Neovasc Inc.
Management's Discussion and Analysis

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

(Expressed in U.S. Dollars)

Q3 2021

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, 2021 and 2020.

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, 2021 and 2020 (included as part of Neovasc's quarterly filing) as well as the audited consolidated financial statements and notes thereto, the MD&A for the years ended December 31, 2020, 2019 and 2018, the Company's Annual Information Form and Annual Report on Form 40-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.

Additional information about the Company, including the Company's audited consolidated financial statements and Annual Information Form, is available on SEDAR at www.sedar.com and in the Company's Annual Report on Form 40-F filed with the U.S. Securities and Exchange Commission (the "SEC") at www.sec.gov.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS

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

- our ability to continue as a going concern;
- our need for significant additional financing and our estimates regarding our capital requirements and future revenues, expenses and profitability;
- our intended use of the net proceeds from the February 2021 offering (the "February 2021 Offering") of units comprised of one Common Share and one common share purchase warrants (the "February 2021 Units");
- our anticipation that the proceeds from the February 2021 offering could be sufficient to extend operations of the Company until June 2024 at the current burn rate and our anticipation that we will likely initiate programs that will require additional significant expenditures and that the cash needs of the Company will likely increase, shortening the time the proceeds will meet the requirements of the Company;
- our estimates regarding our fully diluted share capital and future dilution to shareholders;
- our expectation that our remediation of our material weakness in internal control over financial reporting ("ICFR") as of December 31, 2019, and 2018 will be sufficient;
- our intention to monitor the Company's share price on the Nasdaq and our expectation that the Common Shares will continue to be listed and traded on the Nasdaq;
- our intention to expand the indications for, and markets in 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);
- our clinical development of our products, including the results of current and future clinical trials and studies;
- our anticipation that the Tiara TA and Tiara TF (if and when Tiara TF development is restarted) will receive CE Mark approval in Europe under the Medical Device Regulation ("MDR");
- the ongoing pause in enrollment of, and the anticipated timing of additional implantations in the TIARA-II trial;
- our plans to develop and commercialize products, including the Tiara and the Reducer, and the timing and cost of these development programs;
- our plans to indefinitely pause the development and commercialization of the Tiara transfemoral trans-septal system, including our ability to improve current prototypes, until the Company is in a financial position to restart the development, if at all;
- our ability to grow reimbursements and revenues from the Reducer in a timely manner;
- whether we will receive, and the timing and costs of obtaining, regulatory approvals;
- our belief that the U.S. Food and Drug Administration (the "FDA") approval for Reducer in the United States will not happen in the near future following the 'not approvable' letter for the Reducer received on January 15, 2021 and that a new application to obtain FDA PMA approval for the Reducer will be filed with data from the Investigational Device Exemption ("IDE") study which may take three years or more to complete;

- our ability to enroll patients in the new COSIRA II Reducer IDE study at a sufficiently high rate, that the study will meet its
- endpoint, that the study will be successful and that we will be able to file a new PMA to FDA with the COSIRA II clinical
- study results;
- our ability to obtain US FDA approval for the Reducer, based on the COSIRA II IDE clinical study;
- the cost of post-market regulation and commercialization if we receive necessary regulatory approvals and if we decide to commercialize;
- our ability to enroll patients in our clinical trials and studies in Canada, the United States, Europe, Israel and other markets;
- our ability to advance and complete a potential COSIRA-II IDE pivotal clinical trial in the event that we restart the Tiara TF program;
- our belief that the full PMA application pathway, while costly and likely to take many years, brings the best chance of success for Tiara in the U.S. and that this pathway is currently indefinitely paused;
- our belief that the TIARA-I Early Feasibility study demonstrates the safety of the Neovasc transcatheter mitral valve replacement ("TMVR") system;
- our belief that clinical evidence already available or that may be developed in the future 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 plans to increase Reducer implants in Europe in 2021;
- our expectation that in 2021 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 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 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 composition and compensation of our board of directors and senior management team in the future: and
- the impact of foreign currency exchange rates.

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

- risks around our ability to continue as a going concern;
- risks around our history of losses and significant accumulated deficit;
- risks related to the recent COVID-19 coronavirus outbreak or other health epidemics, which could significantly impact our operations, sales or ability to raise capital or enroll patients in clinical trials and complete certain Tiara TA development milestones on our expected schedule;
- 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 have an effective ICFR as of September 30, 2021 and December 31, 2020, but not December 31, 2019 and 2018;
- risks relating to the possibility that our Common Shares may be delisted from the Nasdaq or the TSX, which could affect their market price and liquidity
- risks relating to our Common Share price being volatile;
- risks relating to our significant indebtedness, and its effect on our financial condition;
- risks relating to the influence of significant shareholders of the Company over our business operations and share price;
- 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;
- risks relating to our ability to establish, maintain and defend intellectual property rights in our products;
- risks relating to results from clinical trials of our products, which may be unfavorable or perceived as unfavorable;

- risks associated with product liability claims, insurance and recalls;
- risks relating to use of our products in unapproved circumstances, which could expose us to liabilities;
- risks relating to competition in the medical device industry, including the risk that one or more competitors may develop more effective or more affordable products;
- risks relating to our ability to achieve or maintain expected levels of market acceptance for our products, as well as our ability to successfully build our in-house sales capabilities or secure third-party marketing or distribution partners;
- risks relating to our ability to convince public payors and hospitals to include our products on their approved products lists;
- risks relating to new legislation, new regulatory requirements and the efforts of governmental and third-party payors to contain or reduce the costs of healthcare;
- risks relating to increased regulation, enforcement and inspections of participants in the medical device industry, including frequent government investigations into marketing and other business practices;
- risks relating to the extensive regulation of our products and trials by governmental authorities, as well as the cost and time delays associated therewith;
- risks relating to post-market regulation of our products;
- risks relating to health and safety concerns associated with our products and our industry;
- risks relating to our manufacturing operations, including the regulation of our manufacturing processes by governmental authorities and the availability of two critical components of the Reducer;
- risks relating to the possibility 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 relating to future changes in financial accounting standards and new accounting pronouncements;
- risks relating to our dependence upon key personnel to achieve our business objectives;
- risks relating to our ability to maintain strong relationships with physicians;
- risks relating to the sufficiency of our management systems and resources in periods of significant growth;
- risks relating to 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;
- risks relating to future issuances of equity securities by us, or sales of Common Shares or conversions of convertible notes, and exercise of warrants, options and restricted stock units by our existing security holders, causing the price of our securities to fall;
- risks relating to anti-takeover provisions in our constating documents which could discourage a third-party from making a takeover bid beneficial to our shareholders.

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 be successful;
- our current positive interactions with regulatory agencies will continue;
- our recruitment to clinical trials and studies will continue, specifically once COVID-19 is properly managed;
- our estimates of the time required to enroll, analyze and report the results of our clinical studies will be consistent with projected timelines;
- our current and future clinical trials and studies will generate the supporting clinical data necessary to achieve approval of marketing authorization applications;
- our current 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;
- our expectation that genericization of markets for the Tiara TA and the Reducer will develop over time;

- our ability to raise additional capital 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 most recent Annual Information Form, which is available on SEDAR at www.sedar.com and as filed with the SEC at www.sec.gov. These factors should be considered carefully, and readers should not place undue reliance on the Company's forward-looking statements. Should one or more of these risks or uncertainties or a risk that is not currently known to us materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this MD&A and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. Investors are cautioned that forward-looking statements are not guarantees of future performance and investors are cautioned not to put undue reliance on forward-looking statements due to their inherent uncertainty.

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

Date: November 9, 2021

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 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.

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 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. $70 million of the proceeds were placed in escrow to fund the damages and interest awards in its litigation with Edwards Lifesciences CardiAQ LLC ("CardiAQ") formerly known as CardiAQ Valve Technologies Inc.

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 CardiAQ (after subtracting the approximately $70 million that the Company had paid into escrow from the proceeds of the sale of the tissue processing technology to Boston Scientific), 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 Information Form and the prospectus supplement, dated November 10, 2017 and the form of 2017 Notes, each as filed or furnished under the Company’s profiles on SEDAR at www.sedar.com and on the SEC’s website at www.sec.gov.

On February 28, 2019, the Company completed an underwritten public offering of 1,111,111 Common Shares, at a price of $4.50 per Common Share, for gross proceeds of approximately $5 million before deducting the underwriting commission and offering expenses payable by the Company (“February 2019 Financing”).

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”).

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.

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

On January 6, 2020, the Company completed a registered direct offering (“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$4.1351 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 ("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 an offering of secured convertible notes (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 offering (“June 2020 Offering”) of an aggregate 3,883,036 units (“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. Each June 2020 Unit consisted of one Common Share and one warrant ("June 2020 Warrant") to purchase one Common Share. Each June 2020 Warrant entitles the holder to acquire one Common Share of the Company at a price of US$2.88 at any time prior to the date which is five years following the date of issuance.

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 (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 has been applied to the US$11,500,000 principal of the 2019 Note, US$72,267 has been paid as a prepayment penalty pursuant to the terms of the 2019 Note and US$65,337 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 12, 2020 the Company completed the registered direct offering (“August 2020 Offering”) of 4,532,772 units (“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 Common Share purchase warrant (each, an "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. Each August 2020 Warrant entitles the holder to acquire one Common Share of the Company at a price of US$2.29 at any time prior to the date which is five years following the date of issuance.

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$1,263,885 has been applied to the remaining US$7,886,659 principal of the 2019 Note, US$25,278 has been paid as a prepayment penalty pursuant to the terms of the 2019 Note and US$30,472 has been paid in accrued interest. In connection with the prepayment of the 2019 Note, the Company also issued to SMG 168,518 Repayment Warrants at an exercise price of US$7.50 per Repayment Warrant in accordance with the terms of the 2019 Note.

On December 10, 2020 the Company completed the registered direct offering (the “December 2020 Offering”) of an aggregate 6,230,803 units (“December 2020 Units”) at a price of US$0.9801 per unit for aggregate gross proceeds to the Company of approximately US$6,100,000 before deducting placement agent’s fee and estimated expenses of the December 2020 Offering payable by the Company. Each December 2020 Unit consisted of one Common Share and one warrant ("December 2020 Warrant") to purchase one Common Share. Each December 2020 Warrant entitles the holder to acquire one Common Share of the Company at a price of US$2.29 at any time prior to the date which is five years following the date of issuance.

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 that time. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company was 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 stayed any further action by the Staff and the Company’s securities continued 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 had regained compliance with Listing Rule 5550(a)(2) pursuant to Listing Rule 5810 for continued listing on the Nasdaq.

On January 15, 2021, the Company received a "not approvable" letter from the FDA regarding its PMA submission for the Reducer. The FDA reviewed Reducer for treatment of patients with refractory angina pectoris despite guideline directed medical therapy, who are unsuitable for revascularization by coronary artery bypass grafting or by percutaneous coronary intervention.

On February 12, 2021, the Company completed the registered direct offering (“the February 2021 Offering”) of 36,000,000 units (“February 2021 Units”) at a price of $2.00 per February 2021 Unit for aggregate gross proceeds to the Company for approximately $72,000,000 before deducting placement agent’s fee and estimated expenses of the February 2021 Offering payable by the Company. Each February 2021 Unit consisted of one Common Share and one half of one warrant ("February 2021 Warrant") to purchase one Common Share. Each February 2021 Warrant entitles the holder to acquire one Common Share of the Company at a price of US$2.30 at any time prior to the date which is five years following the date of issuance.

On December 10, 2020 and December 14, 2020, the Company received additional Notification Letters from the Nasdaq notifying that the Company is not currently in compliance with the Nasdaq’s continued listing requirements which require that an issuer’s listed securities maintain a total market value of US$35 million (the “Market Value Requirements”) and a minimum bid price of at least US$1.00 per share (the “Minimum Bid Price Requirements”), respectively. In accordance with Nasdaq Listing Rules, the Company was given until June 8, 2021 to regain compliance with the Market Value Requirements and until June 14, 2021 to regain compliance with the Minimum Bid Price Requirements. On February 9, 2021, the Company announced that it had received written notification from the Nasdaq notifying the Company that it had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) pursuant to Nasdaq Listing Rule 5810 for continued listing on the Nasdaq. On February 25, 2021, the Company announced that it had received written notification from the Nasdaq notifying the Company that it had regained compliance with the minimum market value requirement under Nasdaq Listing Rule 5550(b)(2) pursuant to Nasdaq Listing Rule 5810 for continued listing on the Nasdaq.

On May 25, 2021, the Company received written notification from the Nasdaq Listing Qualifications Department notifying the Company that it was not in compliance with the $1.00 minimum bid price requirement set forth in the Nasdaq Marketplace Rules. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided 180 calendar days, or until November 22, 2021, to regain compliance. The Company intends, in accordance with Nasdaq Listing Rule 5810(c)(3)(A)(i), to request a second 180-calendar day period, or until May 21, 2022, within which to evidence compliance with the $1.00 bid price requirement following the expiration of the current compliance period.

On June 10, 2021, the Company announced that it had indefinitely paused all product development activities on the Tiara TF device. Concurrent with this decision the Company terminated 40% of its staff and took a provision for obsolete leasehold improvements and equipment related to these activities.

On July 13, 2021, the company announced that it appointed Lisa Becker as Vice President, Regulatory Affairs, Global Angina Therapies and Sarah Gallagher as Vice President, Clinical Affairs. The company believes Ms. Becker and Ms. Gallagher bring significant experience and organizational capability. The two new leaders will be responsible for the ongoing regulatory and clinical efforts at the company.

On September 16, 2021, the Company received FDA approval for the Investigational Device Exemption (IDE) regarding the COSIRA-II IDE Clinical Trial. Following multiple discussions with FDA, the approved protocol for the COSIRA-II study is designed to answer key questions arising from the October 2020 Circulatory Systems Devices Panel Meeting regarding the Reducer.

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 from Boston Scientific. NMI and NUS employ the majority of the employees of the Company. Neovasc Tiara Inc. ("NTI") in Canada holds all the intangible assets related to the Tiara and NML in Israel 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 and pays royalties to the Office of the Chief Scientist ("OCS") in Israel to repay certain research grants funded by the OCS prior to the acquisition of NML in July 2008. NUS, charges NMI for development services performed by its employees to develop the Tiara and the Reducer respectively and these are then passed on through NMI to NTI and NML respectively. Neovasc GmbH conducts sales and marketing activities on behalf of NMI as part of the license agreement between NML and NMI for NMI to manufacture, distribute and sell the Reducer on behalf of NML. Neovasc Management Inc. provides executive management services to Neovasc Inc.

Neovasc's Strategy

The Company's core strategy is to i) expand revenue and global reimbursement for Reducer and initiate a U.S. IDE Study and ii) advance the development program for the Tiara TA transapical system. The Company is focused on providing minimally invasive medical devices (including Reducer and Tiara) for a cardiovascular market that the Company believes is both growing and under-served by current treatment solutions.

Key elements of this strategy include:

- Reducer revenue and reimbursement growth — continuing therapy development of the Reducer, and supplementing the successful COSIRA clinical study with additional clinical experience through the Company's targeted commercial launch of the Reducer in Europe and elsewhere 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.
- Reducer clinical and regulatory development: Initiating enrollment in the recently FDA approved the COSIRA-II U.S. IDE study and expediting ongoing enrollment in the study.
- Tiara regulatory development— with the Company's clinical experience of the Tiara and the clinical data from the TIARA-II multi-center study, the Company is in ongoing discussions with its notified body and is pursuing a regulatory decision for Tiara TA under the European MDRrules. 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.

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 April 25, 2021, 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 at the time of data cut-off April 5, 2021, for the 83 patients treated with the Tiara is 89% with one patient now more than 7 years post implant. The Tiara has successfully treated both functional and degenerative Mitral Regurgitation patients, as well as patients with pre-existing prosthetic aortic valves and mitral surgical annuloplasty rings. On November 15, 2019, TIARA-I study enrollment was closed with 27 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 16 active sites across Germany, Israel, Spain, the Netherlands and the UK., however due to the COVID-19 pandemic restrictions, enrollment continues to be on temporary hold (sites were notified on April 24, 2020 of the temporary hold). The results from our clinical experience to-date continue 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 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, and if the Company decides to commercialize the Tiara TA, the Tiara would be commercially manufactured in the same manner at Neovasc's facility.

Regulatory Status

The Company filed for CE Mark under MDD but was unable to complete the regulatory review process before the expiration of the MDD on May 26, 2021. Therefore, the Company was unable to receive CE Mark under MDD in the first half of 2021. The Company is in ongoing discussions with its notified body and is pursuing a regulatory decision under MDR rules. 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 or that any or all of the sizes will be approved. 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 is an early-stage development product without any regulatory approvals in any country. The Company expects ongoing expenses associated with Tiara TA regulatory, clinical and other functional activities.

The Company has indefinitely paused development activity associated with Tiara TF. There can be no assurance that the Company will re-start development activity with Tiara TF or that it will maintain the development pause.

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 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 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, and 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 ≥ 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, 301 patients have been enrolled across 22 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 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 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 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. COVID-19 had a marked impact on Reducer revenues and we anticipate that the negative impact will be felt throughout 2021. It is unclear how long the negative impact of COVID-19 will persist.

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, and the rest of the world.

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 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.

On January 15, 2021, the Company announced that it had received a not-approvable letter from FDA regarding its PMA submission for the Neovasc Reducer.

On September 16, 2021, the Company received FDA approval for the Investigational Device Exemption (IDE) regarding the COSIRA-II IDE Clinical Trial. Following multiple discussions with FDA, the approved protocol for the COSIRA-II study is designed to answer key questions arising from the October 2020 Circulatory Systems Devices Panel Meeting regarding the Reducer.

Regulatory Status

The Reducer received CE Mark designation November 2011. 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 has not started such a U.S. clinical trial, funding being the largest impediment. The cost of this U.S. clinical trial is expected to be approximately $35 million. The Company expects significant future expenses associated with the clinical studies, and regulatory submissions, for the Reducer. The September 15, 2021 IDE Supplement approval provides FDA approval for the COSIRA-II Study.

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 the FDA to further discuss available clinical evidence for the Reducer, to try to reach agreement on potential options to enter the U.S. Market. The 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.

On January 15, 2021, the Company announced that it had received a not-approvable letter from FDA regarding its PMA submission for the Reducer.

On September 16, 2021, the Company received FDA approval for the Investigational Device Exemption (IDE) regarding the COSIRA-II IDE Clinical Trial. Following multiple discussions with FDA, the approved protocol for the COSIRA-II study is designed to answer key questions arising from the October 2020 Circulatory Systems Devices Panel Meeting regarding the Reducer.

New Products/Components/Cycles

Tiara

The Company has indefinitely paused development activity associated with Tiara TF. There can be no assurance that the Company will re-start development activity with Tiara TF or that it will maintain the development pause.

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 and we are in the process of transitioning manufacture of the device to another similar contract manufacturer. 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.

TRENDS, RISKS AND UNCERTAINTIES

Losses and Additional Funding Requirements

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

The Company has incurred operating losses and comprehensive losses of $6,724,676 and $6,915,962, and $25,989,792 and $19,102,028 for the three and nine months ended September 30, 2021, respectively (2020: $10,168,452 and $10,392,921, and $25,982,927 and $25,300,783, respectively) and has a deficit of $413,963,231 as at September 30, 2021 compared to a deficit of $369,775,383 as at December 31, 2020. As at September 30, 2021 the Company had $55,827,026 in cash and cash equivalents (December 31, 2020: $12,935,860).

During the nine months ended September 30, 2021, the Company raised $72 million in a registered direct offering that closed on February 12, 2021 with estimated net proceeds of $65 million to the Company. The proceeds from the February 2021 Financing could be sufficient to extend the operations of the Company until June 2024 at the current burn rate. However, given the FDA's decision to approve the COSIRA-II clinical study, it is likely that the Company will initiate programs that will require additional significant expenditures and that the increasing cash needs of the Company will likely shorten the time the proceeds will meet the requirements of the Company.

The Company will need to raise additional capital to fund its long-term objectives for the Tiara TA and the Reducer prior to the successful commercialization of these products in the longer term. There is no certainty that the Company will be able to raise additional capital through debt or equity or other means on terms acceptable to the Company or at all. There is also no certainty that the programs will be successfully commercialized, or any required funds will be available to the Company at the time needed or on terms acceptable to the Company. The terms of the required financing may also make it more difficult to obtain additional debt or equity financing in the future.

Given the current nature of the Company's capital structure, the Company can give no assurance that it will be able to obtain additional funds needed in the future, 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 at September 30, 2021. The Company will re-evaluate the going concern risk at each reporting period and will remove the going concern and uncertainty note when the Company can depend on the profitable commercialization of its products or is confident of obtaining additional debt, equity or other financing to fund ongoing operations until profitability is achieved. For a description of the risks relating to the Company's need for additional financing see the Company's Annual Information Form, which is available on SEDAR at www.sedar.com and as filed with the SEC at 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: 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 clinical success of the Tiara; 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 a decrease in the demand or sales for our products. The recent outbreak of the novel coronavirus (COVID-19) has had a negative impact on our operating environment and governmental actions to contain the outbreak may impact our ability to transport or market our products, enroll patients in our clinical studies or adversely affect our ability to raise capital.

FOREIGN OPERATIONS

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, 2021 and 2020.

DISCUSSION OF OPERATIONS AND FINANCIAL CONDITION

Results for the three months ended September 30, 2021 and 2020 follow:

Losses

The operating losses and comprehensive losses for the three months ended September 30, 2021 were $6,724,676 and $6,915,962, respectively, or $0.11 basic and diluted loss per share, as compared with $10,168,452 operating losses and $10,392,921, comprehensive loss, or $0.51 basic and diluted loss per share, for the same period in 2020.

The decrease of $3,443,776 in operating losses can be explained by a $3,381,114 decrease in operating expenses and a $77,002 increase in revenue. The $3,476,959 decrease in the comprehensive loss incurred for the three months ended September 30, 2021 compared to the same period in 2020 can be substantially explained by the $3,443,776 decrease in operating losses.

Revenues

Revenues increased by 12% to $703,420 for the three months ended September 30, 2021, compared to revenues of $626,418 for the same period in 2020. 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 2020. Since March 2020, these restrictions have been increased or decreased on a country-by-country basis depending on the severity of the COVID-19 outbreak in each region at the time. 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 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, 2021 was $164,843 compared to $150,503 for the same period in 2020. The overall gross margin for the three months ended September 30, 2021 was 77%, compared to 76% gross margin for the same period in 2020. The Company continues to focus on Germany where the Company sells the Reducer directly to customers for higher margins.

Expenses

Total expenses for the three months ended September 30, 2021 were $7,263,253 compared to $10,644,367 for 2020, representing a decrease of $3,381,114 or 32%. The decrease in total expenses for the three months ended September 30, 2021 compared to 2020 can be substantially explained by a $2,130,220 decrease in legal and underwriting fees related to the August 2020 financing, a $1,037,944 decrease in employee expenses due to the Company's reduction in force at the end of 2020 and further in June 2021 and an $848,917 decrease in other product development and clinical trial expenses as the Company indefinitely paused all activities related to the Tiara TF transfemoral mitral valve replacement program in June 2021 offset by a $429,528 increase in non-cash share-based payments.

Selling expenses for the three months ended September 30, 2021 were $786,366, compared to $498,671 for 2020, representing an increase of $287,695 or 58%. The increase in selling expenses for the three months ended September 30, 2021 compared to 2020 can be substantially explained by an $81,614 increase in non-cash share-based payments and a $219,262 increase in other expenses incurred for commercialization activities related to the Reducer as the Company increased its selling activities from the COVID-19 driven low point in the comparable period.

General and administrative expenses for the three months ended September 30, 2021 were $2,999,003, compared to $4,642,979 for the same period in 2020, representing a decrease of $1,643,976 or 35%. The decrease in general and administrative expenses for the three months ended September 30, 2021 compared to 2020 can be substantially explained by a $2,130,220 decrease in legal and underwriting fees related to the August 2020 financing offset by a $545,620 increase in non-cash share-based payments.

Product development and clinical trial expenses for the three months ended September 30, 2021 were $3,477,884 compared to $5,502,717 for 2020, representing an decrease of $2,024,833 or 37%. The decrease in product development and clinical trial expenses for the three months ended September 30, 2021 can be substantially explained by a $924,120 decrease in employee expenses due to the Company's reduction in force at the end of 2020 and further in June 2021, an $848,917 decrease in other product development and clinical trial expenses as the Company indefinitely paused all activities related to the Tiara TF transfemoral mitral valve replacement program in June 2021 and a $197,706 decrease in non-cash share-based payments.

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, 2021 was $810,921 compared to other loss of $66,225 for the same period in 2020, an increase of $744,696. The increase in other loss can be substantially explained by a $973,102 increase in other loss related to the accounting treatment of the 2019 Notes, 2020 Notes and the derivative liability warrants offset by a $95,808 decrease in interest payment of the 2019 Convertible Note.

Tax Expense

The tax expense for the three months ended September 30, 2021 and 2020 was $nil. 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, 2021 and 2020 follow:

Losses

The operating losses and comprehensive losses for the nine months ended September 30,2021 were $25,989,792 and $19,102,028, respectively, or $0.31 basic and diluted loss per share, as compared with $25,982,927 operating losses and $25,300,783 comprehensive loss, or $1.69 basic and diluted loss per share, for the same period in 2020. The increase of $6,865 in operating losses can be substantially explained by a $355,180 increase in operating expenses offset by a $344,922 increase in revenue.

The $6,198,755 decrease in the comprehensive loss incurred for the nine months ended September 30, 2021 compared to the same period in 2020 can be substantially explained by a $5,639,584 increase in income related to the accounting treatment of the 2019 Notes, 2020 Notes and the derivative liability warrants and a $415,437 decrease in interest payment on the 2019 Convertible Note.

Revenues

Revenues increased by 24% to $1,788,282 for the nine months ended September 30, 2021, compared to revenues of $1,443,360 for the same period in 2020. 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 2020. Since March 2020, these restrictions have been increased or decreased on a country-by-country basis depending on the severity of the COVID-19 outbreak in each region at the time. Notably, however, the restrictions did not begin until March 2020 and these two COVID-19 free months in our comparative period skew the comparative period and like for like analysis. 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 obtaining appropriate reimbursement 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, 2021 was $346,342 compared to $349,735 for the same period in 2020. The overall gross margin for the nine months ended September 30, 2021 was 81%, compared to 76% gross margin for the same period in 2020. 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, 2021 were $27,431,732 compared to $27,076,552 for 2020, representing an increase of $355,180. The increase in total expenses for the nine months ended September 30, 2021 compared to 2020 can be substantially explained by i) a $2,793,167 increase in non-cash share-based payments, ii) a $593,622 non-cash impairment charge due to fixed assets obsolescence, iii) a $232,416 charge for employee termination expenses (both points ii) and iii) related to the decision to indefinitely pause the development of the Tiara TF device in June 2021) and iv) an $820,146 increase in litigation expenses related to the defense of the ongoing class action litigation offset by a $2,134,309 decrease in employee expenses due to the Company's reduction in force at the end of 2020 and further in June 2021,and a $1,869,706 decrease in legal and underwriting fees related to the 2020 financings.

Selling expenses for the nine months ended September 30, 2021 were $2,257,157, compared to $1,504,714 for 2020, representing an increase of $752,443 or 50%. The increase in selling expenses for the nine months ended September 30, 2021 compared to 2020 can be substantially explained by a $475,356 increase in non-cash share-based payments and a $265,741 increase in other expenses incurred for commercialization activities related to the Reducer as the Company increased its selling activities from the COVID-19 driven low point in the comparable period.

General and administrative expenses for the nine months ended September 30, 2021 were $13,334,376, compared to $10,955,991 for the same period in 2020, representing an increase of $2,378,385 or 22%. The increase in general and administrative expenses for the nine months ended September 30, 2021 compared to 2020 can be substantially explained by i) a $2,705,575 increase in non-cash share-based payments, ii) a $593,622 non-cash impairment charge due to fixed assets obsolescence, iii) a $232,416 charge for employee termination expenses, and iv) an $820,146 increase in litigation expenses offset by a $1,869,706 decrease in legal and underwriting fees related to the 2020 financings.

Product development and clinical trial expenses for the nine months ended September 30, 2021 were $11,840,199 compared to $14,615,847 for 2020, representing a decrease of $2,775,648 or 19%. The decrease in product development and clinical trial expenses for the nine months ended September 30, 2021 can be substantially explained by a $2,073,095 decrease in employee expenses due to the Company's reduction in force at the end of 2020, a $387,764 decrease in non-cash share-based payments and a $250,879 decrease in other product development and clinical trial expenses as the Company indefinitely paused all activities related to the Tiara TF transfemoral mitral valve replacement program in June 2021.

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 Income

The other income for the nine months ended September 30, 2021 was $7,237,638 compared to $1,717,341 for the same period in 2020, an increase of $5,520,297. The increase in the other income can be substantially explained by a $4,976,386 increase in income related to the accounting treatment of the 2019 Notes, 2020 Notes and the derivative liability warrants and a $415,437 decrease in interest payment of the 2019 Convertible Note.

Tax Expense

The tax recovery for the nine months ended September 30, 2021 was $16,128 compared to a $5,997 expense in 2020. 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, 2021:

	September 30, 2021	June 30, 2021	March 31, 2021	December 31, 2020
REVENUE	$ 703,420	$ 633,068	$ 451,794	$ 514,002
COST OF GOODS SOLD	164,843	109,106	72,393	96,504
GROSS PROFIT	538,577	523,962	379,401	417,498
EXPENSES				
Selling expenses	786,366	832,812	637,979	692,089
General and administrative expenses	2,999,003	5,042,804	5,292,569	3,125,162
Product development and clinical trials expenses	3,477,884	3,740,887	4,621,428	5,785,748
	7,263,253	9,616,503	10,551,976	9,602,999
OPERATING LOSS	(6,724,676)	(9,092,541)	(10,172,575)	(9,185,501)
Other (expense)/income	(810,921)	44,131	8,004,428	4,231,989
Tax recovery	-	15,396	732	530,054
LOSS FOR THE PERIOD	$ (7,535,597)	$ (9,033,014)	$ (2,167,415)	$ (4,423,458)
BASIC AND DILLUTED LOSS PER SHARE	$ ($0.11)	$ ($0.13)	$ ($0.04)	$ (0.18)

	September 30, 2020	June 30, 2020	March 31, 2020	December 31, 2019
REVENUE	$ 626,418	$ 284,047	$ 532,895	$ 565,821
COST OF GOODS SOLD	150,503	74,669	124,563	109,449
GROSS PROFIT	475,915	209,378	408,332	456,372
EXPENSES				
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
OPERATING LOSS	(10,168,452)	(8,658,370)	(7,156,105)	(9,573,489)
Other income/(expense)	(66,225)	(1,268,020)	3,051,586	(2,739,008)
Tax recovery/(expense)	-	1,075	(7,072)	(41,688)
LOSS FOR THE PERIOD	$ (10,234,677)	$ (9,925,315)	$ (4,111,591)	$ (12,354,185)
BASIC AND DILLUTED LOSS PER SHARE	$ (0.51)	$ (0.81)	$ (0.38)	$ (1.45)

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 first quarter of 2021 due to the increase in legal expenses and underwriters fees related to the February 2021 financings in that period. We anticipate that product development and clinical trials expenses will be reduced significantly by the decision to indefinitely pause the Tiara TF development program but will increase significantly on the initiation of the COSIRA-II IDE clinical study. Product development and clinical trials expenses will continue to fluctuate on a quarterly basis as we move through different development cycles of our products.

USE OF PROCEEDS

	PROPOSED USE OF NET PROCEEDS	ACTUAL USE OF NET PROCEEDS	
	February 2021 $72M Equity Financing	Use of Proceeds	Remaining to be Spent
Advancement of Reducer	$35,000,000	$1,154,841	$33,845,159
Advancement of Tiara	$15,000,000	$3,881,530	$11,118,470
General corporate and working capital	$15,322,100	$4,458,703	$10,863,397
NET PROCEEDS	$65,322,100	$9,495,074	$55,827,026

The Company used all the proceeds from the December 2020 Financing for continuing operations. The Company has cash on hand of $55,827,026 as at September 30, 2021.

DISCUSSION OF LIQUIDITY AND CAPITAL RESOURCES

Results for the nine months ended September 30, 2021 and 2020 follow:

Neovasc finances its operations and capital expenditures with cash generated from operations and through equity and debt financings. As at September 30, 2021 the Company had cash and cash equivalents of $55,827,026 compared to cash and cash equivalents of $12,935,860 as at December 31, 2020.

The Company's working capital position is $54,823,251, with current assets of $60,218,007 and current liabilities of $5,394,756. The Company may 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 in the future.

Net cash applied to operating activities for the nine months ended September 30, 2021 was $22,727,061, compared to $22,793,297, for the same period in 2020. For the nine months ended September 30, 2021, cash operating expenses were $16,570,301, compared to $20,534,907 for the same period in 2020, a decrease of $3,964,606 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, 2021 was $6,213,556, compared to $2,349,856 in the same period in 2020, a $3,863,700 increase as we sought to decrease our accounts payable following the February 2021 Financing.

During the nine months ended September 30, 2021, the Company received net proceeds of $65,322,100 from the February 2021 Offering and $1,078,623 from the exercise of 2020 Warrants compared to the i) receipt of $30,180,405 from the January 2020 Offering, June 2020 Offering and August 2020 Offering, ii) receipt of $5,000,000 from the 2020 Notes and derivative liability warrants, iii) receipt of $4,973,035 from the exercise of 2017 Warrants, iv) repayment of the 2017 Convertible Note for $2,897,000 and v) repayment of the 2019 Convertible Note for $4,877,225 during the nine months ended September 30, 2020.

The majority of the revenue and expenses of the Company are incurred in the parent and in three of its subsidiaries, NMI, which is located in Canada, Neovasc (US) Inc., which is located in the United States and Neovasc GmbH, which is located in Germany. There were no significant restrictions on the transfer of funds between these entities during the periods ended September 30, 2021 and 2020 and the Company had no complications in transferring funds to and from its subsidiaries in Israel, Germany and the United States.

The Company is exposed to foreign currency fluctuations on $2,235,864 of its cash and cash equivalents and restricted cash held in Canadian dollars and Euros.

SUBSEQUENT EVENTS

The Company has no subsequent events.

OUTSTANDING SHARE DATA

As of August 10, 2021, subsequent to the effect of the share consolidations, the Company had 67,587,079 Common Shares issued and outstanding. The following securities are convertible into Common Shares:

- 18,000,000 February 2021 Warrants with an exercise price of $2.30, 4,402,324 December 2020 Warrants with an exercise price of $0.86, 3,274,579 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 $4.14, 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 $2.01.
- 144,444 2019 Broker Warrants with an exercise price of $5.63, 157,721 January 2020 Broker Warrants with an exercise price of $5.17, 252,397 June 2020 compensation warrants with an exercise price of $3.71, 294,630 August 2020 compensation

warrants with an exercise price of $3.47, 405,002 December 2020 compensation warrants with an exercise price of $1.23 and 2,340,000 February 2021 compensation warrants with an exercise price of $2.50.

- $6,622,774 principal amount of 2019 Notes and additional accrued interest which could convert into 989,978 Common Shares at $7.50 per share and $5,000,000 principal amount of 2020 Notes and additional accrued interest which could convert into 1,975,481 Common Shares at $2.82 per share.
- 2,721,331 restricted share units and 6,082,596 incentive options

Our fully diluted share capital as of the same date is 113,589,045, including any payment in kind interest that may be due and convertible into common shares 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 pending claims, and 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, Edwards Lifesciences CardiAQ LLC ("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. 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 hearing at the Appeals Court was held on February 25, 2021.

On May 20, 2021, the Appeals Court has upheld the first instance judgment of the German Court of June 16, 2017, in which the court had found that CardiAQ had contributed in part to the invention of the Tiara and awarded to CardiAQ co-entitlement rights to the disputed Tiara European patent application. There are no monetary awards associated with these matters (except for a decision on the statutory costs of the proceedings) and no damages award was recognized. Regarding the statutory costs of the proceedings, both parties bear 50% of the costs of the appeal proceedings before the Appeals Court. Neovasc bears the costs of the 2nd appeal proceedings before the German Supreme Court and 50% of the court fees of the first instance proceedings. Neovasc has not appealed this decision to preserve capital and move forward with our new strategic activities. The decision is now final.

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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 three 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 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 not accrued for any future royalty payments in the settlement agreement with Endovalve as the amounts are undeterminable at this time.

Shareholder Litigation

On November 5, 2020, a putative shareholder class action lawsuit was filed in the United States District Court for the Southern District of New York against Neovasc Inc. ("Neovasc"), Fred Colen, Neovasc's CEO, and Christopher Clark, Neovasc's CFO: Gonzalez v. Neovasc Inc., et al., Case No. 7:20-cv-09313 (S.D.N.Y.) (the "Gonzalez Action"). The complaint in the Gonzalez Action purports to bring suit on behalf of a class consisting of all persons and entities that purchased or otherwise acquired Neovasc securities between November 1, 2019 and October 27, 2020, inclusive. On November 25, 2020, a second putative shareholder class action lawsuit was filed in the United States District Court for the Southern District of New York against Neovasc and Messrs. Colen and Clark: Siple v. Neovasc Inc., et al., Case No. 1:20-cv-09948 (S.D.N.Y.) (the "Siple Action"). The complaint in the Siple Action purports to bring suit on behalf of a class consisting of all persons and entities that purchased or otherwise acquired Neovasc securities between October 10, 2018 and October 27, 2020, inclusive.

The complaints in both the Gonzalez Action and the Siple Action contain similar allegations that the defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about Neovasc's business, operations, and prospects. Specifically, the complaints' allegations relate to the premarket approval process with the U.S. Food and Drug Administration for Neovasc's Reducer medical device for the treatment of refractory angina. Both complaints assert the same two causes of action: (i) a violation of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder against all defendants; and (ii) a violation of Section 20(a) of the Exchange Act against Messrs. Colen and Clark.

On January 26, 2021, the court issued an order consolidating the Gonzalez Action and the Siple Action under a new case style: In re Neovasc Inc. Securities Litigation, Case No. 7:20-cv-09313 (S.D.N.Y.) (the "Consolidated Action"). The order also appointed Pratap Golla as Lead Plaintiff and the law firms of Pomerantz LLP and Holzer & Holzer LLC as Co-Lead Counsel for the Class in the Consolidated Action. The order further directed Lead Plaintiff to file a Consolidated Amended Complaint in the Consolidated Action. On March 19, 2021, Lead Plaintiff filed a Consolidated Amended Complaint.

The Consolidated Amended Complaint names Neovasc, Messrs. Colen and Clark, Bill Little, and Shmuel Banai as defendants. The Consolidated Amended Complaint purports to bring suit on behalf of a class consisting of all persons and entities that purchased or otherwise acquired Neovasc securities between October 10, 2018 and January 15, 2021, inclusive. The Consolidated Amended Complaint contains allegations similar to the complaints in the Gonzalez Action and the Siple Action and asserts the same two causes of

action: (i) a violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all defendants; and (ii) a violation of Section 20(a) of the Exchange Act against Messrs. Colen, Clark, Little, and Banai.

Defendants obtained permission to file a motion to dismiss the Consolidated Amended Complaint, which they served on June 14, 2021. Plaintiff served its opposition to the motion to dismiss on July 17, 2021. Defendants' reply in support of their motion to dismiss was served on August 6, 2021.

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, 2021 and 2020, other than those as described elsewhere herein, and those compensation-based payments disclosed in Note 22 Related Party Transactions of the unaudited condensed interim consolidated financial statements for the nine months ended September 30, 2021 and 2020.

RISK FACTORS

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

CRITICAL ACCOUNTING ESTIMATES AND MANAGEMENT JUDGMENT

The preparation of unaudited condensed interim consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the unaudited condensed interim consolidated financial statements and the reported amounts of revenues and expenses during the reporting year. 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 year in which the estimates are revised and in any future years 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. Reducer research and development supplies are expensed as the supplies are used.

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 payments

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. The determination of a transaction to be either forfeited or cancelled requires management judgment, which is dependent on the terms and conditions of the transaction.

Determination of functional currency

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

Deferred tax assets

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

Contingent Liabilities

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

Determination of discount rate to measure lease liabilities

The Company enters into leases with third-party landlords and as a consequence the rate implicit in the relevant lease is not readily determinable. Therefore, the Company uses its incremental borrowing rate as the discount rate for determining its lease liabilities at the lease commencement date. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow over similar terms which requires estimations when no observable rates are available.

Accounting for financing and determination of fair value of derivative liabilities

The determination of the accounting treatment for the financing transactions, most notably for those completed in November 2017, May 2019 and 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 derivative warrant liabilities and convertible notes will be measured at fair value through profit and loss at each year end. The calculations of the fair value of these instruments involves the use of a number of estimates and a complex valuation model. The carrying amounts of these liabilities may change significantly as a result of changes to these estimates. Details of the estimates used as at September 30, 2021 are disclosed in Note 16 of the unaudited condensed interim consolidated financial statements for the nine months ended September 30, 2021 and 2020.

FINANCIAL INSTRUMENTS

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

a) Fair value estimation

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

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

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

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

The following table sets forth the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as at December 31, 2020 and September 30, 2021. 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, 2020:

	Level 1	Level 2	Level 3	Total
Financial liabilities at fair value through profit and loss				
2019 Convertible Notes	$ -	$ -	$ 6,195,357	$ 6,195,357
2020 Convertible notes, warrants and derivative warrant liabilities	$ -	$ -	$ 9,117,147	$ 9,117,147

As at September 30, 2021:

	Level 1	Level 2	Level 3	Total
Financial liabilities at fair value through profit and loss				
2019 Convertible Notes	$ -	$ -	$ 6,565,063	$ 6,565,063
2020 Convertible notes, warrants and derivative warrant liabilities	$ -	$ -	$ 6,558,938	$ 6,558,938
2021 Derivative warrant liabilities	$ -	$ -	$ 722,293	$ 722,293

Presentation of the fair values of the 2020 Convertible notes, warrants and derivative warrant liabilities and 2021 Derivative warrant liabilities are gross of the deferred loss. The deferred loss on the 2020 Convertible notes, warrants and derivative warrant liabilities as at September 30, 2021 is $4,719,013 (December 31, 2020: 7,595,093)

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

	September 30, 2021	December 31, 2020
Assets at amortized cost		
Cash and cash equivalents	**$ 55,827,026**	$ 12,935,860
Accounts receivable	**1,787,257**	987,057
Restricted cash	**484,010**	470,460
Assets at amortized cost	**$ 58,098,293**	$ 14,393,377
Other financial liabilities at amortized cost		
Accounts payable and accrued liabilities (current)	**$ 4,812,486**	$ 7,243,500
Financial liabilities at fair value through profit and loss		
2019 Convertible Notes (current)	**154,531**	38,633
2019 Convertible Notes (non-current)	**6,410,532**	6,156,724
2020 Convertible Notes, warrants and derivative warrant liabilities (current)	**145,688**	37,525
2020 Convertible Notes, warrants and derivative warrant liabilities (non-current)	**6,413,250**	9,079,622
2021 Derivative warrant liabilities (non-current)	**722,293**	-
	$ 18,658,780	$ 22,556,004

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 47% of revenues for the nine months ended September 30, 2021, (nine months ended September 30, 2020: 40%). A 10% change in the foreign exchange rates for the Euro for foreign currency denominated accounts receivable will impact net income for the nine months ended September 30, 2021 by approximately $14,113 (for the nine months ended September 30, 2020: $10,142), and a similar change in foreign currency denominated accounts payable, which are denominated in Canadian dollars and Euros will impact net income by approximately $27,858 and $ 68,951 respectively, as at September 30, 2021 (as at September 30, 2020: $110,531 and $70,469 respectively). 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 $152,604 and $70,983, respectively, as at September 30, 2021 (as at September 30, 2020: $116,451 and $34,263 respectively). 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, 2019 Notes and 2020 Notes that have fixed interest terms.

(d) Liquidity risk

As at September 30, 2021, the Company had $55,827,026 in cash and cash equivalents as compared to cash and cash equivalents of $12,935,860 at December 31, 2020. The Company is dependent on the profitable commercialization of its products or obtaining additional debt, equity or other forms of 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 may obtain additional debt, equity or other forms of financing in future periods. Further into the future the Company is dependent on the profitable commercialization of its products or obtaining additional debt, equity or other forms of financing to fund ongoing operations until profitability is achieved.

On February 12, 2021 the Company received aggregate gross proceeds of $72 million from the February 2021 Financing (see Note 17). The proceeds from the February 2021 Financing could be sufficient to extend the operations of the Company until June 2024 at the current burn rate. However, it is possible that the Company will initiate programs that were on hold given past cash constraints and that the cash needs of the Company will increase, shortening the time the proceeds will meet the requirements of the Company.

Trade payables were aged as follows as at September 30, 2021 and do not include accrued liabilities. All trades payables are current liabilities:

		Total
Current	**$**	**1,066,821**
31-60 days		**332,130**
Over 60 days		**15,029**
	$	**1,413,980**

(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, 2021 is $661,566 (as at December 31, 2020: $322,201). As at September 30, 2021, the Company had $272,905 of trade accounts receivable that were overdue according to the customers' credit terms (as at December 31, 2020: $146,658). During the three and nine months ended September 30, 2021, the Company wrote down $nil of accounts receivable owed by customers (three and nine months ended September 30, 2020: $nil).

The Company may also have credit risk related to its cash and cash equivalents and restricted cash, with a maximum exposure of $56,311,036 as at September 30, 2021 (as at December 31, 2020: $13,406,320). 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

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"). 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. 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.

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 concluded that they are effective in DC&P as at September 30, 2021.

INTERNAL CONTROL OVER FINANCIAL REPORTING

The Company's management, under the supervision of the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), has designed controls and procedures for 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"). 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.

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 both were ineffective as of December 31, 2019 and 2018 as detailed below.

A material weakness is a significant deficiency, or combination of significant deficiencies, that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will occur and not be detected by management before the financial statements are published. Controls can potentially be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in 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. Due to the remediation changes in ICFR as at December 31, 2020, management concluded that ICFR was effective as at December 31, 2020 and as at September 30, 2021.

Material Changes in ICFR

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.

Remediation for Material Weakness in ICFR

In light of the aforementioned material weakness, management conducted a thorough review of all research and development supplies and can conclude that ICFR is effective for the nine months ended September 30, 2021. The Company has developed and implemented a remediation plan; the following actions were implemented to improve ICFR included:

- Flagged all Reducer units scheduled for testing at each period end to ensure they were correctly accounted for as an asset.
- Reviewed all Reducer units included in period expenses as product development and clinical trials expenses to ensure all the units were correctly used in testing during that period.
- Deployed an internal control compliance program, in accordance with COSO, designed to identify potential deficiencies in DC&P and ICFR throughout the nine months ended September 30, 2021, to ensure that deficiencies are identified and remediated in a timely manner.
- Further matured DC&P and ICFR practices in addition to enhancing risk assessment, control design assessment and operating effectiveness testing practices throughout the nine months ended September 30, 2021.

Management's Report on ICFR

As a result of this process the operating effectiveness of ICFR has been strengthened and 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, 2021 fairly present in all material respects and the financial condition and results of operations for the Company in conformity with IFRS.

Management has assessed the effectiveness of the Company's internal control over financial reporting as of September 30, 2021. In making this assessment, management used the criteria set forth by COSO in Internal Control-Integrated Framework (2013). Based on this assessment, management determined that the Company maintained effective internal control over financial reporting as of September 30, 2021.

Auditor attestation on ICFR

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 its Annual Report or in its audited consolidated financial statements for the years ended December 31, 2020, 2019 and 2018.

ADDITIONAL INFORMATION

Additional information about the Company, including the Company's Financial Statements and Annual Report on Form 40-F, are available on SEDAR at www.sedar.com and on the website of the SEC at www.sec.gov.