each year 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, 2019 are disclosed in Note 17 to the Company's consolidated financial statements as at and for the years ended December 2019, 2018 and 2017.

Right of use asset and lease liability

At the commencement date, the Company measures the lease liability at the present value of the lease payments unpaid at that date, discounted using the interest rate implicit in the lease if that rate is readily available. If the interest rate implicit in the lease is not readily available, the Company discounts using the Company's incremental borrowing rate. The Company measures the right-of-use assets at an amount equal to the lease liability adjusted for any prepaid or accrued lease payments that existed at the date of transition.

CHANGES IN ACCOUNTING POLICIES INCLUDING INITIAL ADOPTION

During the year ended December 31, 2019, there have been no changes in accounting policies, except as disclosed herein. The Company has adopted IFRS 16 and IFRIC 23 during the year ended December 31, 2019.

Accounting standard issued and effective January 1, 2019

IFRS 16 - Leases

IFRS 16 'Leases' replaces IAS 17 'Leases' along with three Interpretations (IFRIC 4 'Determining whether an Arrangement contains a Lease', SIC 15 'Operating Leases-Incentives' and SIC 27 'Evaluating the Substance of Transactions Involving the Legal Form of a Lease'). The new standard has been applied using the modified retrospective approach, with the cumulative effect of adopting IFRS 16 being recognized in equity as an adjustment to the opening balance of retained earnings for the current period. Prior periods have not been restated.

For contracts in place at the date of initial application, the Company has elected to apply the definition of a lease from IAS 17 and IFRIC 4 and has not applied IFRS 16 to arrangements that were previously not identified as lease under IAS 17 and IFRIC 4.

The Company has elected to include initial direct costs in the measurement of the right-of-use asset for operating leases in existence at the date of initial application of IFRS 16, being January 1, 2019. At this date, the Company has also elected to measure the right-of-use assets at an amount equal to the lease liability adjusted for any prepaid or accrued lease payments that existed at the date of transition.

The Company performed an impairment review on the right-of-use assets at the date of initial application.

On transition, for leases previously accounted for as operating leases with a remaining lease term of less than 12 months and for leases of low-value assets the Company has applied the optional exemptions to not recognize right-of-use assets but to account for the lease expense on a straight-line basis over the remaining lease term.

On transition to IFRS 16 the weighted average incremental borrowing rate applied to lease liabilities recognized under IFRS 16 was 10%.

The Company has benefited from the use of hindsight for determining the lease term when considering options to extend and terminate leases.

The following is a reconciliation of total operating lease commitments at December 31, 2018 to the lease liabilities recognized at January 1, 2019:

Total operating lease commitments disclosed at December 31, 2018	$	1,431,188
Recognition exemptions:		
Leases of low value assets		-
Leases with remaining lease term of less than 12 months		-
Variable lease payments not recognized		-
Operating lease liabilities before discounting		1,431,188
Discounted using incremental borrowing rate		(142,082)
Operating lease liabilities		1,289,106
Total lease liabilities recognized under IFRS 16 at January 1, 2019	$	1,289,106

For any new contracts entered into on or after January 1, 2019, the Company considers whether a contract is, or contains a lease. A lease is defined as 'a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration'. To apply this definition the Company assesses whether the contract meets three key evaluations which are whether:

- the contract contains an identified asset, which is either explicitly identified in the contract or implicitly specified by being identified at the time the asset is made available to the Company
- the Company has the right to obtain substantially all of the economic benefits from use of the identified asset throughout the period of use, considering its rights within the defined scope of the contract
- the Company has the right to direct the use of the identified asset throughout the period of use. The Company assess whether it has the right to direct 'how and for what purpose' the asset is used throughout the period of use.

Measurement and recognition of leases as a lessee

At the lease commencement date, the Company recognizes a right-of-use asset and a lease liability on the statement of financial position.

The Company depreciates the right-of-use assets on a straight-line basis from the lease commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The Company also assesses the right-of-use asset for impairment when such indicators exist.

At the commencement date, the Company measures the lease liability at the present value of the lease payments unpaid at that date, discounted using the interest rate implicit in the lease if that rate is readily available. If the interest rate implicit in the lease is not readily available, the Company discounts using the Company's incremental borrowing rate.

Lease payments included in the measurement of the lease liability are made up of fixed payments (including in-substance fixed), variable payments based on an index or rate, amounts expected to be payable under a residual value guarantee and payments arising from options reasonably certain to be exercised.

Subsequent to initial measurement, the liability will be reduced for payments made and increased for interest. It is remeasured to reflect any reassessment or modification, or if there are changes in in-substance fixed payments. When the

lease liability is remeasured, the corresponding adjustment is reflected in the right-of-use asset, or profit and loss if the right-of-use asset is already reduced to zero.

The Company has elected to account for short-term leases and leases of low-value assets using the practical expedients. Instead of recognizing a right-of-use asset and lease liability, the payments in relation to these are recognized as an expense in profit or loss on a straight-line basis over the lease term.

On the statement of financial position, right-of-use assets have been included under non-current assets and lease liabilities have been included under current and non-current liabilities.

IFRIC 23 – Uncertainty over Income Tax Treatments

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

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

The adoption of IFRIC 23 on January 1, 2019 has not had a significant impact on the consolidated financial statements.

FINANCIAL INSTRUMENTS

The Company's financial instruments include its cash and cash equivalents, restricted cash, accounts receivable and accounts payable, derivative warrant liability from financing, convertible notes, and accrued liabilities.

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 December 31, 2019, 2018 and 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 December 31, 2017:

	Level 1	Level 2	Level 3	Total
Financial liabilities at fair value through profit and loss				
2017 Convertible Notes	$ -	$ -	$ 20,007,559	$ 20,007,559
Derivative warrant financial liability from financing	$ -	$ -	$ 36,829,030	$ 36,829,030

As at December 31, 2018:

	Level 1	Level 2	Level 3	Total
Financial liabilities at fair value through profit and loss				
2017 Convertible Notes	$ -	$ -	$ 14,617,336	$ 14,617,336
Derivative warrant financial liability from financing	$ -	$ -	$ 190,303	$ 190,303

As at December 31, 2019:

	Level 1	Level 2	Level 3	Total
Financial liabilities at fair value through profit and loss				
2017 Convertible Notes	$ -	$ -	$ 5,400,189	$ 5,400,189
2019 Convertible Notes	$ -	$ -	$ 9,265,480	$ 9,265,480

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

	Note	December 31, 2019	December 31, 2018	December 31, 2017
Amortized cost				
Cash and cash equivalents	6	**$ 5,292,833**	$ 9,242,809	$ 17,507,157
Accounts receivable	7	**715,696**	647,143	1,334,923
Restricted cash	11	**462,874**	439,736	478,260
		$ 6,471,403	$ 10,329,688	$ 19,320,340
Other financial liabilities at amortized cost				
Accounts payable and accrued liabilities (current)	14	**$ 7,794,456**	$ 4,610,560	$ 1,844,955
Accrued liabilities (non-current)	14	**1,186,601**	2,241,979	-
Financial liabilities at fair value through profit and loss				
2017 Convertible Notes (current)	17	**$ 5,400,189**	1,423,224	4,261,597
2019 Convertible Notes (current)	17	**1,090,561**	-	-
Derivative liability from financing (current)		**-**	-	19,997,345
2017 Convertible Notes (non-current)	17	**-**	13,194,112	15,745,962
2019 Convertible Notes (non-current)	17	**8,174,919**	-	-
Derivative warrant liability from financing (non-current)		**-**	190,303	16,831,685
		$ 23,646,726	$ 21,660,178	$ 58,681,544

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 30% of the revenue for the year ended December 31, 2019 (year ended December 2018 and 2017: 23% and 65%, respectively). A 10% change in the foreign exchange rates for the Euro for foreign currency denominated accounts receivable will impact net income as at December 31, 2019 by approximately $6,288 (as at December 30, 2018 and 2017: $6,000 and $50,000, respectively), and a similar change in foreign currency denominated accounts payable, which are denominated in Canadian dollars and Euros will impact net income by approximately $80,654 and $176,569, respectively, as at December 31, 2019 (as at December 30, 2018 $13,000 and $30,000 and as at December 31 2017: $32,000 and $10,000). A similar change in foreign currency denominated cash and cash equivalents, and restricted cash, which are denominated in Canadian dollars and Euros will impact net income by approximately $5,254 and $2,780, respectively, as at December 31, 2019 (as at December 30, 2018 $4,837 and $5,855 and as at December 31 2017: $7,011 and $44,792). 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, accounts payable, 2017 Notes that do not accrue interest or 2019 Notes that have fixed interest terms.

(d) Liquidity risk

As at December 31, 2019, the Company had $5,292,833 in cash and cash equivalents as compared to cash and cash equivalents of $9,242,809 at December 31, 2018. The Company is dependent on the profitable commercialization of its products or obtaining additional debt or equity financing to fund ongoing operations until profitability is achieved.

The Company monitors its cash flow on a monthly basis and compares actual performance to the budget for the period. After receipt of the net proceeds of approximately $3.9 million from the February 2019 financing, $4.2 million from the March 2019 financing, and $11.35 million from the May 2019 financing, the Company expects that its cash on hand as at December 31, 2019 and including the January 2020 Financing (see Subsequent Events) is sufficient to sustain operations until approximately August 2020 at the current burn rate if the 2017 Notes are converted prior to the maturity date. If the 2017 Notes are paid out on the maturity date of May 17, 2020, the Company expects that it will have sufficient cash on hand to sustain operations until June 30, 2020 at the current burn rate. The Company may obtain additional debt or equity financing in future periods. 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.

Trades payables were aged as follows as at December 31, 2019 and do not include accrued liabilities. All trades payables are current liabilities:

		Total
Current	**$**	**1,534,577**
31-60 days		**825,097**
Over 60 days		**1,633,529**
	$	**3,993,203**

The following is an analysis of the contractual maturities of the Company's non-derivative accrued liabilities as at December 31, 2019:

		Within One Year		**Between One and Two Years**
Collaboration, license and settlement agreements (undiscounted)	**$**	**1,250,000**	**$**	**1,250,000**
	$	**1,250,000**	**$**	**1,250,000**

(e) Credit risk

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

The maximum exposure, if all of the Company's customers were to default at the same time is the full carrying value of the trade accounts receivable as at December 31, 2019 is $597,505 (as at December 31, 2018 and 2017: $637,421 and $1,201,292, respectively). As at December 31, 2019, the Company had $148,814 (as at December 31, 2018 and 2017: $311,642 and $588,282, respectively) of trade accounts receivable that were overdue according to the customers' credit terms. During the year ended December 31, 2019 the Company wrote down $64,600, respectively, of accounts receivable owed by customers (year ended December 31, 2018 and 2017: $489,449 and $26,931 respectively).

The Company may also have credit risk related to its cash and cash equivalents and restricted cash, with a maximum exposure of $5,755,707 as at December 31, 2019 (as at December 31, 2018 and 2017: $9,682,545 and $17,985,417, respectively). The Company minimizes its risk to cash and cash equivalents and restricted cash by maintaining the majority of its balances with Canadian Chartered Banks.

DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROL OF FINANCIAL REPORTING

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

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

Non-accelerated filers are exempt from Section 404(b) of the Sarbanes-Oxley Act, which generally requires public companies to provide an independent auditor attestation of management's assessment of the effectiveness of their internal control over financial reporting. The Company qualifies as a non-accelerated filer and therefore has not included an independent auditor attestation of management's assessment of the effectiveness of its internal control over financial reporting in this Annual Report or in its audited consolidated financial statements for the years ended December 31, 2019, 2018 and 2017.

The Company's management, under the supervision of the CEO and CFO, has evaluated both the design and operating effectiveness of its DC&P and ICFR and concluded that a material weakness in DC&P and ICFR occurred for the years ended December 31, 2019, 2018 and 2017 as detailed below.

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

In light of the aforementioned material weakness, management conducted a thorough review of all research and development supplies for the year ended December 31, 2019. As a result of this review, management believes that there are no material inaccuracies or omissions of material fact and, to the best its knowledge, believes that the consolidated financial statements for the year ended December 31, 2019 fairly present in all material respects and financial condition and results of operations for the Company in conformity with IFRS. Due to this material weakness, management concluded that DC&P was not effective as of December 31, 2019, 2018 and 2017.

Material Weakness in ICFR

In 2017 the Company purchased Reducer units for testing and charged the expense to product development and clinical trials expense. Since then the Company has not needed as many testing units as planned and our commercial efforts have grown. In 2019, the Company began selling some of those units originally purchased for testing and expensed in 2017. In order to reflect accurate cost of goods sold, the Company re-allocated the testing units back into inventory and credited the product development and clinical trial period expense in 2019.

The Company's assessment in 2017 concluded that the test units were not an asset to be included in commercial inventory but did not consider whether these testing units could be classified as an alternative assets on the statement of financial position as they still had the potential to produce economic benefits.

In its assessment of the effectiveness of ICFR as of December 31, 2019, 2018 and 2017 the Company determined that there were control deficiencies that constituted a material weakness in ICFR relating to the incorrect determination of testing units as a period expense in product development and clinical trials expenses rather than as an asset classified as research and development supplies. Due to this material weakness, management concluded that ICFR was not effective as of December 31, 2019, 2018 and 2017.

Remediation for Material Weakness in ICFR

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

- Flag all Reducer units scheduled for testing at each period end to ensure they correctly accounted for as an asset.
- Review all Reducer units included in period expenses as product development and clinical trials expenses to ensure all the units were correctly used in testing during that period.
- Deploy an internal control compliance program, in accordance with COSO, designed to identify potential deficiencies in DC&P and ICFR throughout the year ending December 31, 2020, to ensure that deficiencies are identified and remediated in a timely manner.
- Further mature DC&P and ICFR practices in addition to enhancing risk assessment, control design assessment and operating effectiveness testing practices throughout the year ending December 31, 2020.

ADDITIONAL INFORMATION

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