



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

**FOR THE THREE AND NINE MONTHS ENDED  
SEPTEMBER 30, 2020 AND 2019**

(Expressed in U.S. Dollars)

**Q3  
2020**

## **MANAGEMENT’S DISCUSSION AND ANALYSIS**

This Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) covers the unaudited condensed interim consolidated financial statements of Neovasc Inc. (the “Company”, “Neovasc”, “we”, “us”, or “our”) for the three and nine months ended September 30, 2020 and 2019.

This MD&A should be read in conjunction with the unaudited condensed interim consolidated financial statements and notes thereto for the three and nine months ended September 30, 2020 and 2019 (included as part of Neovasc’s quarterly filing) as well as the audited consolidated financial statements and notes thereto and the MD&A for the years ended December 31, 2019, 2018 and 2017 and the Annual Report on Form 20-F.

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.

On December 31, 2019, the Company identified certain accounting differences requiring restatement of previously issued consolidated financial statements for the years ended December 31, 2018 and 2017. The accounting differences are related to Reducer units purchased for research and development during the year ended December 31, 2017 and recognized as product development and clinical trials expenses during that period. Not all of the units were used for product development and clinical trials and during the year ended December 31, 2019, as Reducer revenue increased, the Company used certain of those units in commercial activities. In order to correctly state the cost of goods sold for the year ended December 31, 2019 and the correct period expense for the years ended December 31, 2019, 2018 and 2017 the Company has restated the years ended December 31, 2018 and 2017 to include those Reducer units as research and development supplies assets with potential future economic value at the end of each of those periods. All references relating to financial information for the years ended December 2018 and 2017 have been adjusted to be reflected in this Annual Report.

Additional information about the Company, including the Company’s audited consolidated financial statements and Annual Report on Form 20-F, is available on SEDAR at [www.sedar.com](http://www.sedar.com) and as filed with the U.S. Securities and Exchange Commission (the “SEC”) on the website of the SEC at [www.sec.gov](http://www.sec.gov).

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

This 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 August 2020 offering (the "August 2020 Offering") of units (the "August 2020 Units") comprised of one Common Share and three-quarters of one common share purchase warrants (the "August 2020 Warrants") ;
- our intended use of the net proceeds from the June 2020 offering (the "June Offering") of units (the "June Units") comprised of one Common Share and three-quarters of one common share purchase warrants (the "June 2020 Warrants") ;
- our intended use of the net proceeds from the May 2020 private placement offering (the "May Offering") of secured convertible notes (the "2020 Notes") and common share purchase warrants (the "May 2020 Warrants");
- 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 anticipation that the Tiara will receive CE Mark approval in Europe from the Medical Device Directive in 2021;
- the anticipated timing of additional implantations in the TIARA-II trial and our intention to initiate additional investigational sites in 2021 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 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 related to the recent coronavirus outbreak or other health epidemics, which could significantly impact our operations, sales or ability to raise capital;
- risks relating to our need for significant additional future capital and our ability to raise additional funding;
- risks relating to the sale of a significant number of Common Shares;
- 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 related to the recent COVID-19 outbreak or other health epidemics, which could continue to have a significant impact on our operations, sales or ability to raise capital;
- 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 conflicts of interests among the Company's officers and directors as a result of their involvement with other issuers;
- risks relating to future issuances of equity securities by us, or sales of common shares or conversions of convertible notes by our existing security holders, causing the price of our securities to fall;
- risks relating to the broad discretion in our use of proceeds from an offering of our securities;
- risks relating to our intention to not pay dividends in the foreseeable future; and
- anti-takeover provisions in our constating documents which could discourage a third-party from making a takeover bid beneficial to our shareholders.

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;
- our ability to retain and attract key personnel, including members of our board of directors and senior management team; and
- our estimates and assumptions about the impact that the COVID-19 crisis will have on the Company

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](http://www.sedar.com) and as filed with the SEC at [www.sec.gov](http://www.sec.gov). These factors should be considered carefully, and readers should not place undue reliance on the Company's forward-looking statements. Should one or more of these risks or uncertainties or a risk that is not currently known to us materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this 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: November 5, 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 Offering") and a private placement (the "2017 Private Placement" and collectively with the 2017 Public Offering, the "2017 Financings") 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. 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](http://www.sedar.com) and on the SEC's website at [www.sec.gov](http://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 an offering 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 (the "May 2019 Financing").

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 the registered direct January 2020 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. Each Series A Unit consisted of one Common Share and one warrant (a "January 2020 Warrant") to purchase one common share. Each January 2020 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 "January 2020 Pre-Funded Warrant") and one January 2020 Warrant. Each January 2020 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.

On May 26, 2020, the Company made a final payment of \$2,897,000 to holders of the 2017 Notes and \$1,016,000 in 2017 Notes was converted for the issuance of 500,014 Common Shares. The Company and certain holders of the 2017 Notes have also agreed to a mutual release (the "Settlement") in return for the issuance by the Company, in the aggregate, of 500,000 settlement warrants (the "Settlement Warrants") to such holders.

On May 28, 2020, the Company completed the May Offering of the 2020 Notes with a principal amount of \$5 million, convertible at \$2.815 per Common Share for 1,776,041 Common Shares and 2,573,959 warrants ("May 2020 Warrants") exercisable at \$2.634 per May 2020 Warrant share with a 4-year term. The May Offering was completed in two tranches comprised of an initial closing of US\$4 million aggregate principal amount of 2020 Notes and 2,573,959 May 2020 Warrants and an additional closing of US\$1,000,000 aggregate principal amount of 2020 Notes.

On June 16, 2020, the Company completed the registered direct June Offering of an aggregate 3,883,036 June 2020 Units at a price of \$2.973 per unit for aggregate gross proceeds to the Company of approximately \$11,500,000 before deducting placement agent's fee and estimated expenses of the June Offering payable by the Company.

On July 23, 2020 Strul Medical Group LLC ("SMG") exercised 1,424,049 of the 2,573,959 May 2020 Warrants at an exercise price of US\$2.634 per May 2020 Warrant for aggregate exercise proceeds to the Company of US\$3,750,945.07 (the "Exercise Proceeds"). Using the Exercise Proceeds, the Company has prepaid a portion of the 2019 Notes. The total aggregate amount of the Exercise Proceeds has been applied to the prepayment of the 2019 Note whereby US\$3,613,341.12 has been applied to the US\$11,500,000 principal of the 2019 Note, US\$72,266.82 has been paid as a

prepayment penalty pursuant to the terms of the 2019 Note and US\$65,337.13 has been paid in accrued interest. In connection with the prepayment of the 2019 Note, the Company also issued to SMG 481,778 common share purchase warrants (the "Repayment Warrants") at an exercise price of US\$7.50 per Repayment Warrant in accordance with the terms of the 2019 Note.

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 met the minimum market value requirement. The Notification Letter did 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 (the "Panel"). On February 26, 2020, the Company requested such a hearing and the date of the hearing was 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. On April 30, 2020, the Panel granted the Company's request for an extension through August 17, 2020 to evidence compliance with the \$35 million minimum market value of listed securities requirement for continued listing on the Nasdaq. On June 25, 2020, the Nasdaq Notice confirmed that the Company has regained compliance with Listing Rule 5550(b)(2) pursuant to Listing Rule 5810 as the Company's market value exceeded \$35 million for 10 consecutive business days between May 29, 2020 through June , 2020.

Nasdaq has broad discretionary public interest authority that it can exercise to apply additional or more stringent criteria for the continued listing of the Common Shares, or suspend or delist Common Shares even if the Common Shares meet all enumerated criteria for continued listing on the Nasdaq. The Nasdaq could use this discretionary authority at any time to delist the Common Shares. There can be no assurance that Nasdaq will not exercise such discretionary authority. In addition, there is no assurance that the Company will be able to maintain and/or regain compliance with the Nasdaq Marketplace Rules for continued listing.

On August 12, 2020 the Company completed the registered direct August 2020 Offering of 4,532,772 August 2020 Units at a price of \$2.775 per August 2020 Unit, with each August 2020 Unit comprised of one Common Share and three-quarters of one August 2020 Warrant for aggregate gross proceeds to the Company for approximately \$12,600,000 before deducting placement agent's fee and estimated expenses of the August 2020 Offering payable by the Company.

On August 17, 2020 SMG exercised 501,000 of the remaining 1,149,910 May 2020 Warrants at an exercise price of US\$2.634 per May 2020 Warrant for aggregate exercise proceeds to the Company of US\$1,319,634. Using the Exercise Proceeds, the Company has prepaid a portion of the 2019 Notes. The total aggregate amount of the Exercise Proceeds has been applied to the prepayment of the 2019 Note whereby US\$1,263,884.57 has been applied to the remaining US\$7,886,658.88 principal of the 2019 Note, US\$25,277.69 has been paid as a prepayment penalty pursuant to the terms of the 2019 Note and US\$30,471.74 has been paid in accrued interest. In connection with the prepayment of the 2019 Note, the Company also issued to SMG 168,518 common share purchase warrants at an exercise price of US\$7.50 per Repayment Warrant in accordance with the terms of the 2019 Note.

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 distributor 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 advance Tiara development programs for both the Tiara TA transapical system and the Tiara TF Transfemoral system. Additionally, the Company focuses on expanding revenue and global reimbursement for 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 — with the Company's clinical experience of the Tiara, and the clinical data from the TIARA-II multi-center, the Company has filed for CE Mark under the Medical Device Directive ("MDD"). Completing the TIARA-I study; enrollment in the TIARA-I study was closed on November 15, 2019 with a total of 27 patients treated who will be followed out to 5 years. The Company is targeting a European regulatory decision for Tiara TA in the first half of 2021, although 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. Development of the Tiara transfemoral trans-septal system for preclinical bench and animal studies to successful completion, followed by initiation of a first in human feasibility clinical study in 2021.
- 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 reimbursement initiatives in other international markets. 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.
- Following the FDA Circulatory Systems Devices Panel Meeting held October 27, 2020, the Company does not believe that FDA approval in the United States is likely in the near future.
- 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 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 valves. 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 August 6, 2020, 83 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 83 patients treated with the Tiara (i.e., those treated more than 30 days ago) is 89% with one patient now more than six years and eight months 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 patients treated. 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, the Company believes it has accomplished this objective. The patients that are in follow-up will continue their follow up assessments, adverse event reporting requirements, etc., as per protocol through their 5-year visits. This decision had no impact on the TIARA-II CE Mark Study. There are currently 18 active sites across Germany, Israel, Spain, the Netherlands and the UK with two additional sites close to being activated, however due to the COVID-19 pandemic restrictions, our sites were notified on April 24, 2020 that we were placing enrollment on temporary hold. The results from our clinical experience to-date continues to demonstrate the potential benefit for patients who otherwise have no treatment options.

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 12 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 Company has filed for CE Mark for Tiara TA in Europe under the Medical Device Directive and anticipates a CE Mark decision in the first half 2021. 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.

The Tiara TA and Tiara TF are early-stage development products without any regulatory approvals in any country. The Company intends to continue to fund development of this product as cash flow allows.

## Reducer

The Reducer is a treatment for patients with refractory angina, a painful and debilitating condition that occurs when the coronary vasculature delivers 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 from 1990 to 2010. This reflects the worldwide shift to those chronic diseases associated with an aging 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 refractory 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 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. 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 0.035 inch guidewire. The implant procedure requires minimal training for experienced interventionalists. Once guidewire 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 (all but the mid-section) 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 the medical literature.

The clinical utility of this approach was demonstrated by a number of analogous approaches used in the past that achieved positive clinical outcomes for angina patients by constricting or intermittently blocking the coronary sinus to improve perfusion to the heart muscle. However, these therapies required the use of highly invasive surgery, or leaving a catheter in the heart for a prolonged period, making them impractical or clinically unacceptable for use in modern medical practice. The Reducer was developed to deliver this therapy in a safe, simple and effective manner via a minimally invasive catheter that is consistent with contemporary medical practice.

The Reducer has demonstrated excellent results in multiple animal studies, a first-in-human clinical trial of 15 patients suffering from chronic refractory angina 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 were 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 remained patent with no evidence of migration, and symptom relief was maintained 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 based on the 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  $\geq 2$  CCS classes compared to 8 of 52 [15.4%] of the control patients [p-value = 0.024]). The analysis also showed that patients treated with the Reducer showed a statistically significant improvement of one or more CCS classes compared to the sham control patients (37 of 52 [71.2%] of the Reducer patients showed this improvement compared to 22 of 52 [42.3%] of the control patients [p-value = 0.003]). The COSIRA trial results were published in the *New England Journal of Medicine* in February 2015.

In 2016, Neovasc initiated the REDUCER-I post market 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, 274 patients have been enrolled across 25 centers that are active in Italy, Germany, Austria, Belgium, the Netherlands, the United Kingdom, Spain and Switzerland. Enrollment has been delayed due to the impact of COVID-19 in 2020. 15 patients were enrolled in the third quarter of 2020, compared to 14 patients in the same period last year.

In 2018 an article by Parikh, 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 the sustained improvement in angina class seen at six months and three years, was 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.

Included in the numerous publications of clinical results since the COSIRA study was published in the *New England Journal of Medicine* in 2015, a recent 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.

Based on achieving NUB 1 status in Germany and a general positive reception in the European market, with positive experiences by many physicians from the treatment of their own patients with the Reducer, we are seeing an increase in adoption of the Reducer therapy in Europe. The commercial progress for the Reducer in the third quarter of 2020 was encouraging with a 25% increase in revenue compared to 2019. However, the impact of COVID-19 in the second quarter of 2020 has seen revenue for the nine months ended September 30, 2020 to decrease 5% compared to the same period in the prior year.

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 (though now less likely given the outcome of the FDA panel meeting) and the rest of the world.

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 both patients are doing very well.

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.

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.

On July 9, 2020, the Company announced it had received notification of an FDA Circulatory Systems Devices Panel Meeting scheduled for October 27, 2020.

On October 28, 2020, the Company announced results from the FDA Circulatory Systems Devices Panel Meeting at which the Panel voted 14 to 4 "in favor" that the Neovasc Reducer™ is safe when used as intended and voted 1 to 17 "against" on the issue of a reasonable assurance of effectiveness. The third vote was 13 to 3 "against" (2 abstained) on whether the relative benefits outweighed the relative risks. The FDA will provide the Company with their decision on the PMA at a later date.

### *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.

On October 10, 2018, the Company announced that the FDA had 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 recommended 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.

On October 27, 2020, the FDA Circulatory Systems Devices Panel Meeting was held. The Panel voted 14 to 4 "in favor" that the Neovasc Reducer™ is safe when used as intended and voted 1 to 17 "against" on the issue of a reasonable assurance of effectiveness. The third vote was 13 to 3 "against" (2 abstained) on whether the relative benefits outweighed the relative risks. The FDA will provide the Company with their decision on the PMA.

### **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 be an important advance 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 and 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 initiated Reducer sales in other non-US markets with distribution agreements in several countries.

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**

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 \$10,234,677 and \$10,392,921, and \$24,271,583 and \$25,300,783 for the three and nine months ended September 30, 2020, respectively (2019: \$6,201,977 and \$6,555,186, and \$22,776,830 and \$22,463,857, respectively) and has a deficit of \$390,803,747 at September 30, 2020 compared to a deficit of \$366,532,164 as at December 31, 2019. As at September 30, 2020 the Company had \$14,034,457 in cash and cash equivalents (December 31, 2019: \$5,292,833).

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. These terms may make it more difficult to obtain additional debt or equity financing in the future.

As at September 30, 2020, the Company had approximately \$14 million in cash and cash equivalents. The Company expects that its cash on hand as at September 30, 2020 is sufficient to sustain operations until approximately March 2021 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 see the Company's Annual Report on Form 20-F, which is available on SEDAR at [sedar.com](http://sedar.com) and as filed with the SEC at [www.sec.gov](http://www.sec.gov).

The unaudited condensed interim consolidated financial statements do not reflect adjustments that would be necessary if the going concern assumption were not appropriate. Material adjustments may be necessary to the unaudited condensed interim 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; securities litigation risk and the Company's defense 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 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 its 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 unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2020 and 2019.

### DISCUSSION OF OPERATIONS AND FINANCIAL CONDITION

Results for the three months ended September 30, 2020 and 2019 follow:

#### Losses

The operating losses and comprehensive losses for the three months ended September 30, 2020 were \$10,168,452 and \$10,392,921, respectively, or \$0.51 basic and diluted loss per share, as compared with \$6,993,032 operating losses and \$6,555,186 comprehensive loss, or \$0.83 basic and diluted loss per share, for the same period in 2019. The increase of \$3,175,420 in operating losses can be explained by a \$2,445,057 increase in general and administrative expenses, principally due to legal expenses related to financing activities and a \$725,520 increase in product development and clinical trial expenses, as the Company continues its PMA and CE mark applications for Reducer and Tiara respectively.

The \$3,837,735 increase in the comprehensive loss incurred for the three months ended September 30, 2020 compared to the same period in 2019 can be substantially explained by the \$3,175,420 in increase in operating losses, summarized above and a \$1,036,891 increase in loss related to the accounting treatment of the 2019 Notes, 2020 Notes and the derivative liability warrants.

#### Revenues

Revenues increased by 25% to \$626,418 for the three months ended September 30, 2020, compared to revenues of \$500,498 for the same period in 2019. A restriction on elective procedures, which included Reducer implants was implemented by the hospitals, health authorities or governments of a substantial portion of all our major markets due to COVID-19, which caused Reducer implantations to significantly slow beginning in March. Beginning in June, we saw a return of implants in several of our international markets with a strong rebound in Germany, Italy and other select markets. We have seen many of our markets implement additional restrictions related to COVID-19 as the third quarter came to a close and our future revenues maybe impacted by COVID-19 again. We continue to work on our reimbursement activities in several countries to further streamline 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 in various territories and continuing our market development efforts.

#### Cost of Goods Sold

The cost of goods sold for the three months ended September 30, 2020 was \$150,503 compared to \$137,999 for the same period in 2019. The overall gross margin for the three months ended September 30, 2020 was 76%, compared to 72% gross margin for the same period in 2019. The Company continues to focus on Germany where the Company sells the Reducer direct for higher margins.

#### Expenses

Total expenses for the three months ended September 30, 2020 were \$10,644,367 compared to \$7,355,531 for 2019, representing an increase of \$3,288,836 or 45%. The increase in total expenses for the three months ended September 30, 2020 compared to 2019 can be substantially explained by i) a \$1,966,695 increase in legal costs related to the 2020 financings, ii) a \$618,948 increase in share-based payments as options were granted and iii) a \$518,229 increase in headcount and general 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 September 30, 2020 were \$498,671, compared to \$380,412 for 2019, representing an increase of \$118,259 or 31%. The increase in selling expenses for the three months ended September 30, 2020 compared to 2019 can be substantially explained by a \$72,958 increase in share-based payments as options were granted and a \$45,117 increase in employee expenses as two sales representatives have been added since March 2019. The Company continues to minimize its selling expenses as the cash resources of the Company are still limited.

General and administrative expenses for the three months ended September 30, 2020 were \$4,642,979, compared to \$2,197,922 for the same period in 2019, representing an increase of \$2,445,057 or 111%. The increase in general and administrative expenses for the three months ended September 30, 2020 compared to 2019 can be substantially explained by a \$1,966,695 increase in legal costs related to the 2020 financings, a \$339,639 increase in share-based payments as options were granted and a \$183,337 increase in other expenses.

Product development and clinical trial expenses for the three months ended September 30, 2020 were \$5,502,717 compared to \$4,777,197 for 2019, representing an increase of \$725,520 or 15%. The increase in product development and clinical trial expenses for the three months ended September 30, 2020 can be substantially explained by a \$219,258 increase in employee related expenses, a \$206,351 increase in share-based payments as options were granted and a \$298,971 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 September 30, 2020 was \$66,225 compared to other income of \$775,550 for the same period in 2019, a change of \$841,775. The increase in other loss can be substantially explained by a \$1,036,891 increase in loss related to related to the accounting treatment of the 2019 Notes, 2020 Notes and derivative liability warrants and a \$191,989 increase in interest and penalty expense principally related to the early repayment for the 2019 Notes, offset by a \$487,840 increase in other income related to the Canadian Emergency Wage subsidy received in September.

#### **Tax Expense**

The tax recovery for the three months ended September 30, 2020 was nil compared to a \$15,505 tax recovery in 2019. Neovasc (US) Inc. was established in 2015 to provide clinical trial services to Neovasc Medical Inc. The cross border intercompany charges from Neovasc (US) Inc. to Neovasc Medical Inc. created a taxable profit in Neovasc (US) Inc. and U.S. federal and state taxes were incurred.

#### Results for the nine months ended September 30, 2020 and 2019 follow:

#### **Losses**

The operating losses and comprehensive losses for the nine months ended September 30, 2020 were \$25,982,927 and \$25,300,783, respectively, or \$1.69 basic and diluted loss per share, as compared with \$20,473,591 operating losses and \$22,463,857 comprehensive loss, or \$3.72 basic and diluted loss per share, for the same period in 2019. The increase of \$5,509,336 in operating losses by i) a \$3,613,677 increase in general and administrative expenses ii) a \$1,450,503 increase in product development and clinical trial expenses, iii) a \$361,557 increase in selling expenses.

The \$2,836,926 increase in the comprehensive loss incurred for the nine months ended September 30, 2020 compared to the same period in 2019 can be substantially explained by the \$5,509,336 increase in operating losses as summarized above and a \$1,342,173 increase in other comprehensive losses offset by a \$4,033,475 increase in other income/expense principally related to the accounting treatment of the 2017 Notes, 2019 Notes, 2020 Notes and derivative liability warrants and a \$487,840 increase in other income related to the Canadian Emergency Wage subsidy received in September.

## Revenues

Revenues decreased by 5% to \$1,443,360 for the nine months ended September 30, 2020, compared to revenues of \$1,526,211 for the same period in 2019. A restriction on elective procedures, which included Reducer implants was implemented by the hospitals, health authorities or governments of all our major markets, which caused Reducer implantations to significantly slow beginning in March. Beginning in June, we saw a return of implants in several of our international markets with a strong rebound in Germany, Italy and other select markets. We have seen many of our markets implement additional restrictions related to COVID-19 as the third quarter came to a close and our future revenues maybe impacted by COVID-19 again. We continue to work on our reimbursement activities 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 continuing our market development efforts.

## Cost of Goods Sold

The cost of goods sold for the nine months ended September 30, 2020 was \$349,735 compared to \$348,987 for the same period in 2019. The overall gross margin for the nine months ended September 30, 2020 was 76%, compared to 77% gross margin for the same period in 2019. The Company continues to focus on Germany where the Company sells the Reducer direct for higher margins.

## Expenses

Total expenses for the nine months ended September 30, 2020 were \$27,076,552 compared to \$21,650,815 for 2019, representing an increase of \$5,425,737 or 25%. The increase in total expenses for the nine months ended September 30, 2020 compared to 2019 can be substantially explained by i) a \$2,621,803 increase in legal costs related to the 2020 financings, ii) a \$1,599,516 increase in employee related expenses due to a) an increased in headcount including our COO and b) an increase in the vacation accrual as a direct impact of COVID-1919 delaying vacations, iii) an \$828,131 increase in share-based payments as options were granted and iv) a \$406,135 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.

Selling expenses for the nine months ended September 30, 2020 were \$1,504,714, compared to \$1,143,157 for 2019, representing an increase of \$361,557 or 32%. The increase in selling expenses for the nine months ended September 30, 2020 compared to 2019 can be substantially explained by a \$246,767 increase in employee expenses as two sales representatives have been added since March 2019, and a \$74,634 increase in share-based payments as options were granted. The Company continues to minimize selling expenses as the cash resources of the Company are still limited.

General and administrative expenses for the nine months ended September 30, 2020 were \$10,955,991, compared to \$7,342,314 for the same period in 2019, representing an increase of \$3,613,677 or 49%. The increase in general and administrative expenses for the nine months ended September 30, 2020 compared to 2019 can be substantially explained by an \$2,621,803 increase in legal costs related to the 2020 financings, a \$563,196 increase in employee related expenses due to i) an increased headcount including our COO and ii) an increase in the vacation accrual as a direct impact of COVID-1919 delaying vacations and a \$510,519 increase in share-based payments as options were granted.

Product development and clinical trial expenses for the nine months ended September 30, 2020 were \$14,615,847 compared to \$13,165,344 for 2019, representing an increase of \$1,450,503 or 11%. The increase in product development and clinical trial expenses for the nine months ended September 30, 2020 can be substantially explained by a \$789,553 increase in employee related expenses due to i) an increased headcount and ii) an increase in the vacation accrual as a direct impact of COVID-1919 delaying vacations, a \$242,978 increase in share-based payments as options were granted and a \$406,135 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 income for the nine months ended September 30, 2020 was \$1,717,341 compared to other loss of \$2,316,134 for the same period in 2019, a change of \$4,033,475. The increase in the other income can be substantially explained by a \$4,189,534 increase in income related to the accounting treatment of the 2017 Notes, 2019 Notes, 2020 Notes and derivative liability warrants and a \$487,840 increase in other income related to the Canadian Emergency Wage subsidy received in September offset by a \$729,539 increase in interest and penalty expense related to the 2019 and 2020 Notes.

#### **Tax Expense**

The tax expense for the nine months ended September 30, 2020 was \$5,997 compared to a \$12,895 tax recovery in 2019. Neovasc (US) Inc. was established in 2015 to provide clinical trial services to Neovasc Medical Inc. The cross border intercompany charges from Neovasc (US) Inc. to Neovasc Medical Inc. created a taxable profit in Neovasc (US) Inc. and U.S. federal and state taxes were incurred.

## QUARTERLY INFORMATION

The following is a summary of selected unaudited financial information for the eight fiscal quarters to September 30, 2020:

	September 30, 2020	June 30, 2020	March 31, 2020	December 31, 2019
<b>REVENUE</b>	\$ 626,418	\$ 284,047	\$ 532,895	\$ 565,821
<b>COST OF GOODS SOLD</b>	150,503	74,669	124,563	109,449
<b>GROSS PROFIT</b>	475,915	209,378	408,332	456,372
<b>EXPENSES</b>				
Selling expenses	498,671	452,514	553,529	502,828
General and administrative expenses	4,642,979	3,825,510	2,487,502	2,671,418
Product development and clinical trials expenses	5,502,717	4,589,724	4,523,406	6,855,615
	10,644,367	8,867,748	7,564,437	10,029,861
<b>OPERATING LOSS</b>	(10,168,452)	(8,658,370)	(7,156,105)	(9,573,489)
Other (expense)/income	(66,225)	(1,268,020)	3,051,586	(2,739,008)
Tax (expense)/income	-	1,075	(7,072)	(41,688)
<b>LOSS FOR THE PERIOD</b>	\$ (10,234,677)	\$ (9,925,315)	\$ (4,111,591)	\$ (12,354,185)
<b>BASIC AND DILLUTED LOSS PER SHARE</b>	\$ (0.51)	\$ (0.81)	\$ (0.38)	\$ (1.45)
	September 30, 2019	June 30, 2019	March 31, 2019	December 31, 2018
<b>REVENUE</b>	\$ 500,498	\$ 439,920	\$ 585,793	\$ 523,424
<b>COST OF GOODS SOLD</b>	137,999	66,994	143,994	93,519
<b>GROSS PROFIT</b>	362,499	372,926	441,799	429,905
<b>EXPENSES</b>				
Selling expenses	380,412	394,512	368,233	614,742
General and administrative expenses	2,197,922	2,463,461	2,680,931	5,415,634
Product development and clinical trials expenses	4,777,197	4,148,184	4,239,963	4,653,122
	7,355,531	7,006,157	7,289,127	10,683,498
<b>OPERATING LOSS</b>	(6,993,032)	(6,633,231)	(6,847,328)	(10,253,593)
Other income/(expense)	775,550	(1,287,267)	(1,804,417)	21,862,040
Tax income/(expense)	15,505	(38,980)	36,370	70,961
<b>INCOME/(LOSS) FOR THE PERIOD</b>	\$ (6,201,977)	\$ (7,959,478)	\$ (8,615,375)	\$ 11,679,408
<b>BASIC AND DILLUTED (LOSS)/GAIN PER SHARE</b>	\$ (0.83)	\$ (1.17)	\$ (2.10)	\$ 5.07

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 a new peak in the third quarter of 2020 due to the increase in legal costs related to the 2020 financings. 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	
	June 2020 \$11.5M Equity Financing	Use of Proceeds	Remaining to be Spent
Continuing operations	\$10,084,052	\$7,386,172	\$2,697,880
<b>NET PROCEEDS</b>	\$10,084,052	\$7,386,172	\$2,697,880

	PROPOSED USE OF NET PROCEEDS	ACTUAL USE OF NET PROCEEDS	
	August 2020 \$11.3M Equity Financing	Use of Proceeds	Remaining to be Spent
Continuing operations	\$11,336,577	\$NIL	\$11,336,577
<b>NET PROCEEDS</b>	\$11,336,577	\$NIL	\$11,336,577

The Company used all the proceeds from the May 2020 \$5M Debt Financings for continuing operations. The Company has cash on hand of \$14,034,457 million as at September 30, 2020.

## DISCUSSION OF LIQUIDITY AND CAPITAL RESOURCES

Results for the nine months ended September 30, 2020 and 2019 follow:

Neovasc finances its operations and capital expenditures with cash generated from operations and through equity and debt financings. As at September 30, 2020 the Company had cash and cash equivalents of \$14,034,457 compared to cash and cash equivalents of \$5,292,833 as at December 31, 2019. 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 \$9,036,978 with current assets of \$16,660,377 and current liabilities of \$7,623,399. 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 nine months ended September 30, 2020 was \$22,793,297, compared to \$18,089,177 for the same period in 2019. For the nine months ended September 30, 2020, cash operating expenses were \$20,534,907, compared to \$17,093,583 for the same period in 2019, an increase of \$3,441,324 (principally due to a \$2,621,804 increase in legal costs related to the 2020 financings) as the Company continues to manage its cash flows while still advancing the commercialization and development of its products. Net cash applied to the net change in non-cash working capital items for the nine months ended September 30, 2020 was \$2,349,856, compared to \$1,185,872 in the same period in 2019, a \$1,163,984 increase.

Net cash applied to investing activities for the nine months ended September 30, 2020 was \$256,914 compared to \$176,941 for the same period in 2019, primarily due to an increase in expenditure of property and equipment.

During the nine months ended September 30, 2020, the Company received proceeds of \$30,180,405 from the January 2020, June 2020 and August 2020 Offerings and received \$5,000,000 from the issuance of the 2020 Notes. In addition, the Company received \$4,973,035 from the exercise of May 2020 Warrants, which was used to prepay \$4,877,225 of the 2019 Note and settled the remaining principle on the 2017 Note which matured during the period. For the same period in 2019, the Company received \$1,200,400 from the exercise of 2017 Warrants and \$19,601,526 proceeds from the 2019 financings during the nine months ended September 30, 2019.

The majority of the revenue and expenses of the Company are incurred in the parent and in two of its subsidiaries, NMI, which is located in Canada, and Neovasc (US) Inc. which is located in the United States. There were no significant

restrictions on the transfer of funds between these entities during the periods ended September 30, 2020 and 2019 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 \$1,507,139 of its cash and cash equivalents and restricted cash held in Canadian dollars and Euros.

## **SUBSEQUENT EVENTS**

On October 27, 2020, the Company announced that the United States Food and Drug Administration's (FDA's) Circulatory System Devices Advisory Panel voted 14 to 4 "in favor" that the Neovasc Reducer™ is safe when used as intended, and voted 1 to 17 "against" on the issue of a reasonable assurance of effectiveness. The third vote was 13 to 3 "against" (2 abstained) on whether the relative benefits outweighed the relative risks.

## **OUTSTANDING SHARE DATA**

As of October 28, 2020, subsequent to the effect of the share consolidations, the Company had 22,647,127 Common Shares issued and outstanding. The following securities are convertible into Common Shares:

- 3,399,579 August 2020 Warrants with an exercise price of \$2.69, 2,912,277 June 2020 Warrants with an exercise price of \$2.88, 648,910 May 2020 Warrants with an exercise price of \$2.634, 250,000 January 2020 Warrants with an exercise price of \$4.15, In addition the Company had 650,296 Repayment Warrants with an exercise price of \$7.50 (escalating during the life of the warrant as per the terms of the 2019 Notes) and 500,000 settlement warrants with an exercise price of \$2.634.
- 144,444 2019 Broker Warrants with an exercise price of \$5.625, 157,721 January 2020 broker warrants with an exercise price of \$5.1689, 252,397 June 2020 compensation warrants with an exercise price of \$3.72 and 294,630 August 2020 compensation warrants with an exercise price of \$3.47.
- \$6,622,774 principal amount of 2019 Notes which could convert into 883,037 Common Shares and \$5,000,000 principle amount of 2020 Notes which could convert into 1,776,041 Common Shares.
- 784,000 restricted share units and 2,044,584 options

Our fully diluted share capital as of the same date is 37,345,043, excluding any payment in kind interest that may be due on the outstanding notes.

## **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 (the 'Appeals Court'). 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. On March 30, 2020, the German Supreme Court granted CardiAQ leave to appeal the Appeals Court decision and at a hearing held on August 4, 2020 the German Supreme Court set aside the prior decision of the Appeals Court and remanded the matter back to the Appeals Court for a new hearing and decision. The next hearing at the Appeals Court will be on February 25, 2021.

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

On March 24, 2017, CardiAQ filed a related lawsuit in the 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 \$458,186 as at September 30, 2020 representing the discounted value of future payments anticipated under the settlement agreement with UPenn. 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 \$703,990 as at September 30, 2020 representing the discounted value of future payments anticipated under the settlement agreement with Endovalve. 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 the nine months ended September 30, 2020 and 2019, other than those as described elsewhere herein and those compensation-based payments disclosed in Note 24 Related Party Transactions of the unaudited condensed interim consolidated financial statements for the nine months ended September 30, 2020 and 2019.

## **RISK FACTORS**

A comprehensive list of the risks and uncertainties affecting us can be found in our most recent Annual Report on Form 20-F, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and as filed with the SEC at [www.sec.gov](http://www.sec.gov). Investors are urged to consult and carefully consider these risk factors as an investment in the securities of the Company should be considered a highly speculative investment.

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

The preparation of consolidated financial statements in conformity with IFRS requires management to make estimates and 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 period 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 and in May 2020 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 period end. The calculations of the fair value of these instruments involves the use of a number of estimates and a complex valuation model. The carrying amounts of these liabilities may change significantly as a result of changes to these estimates. Details of the estimates used as at September 30, 2020 are disclosed in Note 17 to the Company's unaudited condensed interim consolidated financial statements as at and for the nine months ended September 30, 2020 and 2019.

#### *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 nine months ended September 30, 2020, the following are changes in accounting policies:

#### **New Accounting Policy – Government assistance and government grants**

Government grants are recognized when there is a reasonable assurance that the grant will be received and that the Company will comply with all conditions related to the grant. A grant without specified future performance conditions is recognized in income when the grant proceeds are receivable. A grant that imposes specified future performance conditions is recognized in income when those conditions are met. Government grants related to current expenses are recognized as income over the period necessary to match them with the related expenses, for which they are intended to compensate, on a systematic basis. Government grants related to specific projects are recognized as income over the period necessary to match them with the related project costs, for which they are intended to compensate, on a systematic basis. Government grants in the form of forgivable loans are treated as a government grant when there is reasonable assurance that the entity will meet the terms for forgiveness of the loan.

Government grants received before the income recognition criteria are satisfied are presented as a liability in the statement of financial position. Government refundable advances provided to the Company to finance research and development activities on a risk-sharing basis are considered part of the Company's operating activities and are therefore presented as cash flows from operating activities in the statement of cash flows.

## 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 September 30, 2020 and December 31, 2019. 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, 2019:

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

As at September 30, 2020:

	Level 1	Level 2	Level 3	Total
<b>Financial liabilities at fair value through profit and loss</b>				
2019 Convertible Notes	\$ -	\$ -	\$ 5,957,564	\$ 5,957,564
2020 Convertible Notes	\$ -	\$ -	\$ 2,796,726	\$ 2,796,726
Derivative liability - warrants	\$ -	\$ -	\$ 1,507,467	\$ 1,507,467

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

	Note	September 30, 2020	December 31, 2019
<b>Amortized cost</b>			
Cash and cash equivalents	6	\$ 14,034,457	\$ 5,292,833
Accounts receivable	7	870,114	715,696
Restricted cash	11	450,331	462,874
		<b>\$ 15,354,902</b>	<b>\$ 6,471,403</b>
<b>Other financial liabilities at amortized cost</b>			
Accounts payable and accrued liabilities (current)	14	\$ 6,997,723	\$ 7,794,456
Accounts payable and accrued liabilities (non-current)	14	-	1,186,601
<b>Financial liabilities at fair value through profit and loss</b>			
2017 Convertible Notes (current)	17	\$ -	\$ 5,400,189
2019 Convertible Notes (current)	17	167,409	1,090,561
2019 Convertible Notes (non-current)	17	5,790,155	8,174,919
2020 Convertible Notes (non-current)	17	2,796,726	-
Derivative liability warrant (non-current)	17	1,507,467	-
		<b>\$ 17,259,480</b>	<b>\$ 23,646,726</b>

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

(b) Foreign exchange risk

A portion of the Company's revenues are derived from product sales in Europe, denominated in Euros. Management has considered the stability of the foreign currency and the impact a change in the exchange rate may have on future earnings during the forecasting process. The Euro represents approximately 40% of revenues for the nine months ended September 30, 2020, respectively (nine months ended September 30, 2019: 31%). A 10% change in the foreign exchange rates for the Euro for foreign currency denominated accounts receivable will impact net income as at September 30, 2020 by approximately \$10,142 (as at September 30, 2019: \$6,180), and a similar change in foreign currency denominated accounts payable, which are denominated in Canadian dollars and Euros will impact net income by approximately \$110,531 and \$70,469 respectively, as at September 30, 2020 (as at September 30, 2019: \$57,151 and \$111,781). 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 \$116,451 and \$34,263, respectively, as at September 30, 2020 (as at September 30, 2019: \$85,470 and \$56,715). 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, or 2019 and 2020 Notes that have fixed interest terms.

(d) Liquidity risk

As at September 30, 2020, the Company had \$14,034,457 in cash and cash equivalents as compared to cash and cash equivalents of \$5,292,833 at December 31, 2019. The Company is dependent on the profitable commercialization of its products or obtaining additional debt or equity financing to fund ongoing operations until profitability is achieved.

The Company monitors its cash flow on a monthly basis and compares actual performance to the budget for the period. The Company expects that its cash on hand as at September 30, 2020 is sufficient to sustain operations until approximately March 2021 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.

Trade payables were aged as follows as at September 30, 2020 and do not include accrued liabilities. All trades payables are current liabilities:

	<u>Total</u>
Current	\$ 1,694,800
31-60 days	962,765
Over 60 days	239,666
	<u>\$ 2,897,231</u>

The following is an analysis of the contractual maturities of the Company's non-derivative accrued liabilities as at September 30, 2020:

	<u>Within One Year</u>	<u>Between One and Two Years</u>
Collaboration, license and settlement agreements (undiscounted)	\$ 1,250,000	\$ -
	<u>\$ 1,250,000</u>	<u>\$ -</u>

(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 the Company's customers were to default at the same time is the full carrying value of the trade accounts receivable as at September 30, 2020 is \$683,582 (as at September 30, 2019: \$541,180). As at September 30, 2020, the Company had \$177,832 (as at September 30, 2019: \$284,744) of trade accounts receivable that were overdue according to the customers' credit terms. During the three and nine months ended September 30, 2020 the Company wrote down \$nil and \$nil, respectively, of accounts receivable owed by customers (three and nine months ended September 30, 2019: \$nil and \$64,600, respectively).

The Company may also have credit risk related to its cash and cash equivalents and restricted cash, with a maximum exposure of \$14,484,788 as at September 30, 2020 (as at December 31, 2019: \$5,755,707). 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 unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2020 and 2019.

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 nine months ended September 30, 2020. 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 unaudited condensed interim consolidated financial statements for the nine months ended September 30, 2020 fairly present in all material respects and the financial condition and results of operations for the Company in conformity with IFRS.

## **ADDITIONAL INFORMATION**

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